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 and Fulphila are leukocyte growth factors indicated: (2-3)

- 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
- To increase survival in patients acutely exposed to myelosuppressive doses of radiation

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

The FDA defines biosimilar as a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product. A manufacturer developing a proposed biosimilar demonstrates that its product is highly similar to the reference product by extensively analyzing the structure and function of both the reference product and the proposed biosimilar. Minor differences between the reference product and the proposed biosimilar in clinically inactive components are acceptable. Manufacturers must also
NEULASTA (pegfilgrastim),
FULPHILA (pegfilgrastim-jmdb)

demonstrate that its proposed biosimilar has no clinically meaningful differences from the reference product in terms of safety, purity, and potency (safety and effectiveness) (4).

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) 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