Udenyca® Onbody™ (pegfilgrastim-cbqv) – New biosimilar approval

- On December 26, 2023, Coherus announced the FDA approval of Udenyca Onbody (pegfilgrastim-cbqv), biosimilar to Neulasta® Onpro® (pegfilgrastim) kit.
    - Udenyca Onbody is the first FDA-approved biosimilar to Neulasta Onpro. Neulasta Onpro contains a prefilled-syringe and an on-body injector (OBI).
    - Biosimilars are available for Neulasta (pegfilgrastim).
- Udenyca Onbody and Neulasta Onpro share the following indication:
    - 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.
- The approval of Udenyca Onbody is based on review of a comprehensive data package and totality of evidence demonstrating a high degree of similarity to its reference product, Neulasta Onpro.
- Udenyca Onbody has been approved as a biosimilar to Neulasta Onpro, *not as* an interchangeable product.
- Warnings and precautions for Udenyca Onbody include splenic rupture, acute respiratory distress syndrome, serious allergic reactions, allergies to acrylics, use in patients with sickle cell disorders, glomerulonephritis, leukocytosis, thrombocytopenia, capillary leak syndrome, potential for tumor growth stimulatory effects on malignant cells, myelodysplastic syndrome and acute myeloid leukemia in patients with breast and lung cancer, potential device failures, aortitis, and nuclear imaging.
- The most common adverse reactions (≥ 5% difference in incidence compared to placebo) with Udenyca Onbody use were bone pain and pain in the extremity.
- The recommended dosage of Udenyca Onbody is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle.
    - A healthcare provider must fill the OBI with Udenyca using the prefilled syringe and then apply the OBI for Udenyca to the patient's skin (abdomen or back of arm).
    - Approximately 27 hours after the OBI for Udenyca is applied to the patient's skin, Udenyca will be delivered over approximately 5 minutes.
    - A missed dose could occur due to an OBI for Udenyca failure or leakage. If the patient misses a dose, a new dose should be administered by single-dose prefilled syringe for manual use, as soon as possible after detection.
- Cohuerus plans to launch Udenyca Onbody in the first quarter of 2024. Udenyca Onbody will be available as 6 mg/0.6 mL in a single-dose prefilled syringe co-packaged with the OBI.