NEULASTA (pegfilgrastim),
FULPHILA (pegfilgrastim-jmdb)

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) and Fulphila (pegfilgrastim-jmdb) are granulocyte colony-stimulating factors (G-CSF) that act 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. Fulphila is a biosimilar to Neulasta (1-3).

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

Fulphila is a leukocyte growth factor indicated to: (3)
- 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

Neulasta and Fulphila are not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation (2-3).

Summary

Neulasta-Fulphila FEP Clinical Rationale
Neulasta (pegfilgrastim) and Fulphila (pegfilgrastim-jmdb) are granulocyte colony-stimulating factors (G-CSF) that act on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation (1-3).

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

References