PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
COLONY STIMULATING FACTORS

Proposed Effective Date: January 1, 2020

Revisions are noted with a ~~strikethrough~~ for deletions and ~~**bold and underline**~~ for additions.

I. Requirements for Prior Authorization of Colony Stimulating Factors

A. Revisions to Prescriptions That Require Prior Authorization

~~Prescriptions for Colony Stimulating Factors that meet any of the following conditions must be prior authorized:~~

All prescriptions for Colony Stimulating Factors must be prior authorized.

1. ~~A prescription for a preferred or non-preferred Colony Stimulating Factor regardless of the quantity prescribed.~~ See the Preferred Drug List (PDL) for the list of preferred ~~and non-preferred~~ Colony Stimulating Factors at:
   ~~www.providersynergies.com/services/documents/PAM_PDL.pdf~~
   https://papdl.com/preferred-drug-list.

2. ~~A prescription for a Colony Stimulating Factor with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:~~
   ~~http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmacyservices/quantitylimitslist/index.htm~~ **The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:**
   http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Colony Stimulating Factor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. ~~The requested medication was written~~ **Is prescribed the Colony Stimulating Factor** by or in consultation with a hematologist or oncologist; **AND**

2. **Is being prescribed the Colony Stimulating Factor for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND** ~~The requested Colony Stimulating Factor is prescribed for an indication listed in:~~

   ~~a. The FDA-approved package insert~~

   ~~**OR**~~

   ~~b. Nationally recognized compendia for medically-accepted indications for off-label use~~

~~**AND**~~

3. ~~The recipient~~ Does not have a **history of a** contraindication to the ~~requested~~ **prescribed** Colony Stimulating Factor**;** **AND**

4. For primary prophylaxis of chemotherapy induced febrile neutropenia in patients with non-myeloid malignancies, **one** of the following:

   a. Will be receiving a chemotherapy regimen with an expected incidence of febrile neutropenia > 20% as defined by the National Comprehensive Cancer Network (NCCN)
   b. Has risk factors for developing febrile neutropenia as defined by the NCCN;

   AND

5. For a prescription for Neulasta (pegfilgrastim), ~~the recipient~~ will not be receiving the medication during the period beginning 14 days before and ending 24 hours after administration of cytotoxic chemotherapy; **AND**

6. ~~For a prescription for Leukine (sargramostim), the recipient is ≥ 55 years of age~~ **Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;** **AND**

7. For a non-preferred Colony Stimulating Factor, has a history of therapeutic failure, contraindication, or intolerance of the preferred Colony Stimulating Factors**; AND**

8. **If a prescription for a Colony Stimulating Factor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.**

~~**OR**~~

9. ~~The recipient does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.~~

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of ~~the request for~~ a prescription for a Colony Stimulating Factor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity

determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the ~~recipient~~ **beneficiary**.

D. References

1. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines) – Hematopoietic Growth Factors, Version 2.2019
2. Neupogen prescribing information, Thousand Oaks, California. Amgen Inc. June 2018.
3. Neulasta Prescribing Information, Thousand Oaks, California. Amgen Inc. April 2019
4. Leukine prescribing information, Bridgewater, NJ. Sanofi-Aventis. March 2018.