



Intravenous Iron Infusion Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Intravenous Iron Infusion		
MNG #: 041	<input checked="" type="checkbox"/> SCO <input checked="" type="checkbox"/> One Care <input checked="" type="checkbox"/> MA Medicare Premier <input checked="" type="checkbox"/> MA Medicare Value <input checked="" type="checkbox"/> RI Medicare Preferred <input checked="" type="checkbox"/> RI Medicare Value <input checked="" type="checkbox"/> RI Medicare Maximum	Prior Authorization Needed? <input checked="" type="checkbox"/> Yes (always required) <input type="checkbox"/> Yes (only in certain situations. See this MNG for details) <input type="checkbox"/> No
Clinical: <input checked="" type="checkbox"/>	Operational: <input type="checkbox"/>	Informational: <input type="checkbox"/>
Benefit Type: <input checked="" type="checkbox"/> Medicare <input type="checkbox"/> Medicaid	Approval Date: 08/05/2020	Effective Date: 12/18/2020
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;	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;	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 is



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defined 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.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance (CCA) follows applicable Medicare and Medicaid regulations and uses InterQual Smart Sheets, 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.

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 Biologics 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).
2. In accordance with the 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure, CCA may approve requests for IV iron replacement in patients with heart failure with a reduced ejection fraction and functional iron deficiency (see 'FID' above) for improvement of their presumed symptoms, quality of life, and functional status.
3. In accordance with the American Academy of Neurology Practice Guideline Summary for the Treatment of Restless Legs Syndrome in Adults, CCA may approve IV ferric carboxymaltose 500 mg given twice 5 days apart for the management of moderate to severe restless legs syndrome symptoms regardless of iron study results.

LIMITATIONS/EXCLUSIONS:

1. 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.



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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).

AUTHORIZATION:

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not signify that the service described by the code is a covered or non-covered health service. 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. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. 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).

HCPCS 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 mg

REGULATORY NOTES:

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.

This MNG references the specific regulations, coverage, limitations, service conditions, and/or prior authorization requirements in the following:



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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>

Disclaimer

This Medical Necessity Guideline is not a rigid rule. As with all of 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.

RELATED REFERENCES:

3. Heidenreich PA, Bozkurt B, Aguilar D et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. *Circulation*; 2022;145(18): e895-e1032.
4. Winkelman JW, Armstrong MJ, Allen RP et al. Practice Guideline Summary: Treatment of Restless Leg Syndrome in Adults. 2016;87(24):2585-93.

REVISION LOG:

REVISION DATE	DESCRIPTION
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.”



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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: Addition of the applicable HCPCS codes.

APPROVALS:

Stefan Topolski

CCA Senior Clinical Lead [Print]

Stefan Topolski

Signature

Medical Director

Title [Print]

10/12/2023

Date

CCA Senior Operational Lead [Print]

Signature

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Date

Nazlim Hagmann

CCA CMO or Designee [Print]

Nazlim Hagmann

Signature

Chief Medical Officer

Title [Print]

10/12/2023

Date