COMMUNITY HEALTH CHOICE

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

Effective Date: 01/01/2025
Medical Care Management Committee Approval: Pending

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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 all pegfilgrastim products including, but not limited to the following*:

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

*Any U.S. FDA-approved and launched pegfilgrastim biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by Community

Preferred Product Criteria

Fulphila is the preferred pegfilgrastim product. Community will provide coverage for the preferred product for members meeting the Diagnosis-Specific Criteria in the policy.

Neulasta, Fylnetra, Nyvepria, Stimufend and Udenyca and all other pegfilgrastim biosimilar products are non-preferred, and are subject to both Preferred Product Criteria and Diagnosis-Specific Criteria. Treatment with a non-preferred pegfilgrastim product 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 preferred pegfilgrastim product resulting in minimal clinical response; AND
        - Physician attests that in his or her clinical opinion, the clinical response would be superior with a non-preferred pegfilgrastim product than the preferred product
    b) Or, both of the following:
        - Patient has a history of intolerance, contraindication, or adverse event to preferred pegfilgrastim product; AND
        - Physician attests that in his or her clinical opinion the same intolerance, contraindication, or adverse event would not be expected to occur with a non-preferred pegfilgrastim product; AND
2. Patient has not had a loss of a favorable response after established maintenance therapy with preferred pegfilgrastim 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
Revision 1	01/01/2025	Revised Preferred Product
Revision 2	02/13/2026	Revised Preferred Product