

SCA Drug Formulary

Appendix B

Multiple Myeloma – Definitions of Refractory and Progressive Disease

Definition of Refractory Multiple Myeloma

Patients on lenalidomide-based or bortezomib-based therapies are considered to have refractory disease when any of the following occur:

- disease progression within 60 days of stopping treatment or progression on any dose, including progression while on maintenance therapy
- non-responsive disease while on treatment (either a minimal response was not achieved or disease progression occurred)

Definition of Multiple Myeloma Disease Progression

Patients who experience an increase of 25% from lowest response value in one or more of the following are considered to have progressive disease:

- serum M-component (the absolute increase must be 5 g/L)
- urine M-component (the absolute increase must be 200 mg/24 h)
- only in patients without measurable serum and urine M-protein levels, the difference between involved and uninvolved free light chain (FLC) levels (the absolute increase must be >100 mg/L)
- bone marrow plasma cell percentage (the absolute percentage must be >10%)
- definite development of new bone lesions or soft tissue plasmacytomas or definite increase in the size of existing bone lesions or soft tissue plasmacytomas
- development of hypercalcemia (corrected serum calcium >2.65 mmol/L) that can be attributed solely to the plasma cell proliferative disorder

Slow gradual biochemical changes, that otherwise would qualify as progression for clinical trials, may not be a reason to change therapy in clinical practice, unless coupled with signs of clinical evidence of progression, such as increased pain, need for supportive measures or renal failure