Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
March 30, 2026	March 30, 2026	*See below

SUBJECT	BY
Prior Authorization of Sickle Cell Anemia Agents – Pharmacy Services	Sally Kozak Deputy Secretary 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: https://www.pa.gov/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents

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 Sickle Cell Anemia Agents 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 Sickle Cell Anemia Agents 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 Sickle Cell Anemia Agents to the appropriate managed care organization.

BACKGROUND/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for Sickle Cell Anemia Agents because Siklos (hydroxyurea) tablet has been moved from non-preferred to preferred on the Statewide Preferred Drug List with an age restriction.

*01-26-53	09-26-54	27-26-43	33-26-46
02-26-43	11-26-43	30-26-43	
03-26-44	14-26-46	31-26-54	
08-26-54	24-26-53	32-26-43	

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/agencies/dhs/departments-offices/omap-info

Prior authorization will continue to be required for beneficiaries 18 years of age or older. The medical necessity guidelines have also been updated with the addition of guidelines to determine medical necessity of a request for a non-preferred hydroxyurea formulation that the beneficiary has a history of therapeutic failure of or a contraindication or an intolerance to the preferred hydroxyurea formulations unless the beneficiary is unable to obtain a dose that is consistent with U.S. Food and Drug Administration-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature with the preferred hydroxyurea formulations.

The revisions to the guidelines to determine medical necessity of prescriptions for Sickle Cell Anemia Agents 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 Sickle Cell Anemia Agents 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 Sickle Cell Anemia Agents) 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/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements

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

I. Requirements for Prior Authorization of Sickle Cell Anemia Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Sickle Cell Anemia Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Sickle Cell Anemia Agent. See the Preferred Drug List (PDL) for the list of preferred Sickle Cell Anemia Agents at: https://papdl.com/preferred-drug-list.

2. A Sickle Cell Anemia Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.pa.gov/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.

3. A prescription for Siklos (hydroxyurea) tablet when prescribed for a beneficiary 18 years of age or older.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Sickle Cell Anemia Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Sickle Cell Anemia Agent 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 that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the Sickle Cell Anemia Agent by or in consultation with a hematologist/oncologist or sickle cell disease specialist; **AND**

5. For Adakveo (crizanlizumab-tmca) or L-glutamine powder, has a history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of hydroxyurea for at least six months; **AND**

6. For Siklos (hydroxyurea) tablet for a beneficiary 18 years of age or older, is unable to obtain a hydroxyurea dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature with the preferred hydroxyurea capsule; **AND**

7. For a non-preferred hydroxyurea Sickle Cell Anemia Agent, **one** of the following:

    a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred hydroxyurea Sickle Cell Anemia Agents that would not be expected to occur with the requested drug
    b. Is unable to obtain a hydroxyurea dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature with the preferred hydroxyurea Sickle Cell Anemia Agents;

    AND

8. If a prescription for a Sickle Cell Anemia Agent 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.

    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.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR SICKLE CELL ANEMIA AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Sickle Cell Anemia Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the requested drug; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed the Sickle Cell Anemia Agent by or in consultation with a hematologist/oncologist or sickle cell disease specialist; **AND**

4. For Siklos (hydroxyurea) tablet for a beneficiary 18 years of age or older, is unable to obtain a hydroxyurea dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature with the preferred hydroxyurea capsule; **AND**

5. For a non-preferred hydroxyurea Sickle Cell Anemia Agent, **one** of the following:

    a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred hydroxyurea Sickle Cell Anemia Agents that would not be expected to occur with the requested drug
    b. Is unable to obtain a hydroxyurea dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature with the preferred hydroxyurea Sickle Cell Anemia Agents;

AND

6. If a prescription for a Sickle Cell Anemia Agent 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.

   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 Sickle Cell Anemia Agent. 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.