Optum Rx®

Releuko® (filgrastim-ayow) – New biosimilar approval

- On February 25, 2022, the FDA approved Kashiv Biosciences' Releuko (filgrastim-ayow), biosimilar to Amgen's Neupogen® (filgrastim).
    - Releuko is the third FDA-approved biosimilar to Neupogen. Sandoz launched the first biosimilar, Zarxio® (filgrastim-sndz) in September 2015, and Pfizer launched Nivestym™ (filgrastim-aafi) in September 2018.
- Releuko, Zarxio, Nivestym and Neupogen share the following indications:
    - 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 significant incidence of severe neutropenia with fever
    - For reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML)
    - To reduce the duration of neutropenia and neutropenia-related clinical sequelae, eg, febrile neutropenia, in patients with non-myeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT)
    - For the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis
    - For chronic administration to reduce the incidence and duration of sequelae of neutropenia (eg, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.
- Neupogen has the additional indication to increase survival in patients acutely exposed to myelosuppressive doses of radiation.
- The approval of Releuko is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Neupogen.
- Releuko has been approved as a biosimilar to Neupogen, *not* as an interchangeable product.
- Similar to Neupogen, Zarxio and Nivestym, Releuko is contraindicated in patients with a history of serious allergic reactions to human granulocyte colony-stimulating factors such as filgrastim products or pegfilgrastim products.
- Warnings and precautions of Releuko include fatal splenic rupture, acute respiratory distress syndrome, serious allergic reactions, sickle cell disorders, glomerulonephritis, alveolar hemorrhage and hemoptysis, capillary leak syndrome, myelodysplastic syndrome and acute myeloid leukemia, thrombocytopenia, leukocytosis, cutaneous vasculitis, potential effect on malignant cells, simultaneous use with chemotherapy and radiation therapy not recommended, nuclear imaging, and aortitis.
- In patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs, the most common adverse reactions (≥ 5% difference in incidence compared to placebo) with Releuko use were pyrexia, pain, rash, cough, and dyspnea.
- In patients with AML, the most common adverse reactions (≥ 2% difference in incidence) with Releuko use were pain, epistaxis, and rash.

Continued . . .

- In patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by BMT, the most common adverse reaction (≥ 5% difference in incidence) with Releuko use was rash.

- In patients with severe chronic neutropenia, the most common adverse reactions (≥ 5% difference in incidence) with Releuko use were pain, anemia, epistaxis, diarrhea, hypoesthesia, and alopecia.

- The recommended dosage of Releuko varies by indication and patient weight, and may be administered by subcutaneous injection or intravenous infusion.

    — Direct administration of less than 0.3 mL (180 mcg) using Releuko prefilled syringe is not recommended due to potential for dosing errors.
    — Refer to the Releuko drug label for additional dosing details.

- Biosciences/Amneal plans to launch Releuko in the third quarter of 2022. Releuko will be available as 300 mcg/mL and 480 mcg/1.6 mL single-dose vials, and as 300 mcg/0.5 mL and 480 mcg/0.8 mL single-dose prefilled syringes with a BD UltraSafe Plus™ Passive Needle Guard.

Optum