STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

PEGFILGRASTIM-JMDB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
PEGFILGRASTIM-JMDB	FULPHILA	45010		GPI-10 (8240157020)	

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 - JMDB (Fulphila)** 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 Fulphila 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)
      2. You are receiving myelosuppressive anti-cancer medications 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 medication: Nyvepria (pegfilgrastim-apgf)

   (Denial text continued on next page)

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PEGFILGRASTIM-JMDB

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 medication: 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 Fulphila and Neulasta.

REFERENCES

- Fulphila [Prescribing Information]. Zurich, Switzerland: Mylan GmbH; March 2021.
- Neulasta [Prescribing Information]. Thousand Oaks, CA: Amgen Inc.; February 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 07/01/23

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