Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: N/A**
Policy Number: PHW.PDL.746	**Effective Date: 01/05/2021** **Revision Date: 10/2021**
Policy Name: Sickle Cell Anemia Agents	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

Q1 2022 annual review: no changes.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Sickle Cell Anemia Agents

Reference Number: PHW.PDL.746
Effective Date: 01/05/2021
Last Review Date: 10/2021

Revision Log

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health and Wellness® that Sickle Cell Anemia Agents are **medically necessary** when the following criteria are met:

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.

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. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**

6. Has a history of therapeutic failure, contraindication, or intolerance to maximum tolerated doses of hydroxyurea for at least 6 months; **AND**

7. 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 PA.CP.PMN.59 Quantity Limit Override

   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 tolerability and a positive clinical response to the medication; **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. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**

5. 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 PA.CP.PMN.59 Quantity Limit Override.

   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.

D. **Approval Duration: 6 months**

E. References

1. Adakveo Package Insert. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2019.
2. Endari Package Insert. Torrance, CA: Emmaus Medical, Inc.; November 2019.
3. Oxbryta Package Insert. San Francisco, CA: Global Blood Therapeutics, Inc.; November 2019.
4. Siklos Package Insert. Bryn Mawr, PA: Medunik USA, Inc.; May 2018

Reviews, Revisions, and Approvals	Date
Q1 2021: policy created according to DHS effective 01/05/2021	11/2020
Q1 2022 annual review: no changes.	10/2021