Gateway Health
It's Wholecare.

Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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**

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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.

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IRON CHELATING AGENTS PRIOR AUTHORIZATION FORM

☐New request ☐Renewal request	Total # of pages: _____	Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:
Medication will be billed via: ☐ Pharmacy ☐ Medical (Jcode:)		Place of Service: ☐ Hospital ☐ Provider's Office ☐ Home ☐ Other	

CLINICAL INFORMATION

Drug name, strength, dosage form:	Beneficiary weight:	
Dose/directions:	Quantity:	Refills:
Diagnosis *(submit documentation)*:	Dx code (*required*):	

INITIAL requests

For a non-preferred Iron Chelating Agent: Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred agent(s) in this class? *Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred agents in this class.*	☐Yes ☐No *Submit documentation.*

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐For treatment of transfusional iron overload:
- ☐If request is for a deferasirox product (Exjade, Jadenu), has documentation of the following lab test results:
  - ☐serum ferritin ☐serum electrolytes ☐CBC
  - ☐serum creatinine x 2 ☐urinalysis to evaluate renal tubular function ☐LFTs
- ☐If request is for deferiprone (Ferriprox), has documentation of the following lab test results:
  - ☐serum ferritin ☐CBC with differential

☐For treatment of non-transfusion-dependent thalassemia syndromes
- ☐Has documentation of the following lab test results:
  - ☐liver iron content ☐serum ferritin x 2 (at least 1 month apart) ☐CBC
  - ☐serum creatinine x 2 ☐urinalysis to evaluate renal tubular function ☐LFTs
  - ☐serum electrolytes

RENEWAL requests

Complete the sections below that are applicable to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐For treatment of transfusional iron overload:
- ☐If request is for a deferasirox product (Exjade, Jadenu), has documentation of the following lab test results:
  - ☐serum ferritin ☐serum electrolytes ☐CBC
  - ☐serum creatinine x 2 ☐urinalysis to evaluate renal tubular function ☐LFTs
- ☐If request is for deferiprone (Ferriprox), has documentation of the following lab test results:
  - ☐serum ferritin ☐CBC with differential
  - ☐LFTs ☐plasma zinc

☐For treatment of non-transfusion-dependent thalassemia syndromes
- ☐Has documentation of the following lab test results:
  - ☐liver iron content ☐serum ferritin x 2 (at least 1 month apart) ☐CBC
  - ☐serum creatinine x 2 ☐urinalysis to evaluate renal tubular function ☐LFTs
  - ☐serum electrolytes

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: