Pegfilgrastim (Neulasta, Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca)

Effective Date: 6/1/2024
Medical Care Management Committee Approval: 3/21/2024

Contents

Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to the following pegfilgrastim products:

HCPCS Code	Description	Maximum Dosage per Administration
J2506	Injection, pegfilgrastim	6 mg
Q5108	Injection, pegfilgrastim-jmdb (Fulphila), biosimilar	6 mg
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar	6 mg
Q5122	Injection, pegfilgrastim-apgf (Nyvepria), biosimilar	6 mg
Q5127	Injection, pegfilgrastim-fpgk (Stimufend), biosimilar	6 mg
Q5111	Injection, pegfilgrastim-cbqv (Udenyca), biosimilar	6 mg

Preferred Product Criteria

Fulphila, Fylnetra, Nyvepria, Stimufend and Udenyca are the preferred pegfilgrastim products. Community will provide coverage for the preferred products for members meeting the Diagnosis-Specific Criteria in the policy.

Neulasta (pegfilgrastim) is non-preferred, and is subject to both Preferred Product Criteria and Diagnosis-Specific Criteria. Treatment with Neulasta (pegfilgrastim) is medically necessary for the indications

specified in this policy when ALL of the following criteria are met:

1. Patient meets one of the following:
    a) Both of the following:
        - History of a trial of Fulphila, Fylnetra, Nyvepria, Stimufend or Udenyca resulting in minimal clinical response; and
        - Physician attests that in his or her clinical opinion, the clinical response would be superior with Neulasta than experienced with Fulphila, Fylnetra, Nyvepria, Stimufend or Udenyca
    b) Or, both of the following:
        - Patient has a history of intolerance, contraindication, or adverse event to either Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca or other pegfilgrastim biosimilar products; and
        - Physician attests that in his or her clinical opinion the same intolerance, contraindication, or adverse event would not be expected to occur with Neulasta; and
2. Patient has not had a loss of a favorable response after established maintenance therapy with Fulphila, Fylnetra, Nyvepria, Stimufend, Udenyca or other pegfilgrastim biosimilar product; and
3. Patient meets the pegfilgrastim diagnosis-specific criteria for the requested indication.

Diagnosis-Specific Criteria

The term pegfilgrastim in the Diagnosis-Specific Criteria refers to Neulasta and all pegfilgrastim biosimilar products. Community utilizes InterQual clinical criteria to determine medical necessity of pegfilgrastim requests. Pegfilgrastim is medically necessary when the InterQual diagnosis-specific criteria for the below requested indications are met:

- Neutropenia
- Hematopoietic Cell Transplantation
- Wilms Tumor – Nephroblastoma

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J2506	Injection, pegfilgrastim
Q5108	Injection, pegfilgrastim-jmdb (fulphila), biosimilar
Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar
Q5122	Injection, pegfilgrastim-apgf (nyvepria), biosimilar
Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar
Q5111	Injection, pegfilgrastim-cbqv (udenyca), biosimilar

Diagnosis Code	Description
D70.1	Agranulocytosis secondary to cancer chemotherapy
D70.2	Other drug-induced agranulocytosis
Z51.11	Encounter for antineoplastic chemotherapy
Z51.89	Encounter for other specified aftercare
Z52.001	Unspecified donor, stem cells
Z52.011	Autologous donor, stem cells
Z52.091	Other blood donor, stem cells
Z94.84	Stem cells transplant status

Policy Revision History

Status	Effective Date	Description
Baseline	6/1/2024	Initial version of pegfilgrastim Preferred Product Policy