

Medical Policy:

Colony Stimulating Factors: Nyvepria™ (pegfilgrastim-apgf)

| POLICY NUMBER | LAST REVIEW | ORIGIN DATE |
|---------------|----------------|------------------|
| MG.MM.PH.326 | March 18, 2025 | February 2, 2021 |

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

- Nyvepria (pegfilgrastim-apgf) is a colony-stimulating factor that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation.
- Nyvepria (pegfilgrastim-apgf) is a biosimilar to Neulasta (pegfilgrastim)

Length of Authorization

Coverage will be provided for six months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

12 billable units per 14 days

Guideline

I. Initial Approval Criteria

Prophylactic use in patients with non-myeloid malignancy †

Nyvepria may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:

Neulasta and Udenyca are the preferred agents for Commercial, Medicaid, and Medicare members.

1. The patient has failed treatment with Neulasta **AND** Udenyca or they are contraindicated; **OR**
2. The patient is continuing previously established therapy with *Nyvepria* for their current chemotherapy regimen.

Coverage for Nyvepria™ (pegfilgrastim-apgf) is provided in the following conditions:

1. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of greater than 20% §; **OR**
2. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of 10% to 20% § **AND** one or more patient-related risk factors ¥;
3. Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia ❖ of <10% **AND** two or more patient related risk factors ¥ **

***Use in this setting is based on clinical judgment.*

Note: Dose-dense therapy, in general, requires growth factor support to maintain dose intensity and schedule. In the palliative setting, consideration should be given to dose reduction or change in regimen.

§ Expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Hematopoietic Growth Factors Clinical Practice Guideline at NCCN.org

¥ Patient risk factors for febrile neutropenia

- Age >65 years receiving full dose intensity chemotherapy
- Prior exposure to chemotherapy or radiation therapy
- Persistent neutropenia (ANC ≤ 1000/mm³)
- Bone marrow involvement by tumor
- Patient has a condition that can potentially increase the risk of serious infection (i.e., HIV/AIDS with low CD4 counts)
- Recent surgery and/or open wounds
- Poor performance status
- Renal dysfunction (creatinine clearance <50 mL/min)
- Liver dysfunction (elevated bilirubin >2.0 mg/dL)
- Chronic immunosuppression in the post-transplant setting, including organ transplant

❖ Febrile neutropenia is defined as:

- Temperature: a single temperature ≥38.3 °C orally or ≥38.0 °C over 1 hour; **AND**
- Neutropenia: <500 neutrophils/mcL or <1,000 neutrophils/mcL and a predicted decline to ≤500 neutrophils/mcL over the next 48 hours

Patient who experienced a neutropenic complication from a prior cycle of the same chemotherapy ‡

†FDA-labeled indication, ‡ Compendia recommended indication

§ expected incidence of febrile neutropenia percentages for myelosuppressive chemotherapy regimens can be found in the NCCN Myeloid Growth Factors Clinical Practice Guideline at NCCN.org

Dosage/Administration

Dosed no more frequently than every 14 days.

| Indication | Dose |
|--|--|
| Patients with Cancer Receiving Myelosuppressive Chemotherapy | <ul style="list-style-type: none">– < 10 kg = 0.1 mg/kg– 10-20 kg = 1.5 mg– 21-30 kg = 2.5 mg– 31-44 kg = 4 mg– 45 kg and up = 6 mg Dosed no more frequently than every 14 days |

*Do not administer within 14 days before and 24 hours after administration of cytotoxic chemotherapy

Limitations/Exclusions: N/A

II. Renewal Criteria

1. Provider attests continued treatment is warranted; **AND**
2. Clinical response to treatment has been shown.

Applicable Procedure Codes

| Code | Description |
|-------|---|
| Q5122 | Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg |

Applicable NDCs

| Code | Description |
|---------------|--------------------------------------|
| 00069-0324-01 | Nyvepria 6mg/0.6mL prefilled syringe |

ICD-10 Diagnoses

| Code | Description |
|----------|---|
| D70.1 | Agranulocytosis secondary to cancer chemotherapy |
| D70.9 | Neutropenia, unspecified |
| T45.1X5A | Adverse effect of antineoplastic and immunosuppressive drugs initial encounter |
| T45.1X5D | Adverse effect of antineoplastic and immunosuppressive drugs subsequent encounter |
| T45.1X5S | Adverse effect of antineoplastic and immunosuppressive drugs sequela |
| Z41.8 | Encounter for other procedures for purposes other than remedying health state |
| Z51.11 | Encounter for antineoplastic chemotherapy |
| Z51.12 | Encounter for antineoplastic immunotherapy |
| Z51.89 | Encounter for other specified aftercare |

Revision History

| Company(ies) | DATE | REVISION |
|-----------------------------|-----------|---|
| EmblemHealth & ConnectiCare | 3/18/2025 | Updated risk factors(patient co-morbidities) for febrile neutropenia. Added to criteria: Patient is undergoing myelosuppressive chemotherapy with an expected incidence of febrile neutropenia of <10% AND two or |

| | | |
|-----------------------------|------------|--|
| | | more patient related risk factors ✕ ** Separated from criteria co-morbidities and created chart to reference, as well as defining febrile neutropenia |
| EmblemHealth & ConnectiCare | 3/21/2024 | Annual Review- No Criteria changes |
| EmblemHealth & ConnectiCare | 5/30/2023 | Annual Review: changed name from “Nyvepria (pegfilrestim-apgf)” to “Colony Stimulating Factors Nyvepria (pegfilrestim-apgf)” |
| EmblemHealth & ConnectiCare | 09/14/2022 | Transferred policy to new template. |
| EmblemHealth & ConnectiCare | 3/16/2021 | Updated renewal criteria |
| EmblemHealth & ConnectiCare | 2/2/2021 | New medical policy |

References

1. Product Information: NYVEPRIA™ subcutaneous injection, pegfilgrastim-apgf subcutaneous injection. Pfizer Inc (per FDA), New York, NY, 2020.