Neulasta

Description

Neulasta (pegfilgrastim)

Background

Neutropenia (<500 neutrophils/mcl or <1,000 neutrophils/mcl and a predicted decline to ≤ 500/mcl over the next 48 hours) and resulting febrile neutropenia (≥ 38.3°C orally or ≥38.0°C over 1 hour) can be induced by myelosuppressive chemotherapy. Febrile neutropenia is a major dose-limiting toxicity of chemotherapy. Major infections, hospitalizations, dose reductions or treatment delays are resultant serious complications (1).

Neulasta (pegfilgrastim) is a granulocyte colony-stimulating factor (G-CSF) that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation. The product is a covalent conjugate of recombinant methionyl human G-CSF (filgrastim) and monomethoxypolyethylene glycol (1).

Regulatory Status

FDA-approved indication: Neulasta is a leukocyte growth factor indicated: (2)

- 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
To increase survival in patients acutely exposed to myelosuppressive doses of radiation, Neulasta is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation (2).

**Related policies**
Granix, Leukine, Neupogen

**Policy**
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Neulasta may be considered **medically necessary** for the prophylaxis or treatment of chemotherapy induced febrile neutropenia and acute radiation syndrome; not be used in combination with another granulocyte colony-stimulating factor (G-CSF).

Neulasta may be considered **investigational** for all other indications.

**Prior-Approval Requirements**

**Diagnoses**

Patient must have **ONE** the following:

1. Prophylaxis for chemotherapy induced febrile neutropenia
2. Treatment of chemotherapy induced febrile neutropenia
3. Acute radiation syndrome

AND the following

a. **NOT** used in combination with another granulocyte colony-stimulating factor (G-CSF)

**Prior – Approval Renewal Requirements**

Same as above

**Policy Guidelines**

**Pre - PA Allowance**

None
Prior - Approval Limits
Duration 6 months

Prior – Approval Renewal Limits
Duration 6 months

Rationale

Summary
Neutropenia (<500 neutrophils/mcl or <1,000 neutrophils/mcl and a predicted decline to ≤ 500/mcl over the next 48 hours) and resulting febrile neutropenia (≥ 38.3°C orally or ≥38.0°C over 1 hour) can be induced by myelosuppressive chemotherapy. Neulasta (pegfilgrastim) is a granulocyte colony-stimulating factor (G-CSF) that acts on hematopoietic cells by binding to specific cell surface receptors, thereby stimulating proliferation, differentiation, commitment, and end cell functional activation (1-2).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Neulasta while maintaining optimal therapeutic outcomes.

References

Policy History
Date Reason
July 2010 ICD-9 code was removed for myelosuppressive chemotherapy, to decrease the incidence of infection as manifested by febrile neutropenia (various), bone marrow transplantation (996.85), peripheral blood progenitor cell collection (various), acceleration of myeloid recovery in patients with non-Hodgkin’s lymphoma, ALL or Hodgkin’s disease undergoing bone marrow transplantation (various), induction chemotherapy in acute myelogenous leukemia (various), mobilization and following transplantation of autologous PBPC (various), myeloid reconstitution after allogenic bone marrow transplantation (various), severe
chronic neutropenia (various) and bone marrow transplantation failure or engraftment delay (996.0-996.5). ICD-9 code was updated for bone marrow transplantation failure or engraftment delay (996.82). ICD-10 code was added for bone marrow transplantation failure or engraftment delay (T86.02).

November 2010 Separation of colony stimulating factors to improve functionality and workflow; remove non-FDA approved indications (including ICD-9 and 10 codes) as follows: Myelodysplastic Syndrome (MDS), Myeloid engraftment following bone marrow transplantation, Myeloid engraftment following hematopoietic stem cell transplantation, Congenital, Cyclic, or Idiopathic Neutropenia, Neutropenia associated with AIDS treatment, and Peripheral progenitor cell yield.

September 2011 Separation of the colony stimulating agents’ criterion; Neulasta is not FDA approved for the same indications as Leukine and Neupogen. Removal of ICD-9 and 10 codes due to lack of specificity.

December 2011 Aligned with Medical Policy

December 2012 Annual Review-editorial updates

March 2014 Annual review and decreased approval and renewal limits to 6 months

March 2015 Annual editorial review and reference update
Addition of not used in combination with another granulocyte colony-stimulating factor (G-CSF)

December 2015 Addition of new indication acute radiation syndrome

March 2016 Annual editorial review
Policy number changed from 5.10.09 to 5.85.09

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 18, 2016 and is effective April 1, 2016.

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