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Indications of Filgrastim & Peg-filgrastim

Adjudication Guideline

Approved by:
Daman

Responsible:
Medical Standards & Research

Related Adjudication Guidelines:
None

Abstract

For Members

Filgrastim and Peg-filgrastim are medicines used to decrease the chance of infection in people who have certain types of cancer and are receiving chemotherapy medications

Chemotherapy medicines may decrease the number of neutrophils (a type of blood cell needed to fight infection), in people who are undergoing bone marrow transplants, and in people who have severe chronic neutropenia (a condition where the number of neutrophils in the blood is low). Filgrastim helps the body in making more neutrophils. Likewise, Peg-filgrastim also stimulates the level of neutrophils.

Filgrastim is also used to prepare the blood for leukapheresis (a treatment in which certain blood cells are removed from the body and then returned to the body following chemotherapy).

Daman covers treatment with Filgrastim and Peg-filgrastim, as per medical necessity and as per policy terms and conditions of each health insurance plan of Daman.

For Medical Professionals

This adjudication rule highlights the coverage of Filgrastim and Peg-filgrastim for all the health insurance plans administered by Daman.

Filgrastim is a granulocyte colony-stimulating factor (G-CSF) analogue used to act on hematopoietic cells by binding to specific cell surface receptors and stimulating proliferation, differentiation commitment, and some end-cell functional activation.

Peg-filgrastim 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 and to increase survival in patients acutely exposed to myelosuppressive doses of radiation.

Scope

This adjudication rule highlights the coverage of Filgrastim for all health insurance plans administered by Daman.

Adjudication Policy

Eligibility / Coverage Criteria

Filgrastim and Peg-filgrastim are covered for all health insurance plans administered by Daman, except for Visitor's and Basic plan (as per availability in the HAAD Basic Drug list – as dated June 2016).

Daman covers **Filgrastim**:

- In patients with non-myeloid malignancies receiving myelosuppressive chemotherapy associated with a significant incidence of severe neutropenia with fever
- For patients with Acute Myeloid Leukemia receiving induction or consolidation chemotherapy
- For cancer patients receiving bone marrow transplant (myeloablative chemotherapy before a bone marrow transplant)
- For mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis in patients undergoing peripheral blood progenitor cell collection and therapy
- To reduce the incidence and duration of sequelae of neutropenia (e.g. fever and infections) in symptomatic patients with congenital neutropenia, cyclic neutropenia or idiopathic neutropenia.

Daman covers **Peg-filgrastim** to:

- Decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs;
- Increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Sub-syndrome of Acute Radiation Syndrome).

Requirements for Coverage

ICD and CPT codes must be coded to the highest level of specificity.

Non-Coverage

Filgrastim and Peg-filgrastim are not covered for Basic Plan as per availability in the HAAD drug list.

- Filgrastim and Peg-filgrastim are not covered for Visitor's Plan.
- Daman will not cover Filgrastim and Peg-filgrastim for below given conditions, as they are contraindicated in these conditions:
  - In patients with known hypersensitivity to E-coli-derived proteins
  - In patients with known hypersensitivity to Filgrastim or to any component of the product.

Payment and Coding Rules

Please apply HAAD payment rules and regulations, and relevant coding manuals for ICD, CPT, etc.

Adjudication Examples

- **Example 1**

Question: A 26 year old male holding an Enhanced Plan card, went to a hospital suffering from fever. Doctor diagnosed him with "drug induced neutropenia" due to chemotherapy, documented with a blood test result, and prescribed Filgrastim for him. Will this claim be paid?

Answer: Yes, the claim will be covered.

- **Example 2**

Question: A 33 year old male holding a Basic Plan card, went to a hospital suffering from fever. He is a known case of Acute Myeloid Leukemia and has recently received chemotherapy. Doctor's diagnosis was "Acute myeloid leukemia with neutropenia." Blood test result was documented, and then Filgrastim was prescribed for him. Is this claim payable?

Answer: No, the claim will be rejected, as Filgrastim is not covered for Basic plan.

- **Example 3**

Question: A 25 year old male holding an Enhanced Plan card was admitted to a hospital for administration of chemotherapy. He is a known case of Acute Myeloid Leukemia. On the first day of admission, the doctor prescribes a chemotherapy regimen plus Filgrastim to be administrated on day 1 of admission. How will you adjudicate this claim?

Answer: The claim will be rejected as Filgrastim should not be administrated in the period 24 hours before the administration of cytotoxic chemotherapy.

Denial codes

Code	Code description
NCOV-001	Diagnosis is not covered
NCOV-002	Pre-existing conditions are not covered
MNEC-003	Service is not clinically indicated based on good clinical practice
MNEC-004	Service is not clinically indicated based on good clinical practice and requires additional information.
MNEC-005	Service / supply may be appropriate but too frequent
PRCE-002	Payment is included in the allowance for another service.

Appendices

A. References

1. http://www.uptodate.com/contents/hematologic-manifestations-of-hiv-infection-neutropenia?source=search_result&search=leukopenia+in+hiv&selectedTitle=1%7E150#H6

2. http://www.accessdata.fda.gov/drugsatfda_docs/label/1998/filgamg040298lb.pdf

3. www.nccn.com

4. National Cancer Institute. NCI drug dictionary: Folfirinox. National Cancer Institute. Available at: http://www.cancer.gov/publications/dictionaries/cancer-drug?CdrID=710968

5. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM235408.pdf

6. http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/125031s180lbl.pdf

7. http://emedicine.medscape.com/article/887140-treatment#showall

B. Revision History

Date	Change(s)
01-07-13	V 1.1: New template
15-07-14	V 2.0 :Disclaimer updated as per system requirements
22-08-16	V2.1 : Review

C. Indications and frequency

1. Filgrastim

Indications		Adult dosage 1 mcg = 100,000 units	Paediatric dosage 1 mcg = 100,000 units
Malignant Neoplasms	Myelosuppressive chemotherapy recipients with non-myeloid malignancies	IV: 5 mcg/kg/day; doses may be increased by 5 mcg/kg (for each chemotherapy cycle) according to the duration and severity of the neutropenia; continue for up to 14 days until the absolute neutrophil count (ANC) reaches 10,000/mm^3. Discontinue if the ANC surpasses 10,000/mm^3 after the expected chemotherapy-induced neutrophil nadir.	IV: 5 mcg/kg/day; doses may be increased by 5 mcg/kg (for each chemotherapy cycle) according to the duration and severity of the neutropenia; continue for up to 14 days until the absolute neutrophil count (ANC) reaches 10,000/mm3. Discontinue if the ANC surpasses 10,000/mm3 after the expected chemotherapy-induced neutrophil nadir.
	Acute myeloid leukaemia (AML) following induction or consolidation chemotherapy		
Bone marrow transplantation		IV infusion: 10 mcg/kg/day (administer ≥24 hours after chemotherapy and ≥24 hours after bone marrow infusion); adjust the dose according to the duration and severity of neutropenia; recommended steps based on neutrophil response: - When ANC >1,000/mm^3 for 3 consecutive days: Reduce dose to 5 mcg/kg/day - If ANC remains >1,000/mm^3 for 3 more consecutive days: Discontinue	IV infusion: 10 mcg/kg/day (administer ≥24 hours after chemotherapy and ≥24 hours after bone marrow infusion); adjust the dose according to the duration and severity of neutropenia; recommended steps based on neutrophil response: - When ANC >1,000/mm^3 for 3 consecutive days: Reduce dose to 5 mcg/kg/day - If ANC remains >1,000/mm^3 for 3 more consecutive days: Discontinue - If ANC decreases to <1,000/mm^3: Resume at 5 mcg/kg/day

	- If ANC decreases to <1,000/mm^3: Resume at 5 mcg/kg/day. - If ANC decreases to <1,000/mm^3 during the 5 mcg/kg/day doses: Increase dose to 10 mcg/kg/day and follow the above steps.	If ANC decreases to <1,000/mm^3 during the 5 mcg/kg/day dose, increasedose to 10 mcg/kg/day and follow the above steps
Peripheral blood progenitor cell collection and therapy	IV infusion: 10 mcg/kg daily, usually for 6 to 7 days (with apheresis occurring on days 5, 6, and 7). Begin at least 4 days before the first apheresis and continue until the last apheresis; discontinue for WBC >100,000/mm^3	IV infusion: 10 mcg/kg daily, usually for 6 to 7 days (with apheresis occurring on days 5, 6, and 7). Begin at least 4 days before the first apheresis and continue until the last apheresis; discontinue for WBC >100,000/mm^3
Severe congenital chronic neutropenia	6 mcg/kg/day in 2 divided doses; adjust the dose based on ANC and clinical response; mean dose: 6 mcg/kg/day	6 mcg/kg/day in 2 divided doses; adjust the dose based on ANC and clinical response; mean dose: 6 mcg/kg/day
Severe idiopathic chronic neutropenia	5 mcg/kg once daily; adjust the dose based on ANC and clinical response; mean dose: 1.2 mcg/kg/day	5 mcg/kg once daily; adjust the dose based on ANC and clinical response; mean dose: 1.2 mcg/kg/day
Severe cyclic chronic neutropenia	5 mcg/kg once daily; adjust the dose based on ANC and clinical response; mean dose: 2.1 mcg/kg/day	5 mcg/kg once daily; adjust the dose based on ANC and clinical response; mean dose: 2.1 mcg/kg/day

2. Peg-filgrastim

The recommended dosage of Peg-filgrastim is a single subcutaneous injection of 6 mg administered once per chemotherapy cycle. For dosing in pediatric patients weighing less than 45 kg, refer to table below:

Body weight	Peg-filgrastim dose	Volume to administer
Less than 10Kg*	See below*	See below*
10 – 20 Kg	1.5 mg	0.15 ml
21 – 30 Kg	2.5 mg	0.25 ml
31 – 44 Kg	4 mg	0.40 ml

*For pediatric patients weighing less than 10 kg, administer 0.1 mg/kg (0.01 mL/kg) of Peg-filgrastim.

Peg-Filgrastim frequency in pediatrics as per weight settings.