Pharmacy Medical Necessity Guidelines: Ferric Citrate (Auryxia™)

Effective: February 9, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Auryxia (ferric citrate) is a phosphate binder indicated for the control of serum phosphorus levels in adult patients with chronic kidney disease receiving dialysis. Auryxia is also an iron replacement product indicated for the treatment of iron deficiency of anemia in adult patients with chronic kidney disease not on dialysis.

COVERAGE GUIDELINES

The plan may authorize coverage of Auryxia for Members when the following criteria are met and limitations do not apply:

1. The Member is diagnosed with hyperphosphatemia associated with chronic kidney disease and is receiving dialysis

AND

2. The Member has tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with at least two generic phosphate binders

OR

1. The Member is diagnosed with iron deficiency of anemia with chronic kidney disease

AND

2. The Member is not receiving dialysis

AND

3. The Member has had an inadequate response or intolerance to a trial of an alternative oral iron therapy (e.g., ferrous sulfate, ferrous fumarate, ferrous gluconate)

LIMITATIONS

None

CODES

None

REFERENCES

1. Auryxia (ferric citrate) [prescribing information]. Boston, MA: Keryx Biopharmaceuticals; December 2019.
2. Berns JS. Treatment of iron deficiency in nondialysis chronic kidney disease (CKD) patients. Available at www.uptodate.com. Accessed 25 April, 2018.

APPROVAL HISTORY

February 10, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. January 1, 2016: Administrative change to rebranded template.
2. February 9, 2016: Renewal criteria removed.
3. February 14, 2017: No changes.
4. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
5. May 8, 2018: Added criteria for the indication of iron deficiency of anemia with chronic kidney disease.
6. March 12, 2019: Effective 7/1/2019, updated criteria for hyperphosphatemia, requiring trial and failure with at least two generic phosphate binders. Updated criteria for iron deficiency of anemia with chronic kidney disease, allowing for trial of any oral iron therapy. Administrative changes made to template.
7. February 11, 2020: No changes.
8. February 9, 2021: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.