Clinical Policy: Ferric Pyrophosphate (Triferic, Triferic Avnu)

Reference Number: PA.CP.PHAR.624
Effective Date: 05/2023
Last Review Date: 04/2024

Description
Ferric Pyrophosphate (Triferic®, Triferic Avnu®) is an iron replacement product.

FDA Approved Indication(s)
Triferic/Triferic Avnu are indicated for the replacement of iron to maintain the hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD).

Limitation(s) of use:
- Triferic/Triferic Avnu is not intended for use in patients receiving peritoneal dialysis.
- Triferic/Triferic Avnu has not been studied in patients receiving home hemodialysis.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Triferic/Triferic Avnu is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Iron Replacement Therapy with Hemodialysis-Dependent Chronic Kidney Disease (must meet all)**:**
1. Diagnosis of iron replacement therapy with HDD-CKD;
2. Transferrin saturation (TSAT) ≤ 30%;
3. Serum ferritin ≤ 500 ng/mL;
4. Documentation that Triferic/Triferic Avnu is not used for peritoneal dialysis or home hemodialysis;
5. Failure of Ferrlecit® and Venofer®, unless clinically significant adverse effects are experienced or both are contraindicated;
6. Dose does not exceed 6.75 mg elemental iron per infusion/injection.

Approval duration: 3 months

B. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Iron Replacement Therapy with Hemodialysis-Dependent Chronic Kidney Disease (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

2. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters (a, b, or c):
    a. Hgb;
    b. TSAT;
    c. Serum ferritin;
3. If request is for a dose increase, new dose does not exceed 6.75 mg elemental iron per infusion/injection.

Approval duration: 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CKD: chronic kidney disease
FDA: Food and Drug Administration
HDD-CKD: hemodialysis-dependent chronic kidney disease
Hgb: hemoglobin
TSAT: transferrin saturation

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Sodium ferric gluconate complex in sucrose (Ferrlecit®)	Adults: 125 mg by IV infusion or injection per dialysis session. - May require a cumulative dose of 1000 mg over 8 dialysis sessions. Children age ≥ 6 years: 1.5 mg/kg administered by IV infusion per dialysis session.	125 mg of elemental iron per dose
iron sucrose (Venofer®)	Adults: 100 mg slow intravenous injection or infusion per consecutive hemodialysis session	Adults: 1000 mg total treatment course

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Pediatric patients ≥ 2 years: 0.5 mg/kg slow IV injection or infusion per dose Q 2 weeks for 12 weeks	Pediatric: 100 mg/dose

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Iron replacement to maintain hemoglobin in patients with hemodialysis-dependent chronic kidney disease	6.75 mg IV administered by slow IV infusion over 3 to 4 hours at each hemodialysis session	Varies Maximum dosage is not defined for hemodialysate use; dose is dependent on dialysate volume used during hemodialysis session.

VI. Product Availability

Drug Name	Availability
Triferic (ferric pyrophosphate solution)	Single dose ampule: 5.44 mg/mL (5 mL)
Triferic (ferric pyrophosphate citrate powder)	Powder packets for injection: 272 mg
Triferic Avnu (ferric pyrophosphate injection)	Injection in single-dose luer lock ampule: 6.75 mg iron (III) per 4.5 mL solution (1.5 mg iron (III) per mL)

VII. References

1. Triferic Prescribing Information. Wixom, MI. Rockwell Medical, Inc.; September 2020. Available from: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=46ec9233-4063-4c48-e054-00144ff8d46c. Accessed February 11, 2024.
2. Triferic Avnu Prescribing Information. Wixom, MI. Rockwell Medical, Inc.; July 2023. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/212860Orig1s001lbl.pdf. Accessed February 11, 2024.

3. KDIGO 2012 clinical practice guideline for anemia in chronic kidney disease. *Kidney International Supplements.* August 2012; 2(4): 279-331.
4. KDIGO 2012 clinical practice guideline for anemia in chronic kidney disease. *Kidney International Supplements.* August 2012; 2(4): 279-331.
5. Aronoff GR, Bennett WM, Blumenthal S, et al; United States Iron Sucrose (Venofer) Clinical Trials Group. Iron sucrose in hemodialysis patients: safety of replacement and maintenance regimens. Kidney Int. 2004 Sep;66(3):1193-8. doi: 10.1111/j.1523-1755.2004.00872.x.
6. Nissenson AR, Lindsay RM, Swan S, et al. Sodium ferric gluconate complex in sucrose is safe and effective in hemodialysis patients: North American Clinical Trial. Am J Kidney Dis. 1999 Mar;33(3):471-82. doi: 10.1016/s0272-6386(99)70184-8.
7. Provenzano R, Schiller B, Rao M, et al. Ferumoxytol as an intravenous iron replacement therapy in hemodialysis patients. Clin J Am Soc Nephrol. 2009 Feb;4(2):386-93. doi: 10.2215/CJN.02840608.
8. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: https://www.clinicalkey.com/pharmacology/. Accessed February 11, 2024.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1443	Injection, ferric pyrophosphate citrate solution (triferic), 0.1 mg of iron
J1444	Injection, ferric pyrophosphate citrate powder, 0.1 mg of iron
J1445	Injection, ferric pyrophosphate citrate solution (triferic avnu), 0.1 mg of iron

Reviews, Revisions, and Approvals	Date
Policy created per February SDC.	04/2023
2Q 2024 annual review: added Triferic Avnu; added Venofer to Appendix B therapeutic alternatives table; updated Section V. Dosage and Administration; references reviewed and updated.	04/2025