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.727	**Effective Date: 01/01/2020** **Revision Date: 10/2021**
Policy Name: Iron Chelating 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: Iron Chelating Agents

Reference Number: PHW.PDL.727
Effective Date: 01/01/2020
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 Iron Chelating Agents are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Iron Chelating Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Iron Chelating Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

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

1. Is being treated for a diagnosis that is indicated 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 is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the Iron Chelating Agent by or in consultation with a specialist (i.e., hematologist); **AND**

5. Has documentation of baseline lab results as recommended in the FDA-approved package labeling; **AND**

6. Does not have a history of a contraindication to the prescribed medication; **AND**

7. For a non-preferred Iron Chelating Agent, has documented therapeutic failure, contraindication, or intolerance of the preferred Iron Chelating Agents approved or medically accepted for the beneficiary's diagnosis.

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 IRON CHELATING AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Iron Chelating 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 the Iron Chelating Agent by or in consultation with a specialist (i.e. hematologist); **AND**

3. Has documentation of results of recent lab monitoring as recommended in the FDA-approved package labeling; **AND**

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

5. Is continuing treatment with the prescribed Iron Chelating Agent based on recent lab results as recommended in the FDA-approved package labeling.

   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 an Iron Chelating 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:
- **New Request: 6 months**
- **Renewal Request: 12 months**

E. References

1. Exjade [Package Insert]. East Hanover, NJ. Novartis. December 2018.
2. Jadenu [Package Insert]. East Hanover, NJ. Novartis. December 2018.
3. Ferriprox [Package Insert]. Weston, FL. ApoPharma USA, Inc. May 2017.
4. Taher, A et al. Guidelines for the management of non transfusion dependent thalassaemia: 2nd Edition. 2017. https://www.thalassemia.org/boduw/wp-content/uploads/2011/09/Guidelines-for-Mgmt-of-NTDT-TIF-2017.pdf. Accessed April 20, 2019.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022 annual review: no changes.	10/2021