

Supplemental Approvals

Generic Name (Trade Name—Company)

November 29, 2018

Pegfilgrastim-cbqv

(Udenyca—Coherus Biosciences)

FDA approves pegfilgrastim biosimilar

Uses/Notes

On November 2, Coherus BioSciences [announced](#) FDA approval of pegfilgrastim-cbqv, the first biosimilar of pegfilgrastim (Neulasta) approved by both FDA and the European Commission (EC) for patients with cancer who are receiving myelosuppressive chemotherapy.

The biosimilar is a pegylated growth colony–stimulating factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. It is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

In clinical trials, the most common adverse reactions (?5% incidence) are bone pain and pain in extremity.

Full prescribing information is available at www.UDENYCA.com.

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