Reference number(s)
1931-A

SPECIALTY GUIDELINE MANAGEMENT

NEULASTA (pegfilgrastim)
FULPHILA (pegfilgrastim-jmdp)
UDENYCA (pegfilgrastim-cbqv)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Neulasta
Neulasta is indicated 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.

Fulphila
Fulphila is indicated 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

Udenyca
Udenyca is indicated 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.

B. Compendial Use
Stem cell transplantation-related indications

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Prevention of neutropenia in cancer patients receiving myelosuppressive chemotherapy
Authorization of 6 months may be granted for prevention of febrile neutropenia when both of the following criteria are met:
1. Member has a non-myeloid malignancy and is currently receiving, or will be receiving myelosuppressive anti-cancer therapy
2. The requested product will not be administered less than 24 hours before or after chemotherapy or radiotherapy

B. Stem cell transplantation-related indications

Authorization of 6 months may be granted for stem cell transplantation-related indications.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Neulasta [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2017.
2. Fulphila [package insert]. Zurich, Switzerland: Mylan; June 2018.
3. Udenyca [package insert]. Redwood City, California: Coherus BioSciences, Inc: November 2018.
4. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed June 15, 2018.
5. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed June 15, 2018.
6. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Myeloid Growth Factors. Version 1.2018. http://www.nccn.org/professionals/physican_gls/pdf/myeloid_growth.pdf. Accessed June 15, 2018.
7. Aapro MS, Bohlius J, Cameron DA, et al. 2010 update of EORTC guidelines for the use of granulocyte-colony stimulating factor to reduce the incidence of chemotherapy-induced febrile neutropenia in adult patients with lymphoproliferative disorders and solid tumors. *Eur J Cancer*. 2011;47(1):8-32.
8. Smith TJ, Bohlke K, Lyman GH, et al. Recommendations for the use of white blood cell growth factors: American Society of Clinical Oncology Clinical Practice Guideline Update. *J Clin Oncol*. 2015;33(28):3199-3212.