NEULASTA
(pegfilgrastim)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Neutropenia (<500 neutrophils/mcl or <1,000 neutrophils/mcl and a predicted decline to ≤ 500/mcl over the next 48 hours) and resulting febrile neutropenia (≥ 38.3°C orally or ≥38.0°C over 1 hour) can be induced by myelosuppressive chemotherapy. Febrile neutropenia is a major dose-limiting toxicity of chemotherapy. Major infections, hospitalizations, dose reductions or treatment delays are resultant serious complications (1).

Neulasta (pegfilgrastim) is a granulocyte colony-stimulating factor (G-CSF) that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. The product is a covalent conjugate of recombinant methionyl human G-CSF (filgrastim) and monomethoxypolyethylene glycol (1).

Regulatory Status
FDA-approved indication: Neulasta is a leukocyte growth factor indicated: (2)
- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation

Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation (2).

Summary
Neutropenia (<500 neutrophils/mcl or <1,000 neutrophils/mcl and a predicted decline to ≤ 500/mcl over the next 48 hours) and resulting febrile neutropenia (≥ 38.3°C orally or ≥38.0°C over 1 hour) can be induced by myelosuppressive chemotherapy. Neulasta (pegfilgrastim) is a granulocyte colony-stimulating factor (G-CSF) that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Neulasta while maintaining optimal therapeutic outcomes.
References
