Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 12, 2024	January 6, 2025	*See below

SUBJECT

Prior Authorization of Colony Stimulating Factors – Pharmacy Services

BY

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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: https://www.pa.gov/en/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents.html.

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. The guidelines to determine the medical necessity of Colony Stimulating Factors will be utilized in the fee-for-service and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of Colony Stimulating Factors to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs and products in therapeutic classes already included on the Statewide Preferred Drug List (PDL).

*01-25-12	09-25-12	27-25-12	33-25-12
02-25-12	11-25-12	30-25-12	
03-25-12	14-25-12	31-25-12	
08-25-13	24-25-12	32-25-12	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/en/agencies/dhs/departments-offices/omap-info.html

- Changes to the statuses of drugs and products on the Statewide PDL from preferred to non-preferred and non-preferred to preferred.
- Therapeutic classes of drugs and products to be added to or deleted from the Statewide PDL.
- New quantity limits.
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 10, 2024, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Colony Stimulating Factors:

- Addition of a guideline that the beneficiary is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- Revision of the guideline that the Colony Stimulating Factor is prescribed by or in consultation with an appropriate specialist (e.g., hematologist, oncologist, transplant specialist).
- Revision of the guideline related to risk factors for developing febrile neutropenia.
- Revision of the guideline to refer to a pegfilgrastim-containing product rather than Neulasta (pegfilgrastim) specifically.
- Revision of the guideline related to the dosing schedule for a pegfilgrastim-containing product.
- Revision of the guideline related to requests for non-preferred Colony Stimulating Factors to consider the beneficiary's diagnosis or indication.

The revisions to the guidelines to determine medical necessity of prescriptions for Colony Stimulating Factors submitted for prior authorization, as recommended by the P&T Committee, 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 and products 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
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements.html

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/clinical-guidelines.html

I. Requirements for Prior Authorization of Colony Stimulating Factors

A. Prescriptions That Require Prior Authorization

All prescriptions for Colony Stimulating Factors must be prior authorized.

B. 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 a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the Colony Stimulating Factor by or in consultation with an appropriate specialist (e.g., hematologist, oncologist, transplant specialist); **AND**

5. Does not have a contraindication to the prescribed Colony Stimulating Factor; **AND**

6. For primary prophylaxis of chemotherapy-induced febrile neutropenia in a beneficiary with non-myeloid malignancy, **one** of the following:

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

   AND

7. For a prescription for a pegfilgrastim-containing product, will be receiving the drug according to a dosing schedule supported by NCCN, other nationally recognized compendia, or peer-reviewed medical literature; **AND**

8. For a non-preferred Colony Stimulating Factor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Colony Stimulating Factors approved or medically accepted for the beneficiary's diagnosis or indication. See the Preferred Drug List

(PDL) for the list of preferred Colony Stimulating Factors at: https://papdl.com/preferred-drug-list; **AND**

9. 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: https://www.pa.gov/en/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.html.

   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. Fulphila Package Insert. Cambridge, MA: Biocon Biologics Inc.; June 2023.
2. Fylnetra Package Insert. Piscataway, NJ: Kashiv BioSciences, LLC; May 2022.
3. Granix Package Insert. Vilnius, Lithuania: UAB Teva Baltics; November 2023.
4. Leukine Package Insert. Lexington, MA: Partner Therapeutics, Inc.; August 2023.
5. National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology (NCCN Guidelines) – Hematopoietic Growth Factors, Version 3.2024.
6. Neulasta Package Insert. Thousand Oaks, California: Amgen Inc.; February 2021.
7. Neupogen Package Insert. Thousand Oaks, California: Amgen Inc.; April 2023.
8. Nivestym Package Insert. Lake Forest, IL: Hospira, Inc., a Pfizer Company; February 2024.
9. Nyvepria Package Insert. Lake Forest, IL: Hospira, Inc., a Pfizer Company; March 2023.
10. Releuko Package Insert. Piscataway, NJ: Kashiv BioSciences, LLC; August 2023.
11. Rolvedon Package Insert. Lake Forest, IL: Spectrum Pharmaceuticals, Inc.; November 2023.
12. Stimufend Package Insert. Lake Zurich, IL: Fresenius Kabi USA, LLC; September 2023.
13. Udenyca Package Insert. Redwood City, CA: Coherus BioSciences, Inc.; December 2023.
14. Zarxio Package Insert. Princeton, NJ: Sandoz Inc.; January 2024.
15. Ziextenzo Package Insert. Princeton, NJ: Sandoz Inc.; March 2021.