Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Exjade (deferasirox), Jadenu (deferasirox), and Ferriprox (deferiprone)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2012 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Exjade (deferasirox), Jadenu (deferasirox), and Ferriprox (deferiprone).

Exjade (deferasirox) and Jadenu (deferasirox)are indicated for the treatment of chronic iron overload due to blood transfusions or due to non-transfusion-dependent thalassemia syndromes.

Ferriprox (deferiprone) is indicated for patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

DEFINITIONS

Absolute Neutrophil Count (ANC) - total white blood cell count (cells/µL) x % (neutrophils + bands). Bands represent immature neutrophils.

POLICY

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It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Exjade (deferasirox), Jadenu (deferasirox), and Ferriprox (deferiprone), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective product:

1. **Exjade and Jadenu (deferasirox):**
   - Must be prescribed by a hematologist
   - For treatment of chronic iron overload due to blood transfusions
     - Must be age 2 years or older
   - For treatment of chronic iron overload due to non-transfusion dependent thalassemia syndromes
     - Must be age 10 years or older
     - Must have a liver iron (Fe) concentration (LIC) of at least 5mg Fe per gram dry weight
     - Must have a serum ferritin greater than 300 mcg/L
   - Must not have a serum creatinine greater than 2 times the age-appropriate upper limit of normal or creatinine clearance less than 40mL/min
   - Must not have high-risk myelodysplastic syndromes (MDS)
   - Must not have advanced malignancies
   - Must have a platelet count ≥50 x 109/L

2. **Ferriprox (deferiprone):**
   - Must be prescribed by a hematologist
   - Must have transfusional iron overload due to thalassemia syndromes or sickle cell disease
   - Must have an adequate trial of an iron chelator such as deferoxamine (Desferal) or deferasirox (Exjade, Jadenu)
   - Must have an assessment of ANC prior to starting deferiprone therapy

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy and that the prescriber is continuing to monitor the patient's ANCE on a weekly basis [for Exjade only].

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Ferriprox [prescribing information]. Toronto, Ontario: Apotex Inc.; October 2011
2. Desferal [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2010
3. Exjade [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2013.
4. Jadenu [prescribing information]. Novartis Pharma AG. East Hanover, NJ. April 2015.
5. Pennell DJ, Berdoukas V, Karagiorga M, et al. Randomized controlled trial of deferiprone or deferoxamine in beta-thalassemia major patients with asymptomatic myocardial siderosis. Blood 2006; 107: 3738-3744
6. Galanello R. Deferiprone in the treatment of transfusion-dependent thalassemia: a review and perspective. Therapeutics and Clinical Risk Management 2007;3(5):795- 805
7. Neufeld EJ. Oral chelators deferasirox and deferiprone for transfusional iron overload in thalassemia major: new data, new questions. Blood 2006;107:3436-3441
8. Porter JB, Shah FT. Iron overload in thalassemia and related conditions: therapeutic goals and assessment of response to chelation therapies. Hematol Oncol Clin N Am 2010; 24;1109-1130
9. Neufeld EJ. Update on iron chelators in thalassemia. Hematology 2010;451-5
10. The Merck Manuals: Online Medical Library. Neutropenia. http://www.merck.com/mmpe/sec11/ch132/ch132b.html?qt=neutropenia&alt=sh. (accessed March 31, 2010).

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*