Colony Stimulating Factors

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

This policy informs prescribers of preferred products and provides an exception process for non-preferred products through prior authorization.

This program applies to the colony stimulating factor products specified in this policy. For the short-acting colony stimulating factors program, Nivestym, Releuko, and Zarxio are the preferred products. For the long-acting colony stimulating factors program, Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca, and Ziextenzo are the preferred products. Coverage for targeted products (short-acting: Neupogen, Granix, Leukine; long-acting: Neulasta syringe for manual injection) is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members requesting treatment with Leukine for an indication that is FDA-approved for the preferred product and to members requesting treatment with Neupogen or Granix for all indications. Neulasta Onpro is excluded from the preferred product requirements.

Table 1. Short-Acting Colony Stimulating Factors

Medication	Generic Name
Preferred Products:	
Nivestym	filgrastim-aafi
Releuko	filgrastim-ayow
Zarxio	filgrastim-sndz

Targeted Products:	
Neupogen	filgrastim
Granix	TBO-filgrastim
Leukine	sargramostim

Table 2. Long-Acting Colony Stimulating Factors

Medication	Generic Name
Preferred Products:	
Fulphila	pegfilgrastim-jmdb
Fylnetra	pegfilgrastim-pbbk
Nyvepria	pegfilgrastim-apfg
Stimufend	pegfilgrastim-fpgk
Udenyca	pegfilgrastim-cbqv
Ziextenzo	pegfilgrastim-bmez
Targeted Products:	
Neulasta syringe for manual injection	pegfilgrastim-apfg

POLICY

EXCEPTION CRITERIA

I. Coverage for the targeted products, Neupogen or Granix, is provided when the member meets one of the following criteria:
   a. Member has failed treatment with all of the preferred products due to a documented intolerable adverse event (e.g., rash, nausea, vomiting) and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)
   b. Member has a documented latex allergy and the prescriber states that the member must use latex-free vials and the member had a documented inadequate response or intolerable adverse effect to Nivestym, Releuko, and Zarxio.
   c. Neupogen or Granix are requested for doses less than 180 mcg and the member had an inadequate response or an intolerable adverse effect to Nivestym, Releuko, and Zarxio.

   Approval will be for **6 months**

II. Coverage for the targeted product, Leukine, is provided when the member has had a documented inadequate response or intolerable adverse effect to any of the preferred products.

   Approval will be for **6 months**

III. Coverage for the targeted product, Neulasta (syringe for manual injection), is provided when the member meets the following criteria:
    a. Member has failed treatment with all of the preferred products due to a documented intolerable adverse effect (e.g., rash, nausea, vomiting) and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the brand and biosimilar medication)

Approval will be for **6 months**

Dosing and Administration
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J1442 – Inj, filgrastim (g-csf), excludes biosimilars, 1 microgram (Neupogen)
- J2820 – Inj, sargramostim (gm-csf), 50 micrograms (Leukine)
- J1447 – Granix TBO-filgrastim
- J2505 - Inj, pegfilgrastim, 6 mg (Neulasta) – deleted 1/1/2022
- J2506 - Inj, pegfilgrastim, excludes biosimilar, 0.5 mg (Neulasta) – effective 1/1/2022
- Q5108 – Inj, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5mg
- Q5101 – Inj, filgrastim-sndz, biosimilar, (Zarxio), 1 microgram
- Q5110 – Inj, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram
- Q5111 – Inj, pegfilgrastim-cbqv, biosimilar, (Udenyca), 0.5mg
- Q5120 – Inj, pegfilgrastim-bmez, biosimilar, (Ziextenzo), 0.5mg
- Q5122 – Inj, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5mg
- Q5125 – Inj, filgrastim-ayow, biosimilar, (Releuko), 1 microgram
- C9058 – Inj, pegfilgrastim-bmez, biosimilar, (Ziextenzo) 0.5mg

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POLICY HISTORY

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