

STANDARD COMMERCIAL DRUG FORMULARY PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-PBBK

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-PBBK	FYLNETRA	48035		GPI-10	
				(8240157060)	

GUIDELINES FOR USE

- 1. Does the patient have a non-myeloid malignancy and meet **ALL** of the following criteria?
 - Therapy is prescribed by or in consultation with a hematologist or oncologist
 - The patient is receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever
 - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

If yes, approve for 12 months by HICL or GPI-10. If no, continue to #2.

- 2. Is the request to increase survival in a patient acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome) and does the patient meet **ALL** of the following criteria?
 - Therapy is prescribed by or in consultation with a hematologist or oncologist
 - The patient had a trial of or contraindication to the preferred agent: Nyvepria (pegfilgrastim-apgf)

If yes, approve for 12 months by HICL or GPI-10. If no, do not approve.

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **PEGFILGRASTIM-PBBK (Fylnetra)** requires the following rule(s) be met for approval:

- A. The request is for ONE of the following:
 - 1. You have a non-myeloid malignancy (cancer not affecting bone marrow)
 - 2. You will be using Fylnetra to increase survival if you have been acutely exposed to myelosuppressive doses of radiation (radiation that affects your blood and bone marrow)
- B. If you have a non-myeloid malignancy, approval also requires:
 - 1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
 - You are receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia (medications that affect the bone marrow and cause low levels of a type of white blood cell) with fever
 - 3. You had a trial of or contraindication (harmful for) to the preferred agent: Nyvepria (pegfilgrastim-apgf)

(Denial text continued on next page)

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PEGFILGRASTIM-PBBK

GUIDELINES FOR USE (CONTINUED)

- C. If the request is to increase survival if you have been acutely exposed to myelosuppressive doses of radiation, approval also requires:
 - 1. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor) or oncologist (a type of cancer doctor)
 - 2. You had a trial of or contraindication (harmful for) to the preferred agent: Nyvepria (pegfilgrastim-apgf)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Fylnetra and Neulasta.

REFERENCES

- Fylnetra [Prescribing Information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC, May 2022.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 10/22

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