pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
August 8, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of Colony Stimulating Factors – Pharmacy Services

BY

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Office of Medical Assistance Programs

IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Colony Stimulating Factors submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Colony Stimulating Factors to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Colony Stimulating Factors to address the U.S. Food and Drug Administration (FDA) expanded approval of Leukine (sargramostim) for autologous peripheral blood

*01-19-27	09-19-25	27-19-23	33-19-25
02-19-22	11-19-21	30-19-21	
03-19-21	14-19-21	31-19-27	
08-19-30	24-19-23	32-19-21	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

progenitor cells and bone marrow transplantation, allogeneic bone marrow transplantation, and treatment of delayed neutrophil recovery or graft failure to include pediatric patients 2 years of age and older and approval of a new indication to increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]). There are no other changes to the medical necessity guidelines.

The revisions to the guidelines to determine medical necessity of Colony Stimulating Factors were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Colony Stimulating Factors are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Colony Stimulating Factors) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook – Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm

I. Requirements for Prior Authorization of Colony Stimulating Factors

A. Revisions to Prescriptions That Require Prior Authorization

All prescriptions for Colony Stimulating Factors must be prior authorized.

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. Is 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**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed the Colony Stimulating Factor by or in consultation with a hematologist or oncologist; **AND**

4. Does not have a history of a contraindication to the prescribed Colony Stimulating Factor; **AND**

5. 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

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

7. For a non-preferred Colony Stimulating Factor, has a history of therapeutic failure, contraindication, or intolerance of the preferred Colony Stimulating Factors. See the Preferred Drug List (PDL) for the list of preferred Colony Stimulating Factors at: https://papdl.com/preferred-drug-list; **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. 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.

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 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 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.