Intravenous Iron Infusion
Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Intravenous Iron Infusion		
MNG #: 041	☒ **CCA Senior Care Options (HMO D-SNP) (MA)** ☒ **CCA One Care (Medicare-Medicaid) (MA)**	**Prior Authorization Needed?** ☒**Yes (always required)** ☐**Yes (only in certain situations. See this MNG for details)** ☐**No**
Benefit Type: ☒ **Medicare** ☐ **Medicaid**	**Original Approval Date:** 08/05/2020	**Effective Date:** 12/18/2020; 10/10/24; 1/1/2025
Last Revised Date: 02/04/2021; 06/30/2021; 07/22/2021; 08/31/2021; 10/14/2021; 05/31/2022; 06/22/2022; 10/12/2023; 10/10/24; 2/12/2025	**Next Annual Review Date:** 08/05/2021; 06/30/2022; 07/22/2022; 08/31/2021; 10/14/2022; 6/22/2023; 10/12/2024; 10/10/25	**Retire Date:**

OVERVIEW:

Iron deficiency anemia (IDA) is a condition characterized by low levels of iron, hemoglobin, and microcytic hypochromic red blood cells that result from impaired absorption, mobilization, or delivery of iron to erythroid precursors. For patients with IDA, this can manifest in symptoms of weakness, headache, fatigue, irritability, depression, and decreased exercise tolerance. If left untreated the anemia may begin to cause ischemia and organ damage.

Intravenous (IV) iron products are colloidal solutions of compounds that contain carbohydrates that bind to elemental iron to increase ferritin, iron, hemoglobin, and hematocrit levels. Unlike oral iron therapies, IV iron is administered directly into the bloodstream so that iron is more readily available to erythroid precursor cells for red blood cell synthesis. As such, it is often used instead of blood transfusion for the treatment of iron deficiency which is less severe and not life-threatening. It may also be used for individuals who cannot tolerate, cannot adhere to, and/or have failed to respond to oral iron therapy.

DEFINITIONS:

Anemia: Condition of markedly decreased hemoglobin concentration that results when the erythropoietic response cannot compensate for the normal or increased loss of red blood cells in circulation. It is defined by hemoglobin levels > 2 standard deviations below the mean. In menstruating women that may be hemoglobin < 12 g/dL; in pregnant women that may be hemoglobin < 11 g/dL; and in men that may be < 13 g/dL.

Iron Deficiency Anemia (IDA): Condition that occurs when iron deficiency has progressed to iron-deficient erythropoiesis and anemia. It is characterized as absolute or functional iron deficiency. Absolute iron deficiency isdefined as a serum ferritin < 30 ng/mL or transferrin saturation (TSAT) < 15%. **Functional iron deficiency (FID)** is defined as a serum ferritin < 100 ng/mL and TSAT < 20% WITH symptoms related to this measurement.

Intravenous Iron Infusion
Medical Necessity Guideline

DECISION GUIDELINES:

Clinical Coverage Criteria:

1. Commonwealth Care Alliance may cover intravenous iron formulations when requested for:
    a. An FDA approved, labeled indication or a use supported in the American Hospital Formulary Service Drug Information (AHFS-DI), NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex DrugDex®, Elsevier/Gold Standard Clinical Pharmacology and Wolters Kluwer Lexi-Drugs® as the acceptable compendia based on CMS' Change Request 6191 (Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen); or

    The compendia listed above will be accepted at the following levels:
    - American Hospital Formulary Service-Drug Information (AHFS-DI) – indication is supportive.
    - NCCN Drugs and Biologics Compendium - indication is a Category 1 or 2A.
    - Micromedex DrugDex® – indication is Class I, Class IIa, or Class IIb.
    - Clinical Pharmacology – indication is supportive.
    - Lexi-Drugs - indication is rated as “Evidence Level A.”

    b. Articles or Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs).

LIMITATIONS/EXCLUSIONS:

1. A maximum of six (6) doses may be requested per authorization. If the member’s signs and symptoms continue to persist with no or minimal improvement, reauthorization requests will require review from a CCA medical director to determine the medical necessity of further IV iron therapy.
2. Upon review, if the drug use is not on the FDA label, does not appear on the American Hospital Formulary Services (AHFS), Elsevier/Gold Standard Clinical Pharmacology, NCCN Drugs and Biologics Compendium, Truven Health Analytics Micromedex DrugDex® Wolters Kluwer Lexi-Drugs® compendium, and/or other reference listed above or there is not an applicable LCD or article covering the off-label use, then the request may be denied.
3. However, determinations as to whether medication is reasonable and necessary for an individual patient may be made on appeal on the same basis as all other such determinations (i.e., with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

CODING:

When applicable, a list(s) of codes requiring prior authorization is provided. This list is for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment.

HCPCS CODE	CODE DESCRIPTION
J1439	Injection, ferric carboxymaltose, 1 mg
J2916	Injection, sodium ferric gluconate complex in sucrose injection, 12.5 mg
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-esrd use)
J1756	Injection, iron sucrose, 1 mg
J1437	Injection, ferric derisomaltose, 10 mg
J1750	Injection, iron dextran, 50 mgtable t

Intravenous Iron Infusion
Medical Necessity Guideline

Disclaimer

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses evidence based InterQual© criteria, when available, to review prior authorization requests for medical necessity. This Medical Necessity Guideline (MNG) applies to all CCA Products unless a more expansive and applicable CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), or state-specific medical necessity guideline exists. Medical Necessity Guidelines are published to provide a better understanding of the basis upon which coverage decisions are made. CCA makes coverage decisions on a case-by-case basis by considering the individual member's health care needs. If at any time an applicable CMS LCD or NCD or state-specific MNG is more expansive than the criteria set forth herein, the NCD, LCD, or state-specific MNG criteria shall supersede these criteria.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. This Medical Necessity Guideline is subject to all applicable Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider's agreement with the Plan (including complying with Plan's Provider Manual specifications).

This Medical Necessity Guideline is not a rigid rule. As with all CCA's criteria, the fact that a member does not meet these criteria does not, in and of itself, indicate that no coverage can be issued for these services. Providers are advised, however, that if they request services for any member who they know does not meet our criteria, the request should be accompanied by clear and convincing documentation of medical necessity. The preferred type of documentation is the letter of medical necessity, indicating that a request should be covered either because there is supporting science indicating medical necessity [supporting literature (full text preferred) should be attached to the request], or describing the member's unique clinical circumstances, and describing why this service or supply will be more effective and/or less costly than another service which would otherwise be covered. Note that both supporting scientific evidence and a description of the member's unique clinical circumstances will generally be required.

REFERENCES:

1. Local Coverage Determination L33394 Drugs and Biologicals, Coverage of, for Label and Off-Label Uses. National Government Services, Inc. Original effective date 10/1/2015, revision effective date 11/7/2019. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33394&ver=44&keywordtype=starts&keyword=biologic&bc=0. Accessed 10/4/2023.
2. National Coverage Determination 110.10 Intravenous Iron Therapy. Effective Date 10/1/2001. Accessed 10/4/2023. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=156&ncdver=1&keywordtype=starts&keyword=iron&bc=0
3. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation*. 2022;145(18):e876-e894. doi:10.1161/CIR.0000000000001062
4. Salah HM, Savarese G, Rosano GMC, Ambrosy AP, Mentz RJ, Fudim M. Intravenous iron infusion in patients with heart failure: a systematic review and study-level meta-analysis. *ESC Heart Fail*. 2023;10(2):1473-1480. doi:10.1002/ehf2.14310
5. Kalra PR, Cleland JGF, Petrie MC, et al. Intravenous ferric derisomaltose in patients with heart failure and iron deficiency in the UK (IRONMAN): an investigator-initiated, prospective, randomised, open-label, blinded-endpoint trial. *Lancet*. 2022;400(10369):2199-2209. doi:10.1016/S0140-6736(22)02083-9
6. Winkelman JW, Armstrong MJ, Allen RP, et al. Practice guideline summary: Treatment of restless legs syndrome

in adults: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2016;87(24):2585-2593. doi:10.1212/WNL.0000000000003388
7. Earley CJ, García-Borreguero D, Falone M, Winkelman JW. Clinical efficacy and safety of intravenous ferric carboxymaltose for treatment of restless legs syndrome: a multicenter, randomized, placebo-controlled clinical trial. *Sleep*. 2024;47(7):zsae095. doi:10.1093/sleep/zsae095
8. American Academy of Neurology. Summary of Evidence-based Guideline for Clinicians Practice Guideline: Treatment of Restless Legs Syndrome in Adults. Accessed October 2, 2024. https://www.aan.com/Guidelines/Home/GuidelineDetail/829
9. Winkelman JW, Berkowski JA, DelRosso LM, et al. Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. Published online September 26, 2024. doi:10.5664/jcsm.11390
10. Winkelman JW, Berkowski JA, DelRosso LM, et al. Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. *J Clin Sleep Med*. Published online September 26, 2024. doi:10.5664/jcsm.11392
11. Muñoz M, Gómez-Ramírez S, Besser M, et al. Current misconceptions in diagnosis and management of iron deficiency. *Blood Transfus*. 2017;15(5):422-437. doi:10.2450/2017.0113-17
12. Koch TA, Myers J, Goodnough LT. Intravenous Iron Therapy in Patients with Iron Deficiency Anemia: Dosing Considerations. *Anemia*. 2015;2015:763576. doi:10.1155/2015/763576
13. Drug Result Page - In-Depth Answers - Dosing/Administration - FDA Uses (by subscription micromedexsolutions.com)

REVISION LOG:

REVISION DATE	DESCRIPTION
1/22/2025	Template update
1/21/2025	UMC Approval
10/10/24	Criteria removed. MNG refers to Micromedix which includes indications for RLS and heart failure
12/31/23	Utilization Management Committee approval
06/22/2022	Clinical coverage guidelines, limitations/exclusions, regulatory notes, and related references updated.
05/30/2022	Template changed to include PA requirements and benefit type. Overview and format updated with numbering. Business owner changed.
08/31/2021	In limitations/exclusions, revised to: "A maximum of six (6) doses may be requested per authorization. Note that this is not specific to one calendar year. If the member's signs and symptoms continue to persist with no or minimal improvement, reauthorization requests will require review from a CCA medical director to determine the medical necessity of further IV iron therapy."
07/15/2021	In limitations/exclusions, addition of "After such time, if the member's signs and symptoms continue to persist, review from a medical director will be required to determine the medical necessity of further IV iron therapy."
07/13/2021	Clinical Coverage Criteria: addition of "all of the following..."
06/30/2021	Definitions: Addition of anemia, ferric carboxymaltose, ferumoxytol, iron deficiency anemia, iron dextran, iron isomaltoside/ferric derisomaltose, iron sucrose, oral iron, and sodium ferric gluconate. Clinical coverage criteria: Defined which IV iron therapies would be covered, under what criteria, and for which conditions. Limitations/Exclusions: Moved the previous clinical coverage criteria authorization information. Added genetic hematochromatosis to the exclusion criteria. Authorization:

Intravenous Iron Infusion
Medical Necessity Guideline

APPROVALS:

David Mello	**Senior Medical Director Utilization Review and Medical Policy**
CCA Senior Clinical Lead [Print]	**Title [Print]**
	**1/13/2025**
Signature	**Date**
Nazlim Hagmann, MD	**Chief Medical Officer**
CCA CMO or Designee [Print]	**Title [Print]**
	**1/13/2025**
Signature	**Date**