Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Intravenous Iron Infusion		
MNG #: 041	☒**SCO** ☒**One Care** ☒ **MAPD-MA Medicare Preferred** ☒ **MAPD-MA Medicare Value** ☒ **MAPD-RI Medicare Preferred** ☒ **MAPD-RI Medicare Value** ☒ **DSNP-RI Medicare Maximus**	**Prior Authorization Needed?** ☒**Yes** ☐**No**
Clinical: ☒	**Operational:** ☐	**Informational:** ☐
Medicare Benefit: ☒**Yes** ☐**No**	**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; 11/4/2021	**Next Annual Review Date:** 08/05/2021; 06/30/2022; 07/22/2022; 08/31/2022; 11/4/2022	**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 or insufficient mobilization and delivery of iron to erythroid precursors. For patients with IDA, this will manifest in symptoms of weakness, headache, fatigue, irritability, depression, and decreased exercise tolerance. If left untreated, the progression of anemia may result in further 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 indicated for the treatment of iron deficiency without severe or life-threatening *anemia*; and for individuals who cannot tolerate, who are unable to adhere to, and/or have failed to respond to oral iron therapy.

The most common IV iron preparations include *iron dextran (Infed), sodium ferric gluconate (Ferrlecit), iron sucrose (Venofer), ferumoxytol (Feraheme), ferric carboxymaltose (Injectafer),* and *iron isomaltoside/ferric derismaltose (Monofer)*. The formulations have similar safety profiles and are equally effective to treat iron deficiency. To determine the most appropriate IV iron preparation for the patient, clinicians should consider the: cost, number of visits and time required to administer a full dose, and the number of doses required for the episode of care (please refer to Exhibit A).

DEFINITIONS:

Anemia: Condition of marked 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.

Medical Necessity Guideline

Ferric Carboxymaltose (Injectafer): Iron replacement product that consists of colloidal iron (III) hydroxide in complex with carboxymaltose that helps release iron. It is indicated for the treatment of IDA in adult patients who have an intolerance or unsatisfactory response to oral iron, and has non-dialysis-dependent chronic kidney disease.

Ferumoxytol (Feraheme): Iron replacement product that consists of a non-stoichiometric magnetite (superparamagnetic iron oxide) coated with a carbohydrate shell that helps to isolate the bioactive iron from plasma components. Ferumoxytol is indicated for treatment of IDA in adult patients who have an intolerance to oral iron and/or who have an unsatisfactory response to oral iron.

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 defined as a serum ferritin < 30 ng/mL or transferrin saturation (TSAT) < 15%. Functional iron deficiency is defined as a serum ferritin < 100 ng/mL and TSAT < 20% with symptoms related to this measurement.

Iron Dextran (Infed): Iron replacement product that contains a complex of ferric hydroxide and dextran that helps to release circulating iron. Iron dextran is indicated for the treatment of IDA in adult and pediatric patients ≥ four months, who have an intolerance to oral iron and who have an unsatisfactory response to oral iron.

Iron Isomaltoside/Ferric Derisomaltose (Monofer): Iron replacement product that contains the complex of iron (III) hydroxide and derisomaltose which allows for the tight binding and slow release of labile free iron. Iron isomaltoside/ Ferric derisomaltose is indicated for the treatment of IDA in adult patients who have an intolerance to oral iron, who have had an unsatisfactory response to oral iron, and who have non-hemodialysis dependent chronic kidney disease.

Iron Sucrose (Venofer): Iron replacement product that contains the complex of polynuclear iron (III)- hydroxide in sucrose. It is indicated for the treatment of IDA in patients with chronic kidney disease (who are non-dialysis-dependent, hemodialysis-dependent, or peritoneal dialysis-dependent).

Oral Iron: Iron replacement product that is used as the first-line treatment for IDA without complicating comorbid conditions. It must be absorbed through the gastrointestinal tract. This administration method avoids the need for intravenous access and eliminates the potential for infusion reactions. The most common products include ferric maltol, ferrous fumarate, ferrous gluconate, ferrous sulfate, and polysaccharide iron complex.

Sodium Ferric Gluconate (Ferrlecit): Iron replacement product that contains a stable sodium salt of ferric ion carbohydrate complex which is used to replete the body content of iron. It is indicated for the treatment of iron deficiency anemia in adult and pediatric patients ≥ six years old, who have chronic kidney disease and are receiving hemodialysis or receiving supplemental epoetin therapy.

Medical Necessity Guideline

DECISION GUIDELINES:

Clinical Coverage Criteria:

Commonwealth Care Alliance may cover **intravenous iron infusions** for their specific FDA-labelled indication(s), when all of the following criteria are met:

- Documentation of the diagnosis and rationale (e.g. inclusion of symptoms, clinical features and laboratory values) of the medical necessity of IV iron therapy,
- The use of the IV iron therapy adheres to the U.S. Food and Administration indication and dosing guidelines,
- Documentation that the member has a history of intolerance, hypersensitivity, contraindication, and/or failure to respond to oral iron therapy (within the last three months), AND
- Documentation that the member has a pathological or anatomical presentation that interferes with oral iron absorption OR may cause exacerbation of an underlying gastrointestinal disorder, OR
    - Examples include: Inflammatory bowel disease, short bowel/short gut syndrome, post-gastric bypass surgery, patients with high hepcidin level, or patients with iron refractory IDA
- For members who have ongoing iron losses where oral iron replenishment or supplementation is inadequate or contraindicated

Commonwealth Care Alliance may consider **intravenous iron infusions** according to their FDA-labelled indication, as medically necessary, once the mentioned criteria have been met for the following conditions:

- Iron deficiency anemia and where the member does not require dialysis,
- Iron deficiency anemia and where the member is receiving supplemental erythropoietin therapy,
- Iron deficiency with or without anemia and heart failure,
- Iron deficiency anemia due to heavy uterine bleeding,
- Chemotherapy-induced anemia and where the member is receiving supplemental erythropoietin therapy,
- Pregnancy and when member's iron stores are depleted such that the mother and/or fetus are at risk of adverse outcomes

LIMITATIONS/EXCLUSIONS:

Commonwealth Care Alliance will limit the following:

- All IV iron therapies used for the episode of care must be in compliance with the U.S. Food and Drug Administration Guidelines for the specific product.
- 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.

Commonwealth Care Alliance will not cover IV iron therapy, for the following conditions, but not limited to:

- Acute mountain sickness,
- Anemia of inflammation,
- Anemia of pregnancy that does not meet the criteria above,
- Post-partum anemia,

Medical Necessity Guideline

- Prophylactic use,
    - To improve function in non-anemic persons undergoing orthopedic surgery
    - To prevent postoperative anemia in persons undergoing bariatric surgery
- Restless legs syndrome,
- Post-operative anemia following major surgery (with the exception of gastric bypass surgery),
- Hemodialysis
    - Note that IV iron therapy is bundled into hemodialysis care and is NOT covered separately as an identified and billable service
- Genetic hematochromatosis or hematochromatosis secondary to iron overload

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 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 servicearea who are medical experts in the appropriate field, review of 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. If at any time a CMS Local or National Coverage Determination (LCD or NCD) is published that conflicts with the criteria set forth herein, the NCD or LCD criteria shall supersede these criteria.

Medical Necessity Guideline

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.

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ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION
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: Addition of the applicable HCPCS codes.

Medical Necessity Guideline

APPROVALS:

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CCA Senior Clinical Lead [Print]	**Title [Print]**
	
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Signature	**Date**