Neulasta, Neulasta Onpro (pegfilgrastim), **Fulphila** (pegfilgrastim-jmdb), Fylnetra (pegfilgrastim-pbbk), Nyvepria (pegfilgrastim-apgf), Stimufend (pegfilgrastim-fpgk), **Udenyca, Udenyca Onbody** (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez)

Preferred products: Fulphila, Udenyca, Udenyca Onbody

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Neutropenia occurs when an individual has an abnormally low level of neutrophils, a type of white blood cell important in fighting off infections. Neutropenia and its complications, including febrile neutropenia and infection, remain major toxicities associated with myelosuppressive systemic cancer chemotherapy. Colony stimulating factors are medications used to stimulate the production of neutrophils. Neulasta (pegfilgrastim) and its biosimilars 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. Fulphila, Fylnetra, Nyvepria, Udenyca, and Ziextenzo are biosimilars to Neulasta. 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 (1-8).

Regulatory Status

FDA-approved indications:

Neulasta and its biosimilars are leukocyte growth factors indicated: (2-8)

- 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 is indicated: (2)

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

Neulasta and its biosimilars are not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation (2-8).

Summary

Neutropenia occurs when an individual has an abnormally low level of neutrophils, a type of white blood cells (WBCs) important in fighting off infections. Neutropenia and its complications,

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

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