


<b>ISSUE DATE</b>  September 5, 2019	<b>EFFECTIVE DATE</b>  January 1, 2020	<b>NUMBER</b>  *See below
<b>SUBJECT</b>  Prior Authorization of Iron Chelating Agents – Pharmacy Services	<b>BY</b>   Sally A. 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: [http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

**PURPOSE:**

The purpose of this bulletin is to:

1. Inform providers of the addition of the Iron Chelating Agents class of drugs to the Preferred Drug List (PDL).
2. Issue new handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Iron Chelating Agents 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 Iron Chelating Agents to the appropriate managed care organization.

*01-19-61	09-19-57	27-19-55	
02-19-55	11-19-54	30-19-53	
03-19-54	14-19-53	31-19-60	
08-19-63	24-19-55	32-19-53	33-19-57

**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>

**BACKGROUND:**

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed clinical literature and makes recommendations relating to the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the PDL;
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

**DISCUSSION:**

During the June 21, 2019, meeting, the P&T Committee recommended that the Department add the Iron Chelating Agents class of drugs to the PDL and proposed guidelines to determine medical necessity of Iron Chelating Agents. The requirement for prior authorization and guidelines to determine medical necessity of Iron Chelating Agents, 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 Iron Chelating 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 Iron Chelating 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 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>

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

**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. See the Preferred Drug List (PDL) for the list of preferred Iron Chelating Agents at: <https://papdl.com/preferred-drug-list>.

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**

MEDICAL ASSISTANCE HANDBOOK  
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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. 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: 2<sup>nd</sup> Edition. 2017. <https://www.thalassemia.org/boduw/wp-content/uploads/2011/09/Guidelines-for-Mgmt-of-NTDT-TIF-2017.pdf>. Accessed April 20, 2019.