Pharmacy Benefit Determination Policy

Policy Subject: G-CSF Agents	**Dates:**
Policy Number: SHS PBD13	**Effective Date:** December 14, 2005
Category: Oncology & Anti-infectives	**Revision Date** March 29, 2018
Policy Type: ☒ **Medical** ☒ **Pharmacy**	**Approval Date:** April 25, 2018
Department: Pharmacy	**Next Review Date:** April 2019
Product (check all that apply):	**Clinical Approval By:**
☒ Group HMO/POS	**Medical Directors**
☒ Individual HMO/POS	Peter Graham, MD
☒ PPO	**Pharmacy and Therapeutics Committee**
☒ ASO	Peter Graham, MD

Policy Statement:

Physicians Health Plan, PHP Insurance & Service Company, and Sparrow PHP will cover G-CSF Agents through the Medical/Pharmacy Benefit based on approval by the Clinical Pharmacist or Medical Director using the following determination guidelines

Drugs and Applicable Coding:

J-code: Neupogen/Granix - J1442 (1U/1mcg); Zarxio - Q5101

Clinical Determination Guidelines:

Document the following with chart notes

A. Myelosuppressive Chemotherapy in Non-myeloid Malignancies
   1. Diagnosis & severity: ↓ incidence of infection in non-myeloid Ca receiving myelosuppressive chemo w significant incidence of neutropenia w fever.
   2. Dosage regimen: Neupogen/Zarxio/Granix (filgrastim SC/IV)
      a. Initial: 5mcg/kg/day SC bolus (15-30") or SC/IV infusion
      b. Titration: ↑ 5mcg/Kg per chemo cycle as needed
      c. Usual: 4-8 mcg/kg/day SC/IV
      d. Duration: 1x/day for ≤ 2 wks. until ANC = 5,000-10,000/mm^3

B. Acute Myeloid Leukemia (AML)
   1. Diagnosis & severity: ↓ time to neutrophil recovery & duration of fever following induction or consolidation chemo. tx of adults w AML
   2. Dosage regimen: Neupogen/Zarxio/Granix (filgrastim SC/IV): (See A2)

C. Bone Marrow Transplant (BMT)
1. Diagnosis & severity: ↓ duration of neutropenia/neutropenia-related events w non-myeloid Ca getting ablative chemo followed by BMT
3. 2. Dosage regimen: Neupogen/Zarxio (filgrastim SC/IV)
a. Initial dose: 10mcg/Kg IV infusion 4-24 hrs or continuous 24hr SC infusion
b. Titration

ANC	Duration	Dose
>1,000mm^3	3 days	↓ to 5mcg/Kg/day
>1,000mm^3	3 more days	discontinue
<1,000mm^3	anytime	resume 5mcg/Kg/day
<1,000mm^3	anytime (on 5mcg/Kg/day)	↑ to 10mcg/Kg/day

D. Peripheral Blood Progenitor Cell (PBPC) collection
1. Diagnosis & severity: ↑ & mobilize hematopoietic PC cells in peripheral blood for apheresis collection.
2. Dosage regimen: Neupogen/Zarxio (filgrastim SC/IV):
a. Usual: 10mcg/Kg/day SC bolus or continuous infusion;
b. Titration: Consider dose modification for WBC ≥100,000/mm^3
c. Duration: ≥4 days pre 1st - last apheresis; usually 6-7 days w apheresis on days 5-7.
d. Monitor: Neutrophil count after day 4 of therapy

E. Severe Chronic Neutropenia (SCN)
1. Diagnosis & severity: ↓ incidence & duration of results of neutropenia (eg fever, infection, oral ulcers) in symptomatic pts w congenital, cyclic or idiopathic neutropenia.
2. Dosage regimen: Neupogen/Zarxio (filgrastim SC/IV):
a. Initial Dose
- Congenital: 6 mcg/Kg/day SC
- Cyclic: 5 mcg/kg day SC
- Idiopathic: 5mcg/Kg/day SC

b. Titration: Based on ANC & clinical course

F. Hematopoietic Radiation Injury Syndrome, Acute
1. Diagnosis & severity: ↑ survival in patients acutely exposed to myelosuppressive doses of radiation
a. Radiation exposure: ≥2 Gray (gy)
b. Absolute lymphocyte count: Significant ↓
c. Neutropenia: Anticipated to be <500/mm^3 for ≥ 7 days
2. Dosage regimen: Neupogen (filgrastim SC/IV):
a. Initial: 10mcg/Kg SC 1x daily within 24 hrs
b. Duration: ANC >1,000mm^3 for 3 CBC's or ANC >10,000mm^3 after radiation-induced nadir

G. Chronic Myeloid Leukemia (CML)/Myelodysplasia: Use has not been established

H. Non-preferred Agent Approval
1. Failed Neupogen/Zarxio/Granix (filgrastim SC/IV): Requires ≥10 daily doses to obtain acceptable ANC
2. Significant adverse effects or administration issues w Neupogen/Zarxio/Granix (filgrastim SC/IV):

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

Drug	Adverse Reactions	Monitoring	REMS
Neupogen Zarxio Grannix Filgrastim SC/IV	• GI: 10% • Heme: Petechia (≤17%), splenomegaly • MSK: Ostealgia (22-33%) • Resp.: Epistaxis (9-15%) • Preg. category: C	• Myelosuppressive Chemo: CBC w diff & plts prior to and 2x wkly during tx • BMT: CBC w diff & plts ≥ 3xwkly • Perip Progenitor Cell Collections: Neutrophil count after 4 days filgrastim tx. • SCN **CBC w diff & plts:** Mo 1/post dose adj: 2x/wk Stable: mnthly x 1 yr, then quarterly **Bone marrow & Karotype/cytogenetics:** prior to & yrly	None needed

References and Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Neupogen/Zarxio/Granix, accessed Mar 2018
2. Lexicomp Online® , Lexi-Drugs® , Hudson, Ohio: Lexi-Comp, Inc.; Neulasta, accessed March, 2018

Approved By:

4/25/18

Peter Graham, MD – PHP Executive Medical Director — Date

4/25/18

Human Resources (Kurt Batteen) — Date