

Disclaimer: The Saskatchewan Cancer Agency Drug Formulary is an information-only resource that identifies the funding status and eligibility requirements of cancer treatment drugs and some supportive drugs used to care for cancer patients in Saskatchewan. It is current only as of the date listed on the Drug Formulary, and is not intended to constitute medical advice.

DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
abemaciclib	tablet	50 mg 100 mg 150 mg		Breast	Breast, Early Stage	High-risk* hormone receptor (HR)–positive, human epidermal growth factor receptor 2 (HER2)–negative, node-positive early breast cancer, including a Ki-67 score of at least 20%, as adjuvant treatment in combination with endocrine therapy  Abemaciclib may be continued for up to 2 years, unacceptable toxicity, or disease progression whichever comes first; endocrine therapy may be continued beyond 2 years to complete the planned duration  (Abemaciclib should not exceed an equivalent of 2 years duration; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	*there must be at least 1 of the following biopsy proven pathologic characteristics to be eligible: <ul style="list-style-type: none"><li>• pathological tumor involvement in ≥ 4 ipsilateral axillary lymph nodes, or</li><li>• pathological tumor involvement in 1 to 3 ipsilateral axillary lymph node(s), and either grade 3 disease or primary tumor size ≥ 5 cm</li></ul> Patients must have fully resected invasive breast cancer without evidence of metastases; definitive surgery of the primary tumor should have been completed within 16 months of initiating treatment  Abemaciclib is <u>not</u> funded in patients with inflammatory breast cancer  Patients remain eligible for CDK 4/6 inhibitors (e.g., palbociclib, ribociclib) for treatment of metastatic breast cancer, provided there has been no disease progression within 6 months following completion of adjuvant Abemaciclib, and all other eligibility criteria are met  Only 1 of abemaciclib or olaparib is funded in patients who meet the eligibility criteria for both therapies in the adjuvant setting
abiraterone	tablet	250 mg 500 mg		Genitourinary	Prostate	Very high-risk non-metastatic prostate cancer in combination with prednisone and androgen deprivation therapy (ADT) in patients who have had no prior systemic therapy for prostate cancer, and who are: <ul style="list-style-type: none"><li>• node positive, OR</li><li>• node negative with 2 of the following: clinical tumor stage T3 or T4; Gleason sum score 8 to 10; PSA ≥ 40 mcg/L</li></ul> Abiraterone may be continued for up to 2 years, unacceptable toxicity, or disease progression whichever comes first	Abiraterone is <u>not</u> funded in patients with non-metastatic prostate cancer who have a biochemical recurrence  Abiraterone is <u>not</u> funded in combination with enzalutamide
				Genitourinary	Prostate (mCSPC)	Metastatic* castration-sensitive prostate cancer (mCSPC) in combination with prednisone and androgen deprivation therapy (ADT) in patients who have had no prior ADT in the metastatic setting, or initiated ADT within 6 months in the metastatic setting with no disease progression  Abiraterone may continue until disease progression or unacceptable toxicity	*metastatic prostate cancer is interpreted as distant metastatic disease (i.e., positive bone scan or metastatic lesions on radiologic imaging for soft tissue; patients with disease limited to regional pelvic lymph nodes only are not eligible)  Patients who previously received adjuvant androgen deprivation therapy (ADT) in the non-metastatic setting are eligible as long as ADT was completed ≥1 year prior to initiation of abiraterone  Use of either concurrent abiraterone, prednisone and docetaxel, or sequential docetaxel followed by abiraterone and prednisone, is funded for patients with newly diagnosed metastatic castration-sensitive prostate cancer (mCSPC)  Patients who received recent docetaxel chemotherapy for the treatment of metastatic castration-sensitive prostate cancer (mCSPC) within the past 3 months are eligible if they have not experienced disease progression  Patients unable to tolerate abiraterone plus prednisone may be switched to either apalutamide or enzalutamide for treatment of mCSPC if there is no disease progression  Patients who experience disease progression on abiraterone plus prednisone for treatment of mCSPC are eligible for enzalutamide for treatment of metastatic castration-resistant prostate cancer (mCRPC) if they are unable to tolerate or are not candidates for other therapeutic choices (i.e., chemotherapy) provided they have previously not experienced disease progression after prior treatment with other androgen receptor-axis therapies (ARATs) (e.g., apalutamide, darolutamide) in any setting
				Genitourinary	Prostate (mCSPC)	Metastatic castration-sensitive prostate cancer (mCSPC) in combination with prednisone, androgen deprivation therapy (ADT) and docetaxel chemotherapy in patients who are newly diagnosed	
				Genitourinary	Prostate (mCRPC)	Metastatic castration-resistant prostate cancer* (mCRPC) in combination with prednisone	*Castration-resistant prostate cancer is defined as 3 consecutive rises in prostate-specific antigen (PSA) at least 1 week apart with the last PSA >2 mcg/L, <u>or</u> progression or appearance of ≥2 lesions on bone scan or in soft tissue, during continuous androgen deprivation therapy (ADT) with castrate testosterone levels (<1.7 nmol/L)  Abiraterone is funded in patients who have experienced disease progression after prior treatment with other androgen receptor-axis therapies (ARATs) (e.g., enzalutamide) in patients who are unable to tolerate or are not candidates for other therapeutic choices (i.e., chemotherapy)

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Abraxane® (paclitaxel nanoparticle albumin bound [nab])	vial	100 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic breast cancer in patients who have experienced previous anaphylaxis or anaphylactoid reactions with conventional paclitaxel or docetaxel infusions or who have significant contraindications to use of taxane pre-medication and in whom further use of a taxane is appropriate	An example of a significant contraindication to taxane pre-medication would be in patients with uncontrolled diabetes
				Breast	Breast, Early Stage	Early stage breast cancer in patients who have experienced previous anaphylaxis or anaphylactoid reactions with conventional paclitaxel or docetaxel infusions or who have significant contraindications to use of taxane pre-medication and in whom further use of a taxane is appropriate	An example of a significant contraindication to taxane pre-medication would be in patients with uncontrolled diabetes
				Gastrointestinal	Pancreas	Locally advanced unresectable or metastatic adenocarcinoma of the pancreas in combination with gemcitabine as first or second-line (after FOLFIRINOX) treatment	
				Gynecology	Multiple	Locally advanced unresectable or metastatic ovarian, fallopian tube, primary peritoneal, endometrial or cervical cancer in combination with platinum-based therapy in patients who have experienced previous anaphylaxis or anaphylactoid reactions with conventional paclitaxel infusions or who have significant contraindications to use of taxane pre-medication and in whom further use of a taxane is appropriate	
acalabrutinib	tablet	100 mg		Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) as a first-line single agent in previously untreated patients who are not candidates for fludarabine-based treatment, including patients who: <ul style="list-style-type: none"><li>• have high-risk factors, including del17p, TP53 mutation, del11q, and unmutated IGHV</li><li>• have a contraindication or intolerance to chemoimmunotherapy</li><li>• are not suitable candidates for intravenous therapy</li></ul>	Patients with known CNS lymphoma, prolymphocytic leukemia, or history or suspicion of Richter syndrome are <u>not</u> eligible  Patients with unacceptable toxicity to acalabrutinib may be switched to ibrutinib or zanubrutinib provided no disease progression has occurred  Acalabrutinib is <u>not</u> funded in combination with obinutuzumab  Venetoclax with or without rituximab is funded as a subsequent line of therapy in patients who have experienced disease progression during first-line acalabrutinib treatment, provided all other funding eligibility criteria are met  Acalabrutinib is <u>not</u> funded as a subsequent treatment in patients who have experienced disease progression during ibrutinib, zanubrutinib or idelalisib treatment  CD20-targeted therapy in combination with chemotherapy is <u>not</u> funded as a subsequent treatment option in patients who have experienced disease progression during first-line treatment with acalabrutinib
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) as a single agent in patients who have received at least 1 prior therapy, which may include prior CD20-targeted therapy in combination with chemotherapy or venetoclax, but excludes prior therapy with idelalisib	Patients with known CNS lymphoma, prolymphocytic leukemia, or history or suspicion of Richter syndrome are <u>not</u> eligible  Patients with unacceptable toxicity to acalabrutinib may be switched to ibrutinib or zanubrutinib provided no disease progression has occurred  Acalabrutinib is <u>not</u> funded as a subsequent treatment in patients who have experienced disease progression during ibrutinib, zanubrutinib or idelalisib treatment  CD20-targeted therapy in combination with chemotherapy is <u>not</u> funded as subsequent treatment option in patients who have experienced disease progression during acalabrutinib treatment
acitretin	capsule	10 mg 25 mg		Hematology	T-Cell Lymphoma	Refractory cutaneous T-cell lymphoma (e.g., mycosis fungoides, Sézary syndrome)	

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afatinib	tablet	20 mg 30 mg 40 mg		Lung	NSCLC (EGFR positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer (NSCLC)	if chemotherapy was initiated as a first-line treatment prior to receiving results of EGFR mutation status, treatment may be switched to afatinib, if clinically appropriate  Other EGFR inhibitors are <u>not</u> funded in any subsequent line of therapy in patients who have experienced disease progression on afatinib, with the exception of osimertinib for tumors with identified T790M mutations
Akynzeo® (netupitant and palonosetron)	capsule	300 mg netupitant  0.5 mg palonosetron		Supportive Care	Supportive Care	Primary prevention of acute and delayed nausea and vomiting in combination with dexamethasone for highly emetogenic* chemotherapy  Secondary prevention of acute nausea and vomiting for moderately emetogenic** chemotherapy where emesis (vomiting) is experienced despite previous treatment with a combination of a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone	*chemotherapy considered highly emetogenic includes single day cisplatin regimens >40 mg/m <sup>2</sup> , single day high dose (≥850 mg/m <sup>2</sup> ) dacarbazine regimens, breast cancer regimens with both anthracycline and cyclophosphamide (e.g., AC, FE <sub>100</sub> C), carboplatin regimens with an AUC (area under the curve) dose ≥4, regimens containing carmustine, and multi-day cisplatin-based regimens (e.g., BEP)  **chemotherapy considered moderately emetogenic includes multi-day cisplatin-based regimens (e.g., BEP), ABVD and CHOP-like regimens  Akynzeo is <u>not</u> funded in patients who: • have chosen to initiate and self-pay for aprepitant, fosaprepitant or Akynzeo at the time of their first chemotherapy cycle which did not meet SCA funding criteria for primary prevention, as their eligibility for secondary prevention cannot be assessed • are receiving low emetogenic chemotherapy, even if emesis (vomiting) was experienced with a previous cycle despite treatment with a combination of a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone
aldesleukin	vial	22 MU		Skin and Melanoma	Melanoma	Unresectable in-transit metastatic melanoma (e.g., rapidly developing in-transit metastases after surgery or multiple in-transit metastases unsuitable for surgical resection) as an intralesional treatment	Also known as interleukin-2 or IL-2
alectinib	capsule	150 mg		Lung	NSCLC (ALK positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as a first-line treatment, or as a second-line treatment in patients who have experienced disease progression or intolerance during crizotinib treatment, including patients who have stable brain metastases (if present)	Patients initiated on alternate systemic treatment before molecular testing results are available may be switched to alectinib once ALK-positivity is confirmed  Alectinib is <u>not</u> funded following 2 prior ALK inhibitor therapies (e.g., disease progression during first-line crizotinib, then second-line ceritinib therapy)  Ceritinib is <u>not</u> funded in patients who experience disease progression during alectinib, given in either the first or second-line treatment settings  Patients who develop intolerance to first-line alectinib may be switched to brigatinib, crizotinib or lorlatinib provided no disease progression has occurred  Patients who develop intolerance to brigatinib, crizotinib or lorlatinib may be switched to first-line alectinib provided no disease progression has occurred
anagrelide	capsule	0.5 mg		Hematology	Myeloproliferative Neoplasm (MPN)	Essential thrombocytosis or polycythemia vera in patients who have elevated platelets despite hydroxyurea treatment or who have an intolerance to hydroxyurea	Anagrelide also has full listing on the Saskatchewan Prescription Drug Plan (SPDP) Formulary

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anastrozole	tablet	1 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, hormone receptor-positive breast cancer in post-menopausal women or in men	See palbociclib or ribociclib for use of anastrozole in combination with CDK4/6 inhibitor therapy  Refer to Appendix C - Definition of Menopause
				Breast	Breast, Early Stage	Early stage, hormone receptor-positive breast cancer in post-menopausal women or in men as: <ul style="list-style-type: none"><li>• adjuvant therapy</li><li>• neoadjuvant therapy in patients not eligible for chemotherapy</li></ul>	Adjuvant therapy includes treatment for 5 to 10 years (upfront strategy), for 2 to 3 years following 2 to 3 years of treatment with tamoxifen for a total of 5 years (switch strategy) or for up to 5 years following 5 years of treatment with tamoxifen (extended strategy)  Refer to Appendix C - Definition of Menopause+I21
				Breast	Ductal Carcinoma In-Situ (DCIS)	Hormone receptor-positive ductal carcinoma in-situ (DCIS) in post-menopausal women or in men for up to 5 years	Anastrozole is <u>not</u> funded for hormone receptor-positive lobular carcinoma in-situ (LCIS)  Refer to Appendix C - Definition of Menopause
				Gynecology	Multiple	Recurrent or progressive, hormone receptor-positive endometrial, epithelial ovarian, fallopian tube or primary peritoneal cancers	
apalutamide	tablet	60 mg 240 mg	STEP	Genitourinary	Prostate (nmCRPC)	Non-metastatic castration-resistant* prostate cancer (nmCRPC) in combination with androgen deprivation therapy (ADT) in patients who: <ul style="list-style-type: none"><li>• have histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation, signet cell features or small cell features</li><li>• have no detectable distant metastases by either CT, MRI or technetium-99m bone scan, including any central nervous system (CNS), vertebral or meningeal involvement, but excluding pelvic lymph nodes &lt;2 cm in short axis (N1) located below the common iliac vessels</li><li>• are at high risk of developing metastases, defined as a prostate-specific antigen doubling time (PSADT) of ≤10 months during continuous ADT</li><li>• have no risk factors for seizure</li><li>• (if applicable) have demonstrated a further rise in prostate-specific antigen (PSA), measured at least 6 weeks after discontinuing treatment with a first generation anti-androgen (e.g., bicalutamide)</li></ul> Apalutamide may continue until radiographic disease progression or unacceptable toxicity	*castration-resistant prostate cancer is defined as 3 consecutive rises in PSA at least 1 week apart with the last PSA >2 mcg/L, during continuous ADT with castrate testosterone levels <1.7 nmol/L)  If biochemical progression (rising PSA) occurs while on apalutamide, appropriate clinical evaluation and/or investigations for metastatic disease should be conducted in a timely manner  If progression to <u>metastatic</u> castration-resistant prostate cancer (mCRPC) occurs during apalutamide treatment for nmCRPC, abiraterone (not enzalutamide) is funded as a subsequent treatment option in patients who are unable to tolerate or are not candidates for other therapeutic choices (i.e., chemotherapy)  If apalutamide was discontinued in the nmCRPC setting (e.g., due to intolerance) <u>prior to</u> development of metastatic disease, either abiraterone or enzalutamide is funded as an option for treatment at the time of progression to mCRPC
				Genitourinary	Prostate (mCSPC)	Metastatic* castration-sensitive prostate cancer (mCSPC) in combination with androgen deprivation therapy (ADT) in patients who have had no prior ADT in the metastatic setting, or initiated ADT within 6 months in the metastatic setting with no disease progression  Apalutamide may continue until disease progression or unacceptable toxicity	*metastatic prostate cancer is interpreted as distant metastatic disease (i.e., positive bone scan or metastatic lesions on radiologic imaging for soft tissue; patients with disease limited to regional pelvic lymph nodes only are not eligible)  Patients who previously received adjuvant androgen deprivation therapy (ADT) in the non-metastatic setting are eligible as long as ADT was completed ≥1 year prior to initiation of apalutamide  Patients who received recent docetaxel chemotherapy for the treatment of metastatic castration-sensitive prostate cancer (mCSPC) within the past 3 months are eligible if they have not experienced disease progression  Patients unable to tolerate apalutamide may be switched to either enzalutamide or abiraterone plus prednisone for treatment of mCSPC if there is no disease progression  Patients who experience disease progression on apalutamide for treatment of mCSPC are eligible for abiraterone plus prednisone for treatment of metastatic castration-resistant prostate cancer (mCRPC) if they are unable to tolerate or are not candidates for other therapeutic choices (i.e., chemotherapy) provided they have previously not experienced disease progression on abiraterone in any setting

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aprepitant	tablet	80 mg 125 mg		Supportive Care	Supportive Care	Primary prevention of acute and delayed nausea and vomiting in combination with a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone for highly emetogenic chemotherapy*	* chemotherapy considered highly emetogenic includes single day cisplatin regimens ≥40 mg/m <sup>2</sup> , single day high dose (≥850 mg/m <sup>2</sup> ) dacarbazine regimens, breast cancer regimens with both anthracycline and cyclophosphamide (e.g., AC, FE <sub>100</sub> C) and regimens containing carmustine or streptozocin
				Supportive Care	Supportive Care	Secondary prevention of acute and delayed nausea and vomiting in combination with a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone for moderately emetogenic chemotherapy* where emesis (vomiting) is experienced despite treatment with a combination of a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone in a previous cycle	* chemotherapy considered moderately emetogenic includes multi-day cisplatin-based regimens (e.g., BEP), ABVD and CHOP-like regimens  Aprepitant is <u>not</u> funded in patients who: • have chosen to initiate and self-pay for aprepitant, fosaprepitant or Akynzeo at the time of their first chemotherapy cycle which did not meet SCA funding criteria for primary prevention, as their eligibility for secondary prevention cannot be assessed • are receiving low emetogenic chemotherapy, even if emesis (vomiting) was experienced with a previous cycle despite treatment with a combination of a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone
				Pediatrics	Supportive Care	Pediatric patients ≥6 months old receiving highly emetogenic chemotherapy, or receiving moderately emetogenic chemotherapy and are unable to receive dexamethasone	
arsenic trioxide	ampoule	10 mg/10 mL		Hematology	Acute Promyelocytic Leukemia (APL)	Low, intermediate or high-risk acute promyelocytic leukemia (APL) characterized by t(15;17) translocation and/or promyelocytic leukemia-retinoic acid receptor alpha (PML/RARα) gene expression as first-line induction and/or consolidation therapy	
				Hematology	Acute Promyelocytic Leukemia (APL)	Relapsed or refractory acute promyelocytic leukemia (APL) as induction and/or consolidation therapy in patients who: • have relapsed after completion of first-line induction therapy, including prior treatment with arsenic trioxide • are refractory to a non-arsenic trioxide-based therapy and have APL characterized by t(15;17) translocation and/or PML/RARα gene expression	
asciminib	tablet	20 mg 40 mg		Hematology	Chronic Myeloid Leukemia (CML)	Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in patients who are in chronic phase (CP) with treatment failure or intolerance to 2 or more prior tyrosine kinase inhibitor (TKI) therapies and have no evidence of T315I or V299L mutations	Patients must <u>not</u> have evidence of accelerated phase (AP) or blast crisis (BC)
asparaginase, <i>Erwinia</i> (crisantaspase)	vial	10,000 units/1 mL		Hematology	Acute Lymphoblastic Leukemia (ALL)	Acute lymphoblastic leukemia (ALL) in pediatric patients who are actively enrolled on a Children's Oncology Group (COG) protocol or are receiving treatment according to a COG protocol without study enrollment (i.e., off study)  Acute lymphoblastic leukemia (ALL) in pediatric and adult patients who have experienced hypersensitivity to <i>E. coli</i> -derived asparaginase	
asparaginase-PEG (see pegaspargase)							

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atezolizumab	vial	840 mg/14 mL 1,200 mg/20 mL		Gastrointestinal	Hepatocellular	Unresectable or metastatic hepatocellular carcinoma (HCC) in combination with bevacizumab as first-line treatment in patients with Child-Pugh A liver function who have stable brain metastases (if any)	Patients with fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC are not eligible  Patients treated with first-line atezolizumab and bevacizumab are eligible for either lenvatinib or sorafenib in the second-line setting  In the clinical setting of toxicity to one of the drugs in the combination, but without evidence of disease progression, treatment may continue with the alternate drug as a single agent if clinically appropriate  If therapy was stopped at time of best response without evidence of disease progression, treatment may be re-started at time of disease progression  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Lung	NSCLC	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous or squamous, non-small cell lung cancer (NSCLC) in patients who: • have experienced disease progression following chemotherapy or, if genomic tumor driver aberrations (e.g., epidermal growth factor receptor [EGFR], anaplastic lymphoma kinase [ALK] or ROS1) are present, after <u>both</u> a targeted agent and chemotherapy • have <u>not</u> received prior treatment with any other immune checkpoint inhibitor (e.g., ipilimumab, nivolumab, pembrolizumab) in the locally advanced or metastatic NSCLC treatment setting • may have received durvalumab for stage III NSCLC, but have had at least a 6 month progression-free interval since completion of durvalumab and confirmation of disease progression  Atezolizumab may be continued until confirmed disease progression or unacceptable toxicity, with a consideration to stop atezolizumab in patients who have responded and whose disease is well-controlled	If atezolizumab was stopped at time of best response without evidence of disease progression, atezolizumab may be re-started at time of disease progression  Subsequent immune checkpoint inhibitor therapy (e.g., pembrolizumab if PD-L1 ≥1%, nivolumab or ipilimumab/nivolumab) is <u>not</u> funded in patients who have experienced disease progression during atezolizumab therapy  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Lung	NSCLC	Adjuvant treatment of stage II-IIIa (AJCC 8th edition) non-small cell lung cancer (NSCLC) following complete resection* and no progression after platinum-based chemotherapy as a single agent in patients whose tumor is positive for programmed death-ligand 1 (PD-L1) in at least 50% of tumor cells (TCs) and does not have an EGFR driver mutation or abnormal ALK gene rearrangement, including:  • fully resected stage II-IIIa NSCLC (AJCC 8th edition) who had a primary tumor >5 cm regardless of nodal status, or whose tumors were node positive regardless of primary tumor size, OR • fully resected stage IIIB NSCLC (AJCC 8th edition) who are stage T3N2 or T4N2 on the basis of a primary tumor >7 cm or diaphragm involvement  Atezolizumab should be initiated within 3-8 weeks following completion of adjuvant platinum-based chemotherapy  Treatment with atezolizumab may continue for up to 48 weeks or until confirmed disease progression or unacceptable toxicity, whichever comes first  (The total number of atezolizumab cycles should not exceed an equivalent of 48 weeks duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 48 weeks from treatment initiation)	*complete tumor resection is defined as no gross disease following surgery and negative surgical margins  Patients who have not had complete surgical resection or have not received adjuvant platinum-based chemotherapy are <u>not</u> eligible  Patients who discontinue platinum-based chemotherapy due to toxicity remain eligible for adjuvant atezolizumab  Patients who received neoadjuvant immune checkpoint inhibitor therapy (e.g., nivolumab) for resectable non-small cell lung cancer (NSCLC) are <u>not</u> eligible for adjuvant atezolizumab
				Lung	SCLC	Extensive-stage small cell lung cancer (ES-SCLC) in combination with etoposide and platinum-based chemotherapy followed by maintenance in previously untreated patients, including patients who have stable brain metastases (if present)	Atezolizumab is only funded for use in combination with etoposide and platinum (cisplatin or carboplatin) chemotherapy; use with alternate chemotherapy is not funded  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment

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avelumab	vial	200 mg/10 mL		Skin and Melanoma	Merkel Cell Carcinoma	Metastatic Merkel cell carcinoma in patients who: • have measurable disease at treatment initiation • have had prior chemotherapy or who are not candidates (e.g., contraindication/intolerance) for first-line chemotherapy • have not received prior treatment with any other immune checkpoint inhibitors  Avelumab may continue for a maximum duration of 12 months <u>after</u> confirmation of a complete response, or until disease progression if a complete response is not achieved, or unacceptable toxicity, whichever occurs first	If avelumab is stopped in the setting of maximum response/stable disease without evidence of disease progression, avelumab may be re-started at time of disease progression, or in the case of intolerance, at the time of toxicity resolution  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Genitourinary	Urothelial, Advanced	Unresectable, locally advanced or metastatic urothelial carcinoma as maintenance treatment in patients whose disease has not progressed following first-line chemotherapy*, including patients who: • have predominantly transitional cell histology arising in the bladder, renal pelvis, ureter or urethra  Avelumab maintenance should be initiated within 4 to 10 weeks after completion of chemotherapy	*patients should have received at least 4-6 cycles of chemotherapy; if a patient is unable to tolerate at least 4 cycles of chemotherapy, there should be confirmation no disease progression has occurred before initiating avelumab maintenance  Patients who received neoadjuvant or adjuvant chemotherapy and experience disease progression within 12 months of completion are <u>not</u> eligible for avelumab  Patients who have received more than one line of chemotherapy for advanced urothelial carcinoma are <u>not</u> eligible for avelumab maintenance  If avelumab is stopped for reasons other than disease progression it may be restarted at any time if disease is still in remission  Patients who experience disease progression during or within 6 months of discontinuing avelumab maintenance therapy are <u>not</u> eligible for second-line pembrolizumab; patients who experience disease progression 6 or more months after previously stopping avelumab maintenance for reasons other than disease progression remain eligible for second-line pembrolizumab  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
axicabtagene ciloleucel (axi-cel)	Cell suspension in patient-specific single infusion bag	2 x 10 <sup>6</sup> anti-CD19 CAR-positive viable T cells/kg body weight in ~68 mL	STEP	Hematology	Large B-cell Lymphoma (LBCL)	Relapsed or refractory* large B-cell lymphoma (LBCL) after 2 or more lines of systemic therapy  Eligible LBCL subtypes include: • diffuse large B-cell lymphoma (DLBCL) • primary mediastinal large B-cell lymphoma (PMBCL) • high-grade B-cell lymphoma (HGBL) • DLBCL arising from indolent lymphoma • follicular large B-cell lymphoma (formerly called follicular lymphoma grade 3B)	*relapsed or refractory disease is defined as 1 of the following: • disease progression after the last regimen or following hematopoietic stem cell transplant (relapsed) • failure to achieve a partial response (PR) or complete response (CR) to the last regimen (refractory)  Patients with primary CNS lymphoma or evidence of Richter transformation are <u>not</u> eligible
axitinib	tablet	1 mg 5 mg		Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) for all histologic subtypes and risk categories* as: • a second-line treatment before or a third-line treatment after nivolumab, in patients who have experienced disease progression during first-line vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor (TKI) treatment (sunitinib or pazopanib) • a third-line treatment in patients with intermediate or poor-risk mRCC who have experienced disease progression with both first-line nivolumab plus ipilimumab and second-line VEGF TKI (sunitinib or pazopanib) treatments	*determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria  Only <u>one</u> of axitinib or cabozantinib is funded in the eligible second or third-line treatment settings  Nivolumab is funded as a third-line treatment in patients who have experienced disease progression after 2 prior VEGF TKI therapies (e.g., sunitinib or pazopanib, followed by axitinib)
				Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) for all histologic subtypes and risk categories* in combination with pembrolizumab as a first-line treatment in patients who: • have not received any prior therapy for mRCC, including any of the immune checkpoint inhibitors (e.g., nivolumab plus ipilimumab) or vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitors (TKIs) (e.g., sunitinib, pazopanib) • have stable brain metastases (if present)  Axitinib may continue until disease progression or unacceptable toxicity, with the pembrolizumab component continued for a maximum duration of 2 years from treatment initiation (including any dose interruption time periods), or until disease progression or unacceptable toxicity, whichever occurs first	*determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria  Patients who experience intolerance to 1 drug in the combination of axitinib plus pembrolizumab may continue with either single agent axitinib until disease progression or unacceptable toxicity, or single agent pembrolizumab for maximum duration of 2 years, or until disease progression or unacceptable toxicity, whichever occurs first  Cabozantinib is funded as a second-line treatment in patients who experience disease progression during first-line combination therapy with axitinib and pembrolizumab  Third-line treatment of any kind is <u>not</u> funded in patients who receive first-line treatment with axitinib plus pembrolizumab followed by second-line cabozantinib

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azacitidine	vial	100 mg		Hematology	Acute Myeloid Leukemia (AML)	Acute myeloid leukemia (AML) in patients who are not candidates for induction chemotherapy	
				Hematology	Acute Myeloid Leukemia (AML)	Acute myeloid leukemia (AML) in patients who: <ul style="list-style-type: none"><li>• experience an inadequate response after induction chemotherapy</li><li>• have myelodysplastic syndrome (MDS)-related changes or blasts of &lt;30%</li><li>• are not candidates for salvage or re-induction chemotherapy</li></ul>	
				Hematology	Acute Myeloid Leukemia (AML)	Acute myeloid leukemia (AML) in patients who achieved a complete response (CR) after induction chemotherapy and are not candidates for any further consolidation chemotherapy or hematopoietic stem cell transplant (HSCT), including those who have myelodysplastic syndrome (MDS)-related changes or adverse-risk cytogenetics	
				Hematology	Acute Myeloid Leukemia (AML)	Relapsed acute myeloid leukemia (AML) following an allogeneic stem cell transplant	
				Hematology	Acute Myeloid Leukemia (AML)	Newly diagnosed acute myeloid leukemia (AML)* in patients who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy, in combination with venetoclax	<p>*newly diagnosed acute myeloid leukemia (AML) patients are eligible regardless of cytogenetic risk provided they are ineligible for induction chemotherapy</p> <p>Patients with high-risk myelodysplastic syndromes (MDS) who are not fit for intensive induction chemotherapy are <u>not</u> eligible</p> <p>Patients previously treated with a hypomethylating agent (e.g., azacitidine, decitabine) or chemotherapy for MDS are <u>not</u> eligible</p> <p>Venetoclax plus azacitidine is <u>not</u> funded as palliative treatment in patients who previously received induction chemotherapy for AML and who have experienced disease relapse</p>
				Hematology	Chronic Myelomonocytic Leukemia (CMML)	Chronic myelomonocytic leukemia (CMML) with 10-29% blasts	
				Hematology	Chronic Myelomonocytic Leukemia (CMML)	Intermediate-2 or high-risk* chronic myelomonocytic leukemia (CMML)	*according to the CMML-specific prognostic scoring system (CPSS)
				Hematology	Chronic Myelomonocytic Leukemia (CMML)	Relapsed chronic myelomonocytic leukemia (CMML) following an allogeneic stem cell transplant	
				Hematology	Myelodysplastic Syndromes (MDS)	Intermediate-1, intermediate-2 or high-risk* myelodysplastic syndromes (MDS)	<p>*according to the International Prognostic Scoring System (IPSS)</p> <p>If using the Revised International Prognostic Scoring System (IPSS-R), the score should be &gt;3.0</p>
azacitidine	tablet	200 mg 300 mg	STEP	Hematology	Acute Myeloid Leukemia (AML)	<p>Maintenance therapy for treatment of adult patients with acute myeloid leukemia (AML)* who have achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRI) following induction therapy with or without consolidation treatment, and who are not candidates for hematopoietic stem transplantation (HSCT)</p> <p>Treatment should be discontinued upon the occurrence of any of the following:</p> <ul style="list-style-type: none"><li>• disease relapse (i.e., appearance of &gt;5% blasts in the bone marrow or peripheral blood)</li><li>• unacceptable toxicity or intolerance</li><li>• patient subsequently becomes eligible for allogeneic bone marrow or stem cell transplantation</li></ul>	<p>*patients must have newly diagnosed acute myeloid leukemia (AML) - de novo, or secondary to prior myelodysplastic syndromes (MDS) or chronic myelomonocytic leukemia (CMML), with intermediate- or adverse-risk cytogenetics</p> <p>Patients are eligible regardless of induction chemotherapy regimen used (e.g., 7+3 with or without gemtuzumab ozogamicin or midostaurin, FLAG-Ida, Vyxeos®), provided all other eligibility criteria are met</p> <p>Patients must have achieved CR or CRI following induction therapy with or without consolidation treatment within 4 months preceding initiation of oral azacitidine</p> <p>Maintenance therapy with oral azacitidine is <u>not</u> funded in patients who achieve CR or CRI following treatment with a non-induction regimen including parenteral azacitidine (or any other hypomethylating agent) with or without venetoclax for initial treatment of AML</p> <p>Dose escalation of oral azacitidine is <u>not</u> funded in patients at the time of disease relapse (i.e., &gt;5% blasts in the bone marrow or peripheral blood)</p> <p>Oral azacitidine is <u>not</u> funded as a substitute for parenteral Azacitidine in other hematologic malignancies</p>



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BCG vaccine	vial	1-8 x 10 <sup>8</sup> CFU's (colony forming units)		Genitourinary	Bladder (non-muscle invasive)	Newly diagnosed or recurrent non-muscle invasive transitional cell bladder cancer in patients who have any of the following: <ul style="list-style-type: none"><li>• stage Tis (carcinoma-in-situ of the high grade flat type)</li><li>• unresectable stage Ta (papillary transitional cell carcinoma)</li><li>• resected stage T1 (superficial invasion of submucosa)</li><li>• high risk stage Ta (multiple recurrences or multiple high grade)</li></ul>	Induction therapy is approved once weekly for 6 weeks, with maintenance therapy starting 3 months after completion of induction therapy approved for up to 3 years for high risk non-muscle invasive bladder cancer (NMIBC) (given once weekly for 3 weeks every 3 months for 2 courses [months 3 and 6], then once weekly for 3 weeks every 6 months for 5 courses [months 12, 18, 24, 30 and 36]), or for up to 1 year for intermediate risk NMIBC (given once weekly for 3 weeks for 3 courses [months 3, 6 and 12])  Ongoing supply shortages of BCG vaccine may cause delays in the timing of maintenance therapy
bendamustine	vial	25 mg 100 mg		Hematology	Blood and Marrow Transplant (BMT)	As part of the BeEAM conditioning regimen prior to autologous stem cell transplant (ASCT)	
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in combination with rituximab in untreated patients or in patients who have previously received chemotherapy in combination with CD20-targeted therapy, but have had a progression-free interval of at least 1 year since the last dose of CD20-targeted therapy	
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) as a single agent in untreated patients who are not candidates for chemotherapy in combination with CD20-targeted therapy	
				Hematology	Non-Hodgkin Lymphoma (NHL)	Low grade non-Hodgkin lymphoma* (NHL) and mantle cell lymphoma with the following eligibility: <ul style="list-style-type: none"><li>• in combination with rituximab as a first-line treatment</li><li>• in combination with rituximab in patients with relapsed disease who are eligible for rituximab re-treatment (e.g., relapsed or progressive disease ≥6 months after last rituximab dose)</li><li>• as a single agent in patients who experienced disease relapse or progression within 6 months of their last rituximab dose (i.e., rituximab-refractory) and who have not previously received bendamustine</li></ul>	*low grade non-Hodgkin lymphoma subtypes include: follicular lymphoma, marginal zone lymphoma, lymphoplasmacytic lymphoma and Waldenstrom macroglobulinemia
				Hematology	Non-Hodgkin Lymphoma (NHL)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), in combination with polatuzumab vedotin and rituximab in adult patients who are not eligible for an autologous stem cell transplant (ASCT) and have been previously treated with at least one prior therapy  Bendamustine in combination with polatuzumab vedotin and rituximab may continue for a maximum of 6 cycles, or until disease progression or unacceptable toxicity, whichever occurs first	

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bevacizumab	vial	100 mg/4 mL 400 mg/16 mL		Gastrointestinal	Colorectal	Locally advanced unresectable or metastatic colorectal cancer with the following eligibility: <ul style="list-style-type: none"><li>• in combination with irinotecan or oxaliplatin-based chemotherapy as a first-line* treatment</li><li>• in combination with a fluoropyrimidine (capecitabine or fluorouracil/leucovorin) as a first-line* treatment in patients who are unsuitable for irinotecan or oxaliplatin-based chemotherapy</li><li>• conversion therapy for borderline resectable colorectal cancer in combination with chemotherapy</li></ul>	<p>* patients with microsatellite instability-high (MSI-H) metastatic colorectal cancer who receive first-line treatment with pembrolizumab are eligible to receive chemotherapy with bevacizumab as the next line of treatment</p> <p>In the clinical setting where bevacizumab was discontinued after best response and disease progression occurred during the planned treatment break or while receiving maintenance fluoropyrimidine therapy, bevacizumab in combination with chemotherapy may be re-started at the time of disease progression</p> <p>Bevacizumab is <u>not</u> funded in the following treatment settings:</p> <ul style="list-style-type: none"><li>• in combination with a subsequent line of chemotherapy when disease progression occurred during therapy with a previous bevacizumab combination chemotherapy regimen</li><li>• in combination with 'pseudo-adjuvant' chemotherapy following metastectomy</li><li>• maintenance therapy during a treatment break following best response to irinotecan or oxaliplatin-based chemotherapy, as a single agent or in combination with fluoropyrimidine therapy</li><li>• as part of neoadjuvant therapy in patients with resectable stage IV colorectal cancer</li><li>• in combination with chemotherapy after first-line panitumumab-based therapy</li></ul>
				Gastrointestinal	Hepatocellular	Unresectable or metastatic hepatocellular carcinoma (HCC) in combination with atezolizumab as first-line treatment in patients with Child-Pugh A liver function who have stable brain metastases (if present)	<p>Patients with fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC are not eligible</p> <p>Patients treated with first-line atezolizumab and bevacizumab are eligible for either lenvatinib or sorafenib in the second-line setting</p> <p>In the clinical setting of toxicity to one of the drugs in the combination, but without evidence of disease progression, treatment may continue with the alternate drug as a single agent if clinically appropriate</p> <p>If therapy was stopped at time of best response without evidence of disease progression, treatment may be re-started at time of disease progression</p>

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bevacizumab	vial	100 mg/4 mL 400 mg/16 mL	STEP	Gynecology	Cervical	Metastatic (stage IVB), persistent or recurrent carcinoma of the cervix for all histologic subtypes, except small cell, in combination with platinum and paclitaxel as a first-line treatment  Bevacizumab in combination with platinum and paclitaxel may continue until complete response, disease progression or unacceptable toxicity, whichever occurs first	Bevacizumab is <u>not</u> funded: • to continue as a single agent if platinum and paclitaxel chemotherapy is interrupted for any reason or discontinued • in combination with any subsequent post-progression chemotherapy, with the exception of patients who discontinued bevacizumab, platinum and paclitaxel combination therapy after achieving a complete response and have maintained a progression-free interval of at least 6 months (i.e., remain platinum-sensitive) and where re-treatment with the combination of bevacizumab, platinum and paclitaxel is appropriate
				Gynecology	Cervical	Persistent, recurrent, or metastatic cervical cancer whose tumors express programmed death ligand 1 (PD-L1) (combined positive score [CPS] ≥ 1) in combination with chemotherapy and pembrolizumab as first-line treatment, including patients with stable brain metastases (if present)	Patients must <u>not</u> have had any prior systemic therapy for advanced or metastatic cervical cancer  Patients that previously received concurrent cisplatin with radiation therapy with curative intent are eligible  Bevacizumab may be continued in combination with pembrolizumab in the event chemotherapy needs to be discontinued due to toxicity; if bevacizumab needs to be discontinued due to toxicity, pembrolizumab may be continued in combination with chemotherapy
			STEP	Gynecology	Ovarian	High-risk* epithelial ovarian, fallopian tube or primary peritoneal cancer in combination with platinum and paclitaxel as a first-line treatment  Bevacizumab is given in combination with paclitaxel and platinum for 5 cycles (if chemotherapy is initiated ≤4 weeks from surgery) or for 6 cycles (if chemotherapy is initiated >4 weeks from surgery), then as a single agent for up to 12 additional cycles, or until disease progression or unacceptable toxicity, whichever occurs first	*stage III suboptimally debulked (≥1 cm residual disease), stage III unresectable or stage IV  Bevacizumab is <u>not</u> funded in combination with neoadjuvant chemotherapy prior to surgery  Bevacizumab in the maintenance phase is <u>not</u> funded in combination with olaparib or niraparib
			STEP	Gynecology	Ovarian	Recurrent, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer (PROC) in combination with paclitaxel, topotecan or pegylated liposomal doxorubicin in patients who: • have received no more than 2 prior chemotherapy regimens, except where more than 2 lines of platinum-based treatments were previously given and all were in the platinum-sensitive setting • have measurable disease that has progressed less than 6 months after completing at least 4 cycles of platinum-based therapy • do not have disease that is primary platinum-refractory (i.e., progressed during platinum therapy) • have not received bevacizumab in the first-line setting • remain sensitive to at least 1 of the approved therapies in combination with bevacizumab (i.e., have not experienced disease progression after treatment with each of paclitaxel, topotecan and pegylated liposomal doxorubicin)	Bevacizumab is <u>not</u> funded to continue as a single agent if chemotherapy is interrupted for any reason or discontinued
bicalutamide	tablet	50 mg		Genitourinary	Prostate		
binimetinib	tablet	15 mg		Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic, BRAF V600 mutation-positive melanoma in <u>combination</u> with encorafenib in patients who: • have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting • may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting • (if applicable) have had a progression-free interval of >6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib) • have stable brain metastases (if present)	If one component of the combination therapy is temporarily or permanently discontinued for toxicity or intolerance, the other drug in the combination should also be discontinued at the same time; in the clinical setting of toxicity to the combination encorafenib and binimetinib, but without evidence of disease progression, treatment may be switched to alternate BRAF-targeted therapy  Alternate BRAF-targeted therapies are not funded in any subsequent line of therapy in patients who have experienced disease progression during combination encorafenib and binimetinib treatment
bleomycin	vial	15 units		Multiple	Multiple		

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blinatumomab	vial	35 mcg		Hematology	Acute Lymphoblastic Leukemia (ALL)	Relapsed or refractory, Philadelphia chromosome- <u>negative</u> (Ph-), CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in <u>adult</u> patients who have <u>not</u> previously received inotuzumab ozogamicin, except in the potentially curative setting, defined as a goal to proceed with hematopoietic stem cell transplant (HSCT), where blinatumomab may be sequenced after inotuzumab ozogamicin due to inadequate response or unacceptable toxicity to inotuzumab ozogamicin therapy  Blinatumomab may be given for up to 2 cycles of induction and 3 cycles of consolidation therapy	Inotuzumab ozagamicin is <u>not</u> funded as a treatment option after blinatumomab, except in the potentially curative setting, defined as a goal to proceed with HSCT, where blinatumomab therapy did not result in an adequate response or where unacceptable toxicity occurred  Only <u>one</u> of blinatumomab or inotuzumab ozagamicin is funded in the palliative setting in patients not eligible for HSCT
				Hematology	Acute Lymphoblastic Leukemia (ALL)	Relapsed or refractory, Philadelphia chromosome- <u>positive</u> (Ph+), CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in <u>adult</u> patients who: • have relapsed after at least 2 tyrosine kinase inhibitor (TKI) treatments for Ph+ ALL, except in the clinical setting of an overt relapse during first-line TKI treatment, defined as the need for re-induction chemotherapy, where blinatumomab may be given as the next therapy • have <u>not</u> previously received inotuzumab ozogamicin, except in the potentially curative setting, defined as a goal to proceed with hematopoietic stem cell transplant (HSCT), where blinatumomab may be sequenced after inotuzumab ozogamicin due to inadequate response or unacceptable toxicity to inotuzumab ozogamicin therapy  Blinatumomab may be given for up to 2 cycles of induction and 3 cycles of consolidation	Inotuzumab ozagamicin is <u>not</u> funded as a treatment option after blinatumomab, except in the potentially curative setting, defined as a goal to proceed with HSCT, where blinatumomab therapy did not result in an adequate response or where unacceptable toxicity occurred  Only <u>one</u> of blinatumomab or inotuzumab ozagamicin is funded in the palliative setting in patients not eligible for HSCT
				Pediatrics	Acute Lymphoblastic Leukemia (ALL)	Relapsed or refractory, Philadelphia chromosome-negative (Ph-) B-cell precursor acute lymphoblastic leukemia (ALL) in <u>pediatric</u> patients who have no active central nervous system disease in the following settings: • second or later relapse • relapse after allogeneic hematopoietic stem cell transplant (HSCT)	
				Hematology	Acute Lymphoblastic Leukemia (ALL)	Philadelphia chromosome-negative (Ph-), CD19 positive (CD19+), B-cell precursor acute lymphoblastic leukemia (BCP-ALL) in adult and pediatric patients who are in first or second hematologic complete remission (CR) and are minimal residual disease positive (MRD+)*  Patients should have received over the course of their treatment for BCP-ALL, a minimum of 3 intensive chemotherapy blocks of a treatment regimen that is age-appropriate and given with curative-intent before proceeding to blinatumomab therapy  Treatment may be given for up to 4 cycles or until unacceptable toxicity, hematologic relapse, MRD relapse, or treatment with hematopoietic stem cell transplant (HSCT)	*MRD+ disease is defined as MRD detected at a level greater than or equal to 0.1% (i.e., >10 <sup>-3</sup> )
bortezomib	vial	3.5 mg		Hematology	Mantle Cell Lymphoma (MCL)	Relapsed or refractory mantle cell lymphoma as single agent therapy in patients who have received at least 1 prior therapy	
				Hematology	Multiple Myeloma	Multiple myeloma as part of an approved treatment protocol in first-line and relapsed treatment settings	
				Hematology	Amyloidosis	Light chain (AL) amyloidosis as part of an approved treatment protocol in first-line and relapsed treatment settings	
				Hematology	Waldenström macroglobulinemia	Waldenström macroglobulinemia in combination with rituximab and dexamethasone	
bosutinib	tablet	100 mg 500 mg		Hematology	Chronic Myeloid Leukemia (CML)	Chronic, accelerated or blast phase, Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in patients who: • have experienced disease progression, disease resistance, or intolerance during prior tyrosine kinase inhibitor (TKI) therapy	

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brentuximab vedotin	vial	50 mg		Hematology	Hodgkin Lymphoma (HL)	Relapsed, CD30-positive Hodgkin lymphoma following an autologous stem cell transplant (ASCT) in patients who (if applicable) did <u>not</u> have evidence of disease progression during or within 12 months from the last dose of brentuximab vedotin given as post-ASCT consolidation therapy	Re-treatment in the relapsed setting is funded in patients who have not experienced disease progression during or within 12 months from the last dose of consolidation brentuximab vedotin
				Hematology	Hodgkin Lymphoma (HL)	CD30-positive Hodgkin lymphoma as post-autologous stem cell transplant (ASCT) consolidation therapy in patients who are at high risk of disease progression, defined as one of the following: • refractory to front-line therapy given prior to ASCT (i.e., progressed during or did not respond to front-line therapy) • relapsed less than 12 months from completion of front-line therapy • relapsed with extranodal disease at any time after completion of front-line therapy  Consolidation brentuximab vedotin should be initiated within 4 to 6 weeks post-ASCT or upon recovery from ASCT and may continue for a maximum of 16 cycles, or until disease progression or unacceptable toxicity, whichever occurs first	If brentuximab vedotin was used as a bridge to ASCT due to insufficient response to salvage chemotherapy, the number of bridging cycles received is subtracted from the funded 16 cycles of consolidation brentuximab vedotin  Brentuximab vedotin is funded for relapsed disease following use of brentuximab vedotin for consolidation therapy post-ASCT provided there was no evidence of disease progression during or within 12 months from the last dose of brentuximab vedotin
				Hematology	Hodgkin Lymphoma (HL)	Stage IV Hodgkin lymphoma in combination with doxorubicin, vinblastine and dacarbazine (AVD) chemotherapy in previously untreated adult patients  Brentuximab vedotin in combination with AVD chemotherapy may continue for up to 6 cycles, or until disease progression or unacceptable toxicity, whichever comes first	Brentuximab vedotin is <u>not</u> funded in the following treatment settings: • stage III Hodgkin lymphoma • nodular lymphocyte-predominant histology • in combination with chemotherapy other than AVD • as maintenance following completion of brentuximab vedotin in combination with AVD chemotherapy
				Hematology	T-Cell Lymphoma	Relapsed, CD30-positive systemic anaplastic large cell lymphoma (sALCL) as single agent therapy in patients who: • have experienced disease progression after at least 1 prior multi-agent chemotherapy regimen and, if previously treated with brentuximab vedotin in the first-line setting, have had a progression-free interval of ≥6 months since the last dose of brentuximab vedotin  Brentuximab vedotin may continue for up to 16 cycles, or until disease progression or unacceptable toxicity, whichever comes first	
				Hematology	T-Cell Lymphoma	CD30-positive systemic anaplastic large-cell lymphoma* (sALCL), peripheral T-cell lymphoma not otherwise specified (PTCL-NOS) or angioimmunoblastic T-cell lymphoma (AITL) in combination with cyclophosphamide, doxorubicin and prednisone (CHP) as a first-line treatment in previously untreated patients  *an International Prognostic Index (IPI) score of ≥2 is required for anaplastic lymphoma kinase (ALK)-positive sALCL  Brentuximab vedotin may continue for up to 8 cycles, or until disease progression or unacceptable toxicity, whichever occurs first	Brentuximab vedotin is <u>not</u> funded in patients with ALK-positive sALCL with an IPI score <2  Brentuximab vedotin may be combined with cyclophosphamide, etoposide and prednisone (CEP) in patients who are not candidates for doxorubicin as part of CHP
				Hematology	T-cell Lymphoma	Relapsed, CD30-positive systemic anaplastic large cell lymphoma (sALCL), peripheral T-cell lymphoma not otherwise specified (PTCL-NOS) or angioimmunoblastic T-cell lymphoma (AITL) as single agent therapy in patients who have experienced disease progression after previous treatment with brentuximab vedotin in combination with chemotherapy in the first-line setting, and have had a progression-free interval of at least 6 months since the last dose of brentuximab vedotin  Brentuximab vedotin may continue for up to 16 cycles, or until disease progression or unacceptable toxicity, whichever comes first	
				Hematology	T-cell Lymphoma	CD30-positive* primary cutaneous anaplastic large cell lymphoma (pcALCL) or mycosis fungoides (MF) as a single agent in adult patients who have received prior systemic therapy**  Brentuximab vedotin may continue for up to 16 cycles, or until disease progression or unacceptable toxicity, whichever comes first	*CD30-positive is defined as ≥10% CD30-positive malignant cells or lymphoid infiltrate  **Brentuximab vedotin is funded in patients with pcALCL who received prior systemic therapy <u>or</u> prior radiation therapy and experienced disease progression  Brentuximab vedotin is <u>not</u> funded for CD30-positive Sézary syndrome or other subtypes of cutaneous T-cell lymphoma  Re-treatment in the relapsed setting is funded in patients who have not experienced disease progression during or within 6 months from the last dose of brentuximab vedotin

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brexucabtagene autoleucel (brexu-cel)	Cell suspension in patient-specific single infusion bag	2 x 10 <sup>6</sup> anti-CD19 CAR-positive viable T cells/kg body weight in ~68 mL	STEP	Hematology	Mantle Cell Lymphoma (MCL)	Relapsed or refractory* mantle cell lymphoma after 2 or more lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor	*relapsed or refractory disease is defined as 1 of the following: <ul style="list-style-type: none"><li>• disease progression after the last regimen or following hematopoietic stem cell transplant (relapsed)</li><li>• failure to achieve a partial response (PR) or complete response (CR) to the last regimen (refractory)</li></ul> Prior treatment must include the following: <ul style="list-style-type: none"><li>• anthracycline or bendamustine; and</li><li>• CD-20 targeted antibody; and</li><li>• Bruton's tyrosine kinase (BTK) inhibitor (e.g., ibrutinib)</li></ul>
		1 x 10 <sup>6</sup> anti-CD19 CAR-positive viable T cells/kg body weight in ~68 mL	STEP	Hematology	Acute Lymphoblastic Leukemia (ALL)	Relapsed or refractory* B-cell precursor acute lymphoblastic leukemia (B-ALL) in patients greater than or equal to 18 years of age who: <ul style="list-style-type: none"><li>*relapsed or refractory B-ALL is defined as 1 of the following:<ul style="list-style-type: none"><li>• primary refractory disease</li><li>• first relapse if first remission ≤12 months</li><li>• relapsed or refractory disease after 2 or more lines of systemic therapy</li><li>• relapsed or refractory disease after allogeneic stem cell transplant (SCT)</li></ul></li></ul>	Patients with relapsed or refractory Philadelphia chromosome positive (Ph+) B-cell precursor acute lymphoblastic leukemia (B-ALL) are funded if they are intolerant to 2 or more tyrosine kinase inhibitors (TKIs), or have relapsed or refractory disease despite treatment with 2 different TKIs  Brexu-cel is <u>not</u> funded in patients with uncontrolled central nervous system (CNS) disease
brigatinib	tablet	30 mg 90 mg 180 mg		Lung	NSCLC (ALK positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as a first-line treatment, including patients who have stable brain metastases (if present)	Patients initiated on alternate systemic treatment before molecular testing results are available may be switched to brigatinib once ALK-positivity is confirmed  Other ALK inhibitor therapies are <u>not</u> funded as a subsequent line of therapy in patients who experienced disease progression on brigatinib  Patients who develop intolerance to brigatinib may be switched to alectinib, crizotinib or lorlatinib provided no disease progression has occurred  Patients who develop intolerance to first-line alectinib, crizotinib or lorlatinib may be switched to brigatinib provided no disease progression has occurred
				Hematology	Blood and Marrow Transplant (BMT)	As part of the conditioning regimen prior to hematopoietic stem cell transplant (HSCT)	
busulfan	vial	60 mg/10 mL		Hematology	Chronic Myeloid Leukemia (CML)	Chronic myeloid leukemia (CML) when alternative treatments are not appropriate	
				Hematology	Chronic Myeloid Leukemia (CML)	Chronic myeloid leukemia (CML) when alternative treatments are not appropriate	
cabazitaxel	vial	60 mg/1.5 mL		Genitourinary	Prostate (mCRPC)	Metastatic castration-resistant prostate cancer (mCRPC) in combination with prednisone in patients who have received prior docetaxel	
cabozantinib	tablet	20 mg 40 mg 60 mg		Gastrointestinal	Hepatocellular	Unresectable or metastatic hepatocellular carcinoma (HCC) as second-line treatment in patients with Child-Pugh A liver function who have experienced disease progression during or after first-line treatment with lenvatinib or sorafenib	Cabozantinib is <u>not</u> funded in the third-line setting after second-line treatment with lenvatinib or sorafenib
				Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) for all histologic subtypes and risk categories* in patients who have received prior vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor (TKI) therapy in the following treatment settings: <ul style="list-style-type: none"><li>• as a second-line treatment before or a third-line treatment after nivolumab, in patients who have experienced disease progression during first-line VEGF TKI (sunitinib or pazopanib) treatment</li><li>• as a third-line treatment in patients with intermediate or poor-risk mRCC who have experienced disease progression with both first-line nivolumab plus ipilimumab and second-line VEGF TKI (sunitinib or pazopanib) treatments</li><li>• as a second-line treatment in patients who have experienced disease progression during axitinib plus pembrolizumab treatment</li></ul>	*determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria  Only <u>one</u> of cabozantinib or axitinib is funded in the eligible second or third-line treatment settings in patients not treated with axitinib and pembrolizumab first-line  Nivolumab is funded as a third-line treatment in patients who have experienced disease progression after 2 prior VEGF TKI therapies (e.g., sunitinib or pazopanib, followed by cabozantinib)  Third-line treatment of any kind is <u>not</u> funded in patients who received first-line axitinib plus pembrolizumab followed by second-line cabozantinib
				Head and Neck	Thyroid	Locally advanced unresectable or metastatic differentiated thyroid carcinoma* (DTC) after disease progression following prior vascular endothelial growth factor receptor (VEGFR)-targeted therapy in patients who are radioactive iodine-refractory (RAI-R) or ineligible, including patients with stable brain metastases (if present)	*patients should have a histologically or cytologically confirmed diagnosis of differentiated thyroid cancer (DTC), including the following subtypes: <ul style="list-style-type: none"><li>• papillary thyroid cancer (PTC) including histological variants of PTC such as follicular variant, tall cell, columnar cell, cribriform-morular, solid, oxyphil, Warthin-like, trabecular, tumor with nodular fasciitis-like stroma, Hürthle cell variant of papillary carcinoma, and poorly differentiated</li><li>• follicular thyroid cancer (FTC) including histological variants of FTC such as Hürthle cell, clear cell, insular, and poorly differentiated</li></ul> Patients should have received no more than 2 prior vascular endothelial growth factor receptor (VEGFR)-targeted therapies (e.g., lenvatinib)  Patients with RET-fusion positive DTC who received selpercatinib are eligible provided all other eligibility criteria are met  Cabozantinib is <u>not</u> funded for medullary thyroid cancer

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capecitabine	tablet	150 mg 500 mg		Multiple	Multiple		
carboplatin	vial	50 mg/5 mL 150 mg/15mL 450 mg/45 mL 600 mg/60 mL		Multiple	Multiple		
carfilzomib	vial	10 mg 30 mg 60 mg	STEP	Hematology	Multiple Myeloma	Multiple myeloma in combination with lenalidomide and dexamethasone (KRd regimen) in patients who have received at least 1 prior treatment, excluding prior carfilzomib-based therapies, and who have <u>not</u> experienced disease progression* during prior treatment with bortezomib or lenalidomide  Carfilzomib, as part of KRd, may continue for up to 18 cycles, or until disease progression or unacceptable toxicity, whichever occurs first, and if there is no evidence of disease progression at the time carfilzomib is stopped, lenalidomide and dexamethasone may continue until disease progression or unacceptable toxicity	*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive disease  Slow gradual biochemical changes that otherwise would qualify as disease progression for clinical trials may not be a reason to change therapy in clinical practice, unless coupled with clinical signs of disease progression, such as increased pain, need for supportive measures or renal failure
				Hematology	Multiple Myeloma	Multiple myeloma in combination with dexamethasone (Kd regimen) in patients who have received at least 1 prior treatment, excluding any prior carfilzomib-based therapy, and who have experienced disease progression* during either lenalidomide or bortezomib therapy, or with both  Carfilzomib, as part of Kd, may continue until disease progression or unacceptable toxicity	*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive disease  Cyclophosphamide may be added to carfilzomib plus dexamethasone
				Hematology	Multiple Myeloma	Relapsed or refractory** multiple myeloma in combination with isatuximab and dexamethasone (IsaKd) in patients who have received at least 1 line of prior therapy	*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive disease  **multiple myeloma must <u>not</u> be refractory to carfilzomib  If a component of IsaKd needs to be discontinued due to intolerance, the remaining components in the regimen may be continued
cemiplimab	vial	250 mg/5 mL 350 mg/7 mL		Skin and Melanoma	Cutaneous Squamous Cell Carcinoma (CSCC)	Locally advanced unresectable or metastatic cutaneous squamous cell carcinoma (CSCC) as a first-line treatment in patients who: • have histologically confirmed invasive CSCC or if mixed histologies are present, the predominant histology is invasive CSCC • are either not candidates for curative surgery or curative radiation therapy (i.e., treatment naïve) or have been previously treated with radiation and/or surgery • may or may not have relapsed or recurrent CSCC previously treated with chemotherapy  Cemiplimab may continue for up to 2 years or until symptomatic disease progression or unacceptable toxicity, which ever occurs first  (The total number of cemiplimab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	Re-treatment with cemiplimab is funded in patients who did not experience disease progression during prior treatment with cemiplimab  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
ceritinib	capsule	150 mg		Lung	NSCLC (ALK positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as a second-line treatment in patients who have experienced disease progression with crizotinib or are intolerant to crizotinib	Ceritinib is <u>not</u> funded in the following settings: • as a third or subsequent line of therapy in patients who received another ALK inhibitor in the second-line setting after crizotinib • as a second or subsequent line of therapy in patients who received first-line treatment with alectinib, brigatinib or lorlatinib

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cetuximab	vial	100 mg/50 mL 200 mg/100 mL		Gastrointestinal	Colorectal	Locally advanced unresectable or metastatic, non-mutated (wild-type) all RAS (NRAS/KRAS) colorectal cancer as a single agent or in combination with irinotecan in patients who have experienced disease progression or have an intolerance/contraindication to prior therapy containing a fluoropyrimidine, oxaliplatin and irinotecan	Cetuximab is <u>not</u> funded for the treatment of patients with wild-type all RAS (NRAS/KRAS) metastatic colorectal cancer in the first-line treatment setting in combination with chemotherapy
				Head and Neck	Squamous	Locally advanced squamous cell head and neck cancer as a first-line treatment in combination with radiation therapy in patients without distant metastases who are deemed unsuitable for cisplatin	
chlorambucil	tablet	2 mg		Hematology	Chronic Lymphocytic Leukemia (CLL)		
cisplatin	vial	50 mg/50 mL 100 mg/100 mL		Multiple	Multiple		
cladribine	vial	10 mg/10 mL		Hematology	Hairy Cell Leukemia		
clodronate	capsule	400 mg		Supportive Care	Supportive Care	Management of symptomatic, lytic bony lesions in patients with metastatic breast cancer as an oral alternative to pamidronate or zoledronic acid	
cobimetinib	tablet	20 mg		Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic BRAF V600 mutation-positive melanoma in <u>combination</u> with vemurafenib in patients who: • have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting • may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting • (if applicable) have had a progression-free interval of ≥6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib) • have stable brain metastases (if present)	In the clinical setting of toxicity to the combination of cobimetinib and vemurafenib, but without evidence of disease progression, treatment may continue, as clinically appropriate, with single agent vemurafenib (not single agent cobimetinib), or switched to alternate BRAF-targeted therapy with the combination of dabrafenib and trametinib or single agent dabrafenib or trametinib  Alternate BRAF-targeted therapies are <u>not</u> funded in any subsequent line of therapy in patients who have experienced disease progression during combination cobimetinib and vemurafenib treatment
cortisone	tablet	5 mg 25 mg		Supportive Care	Supportive Care	Glucocorticoid replacement therapy when required for patients with metastatic adrenocortical carcinoma who are treated with mitotane	
crisantaspase recombinant	vial	10 mg/0.5 mL		Hematology	Acute Lymphoblastic Leukemia (ALL)	Acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) as a component of a multidrug chemotherapeutic regimen in pediatric or adult patients with documented hypersensitivity or silent inactivation to an E. coli derived asparaginase	
crizotinib	capsule	200 mg 250 mg		Lung	NSCLC (ALK positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as a first-line treatment, including patients who have stable brain metastases (if present)	Patients initiated on alternate systemic treatment before molecular testing results are available may be switched to crizotinib once ALK-positivity is confirmed  Only <u>one</u> of alectinib or ceritinib is funded in patients who have experienced disease progression during first-line crizotinib treatment  Patients who develop intolerance to crizotinib may be switched to alectinib, brigatinib or lorlatinib provided no disease progression has occurred  Patients who develop intolerance to first-line alectinib, brigatinib or lorlatinib may be switched to crizotinib provided no disease progression has occurred
				Lung	NSCLC (ROS1 positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, ROS1-positive non-small cell lung cancer (NSCLC) as a first-line treatment in patients who have stable brain metastases (if present)	If chemotherapy was initiated as a first-line treatment prior to receiving results of ROS1 rearrangement status, treatment may be switched to crizotinib, if clinically appropriate  ROS1 testing is conducted by SHA Pathology using immunohistochemistry (IHC) for initial screening; negative IHC results for ROS1 are informative and no confirmatory assay will follow, however, tumors with equivocal or positive IHC results are forwarded for FISH testing for confirmation; treatment decisions should not be based on equivocal or positive IHC results alone  Crizotinib is not funded in patients who have experienced disease progression during first-line entrectinib treatment  Alternate ALK inhibitors (e.g., alectinib, brigatinib, ceritinib) are <u>not</u> funded for ROS1-positive NSCLC



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cyclophosphamide	vial	1 g 2 g		Multiple	Multiple		
	tablet	25 mg 50 mg		Multiple	Multiple		
cypoterone	tablet	50 mg		Genitourinary	Prostate	Prostate cancer when alternative treatments are not appropriate	
cytarabine	vial	100 mg/1 mL 500 mg/5 mL 1 g/10 mL 2 g/20 mL		Hematology	Multiple		
dabrafenib	capsule	50 mg 75 mg		Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic BRAF V600 mutation-positive melanoma as <u>single agent</u> therapy in patients who: • have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting • may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting • (if applicable) have had a progression-free interval of ≥6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib) • have stable brain metastases (if present)	In the clinical setting of toxicity to dabrafenib, but without evidence of disease progression, treatment may be switched to alternate BRAF-targeted therapy (e.g., single agent vemurafenib or trametinib or the combination of vemurafenib and cobimetinib)  Alternate BRAF-targeted therapies are <u>not</u> funded in any subsequent line of therapy in patients who have experienced disease progression during dabrafenib treatment
				Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic BRAF V600 mutation-positive melanoma in <u>combination</u> with trametinib in patients who: • have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting • may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting • (if applicable) have had a progression-free interval of ≥6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib) • have stable brain metastases (if present)	In the clinical setting of toxicity to the combination dabrafenib and trametinib, but without evidence of disease progression, treatment may continue with either dabrafenib or trametinib as a single agent, if clinically appropriate, or switched to alternate BRAF-targeted therapy (e.g., vemurafenib as a single agent or the combination of vemurafenib and cobimetinib)  Alternate BRAF-targeted therapies are <u>not</u> funded in any subsequent line of therapy in patients who have experienced disease progression during combination dabrafenib and trametinib treatment
				Skin and Melanoma	Melanoma	Stage IIIA (limited to lymph node metastases >1 mm) to stage IIID, BRAF V600 mutation-positive cutaneous melanoma (based on 8th edition of the American Joint Committee of Cancer [AJCC] staging system) in combination with trametinib as <u>adjuvant</u> treatment in patients who: • have completely resected disease, including in-transit metastases, with the exception that presence of micro-metastases in regional lymph nodes after sentinel lymph node biopsy is allowed  Dabrafenib and trametinib should start within 12 weeks from surgery and may continue for a maximum duration of 12 months from treatment initiation-or until confirmation of local disease progression, development of metastatic disease or unacceptable toxicity, whichever occurs first  (The total duration of dabrafenib should not exceed an equivalent of 12 months duration; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 12 calendar months from treatment initiation)	Dabrafenib and trametinib adjuvant therapy is <u>not</u> funded in patients with mucosal or ocular melanoma  A one-time switch to adjuvant nivolumab or pembrolizumab is allowed during the first 3 months of combination dabrafenib and trametinib treatment with the total duration of the combined adjuvant BRAF- targeted therapy and immunotherapy remaining at 12 months  Switching to the combination of vemurafenib and cobimetinib is <u>not</u> funded for patients who have experienced intolerance or disease progression during adjuvant treatment with dabrafenib and trametinib  All immunotherapy treatment options are available for patients who relapse on or any time after completion of adjuvant dabrafenib and trametinib therapy  Re-treatment with BRAF targeted therapy for recurrent or metastatic disease is funded if the progression-free interval from the completion of adjuvant dabrafenib and trametinib is ≥6 months
dacarbazine	vial	200 mg 600 mg		Multiple	Multiple		
dactinomycin	vial	0.5 mg		Multiple	Multiple		

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daratumumab	vial	100 mg/5 mL 400 mg/20 mL 1,800 mg/15 mL		Hematology	Multiple Myeloma	<p>Multiple myeloma in patients who are refractory to, or have relapsed after at least 1 prior therapy, excluding any prior daratumumab-based therapy, in <u>only one</u> of the following treatment settings for any one patient:</p> <ul style="list-style-type: none"><li>• in combination with lenalidomide and dexamethasone (DRd regimen) in patients whose disease is <u>not</u> refractory* to lenalidomide</li></ul> <p>Daratumumab, as DRd combination therapy, may continue until disease progression or unacceptable toxicity, or if intolerance occurs to 1 component in the combination, either daratumumab or lenalidomide plus dexamethasone may continue separately until disease progression or unacceptable toxicity</p> <ul style="list-style-type: none"><li>• in combination with bortezomib and dexamethasone (DVd regimen) in patients whose disease is not refractory* to bortezomib</li></ul> <p>Daratumumab, as DVd combination therapy, may continue for up to 8 cycles, with daratumumab continuing as a single agent or in combination with maintenance dosing of bortezomib until disease progression or unacceptable toxicity</p>	<p>Either DRd or DVd can be chosen depending on drug sensitivities</p> <p>*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive Disease</p> <p>Slow gradual biochemical changes that otherwise would qualify as disease progression for clinical trials may not be a reason to change therapy in clinical practice, unless coupled with clinical signs of disease progression, such as increased pain, need for supportive measures or renal failure</p> <p>Daratumumab is <u>not</u> funded in the following settings:</p> <ul style="list-style-type: none"><li>• when the disease is considered refractory to <u>both</u> lenalidomide and bortezomib</li><li>• as a treatment switch in patients intolerant of first-line therapy without evidence of disease progression</li><li>• as a single agent salvage treatment</li><li>• as part of induction prior to hematopoietic stem cell transplant (HSCT) or as consolidation or maintenance following a HSCT</li><li>• treatment of monoclonal gammopathy of undetermined significance (MGUS), smoldering myeloma or amyloidosis without evidence of concomitant myeloma</li></ul>
				Hematology	Multiple Myeloma	<p>Multiple myeloma* as a first-line treatment in combination with lenalidomide and dexamethasone (DRd) in patients who are newly diagnosed and who are not eligible for an autologous stem cell transplant (ASCT)</p> <p>Daratumumab may continue in combination with lenalidomide and dexamethasone until disease progression or unacceptable toxicity</p>	<p>*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive Disease</p> <p>Slow gradual biochemical changes that otherwise would qualify as disease progression for clinical trials may not be a reason to change therapy in clinical practice, unless coupled with clinical signs of disease progression, such as increased pain, need for supportive measures or renal failure</p> <p>Patients who experience intolerance to the lenalidomide portion of daratumumab-lenalidomide-dexamethasone (DRd) without disease progression may continue on daratumumab single agent or switch to daratumumab-cyclophosphamide-bortezomib-dexamethasone (DCyBorD)</p> <p>Daratumumab is <u>not</u> funded in the following settings:</p> <ul style="list-style-type: none"><li>• treatment of monoclonal gammopathy of undetermined significance (MGUS), smoldering myeloma or amyloidosis without evidence of concomitant myeloma</li></ul>
				Hematology	Multiple Myeloma	<p>Multiple myeloma* as a first-line treatment in combination with cyclophosphamide, bortezomib and dexamethasone (DCyBorD) in patients who are newly diagnosed and who are not eligible for an autologous stem cell transplant (ASCT)</p> <p>Daratumumab may continue as a single agent following completion of cyclophosphamide-bortezomib-dexamethasone in the DCyBorD regimen, until disease progression or unacceptable toxicity</p>	<p>*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive Disease</p> <p>Slow gradual biochemical changes that otherwise would qualify as disease progression for clinical trials may not be a reason to change therapy in clinical practice, unless coupled with clinical signs of disease progression, such as increased pain, need for supportive measures or renal failure</p> <p>Patients who experience intolerance to the bortezomib portion of daratumumab-cyclophosphamide-bortezomib-dexamethasone (DCyBorD) without disease progression may continue on daratumumab single agent or switch to daratumumab-lenalidomide-dexamethasone (DRd)</p> <p>Daratumumab is <u>not</u> funded in the following settings:</p> <ul style="list-style-type: none"><li>• treatment of monoclonal gammopathy of undetermined significance (MGUS), smoldering myeloma or amyloidosis without evidence of concomitant myeloma</li></ul>
				Hematology	Amyloidosis	<p>Light chain (AL) amyloidosis* as a first-line treatment in combination with cyclophosphamide, bortezomib and dexamethasone (DCyBorD) in patients who are newly diagnosed</p> <p>Daratumumab is administered in combination with CyBorD for 6 months followed by daratumumab as a single agent (starting in week 25) until disease progression or 24 cycles up to a maximum of 2 years</p> <p>Daratumumab should be discontinued upon occurrence of any of the following:</p> <ul style="list-style-type: none"><li>• evidence of hematologic progression or organ decompensation on treatment</li><li>• unacceptable toxicity</li><li>• maximum of 24 months of treatment</li></ul>	<p>*patients must have measurable disease and at least 1 involved organ</p> <p>Measurable disease is defined by at least one of the following:</p> <ul style="list-style-type: none"><li>• serum M protein greater than or equal to 5 g/L by protein electrophoresis; or</li><li>• abnormal serum free light chain (FLC) ratio (kappa/lambda) in patients with a serum FLC level of at least 50 mg/L; or</li><li>• difference between involved and uninvolved free light chains (dFLC) of greater than or equal to 50 mg/L</li></ul> <p>Daratumumab is <u>not</u> funded in the following settings:</p> <ul style="list-style-type: none"><li>• in patients with prior therapy for AL amyloidosis or multiple myeloma, including medications that target CD38</li><li>• in patients with a previous or current diagnosis of multiple myeloma, including the presence of lytic bone disease, plasmacytomas, greater than 60% plasma cells in the bone marrow, or hypercalcemia</li><li>• where an autologous stem cell transplant (ASCT) is planned during the first 6 cycles of treatment</li></ul>

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darolutamide	tablet	300 mg	STEP	Genitourinary	Prostate (nmCRPC)	Non-metastatic castration-resistant* prostate cancer (nmCRPC) in combination with androgen deprivation therapy (ADT) in patients who: <ul style="list-style-type: none"><li>• have histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation or small cell features</li><li>• have no detectable distant metastases by either CT, MRI or technetium-99m bone scan, including any central nervous system, vertebral or meningeal involvement, but excluding pelvic lymph nodes &lt;2 cm in short axis (N1) located below the common iliac vessels</li><li>• are at high risk of developing metastases, defined as prostate-specific antigen (PSA) doubling time (or PSADT) of ≤10 months during continuous ADT</li><li>• (if applicable) have demonstrated a further rise in PSA, measured at least 6 weeks after discontinuing treatment with a first generation anti-androgen (e.g., bicalutamide)</li></ul> Darolutamide may continue until radiographic disease progression or unacceptable toxicity	*castration-resistant prostate cancer is defined as 3 consecutive rises in PSA at least 1 week apart with the last PSA >2 mcg/L, during continuous ADT with castrate testosterone levels <1.7 nmol/L)  If biochemical progression (rising PSA) occurs while on darolutamide, appropriate clinical evaluation and/or investigations for metastatic disease should be conducted in a timely manner  If progression to <u>metastatic</u> castration-resistant prostate cancer (mCRPC) occurs during darolutamide treatment for nmCRPC, abiraterone (not enzalutamide) is funded as a subsequent treatment option in patients who are unable to tolerate or are not candidates for other therapeutic choices (i.e., chemotherapy)  If darolutamide was discontinued in the nmCRPC setting (e.g., due to intolerance) <u>prior to</u> development of metastatic disease, either abiraterone or enzalutamide is funded as an option for treatment at the time of progression to mCRPC
				Genitourinary	Prostate (mCSPC)	Metastatic castration-sensitive prostate cancer (mCSPC) in combination with docetaxel and androgen deprivation therapy (ADT) in previously untreated patients	Darolutamide is <u>not</u> funded in patients who have received prior treatment with androgen receptor axis-targeted (ARAT) therapy (e.g., abiraterone, apalutamide, enzalutamide), chemotherapy, or immunotherapy for prostate cancer  Darolutamide is <u>not</u> funded in patients who received androgen deprivation therapy (ADT) in the metastatic setting for more than 6 months or if it has been less than 1 year since completing adjuvant ADT in the non-metastatic setting  Darolutamide is also funded in patients with only regional lymph node metastases  Patients who are unable to tolerate docetaxel may continue with darolutamide and ADT
darbepoetin	prefilled syringe	300 mcg/0.6 mL 500 mcg/1 mL		Hematology	Myelodysplastic Syndromes (MDS)	Management of symptomatic anemia in patients with low or intermediate-1 risk* myelodysplastic syndromes (MDS) in patients who have a serum erythropoietin level <500 units/L and/or are receiving <2 units of red blood cell (RBC) transfusions per month  Darbepoetin is initially approved for a therapeutic trial of 12 weeks and may be continued only if evidence of benefit	*based on the International Prognostic Scoring System (IPSS)  Criteria for evaluation of darbepoetin benefit at 12 weeks: <ul style="list-style-type: none"><li>• if transfusion dependent, a decreased transfusion requirement by at least 50%</li><li>• if transfusion independent, an increase in hemoglobin by 10 g/L over baseline or a maintenance of hemoglobin between 110-120 g/L, along with alleviation of symptoms</li></ul> Darbepoetin is <u>not</u> approved for treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies
dasatinib	tablet	20 mg 50 mg 70 mg 80 mg 100 mg 140 mg		Hematology	Acute Lymphoblastic Leukemia (ALL)	Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) as induction and maintenance therapy	
				Hematology	Chronic Myeloid Leukemia (CML)	Chronic, accelerated or blast phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) as: <ul style="list-style-type: none"><li>• a first-line treatment switch in patients who were initiated on imatinib, but are experiencing a suboptimal response by not meeting established therapeutic milestones according to the Canadian Hematology Society (CHS) or European LeukemiaNet (ELN) guidelines</li><li>• a subsequent line of treatment in patients who have experienced disease progression, disease resistance or intolerance to prior tyrosine kinase inhibitor (TKI) therapy</li><li>• a first-line treatment in patients with accelerated or blast phase CML</li></ul>	

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
daunorubicin	vial	20 mg		Hematology	Acute Myeloid Leukemia (AML)		
decitabine-cesazuridine	tablet	35 mg decitabine 100 mg cesazuridine		Hematology	Myelodysplastic Syndromes (MDS)	Intermediate-1, intermediate-2, and high-risk* myelodysplastic syndromes (MDS),including de novo and secondary MDS, with the following French-American-British subtypes: refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia (CMML)	*according to the International Prognostic Scoring System (IPSS)  Decitabine/cesazuridine is <u>not</u> funded in patients with low-risk MDS according to IPSS, or very low- or low-risk MDS according to IPSS-R  Patients may have been previously treated or untreated for myelodysplastic syndromes (MDS)  Decitabine/cesazuridine may be used as a bridge to hematopoietic stem cell transplant for MDS provided all other criteria are met  Decitabine/cesazuridine is <u>not</u> funded for treatment of acute myeloid leukemia (AML)  Decitabine/cesazuridine is <u>not</u> funded in patients who have experienced disease progression on azacitidine for treatment of MDS; conversely, azacitidine is not funded in patients who have experienced disease progression on decitabine/cesazuridine for treatment of MDS  Decitabine/cesazuridine is funded in patients who have experienced disease progression on lenalidomide for patients with MDS and chromosome 5q deletion (del5q)
defibrotide	vial	200 mg/2.5 mL		Supportive Care	Blood and Marrow Transplant (BMT)	Severe or very severe* hepatic veno-occlusive disease (VOD) in adult patients following allogeneic hematopoietic stem cell transplant (HSCT)	*as defined by the European Society for Blood and Marrow Transplantation (EBMT) diagnostic and grading criteria  VOD is also known as sinusoidal obstruction syndrome (SOS)
degarelix	vial	80 mg 120 mg		Genitourinary	Prostate	Prostate cancer as androgen deprivation therapy (ADT) in patients who have <u>not</u> had a bilateral orchiectomy and are suitable candidates for an every 4 week administration schedule	Use of an anti-androgen (e.g., bicalutamide) with initiation of degarelix therapy is <u>not</u> required as degarelix is a gonadotropin-releasing hormone (GnRH) <u>antagonist</u>
dexamethasone	tablet	0.5 mg 2 mg 4 mg		Multiple	Multiple		
	vial	20 mg/5 mL		Supportive Care	Supportive Care		
dexrazoxane	vial	250 mg		Supportive Care	Supportive Care	Reducing (preventing) the incidence and severity of cardiotoxicity associated with the use of doxorubicin for the treatment of metastatic breast cancer or other solid tumors in patients who: • have received at least 300 mg/m <sup>2</sup> of doxorubicin, and • there is an ongoing indication to receive doxorubicin-based chemotherapy	
				Supportive Care	Supportive Care	Management of extravasation resulting from IV anthracycline chemotherapy	
				Pediatrics	Supportive Care	Reducing (preventing) the incidence and severity of cardiotoxicity associated with the use of doxorubicin or other anthracyclines in pediatric patients as specified in Children's Oncology Group (COG) protocols	

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
dinutuximab	vial	17.5 mg/5 mL		Pediatrics	Neuroblastoma	High-risk neuroblastoma in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2) and retinoic acid (RA) in pediatric patients who: • achieved at least a partial response to multi-agent, multi-modal therapy given in the first-line treatment setting • were initially diagnosed as non-high-risk, but subsequently relapsed and received multi-agent, multi-modal therapy for high-risk disease  Dinutuximab as combination treatment may continue for a maximum of 5 cycles, with RA only in the sixth cycle, or until disease progression or unacceptable toxicity, whichever occurs first	First-line treatment for high-risk neuroblastoma includes induction chemotherapy, consideration of surgical resection and high-dose chemotherapy followed by autologous stem cell transplant (ASCT) with or without radiotherapy  Dinutuximab is <u>not</u> funded for treatment of relapsed or refractory neuroblastoma following upfront therapy for high-risk disease  Interleukin-2 may be omitted from post-consolidation therapy with dinutuximab as currently recommended by the Children's Oncology Group  GM-CSF (sargramostim) is not commercially available in Canada and requires Health Canada Special Access Programme (SAP) approval
				Pediatrics	Neuroblastoma	Relapsed or refractory* neuroblastoma in combination with irinotecan, temozolomide and granulocyte-macrophage colony-stimulating factor (GM-CSF) in pediatric patients  Dinutuximab as combination treatment may continue for a maximum of 17 cycles in patients who demonstrate a response or clinical benefit to treatment, or until disease progression or unacceptable toxicity, whichever occurs first  Response is defined as at least a partial response as per the revised International Neuroblastoma Response Criteria (INRC); stable disease with clinical benefit includes symptomatic relief, reduction in pain or improved health-related quality of life	*refractory disease is defined as inadequate response to treatment that included at least 4 cycles of 2 or more chemotherapy agents, including an alkylator and a platinum-containing drug  Patients who received prior systemic treatment for relapsed or refractory high-risk neuroblastoma are <u>not</u> eligible  Patients treated with dinutuximab as part of initial therapy for newly diagnosed high-risk neuroblastoma remain eligible for re-treatment at time of relapsed disease; however, patients who experienced progressive disease during treatment with upfront dinutuximab are <u>not</u> eligible for dinutuximab in the refractory setting  Other chemotherapy backbones (e.g., cyclophosphamide and topotecan) may be used in combination with dinutuximab for patients who cannot tolerate irinotecan and temozolomide  GM-CSF (sargramostim) is not commercially available in Canada and requires Health Canada Special Access Programme (SAP) approval
docetaxel	vial	20 mg/2 mL 80 mg/8 mL 160 mg/16 mL		Multiple	Multiple		
doxorubicin	vial	10 mg/5 mL 50 mg/25 mL 200 mg/100 mL		Multiple	Multiple		
doxorubicin pegylated liposomal	vial	20 mg/10 mL 50 mg/25 mL		Breast	Breast, Advanced	Locally advanced unresectable or metastatic breast cancer as a single agent in patients who have an increased risk of cardiotoxicity with conventional doxorubicin	
				Gynecology	Ovarian	Advanced epithelial ovarian, fallopian tube and primary peritoneal cancer as: • a second or subsequent line of treatment as a single agent in patients who are intolerant to platinum therapy, or who have platinum-resistant or refractory disease • a second-line treatment in combination with carboplatin in patients who have platinum-sensitive disease	
				Gynecology	Ovarian	Platinum-resistant, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (PROC) in combination with bevacizumab	See bevacizumab for funding information of pegylated liposomal doxorubicin in combination with bevacizumab
				Sarcoma	Sarcoma, General	Advanced AIDS-related Kaposi's sarcoma (KS) as a first-line treatment in patients with extensive mucocutaneous or visceral disease	

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
durvalumab	vial	120 mg/2.4 mL 500 mg/10 mL	STEP	Lung	NSCLC	Locally advanced unresectable stage III, squamous or non-squamous, non-small cell lung cancer (NSCLC) following curative-intent, platinum-based concurrent chemoradiation therapy in patients who: <ul style="list-style-type: none"><li>• have received at least 2 cycles of platinum-based chemotherapy concurrently with definitive radiation therapy (defined as a target dose of 54 to 66 Gy)</li><li>• have confirmation that there is no disease progression prior to durvalumab initiation</li><li>• are deemed fit following curative-intent platinum-based concurrent chemoradiation therapy</li></ul> Durvalumab should start within 6 weeks following completion of concurrent chemoradiation therapy and may continue for a maximum of 1 year or until unacceptable toxicity or disease progression, whichever occurs first  (The total number of durvalumab cycles should not exceed an equivalent of 1 year duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 1 calendar year from treatment initiation)	Durvalumab is <u>not</u> approved following <u>sequential</u> chemoradiation therapy  Patients who require longer than 6 weeks after completion of chemoradiation to recover from unresolved toxicities will be considered for initiation of durvalumab on a case-by-case basis  Imaging for disease assessment is required at least every 3 months, or more frequently as clinically indicated  Patients will be eligible for immune checkpoint inhibitor therapy in the metastatic setting <u>only</u> if there has been at least a 6 month progression-free interval between completion of durvalumab and confirmation of disease progression  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Lung	SCLC	Extensive-stage small cell lung cancer (ES-SCLC) in combination with etoposide and platinum-based chemotherapy followed by maintenance in previously untreated patients, including patients who have stable brain metastases (if present)	Durvalumab is only funded for use in combination with etoposide and platinum (cisplatin or carboplatin) chemotherapy; use with alternate chemotherapy is <u>not</u> funded  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
encorafenib	capsule	75 mg		Gastrointestinal	Colorectal	Locally advanced unresectable or metastatic, BRAF V600E* mutation-positive colorectal cancer in combination with panitumumab in patients who have been previously treated with systemic therapy	*mutations other than BRAF V600E are <u>not</u> funded  Patients must have received at least one previous systemic treatment for metastatic colorectal cancer; patients with MSI-high metastatic colorectal cancer who are also BRAF V600E-mutation positive may receive encorafenib in combination with panitumumab as the second or subsequent line of therapy following first-line pembrolizumab  Patients must <u>not</u> have received any prior EGFR inhibitors or BRAF inhibitors  If either encorafenib or panitumumab is temporarily or permanently discontinued for toxicity or intolerance, the alternate drug in the combination should be discontinued, and single agent treatment is not permitted
				Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic, BRAF V600 mutation-positive melanoma in <u>combination</u> with binimetinib in patients who: <ul style="list-style-type: none"><li>• have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting</li><li>• may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting</li><li>• (if applicable) have had a progression-free interval of ≥6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib)</li><li>• have stable brain metastases (if present)</li></ul>	If one component of the combination therapy is temporarily or permanently discontinued for toxicity or intolerance, the other drug in the combination should also be discontinued at the same time; in the clinical setting of toxicity to the combination encorafenib and binimetinib, but without evidence of disease progression, treatment may be switched to alternate BRAF-targeted therapy  Alternate BRAF-targeted therapies are not funded in any subsequent line of therapy in patients who have experienced disease progression during combination encorafenib and binimetinib treatment
enfortumab vedotin	vial	20 mg 30 mg		Genitourinary	Urothelial, Advanced	Locally advanced unresectable or metastatic urothelial carcinoma* (mUC) as a third-line treatment in patients who: <ul style="list-style-type: none"><li>• have experienced disease progression during or following platinum-containing chemotherapy, <u>and</u> PD-1 or PD-L1 inhibitor therapy</li><li>• have stable brain metastases (if present)</li></ul>	*Urothelial carcinoma (including differentiation in squamous cells or multiple types) includes the bladder, renal pelvis, ureter or urethra  Patients must have received a platinum-containing chemotherapy regimen in either the neoadjuvant or adjuvant, locally advanced, or metastatic setting; patients who are not candidates for platinum-containing chemotherapy are eligible if alternate non-platinum-based chemotherapy regimens were administered  Patients who permanently discontinued PD-1 or PD-L1 inhibitor therapy for toxicity reasons are eligible at the time of disease progression

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Enhertu® (trastuzumab deruxtecan)	vial	100 mg		Breast	Breast, Advanced	HER2-positive unresectable or metastatic breast cancer in patients who have received at least 1 prior anti-HER2-based regimen either in the metastatic setting, or in the neoadjuvant or adjuvant setting and developed disease recurrence during or within 6 months of completing neoadjuvant or adjuvant therapy	Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test
							Patients must have been previously treated with trastuzumab and a taxane
							Patients who received prior treatment with an anti-HER2 antibody-drug conjugate (e.g., Kadcyla) in the metastatic setting are <u>not</u> eligible
							Patients who experience disease relapse within 6 months of trastuzumab in the adjuvant setting are eligible as the next line of treatment
							Patients who received prior treatment with Kadcyla in the adjuvant or neoadjuvant setting are eligible for Enhertu as a second-line option (following pertuzumab-trastuzumab-taxane chemotherapy) in the metastatic setting if the initial disease progression occurs greater than or equal to 12 months after completing adjuvant therapy with Kadcyla
							A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2-positive breast cancer
entrectinib	capsule	100 mg 200 mg		Lung	NSCLC	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, ROS1-positive non-small cell lung cancer (NSCLC) as a first-line treatment in patients who have stable brain metastases (if present)	If chemotherapy was initiated as a first-line treatment prior to receiving results of ROS1 rearrangement status, treatment may be switched to entrectinib, if clinically appropriate
							ROS1 testing is conducted by SHA Pathology using immunohistochemistry (IHC) for initial screening; negative IHC results for ROS1 are informative and no confirmatory assay will follow, however, tumors with equivocal or positive IHC results are forwarded for FISH testing for confirmation; treatment decisions should not be based on equivocal or positive IHC results alone
							Entrectinib is not funded in patients who have experienced disease progression during first-line crizotinib treatment
							Alternate ALK inhibitors (e.g., alectinib, brigatinib, ceritinib) are <u>not</u> funded for ROS1-positive NSCLC
				Tumor agnostic	NTRK	Advanced extracranial solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation with no other satisfactory treatment options as a single agent in adult patients who have:  • locally advanced cancer, but where surgical resection is likely to result in severe morbidity; or • locally advanced unresectable cancer; or • metastatic cancer; and • stable brain metastases (if present)	Patients must have a confirmed diagnosis of neurotrophic tyrosine receptor kinase (NTRK) gene fusion; empiric therapy before confirmation of NTRK gene fusion is <u>not</u> funded
							All available standard treatments for that tumor site should have been previously used, and surgery and/or radiation therapy would lead to substantial morbidity
							Patients with primary CNS tumors are <u>not</u> eligible
							Patients that experience disease progression on larotrectinib are <u>not</u> eligible to receive entrectinib, and vice versa

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enzalutamide	capsule	40 mg	STEP	Genitourinary	Prostate (nmCRPC)	Non-metastatic castration-resistant* prostate cancer (nmCRPC) in combination with androgen deprivation therapy (ADT) in patients who: <ul style="list-style-type: none"><li>• have histologically or cytologically confirmed adenocarcinoma of the prostate without neuroendocrine differentiation, signet cell features or small cell features</li><li>• have no detectable distant metastases by either CT, MRI or technetium-99m bone scan, including any central nervous system, vertebral or meningeal involvement, but excluding pelvic lymph nodes &lt;2 cm in short axis (N1) located below the common iliac vessels</li><li>• are at high risk of developing metastases, defined as prostate-specific antigen (PSA) doubling time (or PSADT) of ≤10 months during continuous ADT</li><li>• have no risk factors for seizure</li><li>• (if applicable) have demonstrated a further rise in PSA, measured at least 6 weeks after discontinuing treatment with a first generation anti-androgen (e.g., bicalutamide)</li></ul> Enzalutamide may continue until radiographic disease progression or unacceptable toxicity	*Castration-resistant prostate cancer is defined as 3 consecutive rises in PSA at least 1 week apart with the last PSA >2 mcg/L, during continuous ADT with castrate testosterone levels (<1.7 nmol/L)  If biochemical progression (rising PSA) occurs while on enzalutamide, appropriate clinical evaluation and/or investigations for metastatic disease should be conducted in a timely manner  If progression to metastatic castration-resistant prostate cancer (mCRPC) occurs during enzalutamide treatment for nmCRPC, abiraterone is funded as a subsequent treatment option in patients who are unable to tolerate or are not candidates for other therapeutic choices (i.e., chemotherapy)  If enzalutamide was discontinued in the nmCRPC setting (e.g., due to intolerance) prior to development of metastatic disease, abiraterone is funded as an option for treatment at the time of progression to mCRPC
				Genitourinary	Prostate (mCRPC)	Metastatic castration-resistant* prostate cancer (mCRPC) in patients who have not previously received and experienced disease progression during apalutamide, enzalutamide or darolutamide used in any prior treatment setting and who have no risk factors for seizure	*castration-resistant prostate cancer is defined as 3 consecutive rises in prostate-specific antigen (PSA) at least 1 week apart with the last PSA >2 mcg/L, or progression or appearance of ≥2 lesions on bone scan or in soft tissue, during continuous androgen deprivation therapy (ADT) with castrate testosterone levels (<1.7 nmol/L)
				Genitourinary	Prostate (mCSPC)	Metastatic* castration-sensitive prostate cancer (mCSPC) in combination with androgen deprivation therapy (ADT) in patients who: <ul style="list-style-type: none"><li>• have had no prior ADT in the metastatic setting, or initiated ADT within 6 months in the metastatic setting with no disease progression</li><li>• have no risk factors for seizure</li></ul> Enzalutamide may continue until disease progression or unacceptable toxicity	*metastatic prostate cancer is interpreted as distant metastatic disease (i.e., positive bone scan or metastatic lesions on radiologic imaging for soft tissue; patients with disease limited to regional pelvic lymph nodes only are not eligible)  Patients who previously received adjuvant androgen deprivation therapy (ADT) in the non-metastatic setting are eligible as long as ADT was completed ≥1 year prior to initiation of enzalutamide  Patients who received recent docetaxel chemotherapy for the treatment of metastatic castration-sensitive prostate cancer (mCSPC) within the past 3 months are eligible if they have not experienced disease progression  Patients unable to tolerate enzalutamide may be switched to either apalutamide or abiraterone plus prednisone for treatment of mCSPC if there is no disease progression  Patients who experience disease progression on enzalutamide for treatment of mCSPC are eligible for abiraterone plus prednisone for treatment of metastatic castration-resistant prostate cancer (mCRPC) if they are unable to tolerate or are not candidates for other therapeutic choices (i.e., chemotherapy) provided they have previously not experienced disease progression on abiraterone in any setting
epirubicin	vial	10 mg/5 mL 50 mg/25 mL 200 mg/100 mL		Multiple	Multiple		
eribulin	vial	1 mg/2 mL		Breast	Breast, Advanced	Locally advanced unresectable or metastatic breast cancer in patients who: <ul style="list-style-type: none"><li>• have been previously treated with both a taxane and an anthracycline</li><li>• have received at least 2 prior chemotherapy regimens and experienced disease progression with the most recent therapy</li></ul>	



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erlotinib	tablet	25 mg 100 mg 150 mg		Lung	NSCLC (EGFR positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer (NSCLC)	If chemotherapy was initiated as a first-line treatment prior to receiving results of EGFR mutation status, treatment may be switched to erlotinib, if clinically appropriate  Other EGFR inhibitors are <u>not</u> funded in any subsequent line of therapy after disease progression on erlotinib, with the exception of osimertinib for tumors with identified T790M mutations
etoposide	capsule	50 mg		Multiple	Multiple		
	vial	100 mg/ 5 mL 1 g/50 mL		Multiple	Multiple		
etoposide phosphate	vial	100 mg	SAP	Multiple	Multiple	In patients who have experienced a severe hypersensitivity reaction to conventional etoposide	
everolimus	tablet	2.5 mg 5 mg 10 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic hormone receptor-positive, HER2-negative breast cancer in combination with exemestane in post-menopausal women or in men who: • have experienced disease progression with non-steroidal aromatase inhibitor (anastrozole or letrozole) treatment • have <u>not</u> experienced disease progression during prior exemestane therapy • have <u>not</u> received prior treatment with a CDK4/6 inhibitor (e.g., palbociclib, ribociclib) in combination with endocrine therapy	Patients are eligible for <u>either</u> a CDK4/6 inhibitor (e.g., palbociclib, ribociclib) in combination with endocrine therapy <u>or</u> everolimus with exemestane as a subsequent line of treatment after progression on anastrozole or letrozole therapy alone, not both treatments
				Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) as a second-line treatment in patients who have experienced disease progression during first-line treatment with a vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor (TKI) (sunitinib or pazopanib)	Everolimus is <u>not</u> funded as a subsequent treatment in patients who receive alternate second-line treatment (e.g., axitinib, cabozantinib, nivolumab)  Third-line treatment of any kind is <u>not</u> funded in patients who have received second-line everolimus
				Neuroendocrine	Gastrointestinal or Lung Neuroendocrine Tumor (NET-GIL)	Locally advanced unresectable or metastatic, well-differentiated, neuroendocrine tumors of gastrointestinal or lung origin (NET-GIL) in patients who: • have pathologically confirmed NET-GIL with measurable disease • have documented radiologic disease progression within the previous 6 months, including patients who have experienced disease progression during or within 6 months of their last treatment with any one or a combination of a somatostatin analog, 1 line of chemotherapy and/or peptide receptor radionuclide therapy	Everolimus is <u>not</u> funded in the following settings: • in patients with poorly-differentiated neuroendocrine carcinoma, high grade neuroendocrine carcinoma, adenocarcinoid, pancreatic islet cell carcinoma, insulinoma, glucagonoma, gastrinoma, goblet cell carcinoid, large cell neuroendocrine carcinoma or small cell carcinoma • in patients previously treated with more than 1 line of chemotherapy • in patients who have received prior treatment with mTOR inhibitors (e.g., everolimus, temsirolimus, sirolimus)
				Neuroendocrine	Pancreatic Neuroendocrine Tumor (pNET)	Locally advanced unresectable or metastatic, well or moderately differentiated, pancreatic neuroendocrine tumor (pNET) in patients who have progressive disease	Only <u>one</u> of everolimus or sunitinib is funded for patients with pNET (i.e., sunitinib is not funded as a second-line treatment in patients who have experienced disease progression during everolimus treatment)
exemestane	tablet	25 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, hormone receptor-positive breast cancer as single agent treatment or in combination with everolimus in post-menopausal women or in men	Exemestane is funded in patients who have experienced disease progression during or after treatment with a non-steroidal aromatase inhibitor (anastrozole or letrozole)  See everolimus for funding information of exemestane in combination with everolimus  Refer to Appendix C - Definition of Menopause
				Breast	Breast, Early Stage	Early stage, hormone receptor-positive, breast cancer in post-menopausal women or in men: • as adjuvant therapy • as neoadjuvant therapy in patients not eligible for chemotherapy	Adjuvant therapy includes treatment for 5 to 10 years (upfront strategy), for 2 to 3 years following 2 to 3 years of treatment with tamoxifen for a total of 5 years (switch strategy) or for up to 5 years following 5 years of treatment with tamoxifen (extended strategy)  Refer to Appendix C - Definition of Menopause
				Breast	Ductal Carcinoma In-Situ (DCIS)	Hormone receptor-positive ductal carcinoma in-situ (DCIS) in post-menopausal women or in men for up to 5 years	Exemestane is <u>not</u> funded for hormone receptor-positive lobular carcinoma in-situ (LCIS)  Refer to Appendix C - Definition of Menopause

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fedratinib	capsule	100 mg	STEP	Hematology	Myeloproliferative Neoplasm (MPN)	Intermediate-2 to high-risk* myelofibrosis (MF) in patients who have: • primary MF, post-polycythemia vera MF, or post-essential thrombocythemia MF; <u>and</u> • require treatment of splenomegaly and/or disease-related symptoms from MF; <u>and</u> • have a contraindication or intolerance to ruxolitinib  Fedratinib should be discontinued in patients who demonstrate any one of the following: • progressive increase in spleen size • return of constitutional symptoms • development of serious adverse events • unacceptable toxicity or intolerance	*assessed using the Dynamic International Prognostic Scoring System-Plus (DIPSS-Plus)  Fedratinib is <u>not</u> funded in patients who experience disease progression on or following treatment with ruxolitinib
filgrastim	prefilled syringe  vial	300 mcg/0.5 mL 480 mcg/0.8 mL  300 mcg/1 mL 480 mcg/1.6 mL		Supportive Care	Supportive Care	Prevention or mitigation of neutropenic complications resulting from cancer treatment according to the following indications: • as primary prophylaxis in patients receiving an SCA approved regimen where the documented or expected incidence of febrile neutropenia has been identified as 20% or higher • as secondary prophylaxis in patients receiving curative-intent therapy following at least a 1 week dose delay due to neutropenia or an episode of febrile neutropenia <u>and</u> where further treatment delays and/or dose reductions may result in inferior outcomes • acute myeloid leukemia (AML) following induction therapy in patients age 55 or older to reduce the duration of antibiotic administration and hospital admission and after completion of consolidation therapy to reduce the duration of neutropenia in patients of any age who are in remission • as required by Blood and Marrow Transplant program protocols • prevention or mitigation of neutropenic complications resulting from cancer treatment in pediatric patients as required by Children's Oncology Group (COG) protocols	Also known as granulocyte-colony stimulating factor (G-CSF)  Filgrastim is <u>not</u> funded in the following settings: • in afebrile patients during neutropenia in an attempt to more quickly increase granulocyte counts • as adjunct therapy for the treatment of uncomplicated fever and neutropenia, defined as a fever of less than or equal to 10 days in duration with no evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction (sepsis syndrome) or invasive fungal infection and no uncontrolled malignancies • in patients with aplastic anemia
fludarabine	tablet	10 mg		Hematology	Multiple		
	vial	50 mg		Hematology	Multiple		
fludrocortisone	tablet	0.1 mg		Supportive Care	Supportive Care	Mineralocorticoid replacement therapy when required for patients treated with mitotane	
fluorouracil	vial	5 g/100 mL		Multiple	Multiple		
fosaprepitant	vial	150 mg		Supportive Care	Supportive Care	Primary prevention of acute and delayed nausea and vomiting in combination with a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone for highly emetogenic* chemotherapy  Secondary prevention of acute and delayed nausea and vomiting in combination with a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone for moderately emetogenic** chemotherapy where emesis (vomiting) is experienced despite treatment with a combination of a 5-HT3 antiemetic (e.g., ondansetron) and dexamethasone in a previous cycle	*chemotherapy considered highly emetogenic includes single day cisplatin regimens ≥40 mg/m <sup>2</sup> , single day high dose (≥850 mg/m <sup>2</sup> ) dacarbazine regimens, breast cancer regimens containing both an anthracycline and cyclophosphamide (e.g., AC, FE <sub>100</sub> C) and regimens containing carmustine or streptozocin  **chemotherapy considered moderately emetogenic includes multi-day cisplatin-based regimens (e.g., BEP), ABVD and CHOP-like regimens  Fosaprepitant is <u>not</u> funded in patients who: • have chosen to initiate and self-pay for fosaprepitant, aprepitant or Akynzeo at the time of their first cycle of chemotherapy if they do not meet formulary criteria, as their eligibility for secondary prevention cannot be assessed • are less than 18 years of age, as fosaprepitant has not been evaluated in younger patients • are receiving low emetogenic chemotherapy, even if emesis (vomiting) was experienced with a previous cycle
fulvestrant	prefilled syringe	250 mg/5 mL		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, estrogen receptor-positive, breast cancer in post-menopausal women or in men who are either: • previously untreated and HER2-negative • have experienced disease progression after prior endocrine therapy, excluding prior fulvestrant, regardless of HER2 status	Refer to Appendix C - Definition of Menopause
				Breast	Breast, Advanced	Locally advanced unresectable or metastatic, estrogen receptor-positive, HER2-negative breast cancer in combination with a CDK 4/6 inhibitor (palbociclib or ribociclib) as: • a first-line treatment, independent of prior treatment with endocrine therapy in the adjuvant setting • a subsequent line of therapy in patients who have experienced disease progression after prior treatment, which did <u>not</u> include either a CDK 4/6 inhibitor or fulvestrant	Refer to Appendix C - Definition of Menopause

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gefitinib	tablet	250 mg		Lung	NSCLC (EGFR positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, epidermal growth factor receptor (EGFR) mutation-positive non-small cell lung cancer (NSCLC)	If chemotherapy was initiated as a first-line treatment prior to receiving results of EGFR mutation status, treatment may be switched to gefitinib, if clinically appropriate  Other EGFR inhibitors are <u>not</u> funded in any subsequent line of therapy after disease progression on gefitinib, with the exception of osimertinib for tumors with identified T790M mutations
gemcitabine	vial	200 mg/5 mL 1 g/25 mL 2 g/50 mL		Multiple	Multiple		
gemtuzumab ozogamicin	vial	4.5 mg		Hematology	Acute Myeloid Leukemia (AML)	CD33-positive acute myeloid leukemia (AML) in previously untreated adult patients who have favourable, intermediate or unknown* cytogenetics (based on the European LeukemiaNet [ELN] 2017 risk classification) as: • induction therapy in combination with daunorubicin (or idarubicin) and cytarabine • consolidation therapy following complete remission in combination with either cytarabine or cytarabine and daunorubicin *If gemtuzumab ozogamicin is initiated with unknown cytogenetics and subsequently determined to be adverse, gemtuzumab ozogamicin must be discontinued  Gemtuzumab ozogamicin in combination with daunorubicin (or idarubicin) and cytarabine is given for 1 induction cycle <u>only</u> and for a maximum of 2 cycles of consolidation therapy in combination with either cytarabine or cytarabine and daunorubicin	Gemtuzumab ozogamicin is <u>not</u> approved in combination with daunorubicin (or idarubicin) and cytarabine for a second induction cycle, if required  Gemtuzumab ozogamicin is <u>not</u> funded in the following settings: • in patients who have AML with adverse cytogenetics • re-treatment in patients with relapsed or refractory AML undergoing re-induction and consolidation • in patients with acute promyelocytic leukemia (APL) • in patients with FMS-like tyrosine kinase 3 (FLT3)-mutated AML receiving midostaurin • in patients who develop AML post-cytotoxic therapy (AML-pCT) • in patients receiving alternate induction regimens (e.g., FLAG-Ida, anthracycline combined with high dose cytarabine [i.e., "super 7+3"], azactidine)
gilteritinib	tablet	40 mg	STEP	Hematology	Acute Myeloid Leukemia (AML)	Relapsed or refractory FMS-like tyrosine kinase 3 (FLT3)-mutated* acute myeloid leukemia (AML) as a single agent in adult patients whose AML is confirmed positive for the FLT3 mutation at the time of relapse or determination of refractory disease  Gilteritinib may be given for up to 6 months to allow sufficient time for response and assessment of clinical benefit, then continued as long as clinical benefit is observed, including continuation after hematopoietic stem cell transplant (HSCT) in patients who proceeded to HSCT after gilteritinib initiation, or until disease progression or unacceptable toxicity, whichever occurs first	*confirmation of FLT3 mutation status is required as AML that was positive for the FLT3 mutation at diagnosis can convert to negative in the relapsed or refractory setting and vice-versa  FLT3 mutations eligible include: FLT3-ITD, FLT3-TKD/D835, FLT3-TKD/I836  Patients previously treated with midostaurin are eligible for gilteritinib, provided all other eligibility criteria are met  Patients with therapy-related AML (t-AML) are <u>not</u> eligible for gilteritinib
glucarpidase	vial	1,000 units	SAP	Pediatrics	Supportive Care	Emergency treatment of critically high methotrexate serum concentrations (>1 micromol/L) in patients who are experiencing delayed methotrexate clearance due to impaired renal function according to Children's Oncology Group (COG) protocol	Glucarpidase is <u>not</u> indicated for use in patients who exhibit expected clearance of methotrexate (i.e., serum concentrations of methotrexate within 2 standard deviations of the mean methotrexate excretion curve specific for the last dose of methotrexate administered) or those with normal or mildly impaired renal function because of the potential risk of subtherapeutic exposure to methotrexate  Glucarpidase is not marketed in Canada and requires Health Canada Special Access Programme (SAP) approval through BTG International Inc  Glucarpidase cannot be routinely stocked in the cancer centre pharmacies or hospital, but once an emergency SAP request is initiated, drug can be shipped for on-site delivery within 24 hours
goserelin	depot syringe	3.6 mg 10.8 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, hormone receptor-positive breast cancer with the following eligibility: • as a bridge to oophorectomy in pre-menopausal women • for ovarian suppression in pre-menopausal women who are not candidates for oophorectomy • in combination with an aromatase inhibitor in men	
				Breast	Breast, Early Stage	Early stage (stages I to III), lymph node positive or negative, hormone receptor-positive breast cancer to achieve ovarian suppression prior to use of an aromatase inhibitor in pre-menopausal women where use of a gonadotropin-releasing hormone (GnRH) agonist would be preferred over surgical oophorectomy (e.g., younger age, preservation of fertility, not a surgical candidate)  Goserelin may be initiated at any time in relation to neoadjuvant or adjuvant chemotherapy (e.g., at the start, during or after), but within 8 months following completion of chemotherapy with the aromatase inhibitor initiated after completion of chemotherapy	Evidence suggests that patients who derived the most benefit from the combination of ovarian suppression (surgical or medical) and an aromatase inhibitor had sufficiently high-risk breast cancer that would warrant chemotherapy administration and were less than 35 years of age  For patients who are intolerant of an aromatase inhibitor, tamoxifen may be used in combination with goserelin  Goserelin is <u>not</u> approved for the protection of ovarian function in women of child-bearing age during chemotherapy, but may be covered through the Exception Drug Status (EDS) program of the Saskatchewan Prescription Drug Plan (SPDP)
				Genitourinary	Prostate	Prostate cancer as: • neoadjuvant and/or adjuvant treatment with a maximum therapy duration of 3 years • treatment of metastatic prostate cancer	

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hydrocortisone	vial	100 mg		Multiple	Multiple		
hydroxyurea	capsule	500 mg		Hematology	Multiple		Hydroxyurea is <u>not</u> approved for the treatment of non-malignant disorders; refer to the Saskatchewan Prescription Drug Plan (SPDP) for funding eligibility
ibrutinib	capsule	140 mg		Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) as a single agent in patients who have received at least 1 prior therapy, which may include prior CD20-targeted therapy in combination with chemotherapy or venetoclax, but excludes prior therapy with idelalisib	Patients with known CNS lymphoma, prolymphocytic leukemia, or history or suspicion of Richter syndrome are <u>not</u> eligible  Patients with unacceptable toxicity to ibrutinib may be switched to acalabrutinib or zanubrutinib provided no disease progression has occurred  Ibrutinib is <u>not</u> funded as a subsequent treatment in patients who have experienced disease progression during acalabrutinib, zanubrutinib or idelalisib treatment  CD20-targeted therapy in combination with chemotherapy is <u>not</u> funded as subsequent treatment option in patients who have experienced disease progression during ibrutinib treatment
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) as a first-line single agent in previously untreated patients who are not candidates for fludarabine-based treatment, including patients who: <ul style="list-style-type: none"><li>• have high-risk factors, including del17p, TP53 mutation, del11q, and unmutated IGHV</li><li>• have a contraindication or intolerance to chemoimmunotherapy</li><li>• are not suitable candidates for intravenous therapy</li></ul>	Patients with known CNS lymphoma, prolymphocytic leukemia, or history or suspicion of Richter syndrome are <u>not</u> eligible  Patients with unacceptable toxicity to ibrutinib may be switched to acalabrutinib provided no disease progression has occurred  Venetoclax with or without rituximab is funded as a subsequent line of therapy in patients who have experienced disease progression during first-line ibrutinib treatment, provided all other funding eligibility criteria are met  Ibrutinib is <u>not</u> funded as a subsequent treatment in patients who have experienced disease progression during acalabrutinib, zanubrutinib or idelalisib treatment  CD20-targeted therapy in combination with chemotherapy is <u>not</u> funded as a subsequent treatment option in patients who have experienced disease progression during first-line treatment with ibrutinib
				Hematology	Mantle Cell Lymphoma (MCL)	Relapsed or refractory mantle cell lymphoma (MCL) in patients who: <ul style="list-style-type: none"><li>• have received at least 1 prior rituximab-containing chemotherapy regimen with documented relapse or disease progression following the last treatment</li><li>• have no known central nervous system lymphoma</li></ul>	
idarubicin	vial	5 mg/5 mL 10 mg/10 mL		Hematology	Acute Myeloid Leukemia (AML)		
idelalisib	tablet	100 mg 150 mg		Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in patients who have received at least 1 prior therapy, which may include prior CD20-targeted therapy in combination with chemotherapy and/or venetoclax in combination with rituximab, but excludes prior therapy with ibrutinib	Patients experiencing toxicity to ibrutinib without disease progression may be switched to idelalisib single agent therapy without requirement for rituximab  Idelalisib is not funded as a subsequent treatment in patients who have experienced disease progression during ibrutinib treatment  Venetoclax in combination with rituximab is funded as a subsequent line of therapy in patient who have experienced disease progression during idelalisib treatment, provided all other funding eligibility criteria are met  CD20-targeted therapy in combination with chemotherapy is not funded as subsequent treatment option in patients who have experienced disease progression during idelalisib treatment

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ifosfamide	vial	1 g 3 g		Multiple	Multiple		
Imatinib	tablet	100 mg 400 mg		Hematology	Acute Lymphoblastic Leukemia (ALL)	Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) as induction and maintenance treatment	
				Hematology	Chronic Myeloid Leukemia (CML)	Chronic, accelerated or blast phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) as a first-line treatment	
				Sarcoma	Gastrointestinal Stromal Tumor (GIST)	Locally advanced unresectable or metastatic, c-Kit (CD117)-positive gastrointestinal stromal tumor (GIST) in patients who have not experienced disease progression during adjuvant imatinib therapy	
				Sarcoma	Gastrointestinal Stromal Tumor (GIST)	High-risk surgically resected (R0 or R1), c-Kit (CD117)-positive gastrointestinal stromal tumor (GIST) as adjuvant therapy in patients who have at least one of the following: <ul style="list-style-type: none"><li>• a tumor mass greater than 10 cm in diameter</li><li>• a tumor with greater than 10 mitoses per 50 high power field (HPF)</li><li>• a tumor mass greater than 5 cm in diameter with greater than 5 mitoses per 50 HPF</li><li>• tumor rupture</li></ul> Imatinib adjuvant therapy may continue for up to 3 years, or until disease progression or unacceptable toxicity, whichever occurs first	
				Sarcoma	Gastrointestinal Stromal Tumor (GIST)	Locally advanced, potentially resectable non-metastatic, c-Kit (CD117)-positive gastrointestinal stromal tumor (GIST) as neoadjuvant therapy	
				Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic acral or mucosal melanoma harboring a KIT mutation	
infliximab	vial	100 mg		Hematology	Blood and Marrow Transplant (BMT)	Management of graft-versus-host disease (GVHD) in patients who are refractory to other standard therapies	
Inotuzumab ozogamicin	vial	0.9 mg		Hematology	Acute Lymphoblastic Leukemia (ALL)	Relapsed or refractory, Philadelphia chromosome-negative (Ph-) or Philadelphia chromosome-positive (Ph+), CD22-positive, B-cell precursor acute lymphoblastic leukemia (ALL) in patients who: <ul style="list-style-type: none"><li>• have not previously received blinatumomab, except in the potentially curative setting, defined as a goal to proceed with hematopoietic stem cell transplant (HSCT), where inotuzumab ozogamicin may be sequenced after blinatumomab due to inadequate response or unacceptable toxicity to blinatumomab therapy</li><li>• <u>Ph+ ALL only</u>: have relapsed after at least 2 tyrosine kinase inhibitor (TKI) therapies, except in the clinical setting of an overt relapse during first-line TKI treatment, defined as the need for re-induction chemotherapy, where inotuzumab ozogamicin may be given as the next therapy</li></ul> Inotuzumab ozogamicin may be given for up to 3 cycles in patients proceeding to HSCT or for up to 6 cycles in patients not proceeding to HSCT and who achieve a complete response (CR) or complete response with incomplete count recovery (CRI) and are MRD-negative, or until disease progression or unacceptable toxicity, whichever occurs first	Blinatumomab is <u>not</u> funded as a treatment option after inotuzumab ozogamicin, except in the potentially curative setting, defined as a goal to proceed with HSCT, where inotuzumab ozogamicin therapy did not result in an adequate response or where unacceptable toxicity occurred  Only <u>one</u> of inotuzumab ozogamicin or blinatumomab is funded in the palliative setting in patients not eligible for HSCT

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Ipilimumab	vial	50 mg/10 mL 200 mg/40 mL	STEP	Genitourinary	Renal Cell Carcinoma	Intermediate or poor-risk* metastatic renal cell carcinoma, for all histologic subtypes, in <u>combination</u> with nivolumab followed by nivolumab maintenance as a first-line treatment in previously untreated patients who have an ECOG performance status of 0 or 1  Ipilimumab may be given in combination with nivolumab for up to 4 doses, followed by nivolumab single agent maintenance therapy until disease progression or unacceptable toxicity, with consideration of stopping maintenance nivolumab in patients who have responded and whose disease is well-controlled	*determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria  Repeat treatment with combination ipilimumab and nivolumab is <u>not</u> funded  If nivolumab maintenance therapy was stopped at time of best response without evidence of disease progression, nivolumab may be re-started as a single agent (i.e., ipilimumab cannot be added in combination) at time of disease progression  Vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor(TKI) therapies are funded as second-line (sunitinib or pazopanib) and third-line (axitinib or cabozantinib) treatments in patients who have experienced disease progression during treatment with ipilimumab and nivolumab  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Lung	Mesothelioma	Unresectable* malignant pleural mesothelioma (MPM) in combination with nivolumab in previously untreated patients  Treatment may continue until confirmed disease progression or unacceptable toxicity, or after completing a maximum of 2 years, whichever comes first  (The total number of cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	* Malignant pleural mesothelioma (MPM) must not be amenable to therapy with curative intent (i.e., surgery with or without chemotherapy)  Ipilimumab in combination with nivolumab is <u>not</u> funded in patients with unresectable malignant peritoneal mesothelioma  If ipilimumab in combination with nivolumab is stopped in the setting of maximum response/stable disease or after completion of 2 years of therapy, the combination may be re-started at the time of disease progression for an additional 1 year of therapy  Patients who are unable to tolerate the combination of ipilimumab and nivolumab may continue on single agent nivolumab for up to 2 years, and if discontinued without disease progression it may be re-started at the time of disease progression for an additional 1 year of therapy; re-initiation of ipilimumab at the time of any subsequent disease progression on single agent nivolumab is <u>not</u> funded  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Lung	NSCLC	Locally advanced (not amenable to curative-intent therapy), metastatic or recurrent, squamous or non-squamous, non-small cell lung cancer (NSCLC) in combination with nivolumab and 2 cycles of platinum doublet chemotherapy in previously untreated patients who have no known actionable driver mutations, including patients who: • have stable brain metastases (if present) • have large cell neuroendocrine tumors if treatment is planned using a non-small cell lung cancer (NSCLC) regimen • have any PD-L1 expression or unknown PD-L1 expression  Treatment may continue until confirmed disease progression or unacceptable toxicity, or after completing a maximum of 2 years, whichever comes first  (The total number of cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	Ipilimumab in combination with nivolumab is <u>not</u> funded in the following settings: • typical or atypical carcinoid tumors • disease progression occurring on or within 6 months following completion of consolidation durvalumab for stage III NSCLC • in combination with non-platinum-based chemotherapy  If a patient experiences severe toxicity to the first cycle of platinum-based chemotherapy, ipilimumab in combination with nivolumab may continue without further chemotherapy  If ipilimumab in combination with nivolumab is stopped in the setting of maximum response/stable disease or after completion of 2 years of therapy, the combination may be re-started at the time of disease progression for an additional 1 year of therapy  Patients who are unable to tolerate the combination of ipilimumab and nivolumab may continue on single agent nivolumab for up to 2 years, and if discontinued without disease progression it may be re-started at the time of disease progression for an additional 1 year of therapy; re-initiation of ipilimumab at the time of any subsequent disease progression on single agent nivolumab is <u>not</u> funded  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment

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ipilimumab	vial	50 mg/10 mL 200 mg/40 mL	STEP	Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic, BRAF V600 mutation-negative or positive melanoma in <u>combination</u> with nivolumab followed by nivolumab maintenance in patients who: <ul style="list-style-type: none"><li>• are previously untreated or, if BRAF V600 mutation-positive, may have received prior treatment with BRAF-targeted therapy either in the adjuvant or advanced treatment setting, or may have received prior treatment with a PD-1 inhibitor (nivolumab or pembrolizumab) in the adjuvant setting, but have had a progression-free interval of at least 6 months since the last PD-1 inhibitor dose and confirmation of disease progression</li><li>• have an ECOG performance status of 0 or 1</li><li>• have stable brain metastases, if present</li></ul> Ipilimumab may be given in combination with nivolumab for up to 4 doses, followed by nivolumab single agent maintenance therapy until disease progression or unacceptable toxicity, with consideration of stopping maintenance nivolumab in patients who have responded and whose disease is well-controlled	If nivolumab maintenance therapy was stopped at time of best response without evidence of disease progression, nivolumab may be re-started as a single agent (i.e., ipilimumab cannot be added in combination) at time of disease progression  Further immune checkpoint inhibitor therapy is <u>not</u> funded in patients who have experienced disease progression during nivolumab treatment which was initiated in combination with ipilimumab  Treatment with combination ipilimumab and nivolumab is <u>not</u> funded in the following settings: <ul style="list-style-type: none"><li>• as repeat treatment</li><li>• in patients who have experienced disease progression during or within 6 months from the last dose of PD-1 inhibitor therapy (nivolumab or pembrolizumab) in the adjuvant setting</li><li>• as subsequent treatment in patients who have experienced disease progression during single agent PD-1 inhibitor therapy (nivolumab or pembrolizumab) initiated in the advanced setting</li></ul> Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic, BRAF V600 mutation-negative or positive melanoma as a <u>single agent</u> in patients who: <ul style="list-style-type: none"><li>• have not previously received ipilimumab</li><li>• have experienced disease progression during or after PD-1 inhibitor therapy (nivolumab or pembrolizumab) initiated as <u>single agent</u> therapy in the advanced treatment setting</li><li>• have experienced disease progression during or within 6 months of receiving PD-1 inhibitor therapy (nivolumab or pembrolizumab) in the adjuvant treatment setting</li></ul> Ipilimumab may be given for up to a maximum of 4 doses in a lifetime	Ipilimumab single agent therapy is <u>not</u> funded as a subsequent treatment after PD-1 inhibitor therapy that was initiated in combination with ipilimumab  Ipilimumab is funded for up to 4 doses in a lifetime, and re-treatment is not funded  Patients are <u>not</u> eligible to continue PD-1 inhibitor therapy at the time of disease progression with the addition of ipilimumab  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
irinotecan	vial	40 mg/2 mL 100 mg/5 mL 500 mg/25 mL		Gastrointestinal	Multiple		
isotretinoin	capsule	10 mg 40 mg		Pediatrics	Neuroblastoma	As part of the protocol requirements for dinutuximab therapy in the treatment of neuroblastoma	

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
isatuximab	vial	100 mg/5 mL 500 mg/25 mL		Hematology	Multiple Myeloma	Relapsed or refractory multiple myeloma in combination with carfilzomib* and dexamethasone (IsaKd) in patients who have received at least 1 line of prior therapy	Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive Disease  *multiple myeloma must <u>not</u> be refractory to carfilzomib  Patients with primary refractory multiple myeloma are eligible, provided all other criteria are met  Isatuximab is <u>not</u> funded in patients with monoclonal gammopathy of undetermined significance (MGUS), smoldering myeloma or amyloidosis without evidence of concomitant multiple myeloma  Patients are eligible to receive only one anti-CD38 antibody for the treatment of multiple myeloma in their lifetime  Patients who experienced disease progression on daratumumab are not eligible for isatuximab and vice versa; if daratumumab was discontinued in a prior line of therapy due to intolerance without evidence of disease progression, isatuximab as part of IsaKd may be used provided all other eligibility criteria are met  If a component of IsaKd needs to be discontinued due to intolerance, the remaining components in the regimen may be continued
				Hematology	Multiple Myeloma	Relapsed or refractory* multiple myeloma in combination with pomalidomide and dexamethasone (IsaPd) in patients who have received at least 2 lines of prior therapy, including lenalidomide and a proteasome inhibitor  *must be refractory to the last line of therapy, and not have responded to therapy with lenalidomide and a proteasome inhibitor (e.g., bortezomib, carfilzomib) given alone or in combination; non-response includes disease progression on or within 60 days of stopping treatment, intolerance to lenalidomide or the proteasome inhibitor, or disease progression within 6 months after achieving at least a partial response	Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive Disease  Patients with primary refractory multiple myeloma are eligible, provided all other criteria are met  Isatuximab is <u>not</u> funded in patients with monoclonal gammopathy of undetermined significance (MGUS), smoldering myeloma or amyloidosis without evidence of concomitant multiple myeloma  Patients are eligible to receive only one anti-CD38 antibody for the treatment of multiple myeloma in their lifetime  Patients who experienced disease progression on first-line RVd will be eligible for IsaPd as the next line of therapy  Patients who experienced disease progression on daratumumab are not eligible for isatuximab and vice versa; if daratumumab was discontinued in a prior line of therapy due to intolerance without evidence of disease progression, isatuximab as part of IsaPd may be used provided all other eligibility criteria are met  If a component of IsaPd needs to be discontinued due to intolerance, the remaining components in the regimen may be continued



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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
Kadcyla® (trastuzumab emtansine)	vial	100 mg 160 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, HER2-positive breast cancer as a second-line treatment in patients who: • have experienced disease progression during first-line treatment with trastuzumab (+/- pertuzumab) in the advanced setting • (if applicable) have had disease recurrence during or within 6 months of completing adjuvant trastuzumab therapy	Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test  Further treatment with Kadcyla in the advanced setting is <u>not</u> funded in patients who have experienced disease progression during or within 6 months of completion of Kadcyla in the adjuvant setting  Trastuzumab or Kadcyla therapy initially given in the adjuvant setting is counted as 1 line of treatment for advanced disease if disease recurrence occurs during or within 6 months from completion of adjuvant therapy  Patients who received prior treatment with an anti-HER2 antibody-drug conjugate (e.g., Enhertu) in the metastatic setting are <u>not</u> eligible  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2-positive breast cancer
				Breast	Breast, Early Stage	Early stage, HER2-positive breast cancer as adjuvant therapy in female or male patients who: • have clinical stage T1 to T4, nodal stage N0 to N3, metastases stage M0, but excluding clinical stage T1aN0 or T1bN0 at presentation • have pathologically detected residual invasive disease in the surgical specimen of the breast or axillary lymph nodes following completion of neoadjuvant (pre-operative) chemotherapy in combination with trastuzumab • do <u>not</u> have clinically evident gross residual or recurrent disease following neoadjuvant (pre-operative) chemotherapy and surgery  Kadcyla adjuvant therapy may continue for a maximum of 14 cycles or 1 year of therapy, or until disease progression or unacceptable toxicity, whichever occurs first	Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test  Patients experiencing intolerance to Kadcyla may be switched to trastuzumab to complete 1 year of HER2-targeted adjuvant therapy (i.e., up to a maximum of 17 doses, including pre- and post-operative doses based on an every 3 week schedule)  Patients who experience disease recurrence on or within 6 months of completing adjuvant Kadcyla are eligible for trastuzumab, pertuzumab and taxane chemotherapy  Trastuzumab or Kadcyla therapy initially given in the adjuvant setting is counted as 1 line of treatment for advanced disease if disease recurrence occurs during or within 6 months from completion of adjuvant therapy  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2-positive breast cancer
lanreotide	prefilled syringe	60 mg 90 mg 120 mg		Neuroendocrine	Neuroendocrine	Locally advanced unresectable or metastatic, well to moderately differentiated, low to intermediate grade, somatostatin receptor-positive, gastroenteropancreatic or lung neuroendocrine tumors	
				Neuroendocrine	Neuroendocrine	Management of symptoms related to carcinoid syndrome or hypersecretion of hormones from neuroendocrine tumors in patients who have unresectable disease	
lapatinib	tablet	250 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, HER2-positive breast cancer in combination with capecitabine as: • a second-line treatment in patients who have experienced disease progression during first-line treatment with trastuzumab +/- pertuzumab in the advanced setting • a first-line treatment in patients who have experienced disease relapse either during or within 6 months of completing adjuvant trastuzumab or Kadcyla  Lapatinib may continue as a single agent after best response to combination therapy with capecitabine, until disease progression or unacceptable toxicity	Trastuzumab or Kadcyla therapy given in the adjuvant setting is counted as 1 line of treatment for advanced disease if disease recurrence occurs during or within 6 months from completion of adjuvant therapy  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2 positive breast cancer
larotrectinib	capsule	25 mg 100 mg		Tumor agnostic	NTRK	Advanced solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation with no other satisfactory treatment options as a single agent in adult and pediatric patients who have:	Patients must have a confirmed diagnosis of neurotrophic tyrosine receptor kinase (NTRK) gene fusion; empiric therapy before confirmation of NTRK gene fusion is <u>not</u> funded
	solution	2,000 mg/100 mL				• locally advanced cancer, but where surgical resection is likely to result in severe morbidity; or • locally advanced unresectable cancer; or • metastatic cancer; and • stable brain metastases (if present)	All available standard treatments for that tumor site should have been previously used, and surgery and/or radiation therapy would lead to substantial morbidity  Patients that experience disease progression on entrectinib are <u>not</u> eligible to receive larotrectinib, and vice versa

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lenalidomide	capsule	2.5 mg 5 mg 10 mg 15 mg 20 mg 25 mg		Hematology	Non-Hodgkin Lymphoma (NHL)	Relapsed or refractory indolent lymphoma in combination with rituximab in patients who are not suitable candidates for chemoimmunotherapy	
				Hematology	Multiple Myeloma	Multiple myeloma in combination with dexamethasone in patients who are not candidates for autologous stem cell transplant (ASCT) and who are refractory to, or have relapsed after at least 1 prior line of therapy including bortezomib or are intolerant to bortezomib-based therapy	
				Hematology	Multiple Myeloma	Multiple myeloma in combination with bortezomib and dexamethasone (Rvd) for up to 4 cycles in patients who are eligible for autologous stem cell transplant (ASCT) as: • induction therapy • salvage induction therapy if an adequate response was not achieved (i.e., did not achieve ≥ 50% response) after at least 2 cycles of bortezomib-based (CyBorD) induction therapy	
				Hematology	Multiple Myeloma	Multiple myeloma in combination with bortezomib and dexamethasone (Rvd) for 2 cycles as post-transplant consolidation therapy in patients who achieved a very good partial response (VGPR) or better following autologous stem cell transplant (ASCT)	Rvd consolidation therapy is <u>not</u> funded in the following settings: • in patients for whom a consolidation tandem transplant is planned • in patients who who did not receive CyBorD as part of induction, and were treated with Rvd as part of planned initial induction therapy prior to autologous stem cell transplant (ASCT)
				Hematology	Multiple Myeloma	Multiple myeloma as maintenance treatment following autologous stem cell transplant (ASCT) in patients who were newly diagnosed and who have achieved stable disease or better, with no evidence of disease progression post-transplant	
				Hematology	Multiple Myeloma	Multiple myeloma as maintenance treatment following a second autologous stem cell transplant (ASCT) in patients who did not received maintenance lenalidomide with a previous ASCT	
				Hematology	Multiple Myeloma	Multiple myeloma as a first-line treatment in combination with dexamethasone (Rd regimen) in patients who are not eligible for an autologous stem cell transplant (ASCT)	
			STEP	Hematology	Multiple Myeloma	Multiple myeloma in combination with carfilzomib and dexamethasone (KRd regimen) in patients who have received at least 1 prior treatment and have <u>not</u> experienced disease progression with prior bortezomib and lenalidomide treatment	See carfilzomib for funding information of lenalidomide in combination with carfilzomib
			STEP	Hematology	Multiple Myeloma	Multiple myeloma in combination with daratumumab and dexamethasone (DRd regimen) in patients who have received at least 1 prior therapy (which may have included prior autologous stem cell transplant), are not eligible for a second transplant and whose disease is <u>not</u> refractory to lenalidomide	See daratumumab for funding information of lenalidomide in combination with daratumumab
				Hematology	Multiple Myeloma	Multiple myeloma* as a first-line treatment in combination with bortezomib and low-dose dexamethasone (RVd) in patients who are newly diagnosed and who are not eligible for an autologous stem cell transplant (ASCT)  RVd combination therapy may continue for up 8 cycles, with lenalidomide and dexamethasone continued until disease progression or unacceptable toxicity, whichever occurs first	*Patients with light chain (AL) amyloidosis are <u>not</u> eligible for RVd, however, multiple myeloma patients with coexistent AL amyloidosis and resultant complications of the disease are eligible
				Hematology	Multiple Myeloma	Multiple myeloma* as a first-line treatment in combination with daratumumab and dexamethasone (DRd) in patients who are newly diagnosed and who are not eligible for an autologous stem cell transplant (ASCT)	*Patients with light chain (AL) amyloidosis are <u>not</u> eligible for DRd, however, multiple myeloma patients with coexistent AL amyloidosis and resultant complications of the disease are eligible
				Hematology	Myelodysplastic Syndromes (MDS)	Deletion [5q], low or intermediate-1 risk* myleodysplastic syndromes (MDS) in patients with transfusion-dependent anemia  Pre- and post-therapy transfusion records are required with demonstration of at least a 50% reduction in transfusion requirements at 6 months to support continued lenalidomide therapy	*based on the International Prognostic Scoring System (IPSS)

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lenvatinib	capsule	4 mg 10 mg	STEP	Head and Neck	Thyroid	Locally recurrent or metastatic, radioactive iodine-refractory differentiated thyroid cancer (DTC) in patients who: <ul style="list-style-type: none"><li>• meet the criteria for iodine-131 refractory disease*</li><li>• have radiologic evidence of progression within the previous 13 months</li><li>• are previously untreated or have not received more than 1 prior tyrosine kinase inhibitor (TKI) therapy</li></ul>	*Patients must meet at least 1 of the following criteria for iodine-131 refractory thyroid cancer: <ul style="list-style-type: none"><li>• have at least one measurable lesion without iodine uptake on any iodine-131 scan</li><li>• have at least one measurable lesion that has progressed according to RECIST criteria within 12 months after iodine-131 therapy despite iodine-131 avidity at the time of treatment</li><li>• have had a total lifetime radioactive iodine dose greater than 600 mCi (millicurie)</li></ul> Lenvatinib is <u>not</u> funded in patients with anaplastic or medullary thyroid cancer
				Gastrointestinal	Hepatocellular	Unresectable or metastatic hepatocellular carcinoma (HCC) as a first-line treatment in patients who: <ul style="list-style-type: none"><li>• have histologic, cytologic or clinically confirmed HCC</li><li>• have 1 or more measurable target lesions (if lesions were previously treated with radiotherapy or loco-regional therapy [e.g., transarterial chemo-embolization (TACE)] they must show radiographic evidence of disease progression to be deemed target lesions)</li><li>• have Child-Pugh A liver function <u>and</u> Barcelona Clinic Liver Cancer (BCLC) stage B or C (intermediate or advanced stage HCC with good performance status)</li><li>• have &lt;50% liver involvement with no invasion of the bile duct or main portal vein</li><li>• have <u>not</u> had prior liver transplant or have brain or leptomeningeal involvement</li></ul>	Patients who have received previous loco-regional treatment with TACE and patients who are unable to receive TACE (e.g., co-infection with hepatitis or intermediate stage HCC) remain eligible for lenvatinib as first-line systemic treatment  Only <u>one</u> of lenvatinib or sorafenib is funded as a first-line treatment for HCC (i.e., sorafenib is not funded as a second-line treatment in patients who have experienced disease progression during lenvatinib treatment)  Patients experiencing intolerance to first-line sorafenib treatment with no evidence of disease progression may switch to lenvatinib, providing all other funding criteria are met  Regorafenib is funded as a second-line treatment in patients who have experienced disease progression during lenvatinib treatment, provided all funding criteria for regorafenib are met
				Genitourinary	Renal Cell Carcinoma	Advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma (mRCC) for all histologic subtypes and risk categories* in combination with pembrolizumab as a first-line treatment in patients who: <ul style="list-style-type: none"><li>• have not received any prior therapy for mRCC, including immune checkpoint inhibitor (e.g., nivolumab plus ipilimumab) or vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor (TKIs) (e.g., sunitinib, pazopanib) therapy</li><li>• have stable brain metastases (if present)</li></ul> Lenvatinib may continue until disease progression or unacceptable toxicity; pembrolizumab may continue for up to 2 years from treatment initiation, or until disease progression or unacceptable toxicity, whichever occurs first	*determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria  Patients who received adjuvant immune checkpoint inhibitor therapy (e.g., pembrolizumab) for renal cell carcinoma are eligible provided there has been at least a 6 month progression-free interval from completion of therapy  Patients who experience intolerance to one drug in the combination of lenvatinib plus pembrolizumab may continue with either single agent lenvatinib until disease progression or unacceptable toxicity or single agent pembrolizumab up to a maximum of 2 years, disease progression or unacceptable toxicity, whichever occurs first  If lenvatinib was discontinued due to toxicity during the initial 2 year treatment period, only pembrolizumab may be re-administered at the time of disease progression for an additional 1 year of therapy; if lenvatinib was not previously discontinued due to toxicity, it may be administered concurrently with pembrolizumab during the second course at the time of disease progression  Cabozantinb is funded as a second-line treatment in patients who have experienced disease progression during first-line combination therapy with lenvatinib and pembrolizumab  Third-line treatment of any kind is <u>not</u> funded in patients who have received first-line lenvatinib plus pembrolizumab followed by second-line cabozantinb
				Gynecology	Endometrial	Unresectable or metastatic endometrial carcinoma* that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), after disease progression following prior platinum-based systemic therapy, in combination with pembrolizumab, in patients who: <ul style="list-style-type: none"><li>• are not candidates for curative surgery or radiation</li><li>• have stable brain metastases (if present)</li></ul> Lenvatinib may continue until disease progression or unacceptable toxicity; pembrolizumab may continue for up to 2 years from treatment initiation, or until disease progression or unacceptable toxicity, whichever occurs first	*Patients with pure endometrial sarcoma (e.g., leiomyosarcoma, endometrial stromal sarcoma) are <u>not</u> eligible, however, all other histologies are eligible, including endometrioid, serous, clear cell, mixed carcinoma, undifferentiated carcinoma and carcinosarcoma  Patients who cannot tolerate the combination of pembrolizumab with lenvatinib may continue with either single agent pembrolizumab up to 2 years, disease progression or unacceptable toxicity, or single agent lenvatinib until disease progression or unacceptable toxicity  If lenvatinib was discontinued due to toxicity during the initial 2 year treatment period, only pembrolizumab may be re-administered at the time of disease progression for an additional 1 year of therapy; if lenvatinib was not previously discontinued due to toxicity, it may be administered concurrently with pembrolizumab during the second course at the time of disease progression

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letrozole	tablet	2.5 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, hormone receptor-positive breast cancer in post-menopausal women or in men	See palbociclib or ribociclib for letrozole in combination with CDK 4/6 inhibitor therapy  Refer to Appendix C - Definition of Menopause
				Breast	Breast, Early Stage	Early stage, hormone receptor-positive breast cancer in post-menopausal women or in men: <ul style="list-style-type: none"><li>• as adjuvant therapy</li><li>• as neoadjuvant therapy in patients not eligible for chemotherapy</li></ul>	Adjuvant therapy includes treatment for 5 to 10 years (upfront strategy), for 2 to 3 years following 2 to 3 years of treatment with tamoxifen for a total of 5 years (switch strategy) or for up to 5 years following 5 years of treatment with tamoxifen (extended strategy)  Refer to Appendix C - Definition of Menopause
				Breast	Ductal Carcinoma In-Situ (DCIS)	Hormone receptor-positive ductal carcinoma in-situ (DCIS) in post-menopausal women or in men for up to 5 years	Letrozole is <u>not</u> funded for hormone receptor-positive lobular carcinoma in-situ (LCIS)  Refer to Appendix C - Definition of Menopause
				Gynecology	Multiple	Recurrent or progressive, hormone receptor-positive endometrial, epithelial ovarian, fallopian tube or primary peritoneal cancers	
				Gynecology	Uterine Sarcoma	Advanced, hormone receptor-positive uterine sarcoma in post-menopausal women	Refer to Appendix C - Definition of Menopause
leucovorin	tablet	5 mg		Supportive Care	Supportive Care		
	vial	50 mg/5 mL 500 mg/50 mL		Supportive Care	Supportive Care		
leuprolide (Lupron®)	prefilled syringe	7.5 mg 22.5 mg 30 mg		Genitourinary	Prostate	Prostate cancer as: <ul style="list-style-type: none"><li>• neoadjuvant and/or adjuvant treatment with a maximum therapy duration of 3 years</li><li>• treatment of metastatic prostate cancer</li></ul>	Leuprolide is <u>not</u> approved for the protection of ovarian function in women of child-bearing age during chemotherapy, but may be covered through the Exception Drug Status (EDS) program of the Saskatchewan Prescription Drug Plan (SPDP)
leuprolide (Eligard®)	prefilled syringe	7.5 mg 22.5 mg 30 mg 45 mg		Genitourinary	Prostate	Prostate cancer as: <ul style="list-style-type: none"><li>• neoadjuvant and/or adjuvant treatment with a maximum therapy duration of 3 years</li><li>• treatment of metastatic prostate cancer</li></ul>	
lomustine	capsule	10 mg 40 mg 100 mg		Central Nervous System	Glioma		
lorlatinib	tablet	25 mg 100 mg		Lung	NSCLC (ALK positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) as a first-line treatment, including patients who have stable brain metastases (if present)	Patients initiated on alternate systemic treatment before molecular testing results are available may be switched to lorlatinib once ALK-positivity is confirmed  Other ALK inhibitor therapies are not funded as a subsequent line of therapy in patients who experienced disease progression on lorlatinib  Patients who develop intolerance to lorlatinib may be switched to alectinib, brigatinib or crizotinib provided no disease progression has occurred  Patients who develop intolerance to first-line alectinib, brigatinib or crizotinib may be switched to lorlatinib provided no disease progression has occurred
luspatercept	vial	25 mg 75 mg	STEP	Hematology	Myelodysplastic Syndromes (MDS)	Management of very low- to intermediate-risk* myelodysplastic syndromes (MDS)-associated anemia in patients who: <ul style="list-style-type: none"><li>• have ring sideroblasts; and</li><li>• are red blood cell (RBC) transfusion dependent (RBC transfusions of an average of at least ≥2 units per 8 weeks); and</li><li>• are refractory to or not suitable for erythropoietin-based therapy</li></ul>	*based on the International Prognostic Scoring System - Revised (IPSS-R)  Patients not suitable for erythropoietin-based therapy are defined as patients unlikely to respond to erythropoietin (an endogenous EPO level > 200 units/L in those not previously treated with erythropoiesis-stimulating agents) or who discontinued a prior erythropoiesis-stimulating agent (ESA) due to adverse events or intolerance  Refractory to a prior ESA is defined as a non-response or response that is no longer maintained to a prior ESA-containing regimen of either: <ul style="list-style-type: none"><li>• recombinant human erythropoietin (rHu EPO) ≥ 40,000 international units/week for at least 8 doses</li><li>• darbepoetin alpha ≥ 500 mcg every 3 weeks for at least 4 doses</li></ul> Responding patients should be assessed every 6 months at a minimum, and remain transfusion independent to continue with luspatercept; transfusion independence can be considered maintained if unexpected RBC transfusions are required because of intercurrent illness

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Lutathera® ( <sup>177</sup> Lu-dotate)	vial	7.4 GBq (370 MBq/mL)	STEP	Neuroendocrine	Gastroenteropancreatic Neuroendocrine Tumor (GEP-NET)	Unresectable, well differentiated midgut* neuroendocrine tumors (NET) in patients who have experienced radiographic disease progression during somatostatin analog therapy (e.g., octreotide, lanreotide)  Lutathera ( <sup>177</sup> Lu-dotate) may be given for a maximum of 4 doses or until disease progression or unacceptable toxicity	*midgut NET includes those originating from the jejunioileum or proximal colon  Lutathera ( <sup>177</sup> Lu-dotate) can only be ordered and administered by the Nuclear Medicine department  Lutathera is <u>not</u> funded in the following settings: <ul style="list-style-type: none"><li>• in patients who have foregut, hindgut, pancreatic or lung NET</li><li>• as maintenance therapy or re-treatment after 4 doses</li></ul>
			STEP	Neuroendocrine	Pancreatic Neuroendocrine Tumor (pNET)	Unresectable or metastatic, well differentiated, somatostatin receptor (SSR)-positive pancreatic neuroendocrine tumors (pNETs) in patients who have experienced radiographic disease progression during somatostatin analog therapy (e.g., octreotide, lanreotide)  Lutathera ( <sup>177</sup> Lu-dotate) may be given for a maximum of 4 doses or until disease progression or unacceptable toxicity	Lutathera ( <sup>177</sup> Lu-dotate) can only be ordered and administered by the Nuclear Medicine department  Patients who are not able to receive a somatostatin analog due to a contraindication or severe intolerance (e.g., anaphylaxis) remain eligible  Patients remain eligible for Lutathera if they previously received other systemic therapy for pNET (e.g., everolimus, sunitinib, chemotherapy) provided all other eligibility criteria are met; conversely, patients remain eligible for systemic therapy following discontinuation of Lutathera  Lutathera is <u>not</u> funded as maintenance therapy or re-treatment after 4 doses
medroxyprogesterone	tablet	5 mg 10 mg 100 mg		Gynecology	Endometrial		
megestrol	tablet	40 mg 160 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, progesterone receptor-positive breast cancer	
				Genitourinary	Prostate	Prostate cancer when alternative treatments are not appropriate	
				Gynecology	Endometrial	Recurrent, inoperable or metastatic endometrial cancer	
				Gynecology	Uterine Sarcoma	Advanced hormone receptor-positive uterine sarcoma	
				Supportive Care	Supportive Care	Symptomatic management of: <ul style="list-style-type: none"><li>• anorexia, cachexia or weight loss secondary to advanced cancer only if other standard treatments have not been beneficial</li><li>• hot flashes associated with androgen deprivation therapy in prostate cancer</li></ul>	Megestrol oral suspension is not funded
melphalan	tablet	2 mg		Hematology	Multiple Myeloma		
	vial	50 mg		Hematology	Blood and Marrow Transplant (BMT)		
memantine	tablet	10 mg		Supportive Care	Supportive Care	Prevention of neurocognitive decline in patients with brain metastases receiving whole brain radiation  Memantine may be given for up to 6 months	
mercaptopurine	tablet	50 mg		Hematology	Acute Lymphoblastic Leukemia (ALL)		
mesna	vial	1 g/10 mL		Supportive Care	Supportive Care		
methotrexate	tablet	2.5 mg 10 mg		Multiple	Multiple		
	vial	20 mg/2 mL 50 mg/2 mL 500 mg/20 mL 2.5 g/100 mL		Multiple	Multiple		
methoxsalen	solution	200 mcg/10 mL		Hematology	T-Cell Lymphoma	Cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides) in combination with PUVA light therapy	Methoxalen is prepared by compounding pharmacies with the cost reimbursed to patients on a case-by case basis

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midostaurin	capsule	25 mg		Hematology	Acute Myeloid Leukemia (AML)	Newly diagnosed, FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML) in combination with standard cytarabine and daunorubicin (or idarubicin) induction therapy and cytarabine consolidation therapy	Midostaurin is <u>not</u> funded in the following: <ul style="list-style-type: none"><li>• in combination with alternate induction regimens, such as FLAG-Ida or NOVE-HIDAC</li><li>• as part of re-induction or re-consolidation treatment in patients who have relapsed or have refractory AML</li><li>• as part of induction or consolidation treatment for acute myeloid leukemia post-cytotoxic therapy (AML-pCT) which has occurred after prior chemotherapy for another cancer or disorder</li><li>• as part of maintenance therapy following completion of cytarabine consolidation therapy</li></ul>
mitomycin	vial	20 mg		Gastrointestinal	Anal	Anal cancer as part of combined modality therapy	
				Genitourinary	Bladder (non-muscle invasive)	Non-muscle invasive bladder cancer as intravesical therapy	
				Genitourinary	Bladder (locally advanced)	Muscle-invasive bladder cancer as part of combined modality therapy	
				Miscellaneous	Miscellaneous	Conjunctival melanoma or ocular surface squamous neoplasia (also known as conjunctival-corneal intraepithelial neoplasia [CCIN]) as a topical treatment	
mitotane	tablet	500 mg		Neuroendocrine	Adrenocortical	Unresectable adrenocortical carcinoma, including both functional and non-functional types	
mitoxantrone	vial	20 mg/10 mL		Multiple	Multiple		
nelarabine	vial	5 mg/mL		Pediatrics	T-Cell Acute Lymphoblastic Leukemia (T-ALL)	Intermediate- and high-risk T-cell acute lymphoblastic leukemia (T-ALL) in addition to front-line multi-agent chemotherapy in patients aged 1-30 years  Treatment with nelarabine in combination with multi-agent chemotherapy is permitted for up to 6 courses, and must be discontinued due to disease progression or unacceptable toxicity, whichever comes first	Patients must <u>not</u> have received any chemotherapy (except for steroids or intrathecal chemotherapy) prior to the induction phase  Nelarabine is <u>not</u> funded in patients with low-risk T-cell acute lymphoblastic leukemia (T-ALL)
nilotinib	capsule	150 mg 200 mg		Hematology	Chronic Myeloid Leukemia (CML)	Chronic or accelerated phase, Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) as a second-line treatment in patients who have primary or acquired resistance to imatinib	
				Hematology	Chronic Myeloid Leukemia (CML)	Chronic or accelerated phase, Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) as: <ul style="list-style-type: none"><li>• a first-line treatment switch in patients who were initiated on imatinib, but are experiencing a suboptimal response by not meeting established therapeutic milestones according to the Canadian Hematology Society (CHS) or European LeukemiaNet (ELN) guidelines</li><li>• a subsequent line of treatment in patients who have experienced disease progression, disease resistance or intolerance to prior tyrosine kinase inhibitor (TKI) therapy</li><li>• a first-line treatment in patients with accelerated CML</li></ul>	Nilotinib is <u>not</u> approved for blast phase Ph+ CML or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ALL)
niraparib	capsule, tablet	100 mg		Gynecology	Ovarian	Advanced* epithelial ovarian, fallopian tube or primary peritoneal cancer with high grade serous or endometrioid histology, as single agent maintenance treatment in newly diagnosed patients who: <ul style="list-style-type: none"><li>• have achieved a complete or partial response after at least 4 cycles of first-line platinum-based chemotherapy, confirmed by radiologic imaging within 4 weeks of initiating niraparib maintenance</li><li>• have stable brain metastases (if present)</li></ul> *FIGO (International Federation of Gynecology and Obstetrics) stage III (with or without upfront or interval debulking surgery) or stage IV  Niraparib maintenance therapy should be initiated within 12 weeks from the last chemotherapy treatment and may continue for up to 3 years, or until disease progression or unacceptable toxicity, whichever occurs first	Platinum-based therapy includes intravenous or peritoneal treatment, and treatment given before (neoadjuvant) or after surgery  For patients who received bevacizumab in combination with platinum-based therapy as first-line treatment, <u>only one</u> of bevacizumab or niraparib maintenance is funded (i.e., bevacizumab and niraparib are <u>not</u> funded in combination)  Patients who received non-platinum-based chemotherapy (i.e., platinum contraindication or switched to non-platinum-based chemotherapy in the setting of intolerance) are eligible for niraparib maintenance therapy providing all other criteria are met  Patients with BRCA-mutated disease may be switched to olaparib in cases of unacceptable toxicity to niraparib, provided no disease progression has occurred  Niraparib maintenance therapy is <u>not</u> funded in patients with early stage disease (FIGO stage I to IIC) who may or may not have received adjuvant chemotherapy
				Gynecology	Ovarian	Relapsed, platinum-sensitive*, epithelial ovarian, fallopian tube, or primary peritoneal cancer with high grade serous or endometrioid histology as single agent maintenance treatment in patients who: <ul style="list-style-type: none"><li>• have completed at least 2 previous lines of platinum-based chemotherapy</li><li>• have achieved a complete or partial response to the most recent platinum-based chemotherapy regimen, confirmed by radiologic imaging within 4 weeks of initiating niraparib</li><li>• have received at least 4 cycles of the most recent platinum-based chemotherapy before niraparib initiation</li><li>• have stable brain metastases (if present)</li></ul> Niraparib maintenance therapy should be initiated within 12 weeks of the last chemotherapy treatment and may continue until disease progression or unacceptable toxicity, whichever occurs first	*platinum-sensitive relapsed disease is defined as disease progression occurring 6 months or later after completion of prior platinum-based chemotherapy  Patients who are platinum-sensitive, but received non-platinum-based chemotherapy (i.e., platinum contraindication or switched to non-platinum-based chemotherapy in the setting of intolerance) are eligible for niraparib maintenance therapy providing all other criteria are met  Patients with BRCA-mutated disease may be switched to olaparib in cases of unacceptable toxicity to niraparib, provided no disease progression has occurred

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nivolumab	vial	40 mg/4 mL 100 mg/10 mL	STEP	Gastrointestinal	Esophageal and Gastroesophageal Junction (GEJ)	Stage II or III completely resected esophageal or gastroesophageal junction cancer (GEJ)* in patients who have residual pathologic disease** following completion of neoadjuvant chemoradiotherapy (CRT), as adjuvant treatment  Nivolumab should be initiated within 4 to 16 weeks following complete resection  Treatment with nivolumab may continue for up to 1 year of adjuvant therapy, or until confirmed disease progression or unacceptable toxicity, whichever comes first  (If there are temporary nivolumab dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 1 calendar year from treatment initiation)	*patients must have histologically confirmed predominant adenocarcinoma or squamous cell carcinoma of the esophagus or gastroesophageal junction  **there must be residual pathologic disease, with a tumor and node classification status of ypT1 or ypN1 at minimum  The total number of cycles should not exceed an equivalent of 1 year duration regardless of schedule (e.g., if 240 mg is administered every 2 weeks for 8 doses, then 480 mg would be administered every 4 weeks for 9 doses for a total of 17 doses or 1 year duration)  Patients remain eligible for nivolumab or pembrolizumab for treatment of advanced or metastatic disease, provided there has been no disease progression within 6 months following completion of adjuvant nivolumab, and all other eligibility criteria are met  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Gastrointestinal	Esophageal, Gastroesophageal Junction (GEJ) and Gastric	Locally advanced unresectable or metastatic, HER2-negative gastric adenocarcinoma (GAC), gastroesophageal junction adenocarcinoma (GEJAC) or esophageal adenocarcinoma (EAC) as first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy, including patients with stable brain metastases (if present)  Nivolumab may continue for a maximum duration of 2 years from treatment initiation or until confirmed disease progression or unacceptable toxicity, whichever occurs first  (The total number of nivolumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	Patients must be previously untreated in the advanced or metastatic setting  Only patients with predominant adenocarcinoma histology are eligible  While awaiting HER2 test results, chemotherapy can be started alone, and nivolumab can be added once HER2-negative status is confirmed  Patients are eligible if they have an unknown HER2 status because it cannot be determined; if HER2 status subsequently becomes available and is confirmed positive, nivolumab must be discontinued  Patients who experience disease progression on or within 6 months following completion of adjuvant nivolumab or any other immunotherapy are not eligible  Nivolumab may be continued in combination with one component of the chemotherapy regimen or as a single agent in patients who cannot tolerate chemotherapy  If nivolumab is stopped in the setting of maximum response/stable disease or after completion of 2 years of therapy without disease progression, it may be re-started as a single agent or in combination with chemotherapy at the time of disease progression for an additional 1 year of therapy  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment

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nivolumab	vial	40 mg/4 mL 100 mg/10 mL		Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) as a <u>single agent</u> second or third-line treatment in patients who have experienced disease progression during first-line vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI) therapy (sunitinib or pazopanib) or after both first and second-line VEGF TKI therapy (sunitinib or pazopanib followed by axitinib or cabozantinib)  Nivolumab may be continued until confirmed disease progression or unacceptable toxicity, with a consideration to stop nivolumab in patients who have responded and whose disease is well-controlled	If nivolumab was stopped at the time of best response without evidence of disease progression, nivolumab may be re-started at the time of disease progression  Nivolumab is <u>not</u> funded as a subsequent line of therapy in patients who have experienced disease progression during or after first-line pembrolizumab and axitinib combination therapy  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
			STEP	Genitourinary	Renal Cell Carcinoma	Intermediate or poor-risk* metastatic renal cell carcinoma, for all histologic subtypes, in <u>combination</u> with ipilimumab followed by nivolumab maintenance as a first-line treatment in previously untreated patients who have an ECOG performance status of 0 or 1  Nivolumab may be given in combination with ipilimumab for up to 4 doses, followed by nivolumab single agent maintenance therapy until disease progression or unacceptable toxicity, with a consideration to stop maintenance nivolumab in patients who have responded and whose disease is well-controlled	*Determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria  Repeat treatment with combination ipilimumab and nivolumab is not funded  If nivolumab maintenance therapy was stopped at the time of best response without evidence of disease progression, nivolumab may be re-started as a single agent (i.e., ipilimumab cannot be added in combination) at time of disease progression  Vascular endothelial growth factor (VEGF) receptor tyrosine kinase (TKI) inhibitor therapies are funded in the second-line (sunitinib or pazopanib) or third-line (axitinib or cabozantinib) in patients who have experienced disease progression during or after treatment with ipilimumab and nivolumab combination therapy  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Genitourinary	Urothelial, Adjuvant	<u>Adjuvant</u> treatment of patients with muscle-invasive urothelial carcinoma (UC)* as a single agent in patients who are at high risk of recurrence following radical surgical resection**  Nivolumab should be initiated within 120 days following completion of local therapy; evidence of no recurrence must be confirmed before initiating therapy  Treatment with nivolumab may continue for up to 1 year of adjuvant therapy, or until confirmed disease progression or unacceptable toxicity, whichever comes first  (The total number of nivolumab cycles should not exceed an equivalent of 1 year duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 1 calendar year from treatment initiation, provided there has been no disease progression during the interruption, and the time to complete the planned cycles does not exceed 2 years)	*Urothelial carcinoma includes carcinoma of the renal pelvis, ureter, bladder or urethra  **High risk of recurrence based on pathologic evidence and staging of radical surgery tissue is defined as follows: • have received neoadjuvant cisplatin-based chemotherapy and have stage ypT2-T4a or ypN+ • have not received neoadjuvant cisplatin-based chemotherapy and have stage pT3-T4a or pN+ and are ineligible (based on 2011 Galsky ineligibility criteria <sup>†</sup> ) or decline adjuvant cisplatin-based chemotherapy  <sup>†</sup> Galsky criteria includes any of the following: creatinine clearance <60 mL/min, ≥grade 2 audiometric hearing loss, ≥grade 2 peripheral neuropathy, poor performance status, NYHA class 3 or 4 heart failure  Patients who received a partial cystectomy or partial nephrectomy are eligible provided all other eligibility criteria are met  Patients should have negative margins (R0) following radical surgery  Patients remain eligible for funded immunotherapy options for treatment of advanced or metastatic urothelial cancer, provided there has been no disease progression within 6 months following completion of adjuvant nivolumab, and all other eligibility criteria are met  Patients should be assessed for disease recurrence at least every 3 months, or more frequently as clinically indicated during adjuvant nivolumab therapy
				Head and Neck	Squamous	Locally advanced unresectable or metastatic, head and neck squamous cell cancer (HNSCC) as a <u>single agent</u> in patients who have experienced disease recurrence within 6 months from prior curative-intent neoadjuvant and/or adjuvant platinum-based therapy or have experienced disease progression after prior platinum-based therapy given in the advanced disease setting  Nivolumab may be continued until confirmed disease progression or unacceptable toxicity, with a consideration to stop nivolumab in patients who have responded and whose disease is well-controlled	Patients with intolerance or contraindication to platinum-based therapy will be eligible for nivolumab therapy either after non-platinum chemotherapy or without the requirement for any chemotherapy  If nivolumab was stopped at the time of best response without evidence of disease progression, nivolumab may be re-started at the time of disease progression  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment



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nivolumab	vial	40 mg/4 mL 100 mg/10 mL		Hematology	Hodgkin Lymphoma (HL)	Relapsed or refractory, classical Hodgkin lymphoma* (cHL) as a single agent in patients who have experienced disease progression, excluding central nervous system involvement, after having received <u>both</u> an autologous stem cell transplant (ASCT) and brentuximab vedotin  Nivolumab may be continued until confirmed disease progression or unacceptable toxicity, with a consideration to stop nivolumab in patients who have responded and whose disease is well-controlled	*cHL subtypes include: nodular sclerosis, mixed cellularity, lymphocyte-rich and lymphocyte-depleted  If nivolumab was stopped at the time of best response without evidence of disease progression, nivolumab may be re-started at the time of disease progression  Nivolumab is <u>not</u> funded in patients who have central nervous system lymphoma or nodular lymphocyte-predominant Hodgkin lymphoma  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Lung	Mesothelioma	Unresectable* malignant pleural mesothelioma (MPM) in combination with ipilimumab in previously untreated patients  Treatment may continue until confirmed disease progression or unacceptable toxicity, or after completing a maximum of 2 years, whichever comes first  (The total number of cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	*Malignant pleural mesothelioma (MPM) must not be amenable to therapy with curative intent (i.e., surgery with or without chemotherapy)  Nivolumab in combination with ipilimumab is <u>not</u> funded in patients with unresectable malignant peritoneal mesothelioma  If nivolumab in combination with ipilimumab is stopped in the setting of maximum response/stable disease or after completion of 2 years of therapy, the combination may be re-started at the time of disease progression for an additional 1 year of therapy  Patients who are unable to tolerate the combination of nivolumab and ipilimumab may continue on single agent nivolumab for up to 2 years, and if discontinued without disease progression it may be re-started at the time of disease progression for an additional 1 year of therapy; re-initiation of ipilimumab at the time of any subsequent disease progression on single agent nivolumab is <u>not</u> funded  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment

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nivolumab	vial	40 mg/4 mL 100 mg/10 mL		Lung	NSCLC	<p>Neoadjuvant treatment of adult patients with resectable non-small cell lung cancer (NSCLC) (tumors <math>\geq</math> 4 cm or node positive), in combination with platinum-doublet chemotherapy</p> <p>Treatment with nivolumab in combination with platinum-doublet chemotherapy may continue for up to 3 cycles, until confirmed disease progression or unacceptable toxicity, whichever comes first</p>	<p>Neoadjuvant nivolumab is <u>not</u> funded in the following settings:</p> <ul style="list-style-type: none"><li>• contraindications to platinum-doublet chemotherapy as per clinical judgment</li><li>• unresectable or metastatic disease</li><li>• known EGFR mutations or ALK translocations</li><li>• large cell neuroendocrine carcinoma tumor histology</li></ul> <p>Nivolumab may be continued as a single agent to complete 3 cycles in the event platinum-doublet chemotherapy needs to be discontinued due to intolerance</p> <p>Patients who receive a full course (3 cycles) of nivolumab in the neoadjuvant setting are not eligible for further immunotherapy (e.g., atezolizumab) in the adjuvant setting</p> <p>Patients with stage IIA to IIIB non-small cell lung cancer (NSCLC) who are subsequently found to be EGFR-mutation positive following neoadjuvant nivolumab with platinum-doublet chemotherapy remain eligible for adjuvant osimertinib following neoadjuvant nivolumab with platinum-doublet chemotherapy provided all other eligibility criteria for osimertinib are met</p> <p>Patients who cannot proceed to surgery (e.g., identification of unresectable stage III NSCLC) are eligible for concurrent chemoradiation followed by durvalumab provided all other eligibility criteria are met</p> <p>Patients who are subsequently found to have stage IV disease during or following neoadjuvant nivolumab (e.g., brain metastases, incidental metastases discovered) will be eligible for all funded immunotherapy options for metastatic NSCLC</p>
				Lung	NSCLC	<p>Locally advanced (not amenable to curative-intent therapy), metastatic or recurrent, squamous or non-squamous, non-small cell lung cancer (NSCLC) in combination with ipilimumab and 2 cycles of platinum doublet chemotherapy in previously untreated patients who have no known actionable driver mutations, including patients who:</p> <ul style="list-style-type: none"><li>• have stable brain metastases (if present)</li><li>• have large cell neuroendocrine tumors if treatment is planned using a non-small cell lung cancer (NSCLC) regimen</li><li>• have any PD-L1 expression or unknown PD-L1 expression</li></ul> <p>Treatment may continue until confirmed disease progression or unacceptable toxicity, or after completing a maximum of 2 years, whichever comes first</p> <p>(The total number of cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>Nivolumab in combination with ipilimumab is <u>not</u> funded in the following settings:</p> <ul style="list-style-type: none"><li>• typical or atypical carcinoid tumors</li><li>• disease progression occurring on or within 6 months following completion of consolidation durvalumab for stage III NSCLC</li><li>• in combination with non-platinum-based chemotherapy</li></ul> <p>If a patient experiences severe toxicity to the first cycle of platinum-based chemotherapy, nivolumab in combination with ipilimumab may continue without further chemotherapy</p> <p>If nivolumab in combination with ipilimumab is stopped in the setting of maximum response/stable disease or after completion of 2 years of therapy, the combination may be re-started at the time of disease progression for an additional 1 year of therapy</p> <p>Patients who are unable to tolerate the combination of nivolumab and ipilimumab may continue on single agent nivolumab for up to 2 years, and if discontinued without disease progression it may be re-started at the time of disease progression for an additional 1 year of therapy; re-initiation of ipilimumab at the time of any subsequent disease progression on single agent nivolumab is <u>not</u> funded</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Lung	NSCLC	<p>Locally advanced (not eligible for curative-intent therapy) or metastatic, squamous or non-squamous, non-small cell lung cancer (NSCLC) in patients who:</p> <ul style="list-style-type: none"><li>• have experienced disease progression following chemotherapy, or during or after <u>both</u> targeted therapy and chemotherapy in patients whose tumors express genomic aberrations of either epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or ROS1</li><li>• have not received prior treatment with any other immune checkpoint inhibitor (e.g., pembrolizumab, atezolizumab) in the advanced treatment setting</li><li>• (if applicable) have received durvalumab for stage III NSCLC in the adjuvant treatment setting, but have had at least a 6 month progression-free interval between completion of durvalumab and confirmation of disease progression</li></ul> <p>Nivolumab may be continued until confirmed disease progression or unacceptable toxicity, with a consideration to stop nivolumab in patients who have responded and whose disease is well-controlled</p>	<p>If nivolumab was stopped at the time of best response without evidence of disease progression, nivolumab may be re-started at the time of disease progression</p> <p>Subsequent immune checkpoint inhibitor therapy (e.g., pembrolizumab if PD-L1 <math>\geq</math>1% or atezolizumab) is <u>not</u> funded in patients who have experienced disease progression during nivolumab therapy</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>

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nivolumab	vial	40 mg/4 mL 100 mg/10 mL		Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic, BRAF V600 mutation-negative or positive melanoma as a <u>single agent</u> , first-line immune checkpoint inhibitor therapy in the advanced setting in patients who: <ul style="list-style-type: none"><li>• are previously untreated</li><li>• if BRAF V600 mutation-positive, may have received prior treatment with BRAF-targeted therapy either in the adjuvant or advanced treatment setting</li><li>• may have received prior treatment with a PD-1 inhibitor (e.g., nivolumab or pembrolizumab) in the adjuvant setting, but have had a progression-free interval of at least 6 months since the last dose of the PD-1 inhibitor and confirmation of disease progression</li><li>• have stable brain metastases (if present)</li></ul> Nivolumab may be continued until confirmed disease progression or unacceptable toxicity, with a consideration to stop nivolumab in patients who have responded and whose disease is well-controlled	If nivolumab was stopped at the time of best response without evidence of disease progression, nivolumab may be re-started at the time of disease progression  Single agent ipilimumab is funded as a subsequent treatment option in patients who experience disease progression on nivolumab  Nivolumab is <u>not</u> funded in the following settings: <ul style="list-style-type: none"><li>• in patients who have experienced disease progression on, or after receiving pembrolizumab in the advanced setting</li><li>• in patients who have experienced disease recurrence either during or within 6 months from the last dose of PD-1 inhibitor therapy (nivolumab or pembrolizumab) in the adjuvant setting</li><li>• in patients who stopped pembrolizumab therapy due to significant intolerance or toxicity</li></ul> Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
			STEP	Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic, BRAF V600 mutation-negative or positive melanoma in <u>combination</u> with ipilimumab followed by nivolumab maintenance in patients who: <ul style="list-style-type: none"><li>• are previously untreated or, if BRAF V600 mutation-positive, may have received prior treatment with BRAF-targeted therapy either in the adjuvant or advanced treatment setting, or may have received prior treatment with a PD-1 inhibitor (e.g., nivolumab, pembrolizumab) in the adjuvant setting but have had a progression-free interval of at least 6 months since the last dose of the PD-1 inhibitor and confirmation of disease progression</li><li>• have an ECOG performance status of 0 or 1</li><li>• have stable brain metastases, if present</li></ul> Nivolumab may be given in combination with ipilimumab for up to 4 doses, followed by nivolumab single agent maintenance therapy until disease progression or unacceptable toxicity, with a consideration to stop maintenance nivolumab in patients who have responded and whose disease is well-controlled	If nivolumab was stopped at the time of best response without evidence of disease progression, nivolumab may be re-started at the time of disease progression  Further immune checkpoint inhibitor therapy is <u>not</u> funded in patients who have experienced disease progression on nivolumab which was initiated in combination with ipilimumab  Treatment with combination ipilimumab and nivolumab is <u>not</u> funded in the following settings: <ul style="list-style-type: none"><li>• as repeat treatment</li><li>• in patients who have experienced disease progression during or within 6 months from the last dose of PD-1 inhibitor therapy (e.g., nivolumab, pembrolizumab) in the adjuvant setting</li><li>• as a subsequent treatment in patients who have experienced disease progression on single agent PD-1 inhibitor therapy (e.g., pembrolizumab or nivolumab) initiated in the advanced setting</li></ul> Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Skin and Melanoma	Melanoma	Stage IIIA (limited to lymph node metastases >1 mm) to stage IIID and resected stage IV*, BRAF V600 mutation-negative or positive, cutaneous or mucosal melanoma as <u>adjuvant</u> treatment in patients who: <ul style="list-style-type: none"><li>• have completely resected disease, including in-transit metastases, with the exception that presence of micro-metastases in regional lymph nodes after sentinel lymph node biopsy is allowed</li></ul> Nivolumab should start within 12 weeks from surgery and may continue for up to 1 year of therapy, until confirmed disease progression or unacceptable toxicity, whichever comes first  (The total number of nivolumab cycles should not exceed an equivalent of 1 year duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 1 calendar year from treatment initiation)	*based on the 8th edition of the American Joint Committee of Cancer (AJCC) staging system  Patients should be assessed for disease recurrence at least every 3 months, or more frequently as clinically indicated during adjuvant nivolumab therapy  Nivolumab adjuvant therapy is <u>not</u> funded in patients with ocular or uveal melanoma  For patients with BRAF V600 mutation-positive melanoma, a one-time switch to the combination of dabrafenib and trametinib is allowed during the first 3 months of nivolumab treatment with the total duration of the combined adjuvant immunotherapy and BRAF-targeted therapy remaining at 12 months (including any dose interruption time periods)  Patients are eligible for all immunotherapy options in the relapsed or metastatic setting <u>only</u> if there has been at least a 6 month progression-free interval between completion of adjuvant nivolumab and confirmation of disease progression  For patients with BRAF V600 mutation-positive melanoma, all BRAF-targeted therapy options are funded in patients who relapse or develop metastatic disease at any time during or after receiving nivolumab adjuvant therapy  Ipilimumab single agent therapy is the only immunotherapy option funded in patients who relapse or develop metastatic disease during or within 6 months of receiving the last dose of adjuvant nivolumab

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obinutuzumab	vial	100 mg/40 mL		Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in combination with chlorambucil as a first-line treatment in patients who are not candidates for fludarabine-based treatment	Obinutuzumab in combination with chlorambucil is <u>not</u> funded in patients who have received prior treatment with ibrutinib, idelalisib or venetoclax
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in combination with venetoclax in previously untreated patients who are not candidates for fludarabine-based treatment  Treatment is given for a total of 12 months as a finite treatment - 6 x 28 day cycles of obinutuzumab with venetoclax, followed by 6 months of venetoclax as a single agent, or until disease progression or unacceptable toxicity, whichever occurs first	Fludarabine ineligibility is defined by either a cumulative illness rating scale (CIRS) score greater than 6 or a creatinine clearance (CrCl) less than 70 mL/min  Patients with CD20-negative CLL are <u>not</u> eligible  Patients with known CNS lymphoma or leukemia, prolymphocytic leukemia or history or suspicion of Richter syndrome are <u>not</u> eligible  Re-treatment with venetoclax in combination with obinutuzumab is <u>not</u> funded  Ibrutinib or acalabrutinib is funded as a second-line treatment option, provided all other funding eligibility criteria are met  CD20-targeted therapy in combination with chemotherapy is <u>not</u> funded as a subsequent treatment option
			STEP	Hematology	Non-Hodgkin Lymphoma (NHL)	Rituximab-refractory* low grade non-Hodgkin lymphoma** in combination with chemotherapy, then followed by single agent maintenance therapy  Obinutuzumab in combination with chemotherapy may be given for up to 6 cycles, followed by obinutuzumab single agent maintenance therapy in patients who have responded to, or have stable disease after obinutuzumab plus chemotherapy, for a maximum duration of 2 years, or until disease progression or unacceptable toxicity, whichever occurs first	*Rituximab-refractory non-Hodgkin lymphoma is defined as the following: • no response to, or disease progression during any previous rituximab-containing regimen • disease progression within 6 months of the last rituximab dose, given in either induction or maintenance treatment settings  ** Low grade non-Hodgkin lymphoma subtypes include: follicular lymphoma, marginal zone lymphoma, lymphoplasmacytic lymphoma and Waldenstrom macroglobulinemia
octreotide	vial	0.05 mg/1 mL 0.1 mg/1 mL 1 mg/5 mL		Neuroendocrine	Neuroendocrine	Neuroendocrine tumors as: • initial dose-finding treatment for patients with locally advanced unresectable or metastatic, well to moderately differentiated, low to intermediate grade gastroenteropancreatic or lung neuroendocrine tumors who will be transitioned to a long-acting somatostatin analog • management of breakthrough symptoms in patients stabilized on long-acting somatostatin analog therapy • management of symptoms related to carcinoid syndrome or hypersecretion of hormones from neuroendocrine tumors in patients who have unresectable disease	
	ampoule/vial	0.05 mg/1 mL 0.1 mg/1 mL 0.5 mg/1 mL 1 mg/5 mL		Supportive Care	Supportive Care	Management of severe chemotherapy-induced diarrhea for short-term, outpatient treatment durations of 5 days or less	
	prefilled syringe	10 mg 20 mg 30 mg		Neuroendocrine	Neuroendocrine	Locally advanced unresectable or metastatic, well to moderately differentiated, low to intermediate grade, somatostatin receptor-positive, gastroenteropancreatic or lung neuroendocrine tumors	
olanzapine	tablet	2.5 mg 5 mg 10 mg		Supportive Care	Supportive Care	Prevention of acute and delayed nausea and vomiting in outpatients receiving moderately or highly emetogenic chemotherapy in regimens and doses consistent with the Multinational Association of Supportive Care in Cancer (MASCC) and the American Society of Clinical Oncology (ASCO) guidelines, or in pediatric patients according to the Pediatric Oncology Group of Ontario (POGO) guidelines  Prevention of nausea and vomiting associated with radiation therapy where recommended by MASCC and ASCO guidelines	

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
olaparib	tablet	100 mg 150 mg		Breast	Breast, Early Stage	<p>High-risk* deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative, early stage breast cancer as adjuvant treatment in patients who have been treated with neoadjuvant or adjuvant chemotherapy</p> <p>Olaparib may be continued for up to 1 year, unacceptable toxicity, or disease progression whichever comes first</p> <p>(Olaparib should not exceed an equivalent of 1 year duration; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 1 calendar year from treatment initiation)</p>	<p>*For patients who had initial surgery and received adjuvant chemotherapy, at least 1 of the following criteria must be met:</p> <ul style="list-style-type: none"><li>• If triple-negative breast cancer (TNBC): axillary node-positive, or axillary node-negative disease with pT ≥ 2 cm</li><li>• If hormone-receptor positive, HER2-negative: ≥ 4 pathologically confirmed positive lymph nodes</li></ul> <p>For patients who received neoadjuvant chemotherapy followed by surgery, there must be residual invasive breast cancer in the breast and/or resected lymph nodes (i.e., non-pathologic complete response)</p> <p>Patients must have completed neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes, or both; patients who discontinue neoadjuvant or adjuvant chemotherapy before all planned cycles are administered due to toxicity or other reasons are eligible</p> <p>Olaparib should be initiated within 12 weeks from completion of the last treatment, including surgery, chemotherapy or radiation therapy</p> <p>Olaparib is <u>not</u> funded in combination or sequence with pembrolizumab in triple-negative breast cancer patients who are gBRCA-mutated and who are eligible for both therapies in the adjuvant setting</p> <p>Only 1 of olaparib or abemaciclib is funded in patients who meet the eligibility criteria for both therapies in the adjuvant setting</p>
				Genitourinary	Prostate (mCRPC)	Metastatic castration-resistant prostate cancer (mCRPC) in patients with a deleterious or suspected deleterious germline and/or somatic mutation in the homologous recombination repair (HRR) genes BRCA or ATM, and who have experienced disease progression on or after prior treatment with androgen receptor axis targeted (ARAT) therapy, including patients who have stable brain metastases (if present)	Only documented mutations in BRCA1, BRCA2 and/or ATM that are known to be deleterious or suspected deleterious are eligible for olaparib; mutations described as non-detrimental (e.g., "variants of uncertain or unknown clinical significance" or "variant, favor polymorphism" or "benign polymorphism") are <u>not</u> eligible
				Gynecology	Ovarian	<p>Advanced* BRCA-mutated (germline or somatic) epithelial ovarian, fallopian tube or primary peritoneal cancer with high grade serous or endometrioid histology, as single agent maintenance treatment in newly diagnosed patients who:</p> <ul style="list-style-type: none"><li>• have achieved a complete or partial response after at least 4 cycles of first-line platinum-based chemotherapy, confirmed by radiologic imaging within 4 weeks of initiating olaparib maintenance</li><li>• have stable brain metastases (if present)</li></ul> <p>*FIGO (International Federation of Gynecology and Obstetrics) stage III (with or without upfront or interval debulking surgery) or stage IV</p> <p>Olaparib maintenance therapy should be initiated within 12 weeks from the last chemotherapy treatment and may continue for up to 2 years, or until disease progression or unacceptable toxicity, whichever occurs first</p>	<p>Only documented mutations in BRCA1 and/or BRCA2 that are known to be deleterious or suspected deleterious are eligible for olaparib; mutations described as non-detrimental (e.g., "variants of uncertain or unknown clinical significance" or "variant, favor polymorphism" or "benign polymorphism") are <u>not</u> eligible</p> <p>Platinum-based therapy includes intravenous or peritoneal treatment and treatment given before (neoadjuvant) or after surgery</p> <p>Patients may be switched to niraparib in cases of unacceptable toxicity to olaparib, provided no disease progression has occurred</p> <p>For patients with BRCA-mutated disease who received bevacizumab in combination with platinum-based therapy as first-line treatment, only <u>one</u> of bevacizumab or olaparib maintenance is funded (i.e., bevacizumab and olaparib are <u>not</u> funded in combination)</p> <p>Patients with BRCA-mutated disease who received non-platinum-based chemotherapy (i.e., platinum contraindication or switched to non-platinum-based chemotherapy in the setting of intolerance) are eligible for olaparib maintenance therapy providing all other criteria are met</p> <p>Olaparib maintenance therapy is <u>not</u> funded in patients with early stage disease (FIGO stage I to IIC) who may or may not have received adjuvant chemotherapy</p>
				Gynecology	Ovarian	<p>Relapsed, platinum-sensitive*, BRCA-mutated (germline or somatic) epithelial ovarian, fallopian tube, or primary peritoneal cancer with high grade serous or endometrioid histology as single agent maintenance treatment in patients who:</p> <ul style="list-style-type: none"><li>• have completed at least 2 previous lines of platinum-based chemotherapy</li><li>• have achieved a complete or partial response to the most recent platinum-based chemotherapy regimen, confirmed by radiologic imaging within 4 weeks of initiating olaparib</li><li>• have received at least 4 cycles of the most recent platinum-based chemotherapy before olaparib initiation</li><li>• have stable brain metastases (if present)</li></ul> <p>Olaparib maintenance therapy should be initiated within-12 weeks of the last chemotherapy treatment and may continue until disease progression or unacceptable toxicity, whichever occurs first</p>	<p>Only documented mutations in BRCA1 and/or BRCA2 that are known to be deleterious or suspected deleterious are eligible for olaparib; mutations described as non-detrimental (e.g., "variants of uncertain or unknown clinical significance" or "variant, favor polymorphism" or "benign polymorphism") are <u>not</u> eligible</p> <p>*Platinum-sensitive relapsed disease is defined as disease progression occurring 6 months or later after completion of prior platinum-based chemotherapy</p> <p>Patients who are platinum-sensitive, but received non-platinum-based chemotherapy (i.e., platinum contraindication or switched to non-platinum-based chemotherapy in the setting of intolerance) are eligible for olaparib maintenance therapy providing all other criteria are met</p> <p>Patients may be switched to niraparib in cases of unacceptable toxicity to olaparib, provided no disease progression has occurred</p>

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ondansetron	oral dissolving tablet (ODT)	4 mg 8 mg		Supportive Care	Supportive Care	Prevention of acute and delayed nausea and vomiting in outpatients receiving moderately or highly emetogenic chemotherapy in regimens and doses consistent with the Multinational Association of Supportive Care in Cancer (MASCC) and the American Society of Clinical Oncology (ASCO), or in pediatric patients according to the Pediatric Oncology Group of Ontario (POGO) guidelines  Prevention of nausea and vomiting associated with radiation therapy where recommended by MASCC and ASCO	Use of the oral dissolving tablet (ODT) or solution formulation should be reserved for patients unable to swallow regular tablets
	solution	4 mg/5 mL		Supportive Care	Supportive Care		
	tablet	4 mg 8 mg		Supportive Care	Supportive Care		
	vial	4 mg/2 mL 8 mg/4 mL 40 mg/20 mL		Supportive Care	Supportive Care		
osimertinib	tablet	40 mg 80 mg		Lung	NSCLC (EGFR positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, epidermal growth factor receptor (EGFR) mutation-positive, T790M-positive non-small cell lung cancer (NSCLC) as: • a second-line treatment after confirmation of an acquired T790M mutation in patients who have experienced disease progression during EGFR tyrosine kinase inhibitor (TKI) therapy • a first-line treatment in patients whose tumor is positive for a de novo EGFR T790M mutation	If chemotherapy was initiated as a prior to receiving results of T790M mutation status, treatment may be switched to osimertinib if positive T790M results are identified  Alternate EGFR-targeted therapies (e.g., erlotinib, gefitinib, afatinib) are <u>not</u> funded after osimertinib therapy
				Lung	NSCLC (EGFR positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, epidermal growth factor receptor (EGFR) exon 19 deletion [exon 19 del] or exon 21 [L858R] mutation-positive non-small cell lung cancer (NSCLC) as a first-line treatment	If chemotherapy was initiated as a first-line treatment prior to receiving results of EGFR mutation status, treatment may be switched to osimertinib if eligible mutations are identified  Alternate EGFR-targeted therapies (e.g., erlotinib, gefitinib, afatinib) are <u>not</u> funded after osimertinib therapy  Patients are eligible for osimertinib for treatment of locally advanced unresectable or metastatic NSCLC, provided there has been no disease progression within 6 months following completion of <u>adjuvant</u> osimertinib, and all other eligibility criteria are met
				Lung	NSCLC (EGFR positive)	Stage IB-IIIA (AJCC 7th edition) or stage IB-IIIB (AJCC 8th edition) non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as adjuvant therapy following tumor resection*  Osimertinib should start within 10 weeks of surgery if adjuvant chemotherapy was not given, or within 26 weeks of surgery if adjuvant chemotherapy was given  Osimertinib may continue for a maximum of 3 years, until confirmed disease progression, or unacceptable toxicity, whichever comes first	* patients must have complete resection of the primary tumor, with all gross disease removed at the end of surgery, and negative surgical margins  Osimertinib may be used regardless of whether chemotherapy is administered, but should start after chemotherapy is completed if it was administered  Patients remain eligible for osimertinib for treatment of locally advanced unresectable or metastatic NSCLC, provided there has been no disease progression within 6 months following completion of adjuvant osimertinib, and all other eligibility criteria are met
oxaliplatin	vial	50 mg/10 mL 100 mg/20 mL 200 mg/40 mL		Gastrointestinal	Multiple		

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
paclitaxel	vial	30 mg/5 mL 100 mg/16.7 mL 300 mg/50 mL		Multiple	Multiple		
paclitaxel nanoparticle albumin-bound ( <i>nab</i> ) (see Abraxane®)							
palbociclib	tablet	75 mg 100 mg 125 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, hormone receptor-positive, HER2-negative breast cancer in combination with a non-steroidal aromatase inhibitor (NSAI) (anastrozole or letrozole) as a first-line treatment in post-menopausal women (pre- or peri-menopausal women must have a surgical or chemical-induced menopause) or in men who: • have not received any prior endocrine treatment for advanced disease, but may have received chemotherapy as initial treatment • (if applicable) have had a progression-free interval of at least 1 year from completion of prior neo/adjuvant NSAI therapy (anastrozole or letrozole), or without time restriction in patients who received prior neo/adjuvant tamoxifen or exemestane • have stable brain metastases (if present)	Pre- or peri-menopausal women who have not received a bilateral oophorectomy (surgical-induced menopause) are eligible to receive a gonadotropin releasing hormone (GnRH) agonist (e.g., goserelin) to achieve a chemical-induced menopause  Only <u>one</u> CDK 4/6 inhibitor-based therapy is funded (i.e., either palbociclib or ribociclib in combination with either a non-steroidal aromatase inhibitor or fulvestrant)  Everolimus in combination with exemestane is <u>not</u> funded as subsequent therapy after treatment with a CDK 4/6 inhibitor (palbociclib or ribociclib) in combination with either a NSAI or fulvestrant  Refer to Appendix C - Definition of Menopause
				Breast	Breast, Advanced	Locally advanced unresectable or metastatic, hormone receptor-positive, HER2-negative breast cancer in combination with fulvestrant as a first-line treatment or as a subsequent line of treatment in post-menopausal women (pre- or peri-menopausal women must have a surgical or chemical-induced menopause) or in men who: • are previously untreated, but may have received prior neo/adjuvant endocrine therapy without time restriction on the interval between completion of adjuvant therapy and development of metastatic disease • may have received chemotherapy as initial treatment • may have received more than one line of endocrine therapy for advanced disease, excluding prior fulvestrant and endocrine therapy in combination with a CDK 4/6 inhibitor or everolimus • have stable brain metastases (if present)	Pre- or peri-menopausal women who have <u>not</u> received a bilateral oophorectomy (i.e., surgical-induced menopause) are eligible to receive a gonadotropin releasing hormone (GnRH) agonist (e.g., goserelin) to achieve a chemical-induced menopause  Only <u>one</u> CDK 4/6 inhibitor-based therapy is funded (i.e., either palbociclib or ribociclib in combination with either a non-steroidal aromatase inhibitor or fulvestrant)  Everolimus in combination with exemestane is <u>not</u> funded as subsequent therapy after treatment with a CDK 4/6 inhibitor (palbociclib or ribociclib) in combination with either a NSAI or fulvestrant  Refer to Appendix C - Definition of Menopause
palonosetron	capsule	0.5 mg		Pediatrics	Supportive Care	Prevention of chemotherapy-induced nausea and vomiting in pediatric patients receiving moderately or highly-emetogenic chemotherapy when other options are deemed unsuitable according to Pediatric Oncology Group of Ontario (POGO) guidelines	
	vial	0.25 mg/5 mL		Pediatrics	Supportive Care		
pamidronate	vial	90 mg/10 mL		Supportive Care	Supportive Care	Use in patients with documented bone metastases in conjunction with standard care in order to prevent, delay or reduce complications from bone lesions	
				Hematology	Multiple Myeloma	Multiple myeloma as adjunct therapy to prevent skeletal-related events  Pamidronate may be given for up to 2 years in newly diagnosed patients who have achieved good disease control, however, may be continued longer than 2 years at the discretion of the treating physician based on assessment of disease status	if pamidronate was stopped after 2 years, it may be re-started at any time in patients who have relapsed with new onset skeletal-related events
				Supportive Care	Supportive Care	Management of hypercalcemia related to malignancy for outpatients	Pamidronate is <u>not</u> funded for the prevention or treatment of osteopenia or osteoporosis

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panitumumab	vial	100 mg/5 mL 400 mg/20 mL		Gastrointestinal	Colorectal	Locally advanced unresectable or metastatic, non-mutated (wild-type) all RAS (NRAS/KRAS) colorectal cancer as single agent treatment or in combination with irinotecan in patients who have experienced disease progression or intolerance/contraindication to prior therapy containing a fluoropyrimidine, oxaliplatin and irinotecan	
				Gastrointestinal	Colorectal	Locally advanced unresectable or metastatic, non-mutated (wild-type) all RAS (NRAS/KRAS) colorectal cancer in combination with irinotecan and/or oxaliplatin-based chemotherapy as first-line* treatment in patients who have a contraindication or intolerance to bevacizumab, or as second-line treatment in patients who did not receive bevacizumab previously and have a contraindication or intolerance to bevacizumab	*patients with microsatellite instability-high (MSI-H) metastatic colorectal cancer who receive first-line treatment with pembrolizumab are eligible to receive chemotherapy with panitumumab as the next line of treatment  Contraindication or intolerance to bevacizumab is considered in patients who: • have a high-risk of bleeding or impaired wound healing due to temporal proximity to surgery (e.g., recently received or planned for resectable/potentially resectable liver metastases) • have pre-existing conditions which would be of concern with known class-specific side effects of bevacizumab (e.g., hypertension, thromboembolic events, atrial fibrillation, proteinuria, risk of/or presence of fistulae, risk of/or current GI perforation, unresected primary tumor, active bleeding, non-healing wound, ulcer, recent trauma)
				Gastrointestinal	Colorectal	Locally advanced unresectable or metastatic, BRAF V600E* mutation-positive colorectal cancer in combination with encorafenib in patients who have been previously treated with systemic therapy	*mutations other than BRAF V600E are <u>not</u> funded  Patients must have received at least one previous systemic treatment for metastatic colorectal cancer; patients with MSI-high metastatic colorectal cancer who are also BRAF V600E-mutation positive may receive encorafenib in combination with panitumumab as the second or subsequent line of therapy following first-line pembrolizumab  Patients must not have received any prior EGFR inhibitors or BRAF inhibitors  If either encorafenib or panitumumab is temporarily or permanently discontinued for toxicity or intolerance, the alternate drug in the combination should be discontinued, and single agent treatment is not permitted
pazopanib	tablet	200 mg		Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) for all histologic subtypes and risk categories* as a single agent, first-line vascular endothelial growth factor (VEGF)-receptor tyrosine kinase inhibitor (TKI) treatment	*determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria  Only <u>one</u> of pazopanib or sunitinib is funded as first-line VEGF TKI treatment  Only <u>one</u> of axitinib or cabozantinb, or nivolumab is funded as second-line treatment in patients who have experienced disease progression during first-line VEGF TKI (sunitinib or pazopanib) treatment
				Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) as a second-line treatment in patients previously treated with first-line combination ipilimumab plus nivolumab for intermediate or high-risk disease	Only <u>one</u> of pazopanib or sunitinib is funded as second-line treatment in patients who have experienced disease progression following first-line ipilimumab plus nivolumab treatment  Only <u>one</u> of axitinib or cabozantinib is funded as a third-line treatment in patients who have experienced disease progression after both first-line nivolumab plus ipilimumab and second-line VEGF TKI (sunitinib or pazopanib) treatment
pegaspargase	vial	3,750 units/5 mL		Hematology	Acute Lymphoblastic Leukemia (ALL)	Acute lymphoblastic leukemia (ALL) as a component of a multi-agent chemotherapeutic regimen in pediatric and adult patients	Pegaspargase is derived from <i>E. coli</i>
pegfilgrastim	prefilled syringe	6 mg/0.6 mL		Supportive Care	Supportive Care	Alternative to daily filgrastim (G-CSF) injections in specific chemotherapy regimens of greater than or equal to every 2 weeks frequency where primary or secondary growth factor prophylaxis has been approved (see filgrastim for full eligibility criteria)	Pegfilgrastim is <u>not</u> approved in the following settings: • in febrile patients during neutropenia in an attempt to more quickly increase granulocyte counts • as adjunct therapy for the treatment of uncomplicated fever and neutropenia defined as a fever of less than or equal to 10 days in duration, no evidence of pneumonia, cellulitis, abscess, sinusitis, hypotension, multi-organ dysfunction (sepsis syndrome) or invasive fungal infection and no uncontrolled malignancies • in patients with aplastic anemia
peginterferon alpha-2a	prefilled syringe	180 mcg/0.5 mL		Hematology	Myeloproliferative Neoplasm (MPN)	Myeloproliferative neoplasms (MPNs)* in patients who are not candidates for other therapies	*chronic eosinophilic leukemia, chronic myeloid leukemia (CML), chronic neutrophilic leukemia, essential thrombocythemia, polycythemia vera, primary myelofibrosis
	vial	180 mcg/1 mL					



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pembrolizumab	vial	100 mg/4 mL		Breast	Breast, Early Stage	<p>High-risk* early-stage triple negative** breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment prior to surgery then continued as a single agent as adjuvant treatment after surgery</p> <p>Treatment may continue for up to 1 year of pembrolizumab therapy, until confirmed disease progression or unacceptable toxicity, whichever comes first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 1 year duration, including neoadjuvant and adjuvant doses combined, regardless of schedule)</p>	<p>*High-risk triple-negative breast cancer (TNBC) is defined as clinically node positive or according to the following anatomic stage (AJCC 8th edition) by the physician based on radiological and/or clinical assessment:</p> <ul style="list-style-type: none"><li>• T1c, N1-N2</li><li>• T2-4, N0-N2</li><li>• bilateral and/or multifocal primary tumors are eligible, as well as inflammatory breast cancer; the tumor with the most advanced T stage should be used to assess eligibility</li><li>• if feasible, TNBC should be confirmed for each focus in cases with multi-focal/multi-centric disease</li></ul> <p>** TNBC is defined as breast cancers with &lt;1% expression of estrogen- (ER) and progesterone-receptors (PR), and either HER2 0 to 1+ by immunohistochemistry (IHC) or HER2 IHC 2+ and in-situ hybridization (ISH) negative (not amplified)</p> <p>Breast cancers that are HER2-negative with a low level (defined as 1-10%) of estrogen receptor [ER] or progesterone receptor [PR] expression by IHC will be eligible for treatments funded for TNBC if the medical oncologist considers them to be functionally hormone receptor-negative, however, once a specific treatment pathway is chosen (i.e., TNBC vs. endocrine therapy), funding is <u>not</u> approved to switch between these pathways unless there is a change in tumor biology based on repeat biopsy)</p> <p>Patients must not have had any prior systemic therapy for non-metastatic TNBC</p> <p>Patients with non-metastatic TNBC should be clinically fit for neoadjuvant chemotherapy</p> <p>Pembrolizumab should be used in combination with any taxane- and anthracycline-based chemotherapy in the neoadjuvant setting; single agent pembrolizumab is not approved in the neoadjuvant setting</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Breast	Breast, Advanced	<p>Locally recurrent unresectable or metastatic triple-negative* breast cancer (TNBC) whose tumors express programmed death-ligand 1 (PD-L1) (combined positive score [CPS] ≥ 10) in combination with chemotherapy in patients who:</p> <ul style="list-style-type: none"><li>• have not received prior chemotherapy for metastatic disease</li><li>• have stable brain metastases (if present)</li></ul> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>*Triple-negative breast cancer (TNBC) is defined as breast cancers with &lt;1% expression of estrogen- (ER) and progesterone-receptors (PR), and either HER2 0 to 1+ by immunohistochemistry (IHC) or HER2 IHC 2+ and in-situ hybridization (ISH) negative (not amplified)</p> <p>Breast cancers that are HER2-negative with a low level (defined as 1-10%) of estrogen receptor [ER] or progesterone receptor [PR] expression by IHC will be eligible for treatments funded for TNBC if the medical oncologist considers them to be functionally hormone receptor-negative; however, once a specific treatment pathway is chosen (i.e., TNBC vs. endocrine therapy), funding is <u>not</u> approved to switch between these pathways unless there is a change in tumor biology based on repeat biopsy)</p> <p>Patients who received neo/adjuvant pembrolizumab with chemotherapy for TNBC are eligible for pembrolizumab in the advanced setting provided there has been no disease progression within 6 months following completion of adjuvant therapy and all other eligibility criteria are met</p> <p>If there are delays in obtaining PD-L1 CPS results, patients may be initiated on chemotherapy, and pembrolizumab may be added once PD-L1 CPS ≥ 10 is confirmed</p> <p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started with or without chemotherapy at the time of disease progression for an additional 1 year of therapy</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>

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pembrolizumab	vial	100 mg/4 mL		Gastrointestinal	Colorectal	<p>Locally advanced unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer as first-line treatment as a single agent</p> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Patients who received previous adjuvant chemotherapy for earlier stage colorectal cancer are eligible, regardless of the date of completion of chemotherapy</p> <p>Patients who receive alternate first-line therapy before MSI-H (dMMR) results are available may be switched to pembrolizumab at the time MSI-H (dMMR) status is confirmed</p> <p>Chemotherapy +/- bevacizumab (or panitumumab if RAS and BRAF wild-type, and bevacizumab intolerant/contraindicated) is funded as a second-line treatment in patients who have experienced disease progression during first-line treatment with pembrolizumab</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Gastrointestinal	Esophageal and Gastroesophageal Junction (GEJ)	<p>Locally advanced, unresectable or metastatic HER2-negative esophageal cancer or HER2-negative adenocarcinoma of the gastroesophageal junction (GEJ), in combination with platinum and fluoropyrimidine-based chemotherapy as first-line treatment, including patients who:</p> <ul style="list-style-type: none"><li>• have either adenocarcinoma or squamous cell histology for esophageal cancer</li><li>• have stable brain metastases (if present)</li></ul> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>While awaiting HER2 test results for patients with adenocarcinoma, chemotherapy can be started alone and pembrolizumab can be added once HER2-negative status is confirmed; If HER2 status cannot be determined, patients remain eligible for first-line chemotherapy plus pembrolizumab</p> <p>Patients who received adjuvant immune checkpoint inhibitor therapy (e.g., nivolumab) who experience disease progression on or within 6 months of completion are not eligible for pembrolizumab</p> <p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
pembrolizumab	vial	100 mg/4 mL		Genitourinary	Renal Cell Carcinoma	<p>Adjuvant treatment of patients with renal cell carcinoma* (RCC) at intermediate-high or high-risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions**</p> <p>Treatment may continue for up to 1 year of pembrolizumab therapy, until confirmed disease progression or unacceptable toxicity, whichever comes first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 1 year duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 1 calendar year from treatment initiation)</p>	<p>*patients must have a histologically confirmed diagnosis of renal cell carcinoma (RCC) with a clear cell component, with or without sarcomatoid features</p> <p>** Intermediate-high, high-risk, or M1 NED (no evidence of disease) is defined based on pathologic tumor-node-metastasis (TNM) staging, Fuhrman grading status, and presence of sarcomatoid features as follows:</p> <p><u>Intermediate-high risk</u></p> <ul style="list-style-type: none"><li>• pT2, grade 4 or sarcomatoid, N0, M0</li><li>• pT3, any grade, N0, M0</li></ul> <p><u>High-risk</u></p> <ul style="list-style-type: none"><li>• pT4, any grade, N0, M0</li><li>• pT any stage, any grade, N+, M0</li></ul> <p><u>Stage M1 NED</u></p> <ul style="list-style-type: none"><li>• resection of the primary tumor and solid, isolated, soft-tissue metastases</li></ul> <p>Patients may have had a partial or radical nephrectomy; if applicable, patients with isolated soft tissue metastatic lesions must have complete resection with negative surgical margins at the time of nephrectomy (synchronous) or within 1 year of nephrectomy (metachronous)</p> <p>Pembrolizumab should be initiated within 3 months following surgery</p> <p>Patients remain eligible for all immunotherapy options for treatment of metastatic renal cell carcinoma, provided there has been no disease progression on or within 6 months following completion of adjuvant pembrolizumab, and all other eligibility criteria are met</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Genitourinary	Renal Cell Carcinoma	<p>Advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma (mRCC) for all histologic subtypes and risk categories* in combination with axitinib as a first-line treatment in patients who:</p> <ul style="list-style-type: none"><li>• have not received any prior therapy for mRCC, including immune checkpoint inhibitor (e.g., nivolumab plus ipilimumab) or vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor (TKIs) (e.g., sunitinib, pazopanib) therapy</li><li>• have stable brain metastases (if present)</li></ul> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first, with the axitinib component continued until disease progression or unacceptable toxicity</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>*Determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria</p> <p>Patients who received adjuvant immune checkpoint inhibitor therapy (e.g., pembrolizumab) for renal cell carcinoma are eligible provided there has been at least a 6 month progression-free interval from completion of therapy</p> <p>Patients who experience intolerance to one drug in the combination of axitinib plus pembrolizumab may continue with either single agent axitinib until disease progression or unacceptable toxicity or single agent pembrolizumab up to a maximum of 2 years, disease progression or unacceptable toxicity, whichever occurs first</p> <p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Cabozantinb is funded as a second-line treatment in patients who have experienced disease progression during first-line combination therapy with axitinib and pembrolizumab</p> <p>Third-line treatment of any kind is <u>not</u> funded in patients who have received first-line axitinib plus pembrolizumab followed by second-line cabozantinb</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>

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pembrolizumab	vial	100 mg/4 mL		Genitourinary	Renal Cell Carcinoma	<p>Advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma (mRCC) for all histologic subtypes and risk categories* in combination with lenvatinib as a first-line treatment in patients who:</p> <ul style="list-style-type: none"><li>• have not received any prior therapy for mRCC, including immune checkpoint inhibitor (e.g., nivolumab plus ipilimumab) or vascular endothelial growth factor (VEGF) receptor tyrosine kinase inhibitor (TKIs) (e.g., sunitinib, pazopanib) therapy</li><li>• have stable brain metastases (if present)</li></ul> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first, with the lenvatinib component continued until disease progression or unacceptable toxicity; lenvatinib may continue until disease progression or unacceptable toxicity</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>*Determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria</p> <p>Patients who received adjuvant immune checkpoint inhibitor therapy (e.g., pembrolizumab) for renal cell carcinoma are eligible provided there has been at least a 6 month progression-free interval from completion of therapy</p> <p>Patients who experience intolerance to one drug in the combination of lenvatinib plus pembrolizumab may continue with either single agent lenvatinib until disease progression or unacceptable toxicity or single agent pembrolizumab up to a maximum of 2 years, disease progression or unacceptable toxicity, whichever occurs first</p> <p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Cabozantinb is funded as a second-line treatment in patients who have experienced disease progression during first-line combination therapy with lenvatinib and pembrolizumab</p> <p>Third-line treatment of any kind is <u>not</u> funded in patients who have received first-line lenvatinib plus pembrolizumab followed by second-line cabozantinb</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Genitourinary	Urothelial, Advanced	<p>Locally advanced unresectable or metastatic urothelial carcinoma* (mUC) as a single agent second-line treatment in patients who have experienced disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy</p> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>*Urothelial carcinoma includes carcinoma of the renal pelvis, ureter, bladder or urethra with predominantly transitional cell features on histologic testing</p> <p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Pembrolizumab is funded in patients who previously received alternate non-platinum chemotherapy due to a platinum contraindication</p> <p>Pembrolizumab is <u>not</u> funded in patients who:</p> <ul style="list-style-type: none"><li>• are eligible for curative-intent local therapy</li><li>• have <u>not</u> received any prior chemotherapy for mUC</li></ul> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>

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pembrolizumab	vial	100 mg/4 mL		Gynecology	Cervical	<p>Persistent, recurrent, or metastatic cervical cancer whose tumors express programmed death ligand 1 (PD-L1) (combined positive score [CPS] ≥ 1) in combination with chemotherapy with or without bevacizumab as first-line treatment, including patients with stable brain metastases (if present)</p> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>Patients must <u>not</u> have had any prior systemic therapy for advanced or metastatic cervical cancer</p> <p>Patients that previously received concurrent cisplatin with radiation therapy with curative intent are eligible</p> <p>If there are delays in obtaining PD-L1 CPS results, patients may be initiated on chemotherapy with or without bevacizumab, and pembrolizumab may be added once PD-L1 CPS ≥ 1 is confirmed</p> <p>Pembrolizumab may be continued as a single agent or in combination with bevacizumab (if applicable) in the event chemotherapy needs to be discontinued due to toxicity; if bevacizumab needs to be discontinued due to toxicity, pembrolizumab may be continued in combination with chemotherapy</p> <p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier in the setting of best response, it may be re-started with or without chemotherapy and bevacizumab at the time of disease progression for an additional 1 year of therapy</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Gynecology	Endometrial	<p>Microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) unresectable or metastatic endometrial cancer* after disease progression following prior systemic therapy, as a single agent, including patients who have stable brain metastases (if present)</p> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>*Patients with pure endometrial sarcoma (e.g., leiomyosarcoma, endometrial stromal sarcoma) are <u>not</u> eligible, however, all other histologies are eligible, including endometrioid, serous, clear cell, mixed carcinoma, undifferentiated carcinoma and carcinosarcoma</p> <p>If pembrolizumab is stopped in the setting of maximum response/stable disease or after completion of the initial 2 years of therapy without any disease progression, it may be re-started at the time of disease progression for an additional 1 year of therapy</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Gynecology	Endometrial	<p>Unresectable or metastatic endometrial carcinoma* that is <u>not</u> microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), after disease progression following prior platinum-based systemic therapy, in combination with lenvatinib, in patients who:</p> <ul style="list-style-type: none"><li>• are not candidates for curative surgery or radiation</li><li>• have stable brain metastases (if present)</li></ul> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first; lenvatinib may continue until disease progression or unacceptable toxicity</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>*Patients with pure endometrial sarcoma (e.g., leiomyosarcoma, endometrial stromal sarcoma) are <u>not</u> eligible, however, all other histologies are eligible, including endometrioid, serous, clear cell, mixed carcinoma, undifferentiated carcinoma and carcinosarcoma</p> <p>Patients who cannot tolerate the combination of pembrolizumab with lenvatinib may continue with either single agent pembrolizumab up to 2 years, disease progression or unacceptable toxicity, or single agent lenvatinib until disease progression or unacceptable toxicity</p> <p>If pembrolizumab is stopped in the setting of maximum response/stable disease or after completion of the initial 2 years of therapy without any disease progression, it may be re-started at the time of disease progression for an additional 1 year of therapy</p> <p>If lenvatinib was discontinued due to toxicity during the initial 2 year treatment period, only pembrolizumab may be re-administered at the time of disease progression for an additional 1 year of therapy; if lenvatinib was not previously discontinued due to toxicity, it may be administered concurrently with pembrolizumab during the second course at the time of disease progression</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>

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pembrolizumab	vial	100 mg/4 mL		Head and Neck	Squamous	Locally advanced unresectable or metastatic, head and neck squamous cell cancer (HNSCC) as a first-line treatment in patients who have stable brain metastases (if present) and either: <ul style="list-style-type: none"><li>• as a single agent for tumors with a PD-L1 combined positive score (CPS) ≥1, or</li><li>• in combination with chemotherapy regardless of PD-L1 tumor expression level</li></ul> Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first  (The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, pembrolizumab may be re-started at the time of disease progression and may continue for up to an additional 1 year  Subsequent immune checkpoint inhibitor therapy (e.g., nivolumab) is not funded in patients who have experienced disease progression during pembrolizumab treatment  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Hematology	Hodgkin Lymphoma (HL)	Relapsed or refractory, classical Hodgkin lymphoma* (cHL) as a single agent in adult patients who have experienced disease progression-after having received <u>both</u> an autologous stem cell transplant (ASCT) and brentuximab vedotin  Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever comes first  (The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	*cHL subtypes include: nodular sclerosis, mixed cellularity, lymphocyte-rich and lymphocyte-depleted  Pembrolizumab is <u>not</u> funded in patients who have central nervous system involvement or nodular lymphocyte-predominant Hodgkin lymphoma  If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, pembrolizumab may be re-started at the time of disease progression and may continue for up to an additional 1 year  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment
				Hematology	Hodgkin Lymphoma (HL)	Relapsed or refractory, classical Hodgkin lymphoma* (cHL) as a single agent in adult and pediatric patients who have experienced disease progression after having received an autologous stem cell transplant (ASCT), or who are not candidates for multi-agent salvage chemotherapy and ASCT  Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever comes first  (The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)	*cHL subtypes include: nodular sclerosis, mixed cellularity, lymphocyte-rich and lymphocyte-depleted  Pembrolizumab is <u>not</u> funded in patients who have central nervous system involvement or nodular lymphocyte-predominant Hodgkin lymphoma  If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year  Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment

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pembrolizumab	vial	100 mg/4 mL		Lung	NSCLC	<p>Locally advanced (not eligible for potentially curative-intent therapy) or metastatic, non-squamous or squamous, non-small cell lung cancer (NSCLC) with a PD-L1 Tumor Proportion Score (TPS) ≥50% and no known epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or ROS1 genomic tumor aberrations as a first-line <u>single agent</u> treatment in patients who:</p> <ul style="list-style-type: none"><li>• have <u>not</u> received prior treatment with any other immune checkpoint inhibitor therapy in the advanced treatment setting</li><li>• (if applicable) have received durvalumab for stage III NSCLC in the adjuvant treatment setting, but have had at least a 6 month progression-free interval between completion of durvalumab and confirmation of disease progression</li></ul> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>If PD-L1 TPS is ≥50%, first-line immune checkpoint inhibitor treatment options would include either pembrolizumab single agent or pembrolizumab in combination with chemotherapy</p> <p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Subsequent immune checkpoint inhibitor therapy (e.g., atezolizumab, nivolumab, ipilimumab/nivolumab) is <u>not</u> funded in patients who have experienced disease progression during pembrolizumab treatment</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Lung	NSCLC	<p>Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous or squamous, non-small cell lung cancer (NSCLC) as a <u>single agent</u> second or subsequent line of treatment for tumors with a PD-L1 Tumor Proportion Score (TPS) ≥1% in patients who:</p> <ul style="list-style-type: none"><li>• have experienced disease progression during or after chemotherapy, or during or after <u>both</u> targeted therapy and chemotherapy in patients whose tumors express genomic aberrations of either epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or ROS1</li><li>• have <u>not</u> received prior treatment with any other immune checkpoint inhibitor (e.g., nivolumab, atezolizumab) in the advanced treatment setting</li><li>• (if applicable) have received durvalumab for stage III NSCLC in the adjuvant treatment setting, but have had at least a 6 month progression-free interval between completion of durvalumab and confirmation of disease progression</li></ul> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, pembrolizumab may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Subsequent immune checkpoint inhibitor therapy (e.g., atezolizumab, nivolumab, ipilimumab/nivolumab) is <u>not</u> funded in patients who have experienced disease progression during pembrolizumab treatment</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>

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pembrolizumab	vial	100 mg/4 mL		Lung	NSCLC	<p>Locally advanced (not amenable to curative-intent therapy) or metastatic, <u>non-squamous</u>, non-small cell lung cancer (NSCLC) with <u>no</u> genomic aberrations of either epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK) or ROS1, as a first-line treatment in combination with platinum-based chemotherapy (pemetrexed and platinum preferred) in patients who:</p> <ul style="list-style-type: none"><li>• have not received any prior immune checkpoint inhibitor therapy in the advanced treatment setting</li><li>• (if applicable) have received durvalumab for stage III NSCLC in the adjuvant treatment setting, but have had at least a 6 month progression-free interval between completion of durvalumab and confirmation of disease progression</li></ul> <p>Pembrolizumab is given for 4 to 6 cycles in combination with pemetrexed plus platinum chemotherapy, then may continue with or without maintenance pemetrexed for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>Patients who have initiated platinum-based chemotherapy while waiting for target mutations results which are later negative for any genomic tumor aberrations, pembrolizumab may then be added to chemotherapy, however, pembrolizumab is not approved for addition to single agent maintenance pemetrexed in patients who have already completed pemetrexed and platinum combination therapy</p> <p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Subsequent immune checkpoint inhibitor therapy (e.g., nivolumab, atezolizumab, ipilimumab/nivolumab) is <u>not</u> funded in patients who have experienced disease progression during first line pembrolizumab treatment</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Lung	NSCLC	<p>Locally advanced (not amenable to curative-intent therapy) or metastatic <u>squamous</u> non-small cell lung cancer (NSCLC) as a first-line treatment in combination with platinum-based chemotherapy (carboplatin plus paclitaxel preferred) in patients who:</p> <ul style="list-style-type: none"><li>• have not received any prior immune checkpoint inhibitor therapy in the advanced treatment setting</li><li>• (if applicable) have received durvalumab for stage III NSCLC in the adjuvant treatment setting, but have had at least a 6 month progression-free interval between completion of durvalumab and confirmation of disease progression</li></ul> <p>Pembrolizumab is given for 4 to 6 cycles in combination with platinum-based chemotherapy, then may continue as a single agent for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Subsequent immune checkpoint inhibitor therapy (e.g., atezolizumab, nivolumab) is <u>not</u> funded in patients who have experienced disease progression during pembrolizumab treatment</p> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>



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pembrolizumab	vial	100 mg/4 mL		Skin and Melanoma	Melanoma	<p>Locally advanced unresectable or metastatic, BRAF V600 mutation-negative or positive melanoma as a single agent, first-line immune checkpoint inhibitor therapy in the advanced setting in patients who:</p> <ul style="list-style-type: none"><li>• are previously untreated</li><li>• if BRAF V600 mutation-positive, may have received prior treatment with BRAF-targeted therapy either in the adjuvant or advanced treatment setting</li><li>• may have received prior treatment with a PD-1 inhibitor (e.g., nivolumab or pembrolizumab) in the adjuvant setting, but have had a progression-free interval of at least 6 months since the last dose of the PD-1 inhibitor and confirmation of disease progression</li><li>• have stable brain metastases (if present)</li></ul> <p>Pembrolizumab may continue for up to 2 years from treatment initiation, or until confirmed disease progression or unacceptable toxicity, whichever occurs first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 2 years duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 2 calendar years from treatment initiation)</p>	<p>If pembrolizumab was stopped after completion of 2 years of therapy or earlier at the time of best response, it may be re-started at the time of disease progression and may continue for up to an additional 1 year</p> <p>Single agent ipilimumab is funded as a subsequent treatment option in patients who have experienced disease progression during pembrolizumab treatment</p> <p>Pembrolizumab is <u>not</u> funded in the following settings:</p> <ul style="list-style-type: none"><li>• in patients who have experienced disease progression on, or after receiving nivolumab as a single agent or in combination with ipilimumab</li><li>• in patients who have experienced disease recurrence either during or within 6 months from the last dose of PD-1 inhibitor therapy (nivolumab or pembrolizumab) in the adjuvant setting</li><li>• in patients who stopped nivolumab due to significant intolerance or toxicity</li></ul> <p>Refer to Appendix A - Immune Checkpoint Inhibitor Therapy Monitoring and Disease Assessment</p>
				Skin and Melanoma	Melanoma	<p>Stage IIB and IIC* cutaneous or mucosal melanoma following complete resection as <u>adjuvant</u> treatment in adult and pediatric (12 years and older) patients</p> <p>Pembrolizumab should start within 12 weeks from surgery and may continue for up to 1 year of therapy, until confirmed disease progression or unacceptable toxicity, whichever comes first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 1 year duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 1 calendar year from treatment initiation)</p>	<p>*based on the 8th edition of the American Joint Committee of Cancer (AJCC) staging system</p> <p>Pembrolizumab is <u>not</u> funded as adjuvant therapy in patients with ocular or uveal melanoma</p> <p>Patients are eligible for all immune checkpoint inhibitor options in the adjuvant setting if they experience subsequent progression to stage III or IV melanoma and all disease is completely resected, or in the metastatic setting, <u>only</u> if there has been at least a 6 month progression-free interval between completion of adjuvant pembrolizumab and confirmation of disease progression</p> <p>Ipilimumab single agent therapy is the only immune checkpoint inhibitor option funded in patients who develop metastatic disease during or within 6 months of receiving the last dose of adjuvant pembrolizumab</p> <p>Patients should be assessed for disease recurrence at least every 3 months, or more frequently as clinically indicated during adjuvant pembrolizumab therapy</p>
				Skin and Melanoma	Melanoma	<p>Stage IIIA to stage IIID and resected stage IV*, BRAF V600 mutation-negative or positive, cutaneous or mucosal melanoma as <u>adjuvant</u> treatment in patients who:</p> <ul style="list-style-type: none"><li>• have completely resected disease, including in-transit metastases, with the exception that presence of micro-metastases in regional lymph nodes after sentinel lymph node biopsy is allowed</li></ul> <p>Pembrolizumab should start within 12 weeks from surgery and may continue for up to 1 year of therapy, until confirmed disease progression or unacceptable toxicity, whichever comes first</p> <p>(The total number of pembrolizumab cycles should not exceed an equivalent of 1 year duration, regardless of schedule; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 1 calendar year from treatment initiation)</p>	<p>*based on the 8th edition of the American Joint Committee of Cancer (AJCC) staging system</p> <p>Pembrolizumab adjuvant therapy is <u>not</u> funded in patients with ocular or uveal melanoma</p> <p>For patients with BRAF V600 mutation-positive melanoma, a one-time switch to the combination of dabrafenib and trametinib is allowed during the first 3 months of pembrolizumab treatment with the total duration of the combined adjuvant immunotherapy and BRAF-targeted therapy remaining at 12 months (including any dose interruption time periods)</p> <p>Patients are eligible for all immune checkpoint inhibitor options in the relapsed or metastatic setting <u>only</u> if there has been at least a 6 month progression-free interval between completion of adjuvant pembrolizumab and confirmation of disease progression</p> <p>For patients with BRAF V600 mutation-positive melanoma, all BRAF-targeted therapy options are funded in patients who relapse or develop metastatic disease at any time during or after receiving pembrolizumab adjuvant therapy</p> <p>Ipilimumab single agent therapy is the only immune checkpoint inhibitor option funded in patients who relapse or develop metastatic disease during or within 6 months of receiving the last dose of adjuvant pembrolizumab</p> <p>Patients should be assessed for disease recurrence at least every 3 months, or more frequently as clinically indicated during adjuvant pembrolizumab therapy</p>

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
pemetrexed	vial	100 mg 500 mg		Lung	Mesothelioma	Unresectable malignant mesothelioma in combination with platinum	
				Lung	NSCLC	Locally advanced (not amenable to curative-intent therapy) or metastatic, <u>non-squamous</u> non-small cell lung cancer (NSCLC) in combination with platinum chemotherapy, which may be followed by single agent maintenance therapy or as a single agent treattent option	Non-squamous histology must be <u>confirmed</u> to be eligible for any pemetrexed treatment options
				Lung	NSCLC	Stage IB-IIIB (AJCC 8th edition) <u>non-squamous</u> non-small cell lung cancer (NSCLC) in combination with platinum chemotherapy as adjuvant therapy following complete tumor resection	Non-squamous histology must be <u>confirmed</u> to be eligible for any pemetrexed treatment options
pertuzumab	vial	420 mg/14 mL		Breast	Breast, Advanced	<p>Locally advanced unresectable or metastatic, HER2-positive breast cancer in combination with a taxane and trastuzumab in patients who:</p> <ul style="list-style-type: none"><li>• have not received prior HER2 targeted therapy or chemotherapy for advanced disease</li><li>• (if applicable) have had a relapse-free interval of at least 6 months from the last dose of trastuzumab given in the neo/adjuvant setting</li></ul> <p>Pertuzumab in combination with taxane and trastuzumab may be given for up to 8 cycles, then if evidence of disease response, pertuzumab with trastuzumab may continue as maintenance therapy until disease progression or unacceptable toxicity, whichever occurs first</p>	<p>Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test</p> <p>Pertuzumab is <u>not</u> funded in combination with a taxane and trastuzumab in patients who have experienced disease relapse on or within 6 months from the last dose of neo/adjuvant trastuzumab</p> <p>Pertuzumab is funded in combination with a taxane and trastuzumab in patients who have experienced disease relapse on or within 6 months from the last dose of adjuvant Kadcyla</p> <p>Trastuzumab or Kadcyla therapy initially given in the adjuvant setting is counted as 1 line of treatment for advanced disease if disease recurrence occurs during or within 6 months from completion of adjuvant therapy</p> <p>A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2 positive breast cancer</p>
plerixafor	vial	24 mg/1.2 mL		Hematology	Blood and Marrow Transplant (BMT)	Adjunct therapy for hematopoietic stem cell mobilization in patients identified at being at high risk of having an unsuccessful stem cell harvest attempt with either filgrastim plus chemotherapy or filgrastim alone	
polatuzumab vedotin	vial	30 mg 140 mg		Hematology	Non-Hodgkin Lymphoma (NHL)	<p>Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), in combination with bendamustine and rituximab* in adult patients who are not eligible for an autologous stem cell transplant (ASCT) and have been previously treated with at least one prior therapy</p> <p>Polatuzumab vedotin in combination with bendamustine and rituximab may continue for a maximum of 6 cycles, or until disease progression or unacceptable toxicity, whichever occurs first</p>	<p>*Rituximab in combination with polatuzumab vedotin and bendamustine is funded independent of duration from last dose of rituximab</p> <p>Polatuzumab vedotin is funded in the following settings if all other eligibility criteria are met:</p> <ul style="list-style-type: none"><li>• in patients who previously received an autologous stem cell transplant (ASCT)</li><li>• as a "bridge" to chimeric antigen T-cell (CAR-T) therapy</li><li>• in patients who previously received CAR-T therapy provided they are transplant-ineligible</li><li>• in patients with transformed follicular lymphoma to DLBCL and those with HIV-related DLBCL</li></ul> <p>Polatuzumab vedotin is <u>not</u> funded in the following settings:</p> <ul style="list-style-type: none"><li>• as a "bridge" to ASCT in transplant-eligible patients</li><li>• in patients with active central nervous system (CNS) lymphoma</li><li>• in combination with regimens other than bendamustine and rituximab</li><li>• in combination with obinutuzumab</li></ul>
pomalidomide	capsule	1 mg 2 mg 3 mg 4 mg		Hematology	Multiple Myeloma	Multiple myeloma in combination with dexamethasone in patients who have experienced disease progression after <u>both</u> proteasome inhibitor (e.g., bortezomib) and lenalidomide-based therapies and have demonstrated disease progression during the most recent treatment	<p>*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive disease</p> <p>Cyclophosphamide may be added to pomalidomide plus dexamethasone</p>
				Hematology	Multiple Myeloma	Relapsed or refractory multiple myeloma in patients who have received at least 2 lines of prior therapy, including lenalidomide and a proteasome inhibitor, in combination with isatuximab and dexamethasone (IsaPd)	<p>*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive disease</p> <p>Patients who experience disease progression on first-line RVD will be eligible for IsaPd as the next line of therapy</p> <p>If a component of IsaPd needs to be discontinued due to intolerance, the remaining components in the regimen may be continued</p>

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ponatinib	tablet	15 mg 45 mg		Hematology	Acute Lymphoblastic Leukemia (ALL)	Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) in patients who: <ul style="list-style-type: none"><li>• have experienced disease resistance or progression after a second generation tyrosine kinase inhibitor (TKI); or</li><li>• have confirmed T315i mutation-positive disease, independent of prior TKI therapy; or</li><li>• have an intolerance or contraindication to other TKI therapies</li></ul>	
				Hematology	Chronic Myeloid Leukemia (CML)	Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) according to the following eligibility: <ul style="list-style-type: none"><li>• patients with chronic phase Ph+ CML who have experienced disease resistance, progression, or intolerance to at least 2 prior lines of tyrosine kinase inhibitor (TKI) therapy; or</li><li>• patients with accelerated phase or blast phase Ph+ CML who have experienced disease resistance or progression after a second generation TKI therapy; or</li><li>• patients with confirmed T315i mutation-positive disease, independent of prior TKI therapy</li></ul>	
pralatrexate	vial	20 mg/1 mL 40 mg/2 mL		Hematology	T-Cell Lymphoma	Relapsed or refractory peripheral T-cell lymphoma (PTCL) for all histologic subtypes* in patients who have received previous treatment (which may have included prior hematopoietic stem cell transplant, but excludes prior romidepsin) and who are ineligible for transplant at time of relapse	*Peripheral T-cell lymphomas (PTCL) subtypes include: <ul style="list-style-type: none"><li>• peripheral T-cell lymphoma, not otherwise specified (PTCL, NOS)</li><li>• anaplastic large cell lymphoma, primary systemic type (sALCL), ALK negative or positive</li><li>• angioimmunoblastic T-cell lymphoma (AITL)</li><li>• extranodal NK/T cell lymphoma, nasal type</li><li>• enteropathy-associated T-cell lymphoma (EATL)</li><li>• hepatosplenic T-cell lymphoma</li><li>• subcutaneous panniculitis-like T-cell lymphoma</li><li>• cutaneous γ-δ T-cell lymphoma</li><li>• transformed mycosis fungoides (but not cutaneous T-cell mycosis fungoides)</li></ul>
prednisolone	liquid	1 mg/1 mL		Pediatrics	Multiple	Pediatric patients unable to swallow oral prednisone tablets	
prednisone	tablet	1 mg 5 mg 50 mg		Multiple	Multiple		
procarbazine	capsule	50 mg		Multiple	Multiple		
radium-223	vial	6,600 kBq/6 mL	STEP	Genitourinary	Prostate	Metastatic castration-resistant prostate cancer (mCRPC) in patients with symptomatic bone metastases with the following inclusion criteria: <ul style="list-style-type: none"><li>• ECOG performance status of 0, 1 or 2</li><li>• recent consultation with a medical oncologist regarding systemic therapy options</li><li>• adequate initial hematologic parameters, defined as hemoglobin &gt;100 g/L, platelets &gt;100 x 10<sup>9</sup>/L and absolute neutrophil count (ANC) &gt;1.5 x 10<sup>9</sup>/L, with hematologic parameters of platelets &gt;50 x 10<sup>9</sup>/L; ANC &gt;1 x 10<sup>9</sup>/L for subsequent doses</li></ul>	Radium-223 can only be ordered and administered by the Nuclear Medicine department  Radium-223 is <u>not</u> funded in patients who: <ul style="list-style-type: none"><li>• are receiving chemotherapy, abiraterone or enzalutamide</li><li>• have a history or presence of visceral metastases</li><li>• have presence of malignant lymph nodes &gt;3 cm in diameter</li><li>• have active inflammatory bowel disease or significant fecal incontinence</li><li>• have untreated spinal cord compression or fracture requiring orthopedic stabilization</li></ul>

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raltitrexed	vial	2 mg		Gastrointestinal	Colorectal	Locally advanced unresectable or metastatic colorectal cancer as a single agent treatment in patients who have an intolerance or contraindication to fluoropyrimidine therapy (fluorouracil or capecitabine)	
				Lung	Mesothelioma	Malignant mesothelioma in combination with cisplatin as a first-line treatment	
ramucirumab	vial	100 mg/10 mL 500 mg/50 mL		Gastrointestinal	Gastric	Locally advanced unresectable or metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction (GEJ) in combination with paclitaxel in patients who have experienced disease progression following first-line chemotherapy	Ramucirumab is only approved in combination with paclitaxel and is <u>not</u> funded as single agent therapy: <ul style="list-style-type: none"><li>• If a temporary interruption of paclitaxel is required due significant toxicity, despite appropriate dose reduction, ramucirumab may be continued until paclitaxel can be re-started</li><li>• If serious, unmanageable toxicity to paclitaxel requires permanent discontinuation, ramucirumab may be continued as a single agent until disease progression</li><li>• If paclitaxel is discontinued for reasons other than serious, unmanageable toxicity (e.g., in the clinical setting of maintenance therapy following response to combination therapy, patient refusal to continue paclitaxel, etc.), ramucirumab is <u>not</u> funded to continue as single agent therapy</li></ul>
regorafenib	tablet	40 mg		Gastrointestinal	Gastrointestinal Stromal Tumor (GIST)	Locally advanced unresectable or metastatic gastrointestinal stromal tumor (GIST) as a subsequent line of treatment in patients who have experienced disease progression on, or intolerance to <u>both</u> imatinib and sunitinib	
				Gastrointestinal	Hepatocellular	Unresectable hepatocellular carcinoma (HCC) as a second-line treatment in patients who: <ul style="list-style-type: none"><li>• have experienced disease progression during first-line treatment with either lenvatinib or sorafenib, and if previously treated with sorafenib, have tolerated a daily dose of &gt;400 mg for &gt;20 days of the last 28 days of treatment</li><li>• have Child-Pugh A liver function</li></ul>	
ribociclib	tablet	200 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, hormone receptor-positive, HER2-negative breast cancer in combination with a non-steroidal aromatase inhibitor (NSAI) (anastrozole or letrozole) as a first-line treatment in post-menopausal women (pre- or peri-menopausal women must have a surgical or chemical-induced menopause) or in men who: <ul style="list-style-type: none"><li>• have not received any prior endocrine treatment for advanced disease, but may have received chemotherapy as initial treatment</li><li>• (if applicable) have had a progression-free interval of at least 1 year from completion of prior neo/adjuvant NSAI therapy (anastrozole or letrozole), or without time restriction in patients who received prior neo/adjuvant tamoxifen or exemestane</li><li>• have stable brain metastases (if present)</li></ul>	Pre- or peri-menopausal women who have not received a bilateral oophorectomy (surgical-induced menopause) are eligible to receive a gonadotropin releasing hormone (GnRH) agonist (e.g., goserelin) to achieve a chemical-induced menopause  Only <u>one</u> CDK 4/6 inhibitor (ribociclib or palbociclib) in combination with a NSAI is funded in the first-line setting  Everolimus in combination with exemestane is <u>not</u> funded as subsequent therapy after treatment with a CDK 4/6 inhibitor (ribociclib or palbociclib) in combination with either a NSAI or fulvestrant  Refer to Appendix C - Definition of Menopause
				Breast	Breast, Advanced	Locally advanced unresectable or metastatic, hormone receptor-positive, HER2-negative breast cancer in combination with fulvestrant as a first-line treatment or as a subsequent line of treatment in post-menopausal women (pre- or peri-menopausal women must have a surgical or chemical-induced menopause) or in men who: <ul style="list-style-type: none"><li>• are previously untreated, but may have received prior neo/adjuvant endocrine therapy without time restriction on interval between completion of adjuvant therapy and development of metastatic disease</li><li>• may have received chemotherapy as initial treatment for advanced disease</li><li>• may have received more than one line of endocrine therapy for advanced disease, excluding prior fulvestrant and endocrine therapy in combination with a CDK 4/6 inhibitor or everolimus</li><li>• have stable brain metastases (if present)</li></ul>	Pre- or peri-menopausal women who have not received a bilateral oophorectomy (surgical-induced menopause) are eligible to receive a gonadotropin releasing hormone (GnRH) agonist (e.g., goserelin) to achieve a chemical-induced menopause  Only <u>one</u> CDK 4/6 inhibitor-based therapy is funded (i.e., either ribociclib or palbociclib in combination with either a non-steroidal aromatase inhibitor or fulvestrant)  Everolimus in combination with exemestane is <u>not</u> funded as subsequent therapy after treatment with a CDK 4/6 inhibitor (ribociclib or palbociclib) in combination with either a NSAI or fulvestrant  Refer to Appendix C - Definition of Menopause
ripretinib	tablet	50 mg		Sarcoma	Gastrointestinal Stromal Tumor (GIST)	Advanced gastrointestinal stromal tumors (GIST) in patients who experience disease progression on or intolerance to imatinib, sunitinib and regorafenib, and have stable brain metastases (if present)	

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rituximab	vial	<u>Intravenous</u> 100 mg/10 mL 500 mg/50 mL  <u>Subcutaneous</u> 1,400 mg/11.7 mL 1,600 mg/13.4 mL		Hematology	Blood and Marrow Transplant (BMT)	Relapsed CD20-positive lymphoma in combination with chemotherapy for up to 4 cycles as salvage therapy intended as a bridge to stem cell transplant independent of the time interval since the last dose of rituximab-based therapy	
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in combination with fludarabine and cyclophosphamide (FCR) in patients who: • are 70 years of age or less and have a creatinine clearance of 70 mL/min or greater and a CIRS score less than or equal to 6 • have not received any prior therapy, or may have been previously treated, but have either not received any CD20-targeted therapy or have had a treatment-free interval of greater than 3 years since previous FCR treatment • have not received any prior targeted therapy for CLL/SLL, including acalabrutinib, ibrutinib, zanubrutinib, idelalisib or venetoclax	Maintenance rituximab therapy is not approved for CLL/SLL
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in combination with bendamustine (BR) in patients who: • have not received any prior therapy, or may have been previously treated, but have either not received any prior CD20-targeted therapy or have had a treatment free interval of at least 1 year since the last BR treatment • have not received any prior targeted therapy for CLL/SLL, including acalabrutinib, ibrutinib, zanubrutinib, idelalisib or venetoclax	Maintenance rituximab therapy is not approved for CLL/SLL
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in combination with venetoclax for up to 6 cycles in patients who have received at least 1 prior therapy	See venetoclax for funding information of rituximab in combination with venetoclax  Subsequent rituximab-based chemotherapy is <u>not</u> funded following rituximab in combination with venetoclax
				Hematology	Hairy Cell Leukemia	Hairy cell leukemia (HCL) as part of initial treatment or for relapsed/refractory disease as consolidation following cladribine  Rituximab is approved for up to 4 doses	
				Hematology	Hodgkin Lymphoma (HL)	CD20-positive, lymphocyte-predominant Hodgkin lymphoma in combination with chemotherapy	
				Hematology	Non-Hodgkin Lymphoma (NHL)	CD20-positive, low grade non-Hodgkin lymphoma* (NHL) or mantle cell lymphoma as a single agent, given once weekly for 4 doses, in patients who are not candidates for alternate treatment options and are either rituximab naive or have had at least a 6 month progression-free interval since the last rituximab dose	*low grade non-Hodgkin lymphoma subtypes include: follicular lymphoma, marginal zone lymphoma, lymphoplasmacytic lymphoma and Waldenstrom macroglobulinemia
				Hematology	Non-Hodgkin Lymphoma (NHL)	CD20-positive, diffuse large B-cell lymphoma (DLBCL) or transformed lymphoma in combination with chemotherapy	Rituximab maintenance therapy is <u>not</u> funded for DLBCL  Re-treatment with a rituximab-containing regimen is funded in patient who have a progression-free interval of at least 6 months from their last dose of rituximab
				Hematology	Non-Hodgkin Lymphoma (NHL)	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), in combination with polatuzumab vedotin and bendamustine in adult patients who are not eligible for an autologous stem cell transplant (ASCT) and have been previously treated with at least one prior therapy  Rituximab in combination with polatuzumab vedotin and bendamustine may continue for a maximum of 6 cycles, or until disease progression or unacceptable toxicity, whichever occurs first	Rituximab in combination with polatuzumab vedotin and bendamustine is funded independent of duration from last dose of rituximab

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rituximab	vial	Intravenous 100 mg/10 mL 500 mg/50 mL  Subcutaneous 1,400 mg/11.7 mL 1,600 mg/13.4 mL		Hematology	Non-Hodgkin Lymphoma (NHL)	CD20-positive, low grade non-Hodgkin lymphoma* or mantle cell lymphoma in combination with chemotherapy as first-line induction therapy, or as re-induction therapy provided there has been a progression-free interval of ≥6 months from the last dose of rituximab	*low grade non-Hodgkin lymphoma subtypes include: follicular lymphoma, marginal zone lymphoma, lymphoplasmocytic lymphoma and Waldenstrom macroglobulinemia
				Hematology	Non-Hodgkin Lymphoma (NHL)	CD20-positive Burkitt's lymphoma in combination with chemotherapy	
				Hematology	Non-Hodgkin Lymphoma (NHL)	CD20-positive, primary CNS (central nervous system) lymphoma as part of induction therapy	
				Hematology	Non-Hodgkin Lymphoma (NHL)	CD20-positive, low grade non-Hodgkin lymphoma* or transplant-ineligible mantle cell lymphoma as maintenance therapy in patients who: • have achieved at least a partial response (i.e., a 50% or greater reduction in total disease burden) following the first induction rituximab plus chemotherapy treatment (first maintenance therapy) • have had a progression-free interval ≥3 years since the last rituximab dose (either in combination with chemotherapy or after the first maintenance therapy) and have achieved at least a partial response (i.e., a 50% or greater reduction in total disease burden) after a second re-induction rituximab plus chemotherapy treatment (second maintenance therapy)  Rituximab as maintenance therapy is initiated within 3 to 6 months of completing induction therapy, provided there has been no interval disease progression, and is given every 3 months for up to 2 years, or until disease progression or unacceptable toxicity, whichever occurs first	*low grade non-Hodgkin lymphoma subtypes include: follicular lymphoma, marginal zone lymphoma, lymphoplasmocytic lymphoma and Waldenstrom's macroglobulinemia  Rituximab maintenance therapy is <u>not</u> approved for transformed lymphoma or chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL)  (see separate maintenance therapy indication for mantle cell lymphoma following autologous stem cell transplant)
				Hematology	Non-Hodgkin Lymphoma (NHL)	Relapsed or refractory indolent lymphoma in combination with lenalidomide in patients who are not suitable candidates for chemoimmunotherapy	
				Hematology	Mantle Cell Lymphoma (MCL)	Mantle cell lymphoma as maintenance therapy in patients who have responded to treatment with induction chemotherapy followed by an autologous stem cell transplant (ASCT)  Rituximab as maintenance therapy is initiated within 3 to 6 months of the ASCT, provided there has been no interval disease progression, and is given every 3 months for up to 3 years, or until disease progression or unacceptable toxicity, whichever occurs first	
				Hematology	Multiple	Autoimmune hemolytic anemia (AIHA) or immune thrombocytopenic purpura (ITP) as a single agent in patients with an underlying malignancy who: • have a low burden of cancer that does not require active systemic treatment • are refractory to corticosteroids  Rituximab is administered intravenously weekly for 4 doses	

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
ruxolitinib	tablet	5 mg 10 mg 15 mg 20 mg	STEP	Hematology	Myeloproliferative Neoplasm (MPN)	Intermediate to high-risk* myelofibrosis (MF) in patients who have: • primary MF, post-polycythemia vera MF, or post-essential thrombocythemia MF; <u>and</u> • require treatment of splenomegaly and/or disease-related symptoms from MF; <u>and</u> • are previously untreated or are refractory to other therapies (e.g., anagrelide, hydroxyurea, interferon)	*assessed using the Dynamic International Prognostic Scoring System-Plus (DIPSS-Plus)  Ruxolitinib is <u>not</u> funded in patients who have experienced disease progression on or following fedratinib
			STEP	Hematology	Myeloproliferative Neoplasm (MPN)	Polycythemia vera in patients who have resistance or intolerance to hydroxyurea according to the modified European LeukemiaNet (ELN) criteria*	*modified European LeukemiaNET (ELN) criteria for resistance or intolerance to hydroxyurea: <u>Resistance</u> : after 3 months of at least 2 g/day of hydroxyurea, or at the maximally tolerated hydroxyurea dose if that dose is less than 2 g/day, there is one or more of the following: • need for phlebotomy to maintain the hematocrit less than 45% • uncontrolled myeloproliferation (platelet count >400 x 10 <sup>9</sup> /L and WBC >10 x 10 <sup>9</sup> /L) • massive splenomegaly not reduced by at least 50%, as measured by palpation  <u>Intolerance</u> : during treatment with hydroxyurea at the lowest dose required to achieve a response ( <i>i.e.</i> , hematocrit less than 45% without phlebotomy and/or all of the following: platelets <400 x 10 <sup>9</sup> /L, WBC <10 x 10 <sup>9</sup> /L, and non-palpable spleen), there is 1 or more of the following: • ANC <1 x 10 <sup>7</sup> /L or platelets <100 x 10 <sup>7</sup> /L or hemoglobin <100 g/L • presence of leg ulcers • non-hematologic hydroxyurea toxicities (e.g., mucocutaneous manifestations, gastrointestinal symptoms, pneumonitis or fever) that are grade 3 to 4, or grade 2 for more than 1 week • permanent discontinuation or significant interruptions of hydroxyurea therapy, or hospitalization due to hydroxyurea toxicity
				Hematology	Blood and Marrow Transplant (BMT)	Corticosteroid-refractory or corticosteroid-dependent acute graft-versus-host disease (aGvHD)* in adult and pediatric patients aged 12 and older  Ruxolitinib should be discontinued upon the occurrence of any of the following: • progression of aGvHD, defined as worsening of aGvHD symptoms or occurrence of new aGvHD symptoms • addition of systemic therapies (other than calcineurin inhibitors) for aGvHD after day 28 • recurrence or relapse of underlying hematological malignancy • unacceptable toxicity	*Patients must have clinically diagnosed grade II to IV aGvHD according to the NIH criteria  Corticosteroid-refractory or -dependent aGvHD is defined as follows: <u>Corticosteroid refractory</u> (at least 1 or more of the following criteria) 1. Progressing based on organ assessment after at least 3 days compared to organ stage at the time of initiation of a high-dose systemic corticosteroid +/- a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) for the treatment of grade II to IV aGvHD 2. Failure to achieve, at a minimum, a partial response based on organ assessment after 7 days compared to organ stage at the time of initiation of a high-dose systemic corticosteroid +/- a calcineurin inhibitor for the treatment of grade II to IV aGvHD 3. Failure of a corticosteroid taper, defined as fulfilling either of the following criteria: i. requirement for an increase in the corticosteroid dose to methylprednisolone ≥ 2 mg/ kg per day (or equivalent prednisone dose of ≥ 2.5 mg/kg per day) ii. failure to taper the methylprednisolone dose to < 0.5 mg/kg per day (or equivalent prednisone dose of < 0.6 mg/kg per day) for a minimum of 7 days  <u>Corticosteroid dependence</u> • inability to taper prednisone under 2 mg/kg per day after an initially successful treatment of at least 7 days or as the recurrence of aGvHD activity during the steroid taper
				Hematology	Blood and Marrow Transplant (BMT)	Chronic graft-versus-host disease (cGvHD)* in adults and pediatric patients aged 12 years and older who have inadequate response to corticosteroids or other systemic therapies  Ruxolitinib should be discontinued upon the occurrence of any of the following: • progression of cGvHD, defined as worsening of cGvHD symptoms or occurrence of new cGvHD symptoms • lack of clinical benefit (complete response, partial response, or stable disease with significant reduction in steroid dose) after 6 months of therapy • recurrence or relapse of underlying hematological malignancy • unacceptable toxicity	*Patients must have clinically diagnosed moderate to severe cGvHD according to the NIH consensus criteria: Mild: involves ≤2 organs/sites with no clinically significant functional impairment Moderate: involves 3 organs/sites with no clinically significant functional impairment, or ≤1 organ/site with clinically significant functional impairment, but no major disability Severe: major disability caused by cGvHD  Inadequate response to corticosteroids or steroid refractoriness for cGvHD is defined as follows: • a lack of response or disease progression after administration of at least 1 mg/kg/day of prednisone (or equivalent) for at least 1 week; or • disease persistence without improvement despite continued treatment with prednisone at > 0.5 mg/kg/day or 1 mg/kg/ every other day (or equivalent) for at least 4 weeks; or • an increase of the prednisone dose to > 0.25 mg/kg/day (or equivalent) after 2 unsuccessful attempts to taper the dose

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sacituzumab govitecan	vial	180 mg		Breast	Breast, Advanced	Unresectable locally advanced or metastatic triple-negative* breast cancer (mTNBC) who have received 2 or more prior therapies, at least 1 of them for metastatic disease, including patients with stable brain metastases (if present)	<p>*Triple-negative breast cancer (TNBC) is defined as &lt;1% expression of estrogen- (ER) and progesterone- receptors (PR), and either HER2 0 to 1+ by immunohistochemistry (IHC) or HER2 IHC 2+ and in-situ hybridization (ISH) negative (not amplified)</p> <p>Breast cancers that are HER2-negative with a low level (defined as 1-10%) of estrogen receptor [ER] or progesterone receptor [PR] expression by IHC will be eligible for treatments funded for TNBC if the medical oncologist considers them to be functionally hormone receptor-negative; however, once a specific treatment pathway is chosen (i.e., TNBC vs. endocrine therapy), funding is <u>not</u> approved to switch between these pathways unless there is a change in tumor biology based on repeat biopsy)</p> <p>Patients should have been previously treated with a taxane in either the adjuvant, neoadjuvant or advanced setting; patients who have a medical contraindication or intolerance to previous taxane are eligible</p>
sargramostim (GM-CSF)	vial	500 mcg/1 mL	SAP	Pediatrics	Neuroblastoma	As part of the protocol requirements for dinutuximab therapy in the treatment of neuroblastoma	GM-CSF is not commercially available in Canada and requires Health Canada Special Access Programme (SAP) approval
selinexor	tablet	20 mg		Hematology	Multiple Myeloma	Multiple myeloma in patients who have received at least 1 prior therapy, in combination with bortezomib and dexamethasone (SVd)	<p>*Refer to Appendix B - Multiple Myeloma Definitions of Refractory and Progressive Disease</p> <p>Patients with plasma cell leukemia or systemic light chain amyloidosis are eligible</p> <p>Patients who are refractory to bortezomib are <u>not</u> eligible</p> <p>Prior treatment with bortezomib (or other proteasome inhibitors) is permitted, provided all of the following criteria are met:</p> <ul style="list-style-type: none"><li>• the best response achieved with prior bortezomib at any time was equal to or greater than a partial response, and the last proteasome inhibitor therapy (alone or in combination) was equal to or greater than a partial response</li><li>• bortezomib was not discontinued due to grade ≥ 3 related toxicity</li><li>• there must be a proteasome inhibitor treatment–free interval of at least 6 months before the first day of SVd</li></ul>
selpercatinib	capsule	40 mg 80 mg		Head and Neck	Thyroid	Advanced (not amenable to surgery or radioactive iodine therapy) or metastatic, rearranged during transfection (RET) fusion-positive differentiated thyroid cancer (DTC) following prior treatment with lenvatinib or sorafenib*, as a single agent	<p>Patients who are refractory to radioactive iodine therapy and/or unable to undergo surgery, or who have a contraindication to radioactive iodine therapy, and patients who are intolerant to first-line treatment with lenvatinib are eligible</p> <p>*Sorafenib is <u>not</u> funded for differentiated thyroid cancer</p>
				Head and Neck	Thyroid	Unresectable advanced or metastatic, rearranged during transfection (RET) mutant-positive medullary thyroid cancer (MTC) in patients who have progressed on, are intolerant to, or have a contraindication to first-line therapy, as a single agent	<p>Patients may or may not have been previously treated with vandetinib or cabozantinib*</p> <p>*Cabozantinib is <u>not</u> funded for medullary thyroid cancer</p>
				Lung	NSCLC (RET positive)	Locally advanced (not amenable to curative-intent therapy) or metastatic, non-squamous, rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as first-line treatment or after previous systemic therapy, as a single agent including patients who have stable brain metastases (if present)	
siltuximab	vial	100 mg 400 mg	STEP	Hematology	Castleman Disease	Multicentric Castleman disease in patients who are negative for both the human immunodeficiency virus (HIV) and human herpes virus-8 (HHV-8) and who have not previously received IL-6 receptor antagonist therapy (e.g., tocilizumab)	
sorafenib	tablet	200 mg		Gastrointestinal	Hepatocellular	Unresectable or metastatic hepatocellular carcinoma (HCC) as a first-line treatment in patients with Child-Pugh A liver function	<p>Only <u>one</u> of sorafenib or lenvatinib is funded as a first-line treatment for HCC (i.e., lenvatinib is not funded as a second-line treatment in patients who have experienced disease progression during sorafenib treatment)</p> <p>Patients experiencing intolerance to first-line lenvatinib treatment with no evidence of disease progression may switch to sorafenib, providing all other funding criteria are met</p> <p>Regorafenib is funded as a second-line treatment in patients who have experienced disease progression during sorafenib treatment, provided all funding criteria for regorafenib are met</p>



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sunitinib	tablet	12.5 mg 25 mg 50 mg		Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) for all histologic subtypes and risk categories* as a single agent, first-line vascular endothelial growth factor (VEGF)-receptor tyrosine kinase inhibitor (TKI) treatment	*determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria  Only <u>one</u> of pazopanib or sunitinib is funded as first-line VEGF TKI treatment  Only <u>one</u> of axitinib or cabozantinb, or nivolumab is funded as a second-line treatment in patients who have experienced disease progression during first-line VEGF TKI (sunitinib or pazopanib) treatment
				Genitourinary	Renal Cell Carcinoma	Metastatic renal cell carcinoma (mRCC) as a second-line treatment in patients previously treated with first-line combination ipilimumab plus nivolumab for intermediate or high-risk disease	Only <u>one</u> of pazopanib or sunitinib is funded as second-line treatment in patients who have experienced disease progression following first-line ipilimumab plus nivolumab treatment  Nivolumab is funded as a third-line treatment in patients who have experienced disease progression after both first-line combination nivolumab plus ipilimumab and second-line VEGF TKI (sunitinib or pazopanib) treatment
				Neuroendocrine	Pancreatic Neuroendocrine Tumor (pNET)	Locally advanced unresectable or metastatic, well or moderately differentiated pancreatic neuroendocrine tumor (pNET) in patients who have progressive disease	Only <u>one</u> of sunitinib or everolimus is funded for patients with pNET (i.e., everolimus is not funded as a second-line treatment in patients who have experienced disease progression during sunitinib treatment)
				Sarcoma	Gastrointestinal Stromal Tumor (GIST)	Locally advanced unresectable or metastatic c-Kit (CD117)-positive gastrointestinal stromal tumor (GIST) in patients who have experienced disease progression during imatinib treatment given in either the adjuvant or advanced setting	Regorafenib is funded as a subsequent treatment in patients who have experienced disease progression during sunitinib treatment  Sunitinib is <u>not</u> funded as an alternate therapy in patients who experience intolerance or toxicity to imatinib in the <u>adjuvant</u> setting
tamoxifen	tablet	20 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic hormone receptor-positive breast cancer	
				Breast	Breast, Early Stage	Early stage hormone receptor-positive breast cancer as adjuvant therapy	Adjuvant therapy includes treatment for 5 to 10 years (upfront strategy), or for 2 to 3 years prior to 2 to 3 years of treatment with an aromatase inhibitor (anastrozole, letrozole or exemestane) for a total of 5 years (switch strategy) or for up to 5 years prior to a further 5 years of aromatase inhibitor treatment (extended strategy)
				Breast	Ductal Carcinoma In-Situ (DCIS)	Hormone receptor-positive ductal carcinoma in-situ (DCIS) for up to 5 years	Tamoxifen is <u>not</u> funded for hormone receptor-positive lobular carcinoma in-situ (LCIS)
				Gynecology	Multiple	Recurrent or progressive, hormone receptor-positive endometrial, epithelial ovarian, fallopian tube or primary peritoneal cancers	
				Sarcoma	Sarcoma, General	Recurrent desmoid tumor or aggressive fibromatosis	
tebentafusp	vial	100 mcg/ 0.5 mL		Skin and Melanoma	Melanoma	Human leukocyte antigen (HLA)-A*02:01-positive unresectable or metastatic uveal melanoma (mUM) in the first-line setting, including patients with stable brain metastases (if present)	Patients may continue to receive tebentafusp following any localized treatments (e.g., stereotactic radiosurgery) to control central nervous system (CNS) metastases  The first 3 doses of tebentafusp must be administered in an inpatient setting to allow for a sufficient observation period and management of potential cytokine release syndrome
temozolomide	capsule	5 mg 20 mg 100 mg 140 mg 250 mg		Multiple	Multiple		
temsirolimus	vial	25 mg		Genitourinary	Renal Cell Carcinoma	Poor-risk* metastatic renal cell carcinoma (mRCC) as a first line treatment in patients who are not candidates for other available treatment options	*determination of risk category (favorable, intermediate or poor) is based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria
thioguanine	tablet	40 mg		Hematology	Acute Lymphoblastic Leukemia (ALL)		
thiotepa	vial	15 mg 100 mg		Hematology	Blood and Marrow Transplant (BMT)	Primary or secondary CNS (central nervous system) lymphoma as part of an approved conditioning regimen prior to autologous stem cell transplant (ASCT)  Haplo-identical hematopoietic stem cell transplant (haplo-HSCT) as part of an approved conditioning regimen	
				Hematology	Non-Hodgkin Lymphoma (NHL)	CNS (central nervous system) lymphoma as part of an approved chemotherapy regimen in patients who are not eligible for autologous stem cell transplant (ASCT)	

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tisagenlecleucel (tisa-cel)	Cell suspension in patient-specific infusion bag(s)	2.0 x 10 <sup>6</sup> to 6.0 x 10 <sup>6</sup> anti-CD19 CAR-positive viable T cells in ~10-50 mL	STEP	Hematology	Large B-cell Lymphoma (LBCL)	Relapsed or refractory* large B-cell lymphoma (LBCL) after 2 or more lines of systemic therapy  Eligible LBCL subtypes include: <ul style="list-style-type: none"><li>• diffuse large B-cell lymphoma (DLBCL)</li><li>• primary mediastinal large B-cell lymphoma (PMBCL)</li><li>• high-grade B-cell lymphoma (HGBL)</li><li>• DLBCL arising from indolent lymphoma</li><li>• follicular large B-cell lymphoma (formerly called follicular lymphoma grade 3B)</li></ul>	*relapsed or refractory disease is defined as 1 of the following: <ul style="list-style-type: none"><li>• disease progression after the last regimen or following hematopoietic stem cell transplant (relapsed)</li><li>• failure to achieve a partial response (PR) or complete response (CR) to the last regimen (refractory)</li></ul> Patients with primary CNS lymphoma or evidence of Richter transformation are <u>not</u> eligible
			STEP	Hematology	Acute Lymphoblastic Leukemia (ALL)	Relapsed or refractory* B-cell precursor acute lymphoblastic leukemia (B-ALL) in patients less than or equal to 25 years of age who:  *relapsed or refractory B-ALL is defined as 1 of the following: <ul style="list-style-type: none"><li>• primary refractory disease</li><li>• first relapse if first remission ≤12 months</li><li>• relapsed or refractory disease after 2 or more lines of systemic therapy</li><li>• relapsed or refractory disease after allogeneic stem cell transplant (SCT)</li></ul>	Patients must have ≥5% lymphoblasts in bone marrow  Patients with Philadelphia chromosome-positive (Ph+) B-cell acute lymphoblastic leukemia (ALL) are eligible if they are intolerant to or have failed 2 or more lines of tyrosine kinase inhibitors (TKI) or if TKI therapy is contraindicated  Burkitt's lymphoma/leukemia and active central nervous system disease are <u>not</u> funded
thyrotropin	vial	0.9 mg/1 mL		Head and Neck	Supportive Care	In newly diagnosed thyroid cancer patients prior to ablation therapy	
topotecan	vial	4 mg		Multiple	Multiple		
trametinib	tablet	0.5 mg 1 mg 2 mg		Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic BRAF V600 mutation-positive melanoma as a <u>single agent</u> in patients who: <ul style="list-style-type: none"><li>• have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting</li><li>• may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting</li><li>• (if applicable) have had a progression-free interval of ≥6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib)</li><li>• have stable brain metastases (if present)</li></ul>	In the clinical setting of toxicity to trametinib, but without evidence of disease progression, treatment may be switched to alternate BRAF-targeted therapy (e.g., single agent dabrafenib or vemurafenib, or the combination of vemurafenib and cobimetinib)  Alternate BRAF-targeted therapies are not funded in any subsequent line of therapy in patients who have experienced disease progression during trametinib treatment
				Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic BRAF V600 mutation-positive melanoma in <u>combination</u> with dabrafenib in patients who: <ul style="list-style-type: none"><li>• have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting</li><li>• may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting</li><li>• (if applicable) have had a progression-free interval of ≥6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib)</li><li>• have stable brain metastases (if present)</li></ul>	In the clinical setting of toxicity to the combination of dabrafenib and trametinib, but without evidence of disease progression, treatment may be continued, as clinically appropriate, with either single agent dabrafenib or trametinib, or switched to alternate BRAF-targeted therapy with the combination of vemurafenib and cobimetinib or single agent vemurafenib  Alternate BRAF-targeted therapies are not funded in any subsequent line of therapy in patients who have experienced disease progression during dabrafenib and trametinib treatment
				Skin and Melanoma	Melanoma	Stage I/IIA (limited to lymph node metastases >1 mm) to stage II/ID*, BRAF V600 mutation-positive cutaneous melanoma in <u>combination</u> with dabrafenib as <u>adjuvant</u> treatment in patients who: <ul style="list-style-type: none"><li>• have completely resected disease, including in-transit metastases, with the exception that presence of micro-metastases in regional lymph nodes after sentinel lymph node biopsy is allowed</li></ul> Dabrafenib and trametinib should start within 12 weeks from surgery and may continue for a maximum duration of 12 months from treatment initiation or until confirmation of local disease progression, development of metastatic disease or unacceptable toxicity, whichever occurs first  (The total duration of trametinib should not exceed an equivalent of 12 months duration; if there are temporary dose delays or interruptions, treatment may be continued to complete all planned cycles even if it exceeds 12 calendar months from treatment initiation)	*based on the 8th edition of the American Joint Committee of Cancer (AJCC) staging system  Dabrafenib and trametinib adjuvant therapy is <u>not</u> funded in patients with mucosal or ocular melanoma  A one-time switch to adjuvant nivolumab or pembrolizumab is allowed during the first 3 months of combination dabrafenib and trametinib treatment with the total duration of the combined adjuvant BRAF- targeted therapy and immunotherapy remaining at 12 months  Switching combination vemurafenib and cobimetinib is <u>not</u> funded for patients who have experienced intolerance or disease progression during adjuvant dabrafenib and trametinib therapy  All immunotherapy treatment options are available for patients who relapse on, or any time after completion of adjuvant dabrafenib and trametinib therapy  Re-treatment with BRAF-targeted therapy for recurrent or metastatic disease is funded if the progression-free interval from the completion of adjuvant dabrafenib and trametinib is ≥6 months

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trastuzumab	vial	440 mg		Breast	Breast, Advanced	Locally advanced or metastatic, HER2-positive breast cancer in combination with chemotherapy (taxane preferred) as a first-line treatment in patients who: <ul style="list-style-type: none"><li>• have not received prior HER2-targeted therapy for advanced disease</li><li>• (if applicable) have had a relapse-free interval of at least 6 months from the last dose of HER2 targeted therapy (trastuzumab or Kadcyla) given in the neo/adjuvant setting</li></ul> Trastuzumab may continue as single agent maintenance therapy after best response to combination with chemotherapy, until disease progression or unacceptable toxicity	Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test  Second-line HER2-targeted therapies in patients who have experienced disease progression during first-line trastuzumab include <u>one</u> of Kadcyla, trastuzumab with alternate chemotherapy or lapatinib plus capecitabine  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2 positive breast cancer
				Breast	Breast, Advanced	Locally advanced or metastatic, HER2-positive breast cancer in combination with alternate chemotherapy as a second-line treatment option in patients who: <ul style="list-style-type: none"><li>• have experienced disease progression following first-line trastuzumab plus chemotherapy treatment, excluding trastuzumab in combination with pertuzumab</li><li>• (if applicable) have experienced disease relapse during or within 6 months from completing trastuzumab in the adjuvant setting (excluding Kadcyla)</li></ul> Trastuzumab may continue as single agent maintenance therapy after best response to combination with chemotherapy, until disease progression or unacceptable toxicity	Adjuvant trastuzumab therapy is counted as 1 line of treatment for advanced disease, if disease recurrence occurs within 6 months from completion of adjuvant trastuzumab  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2 positive breast cancer
				Breast	Breast, Advanced	Locally advanced unresectable or metastatic, HER2-positive breast cancer in combination with a taxane and pertuzumab in patients who: <ul style="list-style-type: none"><li>• have not received prior HER2-targeted therapy or chemotherapy for advanced disease</li><li>• (if applicable) have had a relapse-free interval of at least 6 months from the last dose of trastuzumab given in the neo/adjuvant setting</li></ul> Trastuzumab in combination with taxane and pertuzumab may be given for up to 8 cycles, then if evidence of disease response, trastuzumab and pertuzumab may continue as maintenance therapy until disease progression or unacceptable toxicity, whichever occurs first	Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test  Trastuzumab is <u>not</u> funded in combination with taxane and pertuzumab in patients who have experienced disease relapse on or within 6 months from the last dose of neo/adjuvant trastuzumab  Trastuzumab is funded in combination with taxane and pertuzumab in patients who have experienced disease relapse on or within 6 months from the last dose of adjuvant Kadcyla, however, no further HER2-targeted therapies are funded subsequently  Trastuzumab or Kadcyla therapy initially given in the adjuvant setting is counted as 1 line of treatment for advanced disease if disease recurrence occurs during or within 6 months from completion of adjuvant therapy  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2 positive breast cancer
				Breast	Breast, Advanced	Locally advanced unresectable or metastatic, HER2-positive breast cancer in combination with tucatinib and capecitabine in patients who: <ul style="list-style-type: none"><li>• have received prior treatment with trastuzumab, pertuzumab, and a HER2-targeted antibody-drug conjugate (e.g., Kadcyla, Enhertu)</li><li>• have brain metastases (if present)</li></ul>	Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test  Treatment with tucatinib may continue if discontinuation is required for one of trastuzumab or capecitabine due to toxicity; if trastuzumab and capecitabine are both discontinued, tucatinib should also be discontinued  Trastuzumab and capecitabine may be continued, and tucatinib may be discontinued in the event of unacceptable toxicity attributed to tucatinib  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2 positive breast cancer
				Breast	Breast, Early Stage	High-risk*, early and locally advanced, HER2-positive breast cancer as adjuvant therapy initiated in combination with, or following adjuvant or neoadjuvant chemotherapy  Trastuzumab may be given for up to 17 doses (every 3 week schedule) administered within a time period not exceeding 14 months from initiation of therapy	*high-risk is defined as either node-positive or node-negative with tumors $\geq$ T1b with other features that qualify for use of adjuvant chemotherapy  Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test  Trastuzumab is <u>not</u> funded as a single agent for adjuvant therapy of HER2 positive breast cancer in patients who are ineligible for, or who decline chemotherapy  Trastuzumab or Kadcyla therapy initially given in the adjuvant setting is counted as 1 line of treatment for advanced disease if disease recurrence occurs during or within 6 months from completion of adjuvant therapy  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2-positive breast cancer

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trastuzumab	vial	440 mg		Gastrointestinal	Gastric	Locally advanced unresectable or metastatic, HER2-positive gastric cancer, adenocarcinoma of the gastroesophageal junction (GEJ), or esophagus in combination with cisplatin and fluoropyrimidine, FOLFOX or CAPOX as a first-line treatment  Trastuzumab may continue as single agent maintenance therapy after best response to combination with chemotherapy, until disease progression or unacceptable toxicity	
				Gynecology	Endometrial	Locally advanced unresectable or metastatic, HER2-positive serous endometrial cancer in combination with paclitaxel and carboplatin as a first or subsequent line of treatment  Trastuzumab may continue as single agent maintenance therapy after best response to combination with chemotherapy, until disease progression or unacceptable toxicity	Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test  Trastuzumab is <u>not</u> funded in the following settings: <ul style="list-style-type: none"><li>• in patients who have experienced disease relapse within 6 months from the last dose of previous treatment with paclitaxel and carboplatin chemotherapy without trastuzumab</li><li>• in combination with alternate chemotherapy in patients who have experienced disease progression during trastuzumab therapy, either in combination with chemotherapy or as single agent maintenance therapy</li></ul>
trastuzumab deruxtecan (see Enhertu®)							
trastuzumab emtansine (see Kadcyla®)							
treosulfan	vial	1 g 5 g		Hematology	Blood and Marrow Transplant (BMT)	Multiple myeloma in combination with fludarabine as part of the conditioning regimen prior to allogeneic stem cell transplant	
tretinoin	capsule	10 mg		Hematology	Acute Promyelocytic Leukemia (APL)	Acute promyelocytic leukemia (APL) as part of induction, consolidation and maintenance therapy	Also referred to as ATRA or all-trans retinoic acid
trifluridine-tipiracil	tablet	15 mg/6.14 mg trifluridine/tipiracil  20 mg/8.19 mg trifluridine/tipiracil		Gastrointestinal	Gastric	Locally advanced unresectable or metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction (GEJ) in patients who: <ul style="list-style-type: none"><li>• have received at least 2 prior lines of chemotherapy in the advanced treatment setting, including both a fluoropyrimidine and a platinum, and either a taxane or irinotecan, and if eligible, also HER2-targeted therapy</li><li>• do <u>not</u> have brain metastases</li></ul>	Patients who are unsuitable for platinum-based therapy and are treated with alternate chemotherapy are eligible, provided they have received at least 2 lines of chemotherapy  Pre-operative neoadjuvant and/or post-operative adjuvant chemotherapy or chemoradiotherapy will be counted as 1 line of therapy for advanced disease in patients who have experienced disease recurrence during or within 6 months of completion of adjuvant chemotherapy (note: in cases where pre- and post-operative chemotherapy is administered, this applies only if the same regimen was administered both pre- and post-operatively)
tucatinib	tablet	50 mg 150 mg		Breast	Breast, Advanced	Locally advanced unresectable or metastatic, HER2-positive breast cancer in combination with trastuzumab and capecitabine in patients who: <ul style="list-style-type: none"><li>• have received prior treatment with trastuzumab, pertuzumab, and a HER2-targeted antibody-drug conjugate (e.g., Kadcyla, Enhertu)</li><li>• have brain metastases (if present)</li></ul>	Confirmed HER2 positivity includes a positive result from either one or both of IHC or ISH (e.g., FISH) assessed by a validated test  Treatment with tucatinib may continue if discontinuation is required for one of trastuzumab or capecitabine due to toxicity; if trastuzumab and capecitabine are both discontinued, tucatinib should also be discontinued  Trastuzumab and capecitabine may be continued, and tucatinib may be discontinued in the event of unacceptable toxicity attributed to tucatinib  A maximum of 3 lines of HER2-targeted therapy is funded in patients with advanced HER2 positive breast cancer

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
vandetanib	tablet	100 mg 300 mg	STEP	Head and Neck	Thyroid	Locally advanced unresectable or metastatic, hereditary or sporadic, medullary thyroid cancer (MTC) in symptomatic patients with progressive disease who: • have measureable disease for assessment of tumor response and clinical benefit • (if applicable) have completed treatment for brain metastases or spinal cord compression at least 4 weeks before the first vandetanib dose and have been stable without steroid treatment for at least 10 days	Vandetanib is only available through a controlled program (referred to as the Caprelsa Restricted Distribution Program at <a href="http://www.caprelsa.ca/rdp">www.caprelsa.ca/rdp</a> ) and only prescribers and pharmacies* registered with the program and completed the certification are able to prescribe and dispense vandetanib *the SCA pharmacies are not registered to dispense vandetanib  Only patients who are enrolled and meet all of the requirements of the Caprelsa Restricted Distribution Program can receive vandetanib
vemurafenib	tablet	240 mg		Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic BRAF V600 mutation-positive melanoma as <u>single agent</u> , therapy in patients who: • have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting • may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting • (if applicable) have had a progression-free interval of ≥6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib) • have stable brain metastases (if present)	In the clinical setting of toxicity to vemurafenib, but without evidence of disease progression, treatment may be switched to alternate BRAF-targeted therapy (e.g., single agent dabrafenib or trametinib, or the combination of dabrafenib and trametinib)  Alternate BRAF-targeted therapies are <u>not</u> funded in any subsequent line of therapy in patients who have experienced disease progression during vemurafenib treatment
				Skin and Melanoma	Melanoma	Locally advanced unresectable or metastatic BRAF V600 mutation-positive melanoma in <u>combination</u> , with cobimetinib in patients who: • have not experienced disease progression during prior BRAF-targeted therapy used in the advanced treatment setting • may or may not have received prior immune checkpoint inhibitor therapy in either the advanced or adjuvant treatment setting • (if applicable) have had a progression-free interval of ≥6 months from completion of adjuvant BRAF-targeted therapy (dabrafenib and trametinib) • have stable brain metastases (if present)	In the clinical setting of toxicity to combination vemurafenib and cobimetinib therapy, but without evidence of disease progression, treatment may continue with vemurafenib as a single agent, if clinically appropriate, or switched to alternate BRAF-targeted therapy (e.g., single agent dabrafenib or trametinib or the combination of dabrafenib and trametinib)  Alternate BRAF-targeted therapies are <u>not</u> funded in any subsequent line of therapy in patients who have disease progression with combination vemurafenib and cobimetinib treatment

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
venetoclax	tablet	10 mg 50 mg 100 mg		Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) as a single agent in patients who have received at least 1 prior therapy and who have experienced disease progression during ibrutinib, acalabrutinib or idelalisib therapy	Patients who experience intolerance to ibrutinib or idelalisib as determined by the treating physician, but with no evidence of disease progression, will be eligible for single agent venetoclax
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in combination with rituximab in patients who have received at least 1 prior therapy, and if previously treated with and responded to CD20-targeted containing therapy (e.g., FCR, BR, chlorambucil plus obinutuzumab), must have had a progression-free interval of 12 months or longer since the last CD20-targeted therapy  Venetoclax when initially given in combination with 6 cycles of rituximab may continue for up to 2 years, or until disease progression or unacceptable toxicity, whichever occurs first	Patients who have experienced disease progression less than 12 months from completion of CD20-targeted therapy are eligible for second-line ibrutinib or acalabrutinib therapy and third-line venetoclax single agent therapy  Addition of rituximab to venetoclax is <u>not</u> approved in patients who are experiencing disease progression on venetoclax single agent therapy  Re-treatment with venetoclax plus rituximab is funded as an option at the time of relapse if the progression-free interval was at least 12 months for patients who responded and completed 2 years of venetoclax therapy  Venetoclax plus rituximab is funded as a third-line treatment option if ibrutinib or acalabrutinib is chosen as a second-line therapy and conversely, ibrutinib or acalabrutinib is funded as a third-line treatment option if venetoclax plus rituximab is chosen as a second-line therapy, provided all other funding eligibility criteria are met
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) in combination with obinutuzumab in previously untreated patients who are not candidates for fludarabine-based treatment*  Treatment is given for a total of 12 months as a finite treatment - 6 x 28 day cycles of obinutuzumab with venetoclax, followed by 6 months of venetoclax as a single agent, or until disease progression or unacceptable toxicity, whichever occurs first	*Fludarabine ineligibility is defined by either a cumulative illness rating scale (CIRS) score greater than 6 or a creatinine clearance (CrCl) less than 70 mL/min  Patients with CD20-negative CLL are <u>not</u> eligible  Patients with known CNS lymphoma or leukemia, prolymphocytic leukemia or history or suspicion of Richter syndrome are <u>not</u> eligible  Re-treatment with venetoclax, either in combination with rituximab (or as monotherapy for patients previously treated with ibrutinib or acalabrutinib), in the relapsed setting is approved as a treatment option if no disease progression was experienced during treatment or within 12 months after completion of first-line venetoclax plus obinutuzumab in previously untreated patients  Re-treatment with venetoclax in combination with obinutuzumab is <u>not</u> funded  Ibrutinib or acalabrutinib is funded as a subsequent treatment option, provided all other funding eligibility criteria are met  CD20-targeted therapy in combination with chemotherapy is <u>not</u> funded as a subsequent treatment option
				Hematology	Acute Myeloid Leukemia (AML)	Newly diagnosed acute myeloid leukemia (AML)* in combination with azacitidine in patients who are 75 years or older, or who are less than 75, but have comorbidities or other factors that preclude use of intensive induction chemotherapy	*Newly diagnosed acute myeloid leukemia (AML) patients are eligible regardless of cytogenetic risk provided they are ineligible for induction chemotherapy  Patients with high-risk myelodysplastic syndromes (MDS) who are not fit for intensive induction chemotherapy are <u>not</u> eligible  Patients previously treated with a hypomethylating agent (e.g., azacitidine, decitabine) or chemotherapy for MDS are <u>not</u> eligible  Venetoclax plus azacitidine is <u>not</u> funded as palliative treatment in patients who previously received induction chemotherapy for AML and who have experienced disease relapse

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
vinblastine	vial	10 mg/10 mL		Multiple	Multiple		
vincristine	vial	1 mg/1 mL 2 mg/2 mL 5 mg/5 mL		Multiple	Multiple		
vinorelbine	vial	10 mg/1 mL 50 mg/5 mL		Multiple	Multiple		
vismodegib	capsule	150 mg		Skin and Melanoma	Basal Cell	Locally advanced or metastatic basal cell cancer (BCC) (including basal cell nevus syndrome or Gorlin syndrome in patients who are 18 years of age or older) in patients who are not candidates for surgery or radiotherapy, based on decisions made by a multi-disciplinary team that includes surgeons, dermatologists, radiation oncologists and medical oncologists	
Vyxeos® (liposomal daunorubicin and cytarabine)	vial	44 mg daunorubicin  100 mg cytarabine		Hematology	Acute Myeloid Leukemia (AML)	Newly diagnosed acute myeloid leukemia post-cytotoxic therapy (AML-pCT)* or AML with myelodysplasia-related changes (AML-MRC)** in adult patients deemed fit for intensive chemotherapy  Vyxeos is funded for up to 2 cycles of induction therapy; patients who achieve a complete remission (CR) or complete remission with incomplete blood count recovery (CRI) during induction are eligible for up to 2 additional cycles of consolidation therapy	*Patients with acute myeloid leukemia post-cytotoxic therapy (AML-pCT) must have a documented history of prior cytotoxic therapy for an unrelated disease  **Patients with acute myeloid leukemia with myelodysplasia-related changes (AML-MRC) must have one of the following: bone marrow documentation of prior MDS, prior chronic myelomonocytic leukemia (CMML), de novo AML with karyotypic abnormalities characteristic of MDS, or de novo AML with multilineage dysplasia  Vyxeos is <u>not</u> funded in combination with other anti-cancer therapies  Vyxeos is <u>not</u> funded in patients previously treated with azacitidine with or without venetoclax for t-AML or AML-MRC

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DRUG	DOSAGE FORM	STRENGTH	SPECIAL STATUS	DISEASE SITE GROUP	CANCER SITE	FUNDED INDICATIONS and ELIGIBILITY REQUIREMENTS	FUNDING NOTES
zanubrutinib	capsule	80 mg		Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) as a first-line single agent in previously untreated patients who are not candidates for fludarabine-based treatment, including patients who: <ul style="list-style-type: none"><li>• have high-risk factors, including del17p, TP53 mutation, del11q, and unmutated IGHV</li><li>• have a contraindication or intolerance to chemoimmunotherapy</li><li>• are not suitable candidates for intravenous therapy</li></ul>	Patients with known CNS lymphoma, prolymphocytic leukemia, or history or suspicion of Richter syndrome are <u>not</u> eligible  Patients with unacceptable toxicity to zanubrutinib may be switched to acalabrutinib or ibrutinib provided no disease progression has occurred  Venetoclax with or without rituximab is funded as a subsequent line of therapy in patients who have experienced disease progression during first-line zanubrutinib treatment, provided all other funding eligibility criteria are met  Zanubrutinib is <u>not</u> funded as a subsequent treatment in patients who have experienced disease progression during acalabrutinib, ibrutinib or idelalisib treatment  CD20-targeted therapy in combination with chemotherapy is <u>not</u> funded as a subsequent treatment option in patients who have experienced disease progression during first-line treatment with zanubrutinib
				Hematology	Chronic Lymphocytic Leukemia (CLL)	Chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) as a single agent in patients who have received at least 1 prior therapy, which may include prior CD20-targeted therapy in combination with chemotherapy or venetoclax, but excludes prior therapy with idelalisib	Patients with known CNS lymphoma, prolymphocytic leukemia, or history or suspicion of Richter syndrome are <u>not</u> eligible  Patients with unacceptable toxicity to zanubrutinib may be switched to acalabrutinib or ibrutinib provided no disease progression has occurred  Zanubrutinib is <u>not</u> funded as a subsequent treatment in patients who have experienced disease progression during acalabrutinib, ibrutinib or idelalisib treatment  CD20-targeted therapy in combination with chemotherapy is <u>not</u> funded as subsequent treatment option in patients who have experienced disease progression during zanubrutinib treatment
				Hematology	Waldenström macroglobulinemia	Relapsed or refractory Waldenström macroglobulinemia after at least 1 prior line of therapy	Patients with CNS lymphoma secondary to Waldenström macroglobulinemia are eligible  Patients with evidence of disease transformation to a higher-grade lymphoma are <u>not</u> eligible  Patients who experienced disease progression on treatment with a BTK inhibitor (e.g., ibrutinib) are <u>not</u> eligible; if a patient discontinued an alternate BTK inhibitor for reasons of intolerance, they remain eligible for zanubrutinib
zoledronic acid	vial	4 mg/5 mL		Breast	Breast, Early Stage	High-risk, early stage breast cancer as adjuvant therapy in post-menopausal women (natural or induced by ovarian ablation or suppression) who: <ul style="list-style-type: none"><li>• received adjuvant or neoadjuvant chemotherapy, or were candidates for chemotherapy based on risk of recurrence, but due to patient factors (e.g., co-morbidities) could not receive chemotherapy</li><li>• have node-negative disease, but have an Oncotype DX recurrence score indicating a high-risk of recurrence and a positive benefit from chemotherapy</li><li>• have node-positive disease, regardless of Oncotype DX recurrence score</li></ul> Zoledronic acid adjuvant therapy should begin within 1 year from surgery or completion of chemotherapy and is given every 6 months for up to 3 years	Zoledronic acid adjuvant therapy is <u>not</u> funded in patients who have node-negative disease and a low Oncotype DX recurrence score  Zoledronic acid is <u>not</u> funded for prevention or treatment of osteopenia or osteoporosis in cancer patients  Refer to Appendix C - Definition of Menopause
				Genitourinary	Supportive Care	Prevention of skeletal-related events in patients with metastatic castration-resistant prostate cancer with 1 or more documented bony metastases	
				Hematology	Blood and Marrow Transplant (BMT)	Prevention or treatment of osteoporosis in patients who have undergone an allogeneic stem cell transplant	
				Hematology	Multiple Myeloma	Multiple myeloma as adjunct therapy to prevent skeletal-related events  Zoledronic acid may be given for up to 2 years in newly diagnosed patients who have achieved good disease control, however, may be continued longer than 2 years at the discretion of the treating physician based on assessment of disease status	If zoledronic acid was stopped after 2 years, it may be re-started at any time in patients who have relapsed with new onset skeletal-related events
				Multiple	Supportive Care	Prevention of skeletal-related events in patients with solid tumor malignancies, including breast cancer, lung cancer and renal cell carcinoma (excludes metastatic castration-sensitive prostate cancer), who have documented bone metastases	
				Supportive Care	Supportive Care	Management of hypercalcemia related to malignancy for outpatients	