Medical Necessity Guidelines:
Nyvepria™ (pegfilgrastim-apgf)

Effective: January 1, 2023

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Pegfilgrastim is a colony stimulating factor (CSF) that acts on hematopoietic cells by binding to specific cell surface receptors thereby, stimulating proliferation, differentiation, commitment, and end cell functional activation.

Pegfilgrastim is approved by the Food and Drug Administration 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. Prophylactic use of pegfilgrastim in patients undergoing chemotherapy reduces the risk of febrile neutropenia and infections. Prophylactic therapy can be considered for patients receiving myelosuppressive chemotherapy if the risk of febrile neutropenia is 20% or greater.

Fulphila (pegfilgrastim-jmdb), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez) and Nyvepria (pegfilgrastim-apgf) are leukocyte growth factors 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 (pegfilgrastim-jmdb), Udenyca (pegfilgrastim-cbqv), Ziextenzo (pegfilgrastim-bmez) and Nyvepria (pegfilgrastim-apgf) are biosimilar* to Neulasta (pegfilgrastim).

*Biosimilar means that the biological product is approved based on data demonstrating that it is highly like an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of pegfilgrastim-jmdb, pegfilgrastim-cbqv, pegfilgrastim-bmez and pegfilgrastim-apgf has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information).

Food and Drug Administration (FDA) Approved Indications:

- Nyvepria™ (pegfilgrastim-apgf) is a leukocyte growth factor 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.

Limitations of Use: NyvepriaTM (pegfilgrastim-apgf) is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation.

STEP THERAPY:

Some medically administered Part B drugs may have additional requirements or limits on coverage. These requirements and limits may include step therapy. This is when we require you to first try certain preferred drugs to treat your medical condition before we will cover another non-preferred drug for that condition.

This policy supplements Medicare Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) for the purpose of determining coverage under Medicare Part B medical benefits and applies a step therapy for Nyvepria™ (pegfilgrastim-apgf).

This policy applies a step therapy for NyvepriaTM (pegfilgrastim-apgf). This list indicates the common uses for which the Nyvepria™ (pegfilgrastim-apgf) is prescribed. This list can change from time to time.

Drug Class	Non-Preferred Product(s)	Preferred Product(s)
Pegfilgrastim	Nyvepria™ (pegfilgrastim-apgf)	Fulphila (pegfilgrastim-jmdb)
		Neulasta® (pegfilgrastim)

Clinical Guideline Coverage Criteria

The Plan may authorize coverage of Nyvepria™ (pegfilgrastim-apgf) for Members when documentation of **one** (1) of the following criteria is met:

1. History of prior treatment with Fulphila™ (pegfilgrastim-jmdb) **or** Neulasta® (pegfilgrastim) resulting in a substandard response to therapy

OR

2. History of intolerance **or** adverse event to treatment with Fulphila™ (pegfilgrastim-jmdb) or Neulasta® (pegfilgrastim)

OR

3. Rationale that treatment with Fulphila™ (pegfilgrastim-jmdb) or Neulasta® (pegfilgrastim) is not clinically appropriate (Note: Convenience does not qualify as clinical rationale for inappropriateness of Fulphila or Neulasta)

OR

4. Continuation of prior therapy with Nyvepria™ (pegfilgrastim-apgf) within the past 365 days

Note: Refer to Center for Medicare and Medicaid Local Coverage Determination (LCD) for Pegfilgrastim at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33747&ver=35&bc=CAAAAAAAAAAA

Limitations

- The health plan may authorize coverage of Nyvepria (pegfilgrastim-apgf) for up to 6 months if coverage criteria are met
- Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (Nyvepria), 0.5 mg

References:

1. Local Coverage Determination (LCD): Pegfilgrastim (L33747). Centers for Medicare and Medicaid Services (CMS). Published online October 1, 2015. Accessed May 24, 2022, at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33747&ver=35&bc=CAAAAAAAAAAA.
2. NyvepriaTM(pegfilgrastim-apgf) [package insert]. Lake Forest, IL: Hospira, Inc..; Last updated in Oct 2021. Accessed May 17, 2022, at https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761111lbl.pdf.
3. Fulphila (pegfilgrastim-jmdb) [package insert]. Mylan GmbH Zurich, Switzerland CH-8050, U.S. License No. 2062; Last updated in October 2021. Accessed May 17, 2022, at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=3ea915d7-2feb-4e75-91f7-913c965b7d8a&type=display.
4. Neulasta® (pegfilgrastim) [package insert]. Thousand Oaks, CA. Amgen Inc; Last updated in February 2021. Accessed May 17, 2022, at https://www.pi.amgen.com/-/media/Project/Amgen/Repository/pi-amgen-com/neulasta/neulasta_pi_hcp_english.pdf.
5. Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage. Washington, DC. Centers for Medicare & Medicaid Services (CMS). August 7, 2018. Accessed online on May 25, 2022, at https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.