ROCKY MOUNTAIN HEALTH PLANS®
We understand Colorado. We understand you.

UNIFORM PHARMACY PRIOR AUTHORIZATION REQUEST FORM

CONTAINS CONFIDENTIAL PATIENT INFORMATION

Complete this form in its entirety and send to Rocky Mountain Health Plans at 858-357-2538

☐ **Initial Request** ☐ **Renewal** ☐ **Appeal/Redetermination**[1]

☐ **Urgent**[2] ☐ **Non-Urgent**

Requested Drug Name: Ferriprox® (deferiprone) – Medicare Part D

Patient Information:	**Prescribing Provider Information:**
Patient Name:	Prescriber Name:
Member/Subscriber Number:	Prescriber Fax:
Policy/Group Number:	Prescriber Phone:
Patient Date of Birth (MM/DD/YYYY):	Prescriber Pager:
Patient Address:	Prescriber Address:
Patient Phone:	Prescriber Office Contact:
Patient Email Address:	Prescriber NPI:
	Prescriber DEA:
Prescription Date:	Prescriber Tax ID:
	Specialty/Facility Name (If applicable):
	Prescriber Email Address:

Prior Authorization Request for Drug Benefit

Patient Diagnosis and ICD Diagnostic Code(s):

Drug(s) Requested (with J-Code, if applicable):

Strength/Route/Frequency:

Unit/Volume of Named Drug(s):

Start Date and Length of Therapy:

Location of Treatment: (e.g. provider office, facility, home health, etc.) including name, Type 2 NPI (if applicable), address and tax ID:

Clinical Criteria for Approval, Including other Pertinent Information to Support the Request, other Medications Tried, Their Name(s), Duration, and Patient Response:

Ferriprox® (deferiprone)

Diagnosis *(documentation supportive of diagnosis required)*

☐ Transfusional iron overload due to thalassemia syndromes

☐ Other (please state): _____

Clinical Consideration *(for approval, please indicate and provide documentation of the following):*

☐ Patient failed other chelation therapy (e.g. deferoxamine). *List therapy failed:*_____

***Documentation of serum ferritin concentration > 2500 mcg/L also required**

☐ Patient was intolerant to other chelation therapy.

Note: Ferriprox is indicated as 2nd line therapy when current chelation therapy is inadequate.

☐ For use in clinical trial? (If yes, provide trial name and registration number):			
Drug Name (Brand Name and Scientific Name)/Strength:			
Dose:	Route:	Frequency:	
Quantity:	Number of Refills:		
Product will be delivered to: ☐ Patient's Home ☐Physician Office		Other:	
Prescriber or Authorized Signature:		Date:	
Dispensing Pharmacy Name and Phone Number:			
☐ **Approved** ☐ **Denied**			
If denied, provide reason for denial, and include other potential alternative medications, if applicable, that are found in the formulary of the carrier:			

1. Appeal/redetermination requests can be made for this medication within 60 calendar days from the date on the faxed/written denial notice you received at the time of the original request.

2. A request for prior authorization that if determined in the time allowed for non-urgent requests could seriously jeopardize the life or health of the covered person or the ability of the covered person to regain maximum function, or subject the person to severe pain that cannot be adequately managed without the drug benefit contained in the prior authorization request.

Ferriprox® (deferiprone)

CLASSIFICATION

- Heavy Metal Chelator

DESCRIPTION

- Deferiprone is a chelating agent that binds with ferric ions (iron III) to form neutral 3:1 (deferiprone: iron) complexes stable over a large range of pH values.
- It is indicated for the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.
- FDA approval is based on reduction in serum ferritin levels; there are no controlled trials demonstrating a direct benefit, such as improvement in disease-related symptoms, functioning, or increased survival.
- In a prospective, pooled analysis of several studies (n=236), deferiprone therapy reduced serum ferritin levels by ≥20% in 50% of patients with transfusion-dependent iron overload and who failed previous chelation therapy or chelation therapy was considered inadequate due to poor tolerance. Inadequate response was defined as serum ferritin concentrations that remained above 2500mcg/L or intolerance of other iron chelation therapy.
- Deferiprone therapy was clinically effective and fairly well tolerated in a nonrandomized, controlled study of 41 transfusion-dependent patients with beta thalassemia and hemoglobin E-beta thalassemia (average 10.6 years old for deferiprone group and 7.3 years old for the control group). After 12 months of deferiprone therapy, a significant decrease in serum ferritin levels from 3358 to 1525 ng/mL ($p < 0.05$) and a significant increase in urinary iron excretion from 1.41 to 14.95 mg/day ($p < 0.005$) were observed. In the control group, serum ferritin levels increased by 9 ng/mL and urinary iron excretion by 0.81 mg/day compared to baseline values.
- Black Box Warning: Agranulocytosis/neutropenia that can lead to serious infections and death. The incidence of agranulocytosis was 1.7% in pooled clinical trials.
- Adverse events (incidence ≥ 5%) during clinical trials were chromaturia (14.6%), nausea (12.6%), vomiting (9.8%), abdominal pain (10.4%), increased alanine aminotransferase (7.5%), arthralgia (9.8%), and neutropenia (6.2%).

FORMULARY COVERAGE

Prior authorization:	Required
Good Health Formulary:	Tier 5
Commercial Formulary:	Tier 4
Medicare Part D coverage:	Tier 5

COVERAGE CRITERIA

Ferriprox® (deferiprone) meets the definition of **medical necessity** for any FDA approved indication, not otherwise excluded from Part D, including the following:

Transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

- Ferriprox was FDA approved as 2nd line therapy when current chelation therapy (e.g. deferoxamine) is inadequate; therefore, the following documentation is required:
  - Documentation of diagnosis.
  - Supporting documentation of other chelation therapy that failed.

    - Labs demonstrating failure of serum ferritin concentration to fall below 2500mcg/L while on that therapy.
- If patient was intolerant to other chelation therapy, documentation of trial and intolerance is required.
- Coverage authorization period is granted in 1 year intervals.

Ferriprox® (deferiprone) is considered **experimental** for the following:
- Any condition or diagnosis not FDA approved or Compendia supported including Falciparum malaria and acute iron toxicity due to inconclusive evidence in favor of efficacy.
- Safety and effectiveness have not been established for the treatment of transfusional iron overload in patients with other chronic anemias.

Required Provider Specialty:
- No Specialty Provider requirement

DOSAGE/ADMINISTRATION

Adult Dosing:
- *Transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate*:
    - Recommended initial dose: 25 mg/kg orally three times daily (TID) for a total of 75 mg/kg/day
    - Maximum dose: 33 mg/kg TID for a total of 99 mg/kg/day
    - Dose adjustments should be tailored to the individual patient's response and therapeutic goals (maintenance or reduction of body iron burden).
    - Round the dose to the nearest 250 mg (half-tablet)
    - Monitor serum ferritin concentrations every 2 to 3 months.
    - If the serum ferritin falls consistently below 500 mcg/L, consider temporarily interrupting therapy.

Pediatric Dosing (**safety and efficacy has not been established in pediatric patients**):
- *Transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate*: Oral deferiprone therapy was clinically effective and fairly well tolerated in 20 thalassemic patients with a mean age of 10.6 years. Therapy was started with a dosage of 37 milligrams per kilogram body weight per day (mg/kg/day), and the daily dose was gradually increased to 75 mg/kg/day. The drug was administered as 500 milligram capsules in 2 to 4 divided doses.

PRECAUTIONS

Black Box Warning: Agranulocytosis/Neutropenia
- Deferiprone can cause agranulocytosis that can lead to serious infections and death. Neutropenia may precede the development of agranulocytosis.
- Measure the absolute neutrophil count (ANC) before starting deferiprone therapy and monitor the ANC weekly on therapy. Interrupt deferiprone therapy if neutropenia develops.
- Interrupt deferiprone if infection develops, and monitor the ANC more frequently. Advise patients taking deferiprone to report immediately any symptoms indicative of infection.

Contraindications:
- Hypersensitivity to deferiprone or any components of the formulation.

Precautions:
- Concomitant use of drugs associated with neutropenia or agranulocytosis should be avoided.

- Elevated serum hepatic transaminases have been reported; 7.5% of patients in clinical studies developed increased alanine aminotransferases (ALT) values. Monitoring recommended and interruption of therapy may be necessary.
- Pregnancy Category D: pregnancy should be avoided
- A thorough QT study has not been conducted, however, torsades de pointes has been reported; use with caution in patients at increased risk for prolonged cardiac QT interval (e.g. bradycardia, cardiac hypertrophy, or congestive heart failure; hypokalemia, hypomagnesemia, or concomitant use of diuretics).
- Decreases in zinc levels have been reported; monitoring recommended and supplementation may be necessary.

Billing/Coding information

HCPCS Coding:

J8499	Prescription drug, oral, non-chemotherapeutic, Not otherwise specified

COST

- AWP (July 2012): Ferriprox 25mg/kg PO TID for 70kg patient (315 tablets): $11,970/month
- AWP (May 2015): Ferriprox 25mg/kg PO TID for 70kg patient (315 tablets): $17, 136/month

COMMITTEE APPROVAL

- July 2012

GUIDELINE UPDATE INFORMATION

July 2012	Prior authorization and coverage policy created
August 2015	AWP updated

REFERENCES

- DRUGDEX®, accessed 07/15/2012, 8/27/15
- Product Information: Ferriprox® (deferiprone), tablet for oral use. ApoPharma USA, Inc., Rockville, MD, 2015.
- UpToDate®. Chelation therapy for iron overload states. Topic 7146 Version 16.0. http://www.uptodate.com/contents/chelation-therapy-for-iron-overload-states?source=search_result&search=chelation+therapy+for+iron+overload+states&selectedTitle=1%7E150#H19. Accessed 7/24/2012.