Pharmacy Policy Bulletin: J-1087 Accrufer (ferric maltol) – Commercial and Healthcare Reform	
Number: J-1087	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.)** **1.** Other Managed Drugs = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1087-006	**Original Date:** 11/06/2019
Effective Date: 10/28/2024	**Review Date:** 10/02/2024

Drugs Product(s):	• Accrufer (ferric maltol)
FDA-Approved Indication(s):	• Treatment of iron deficiency in adults

Background:	• Accrufer delivers iron for uptake across the intestinal wall and transfer to transferrin and ferritin. • Iron deficiency is the most common nutritional disorder in the world and is characterized by low iron stores and a hemoglobin level two standard deviations below normal. Iron deficiency often manifests in the form of paleness, fatigue, headache, atrophic glossitis, and dyspnea. • Due to its broad indication, Accrufer may be used in multiple patient populations in which anemia is a common extra-intestinal manifestation, such as inflammatory bowel disease (IBD), chronic kidney disease (CKD), heart failure, or chemotherapy. • Generally, the normal hemoglobin range is 12.0 to 15.5 g/dL for women and 13.5 to 17.5 g/dL for men. • Prior authorization may be utilized to ensure appropriate use for the treatment of iron deficiency. Eating iron rich foods such as tuna, eggs, lean ground beef, spinach, brown rice, lentils and many others can increase iron levels without the need for medication. Example over-the-counter iron supplements include ferrous sulfate, ferrous gluconate, and ferrous fumarate. • According to the National Heart, Lung, and Blood Institute, and the American Family Physician (AAFP) guidelines on iron deficiency, the initial recommendation for iron deficiency is a diet change. These guidelines suggest eating iron-rich foods and increasing vitamin C intake. If the deficiency is large enough, guidelines recommend taking oral iron supplements, but if the deficiency is severe, IV iron replacement therapy may be necessary over oral iron supplements.

	• It is recommended to take oral iron to replenish iron stores in the body for at least 3 months after the initial episode of iron deficiency. The initial episode can be fixed by any means of iron replacement (intravenous or oral). It is recommended to re-evaluate every 3 months to replenish the iron stores in the body.
	• Prescribing Considerations:
	  ○ Avoid use in patients with an active inflammatory bowel disease flare.
	  ○ For oral drugs where reduction in bioavailability is a concern, separate the administration of Accrufer by at least 4 hours.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Accrufer may be approved when all of the following criteria are met **(A., B., and C.)**:

A. The member is 18 years of age or older.

B. There is clinical documentation supporting the iron deficiency diagnosis (ICD-10: D50.8, D50.9) including one (1) of the following **(1. or 2.)**:

1. If female, hemoglobin level less than 12 g/dL.

2. If male, hemoglobin level less than 13 g/dL.

C. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following **(1. and 2.)**:

1. Dietary modification to include iron rich foods.

2. Over-the-counter iron replacement therapy for at least 3 months.

II. Reauthorization

When a benefit, reauthorization of Accrufer may be approved when the following criteria is met **(A.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

I. Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

II. Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Accrufer [package insert]. Austin, TX: Shield Therapeutics, Inc.; March 2022.
2. American Family Physician. 2013. Iron Deficiency anemia: evaluation and management. Available at: https://www.aafp.org/afp/2013/0115/p98.pdf. Accessed August 14, 2024.
3. National Heart, Lung, and Blood Institute. Iron-Deficiency Anemia. Available at: https://www.nhlbi.nih.gov/health-topics/iron-deficiency-anemia. Accessed August 14, 2024.
4. Lopez A, Cacoub P, Macdougall IC, Peyrin-Biroulet L. Iron Deficiency anemia. *Lancet.* 2016;387(10021):907-916.