DRUG DETERMINATION POLICY

Title: DDP-15 G-CSF Agents

Effective Date: 06/03/2020

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve Benefits. Coverage depends on the specific Benefit plan. Pharmacy Benefit Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Granulocyte colony-stimulating factor (G-CSF) agents are specialty drugs indicated for a number of diagnoses and are associated with significant toxicity. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of toxicity, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

A. Filgrastim (Nivestym)
    1. Status: preferred agent (brand Nivestym).
    2. Quantity limits:
        a. Covered without prior authorization: ten syringes per 24 days.
        b. Prior authorization required: greater than ten syringes per 24 days.
    3. Excluded filgrastim products: Neupogen, Zarxio, Granix.
        a. All preferred products contraindicated, failed or had significant adverse effects.

B. Pegfilgrastim (brand-names: Neulasta, Fulphila, Udenyca, Ziextenzo)
    1. Status: non-preferred agent.
    2. Diagnosis and severity:

a. Prevention of chemotherapy-induced neutropenia: to decrease the incidence of infections in patients with non-myeloid malignancies receiving myelosupressive cancer chemotherapy associated with significant incidence of febrile neutropenia.

b. Hematopoietic radiation injury syndrome, acute: to increase survival in patients acutely exposed to myelosuppressive doses of radiation (must meet all below):

i. Radiation exposure: at least two Gray.

ii. Absolute lymphocyte count: significant decrease.

iii. Neutropenia: anticipated to be less than 500/mm^3 for at least seven days.

3. Non-preferred pegfilgrastim approval (must meet one below):

a. Failure of filgrastim: required greater ten days of daily filgrastim therapy to obtain acceptable absolute neutrophil count (ANC).

b. Significant adverse effects or administration issues with filgrastim.

c. Significant physical limitation that limits ability to perform daily injections with no other individual able to perform injection.

4. Dosage regimen.

a. Adult:

i. Prevention of chemotherapy-induced neutropenia: 6mg subcutaneous (SC) once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy.

ii. Hematopoietic radiation injury, acute: 6mg SC weekly for two doses.

b. Pediatric:

i. Prevention of chemotherapy-induced neutropenia: once dose subcutaneous (SC) once per chemotherapy cycle, beginning at least 24 hours after completion of chemotherapy.

ii. Hematopoietic radiation injury, acute: subcutaneous (SC) weekly for two doses.

iii. Dose by weight:

Weight (Kg)	Route	Dose	Volume
Below 10	Subcutaneous (SC)	0.1 mg/kg	0.01 mL/kg
10 to 20	SC	1.5 mg	0.15 ml
21 to 30	SC	2.5 mg	0.25 ml
31 to below 45	SC	4 mg	0.4 ml
Over 45	SC	6mg	0.6 ml

C. Approval.

1. Duration: six months or less depending on the number of cycles.

2. Billing: through the outpatient prescription drug benefit only.

4.0 Coding:

Filgrastim and pegfilgrastim products are covered under the outpatient prescription drug benefit only.

5.0 Unique Configuration/Prior Approval/Coverage Details:

None.

6.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Neupogen/Zarxio/Granix, accessed March 2020.
2. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Neulasta, accessed March, 2020.

7.0 Appendices:

See page 4.

8.0 Revision History:

Original Effective Date: December 14, 2005

Next Review Date: 06/03/2021

Revision Date	Reason for Revision
March 2019	Transfer to new format
April 2019	Presented and approved at P & T Workgroup
12/19	Off cycle review; addition of biosimilars; change to consistent verbiage, replace abbreviations.
3/20	Annual review; revised indication, added adult and pediatric dosage regimen

Appendix I: Monitoring & Patient Safety - Adverse Reactions and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Pegfilgrastim (Neulasta, Fulphila, Udenyca, Ziextenzo)	• Musculoskeletal: ostealgia (31%) • Pregnancy Category: C	• Gastro-Intestinal (GI): abdominal pain • Hematology: monitor for sickle cell crisis, splenomegaly • Hypersensitivity • Musculoskeletal: shoulder pain • Pregnancy: adverse event in animal studies • Renal: glomerulonephritis • Respiratory: pulmonary infiltrates, respiratory distress • Myelosuppressive chemo: complete blood count (CBC) with difference & platelets prior to and as needed • Hematopoietic radiation injury syndrome: CBC at baseline, established absorbed radiation dose	None needed