Medical Necessity Guideline

Medical Necessity Guideline (MNG) Title: Intravenous Iron Infusion MNG		
MNG #: 041	**☒SCO ☒One Care**	**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	**Next Annual Review Date:** 08/05/2021; 02/04/2022	**Retire Date:**

OVERVIEW:

Intravenous iron is a rapid way to raise low iron levels in the human body. It has been shown to be safe in most patients and is used when oral iron supplements have not successfully corrected a member's anemia.

A Medicare LCD allows intravenous iron therapy for members with anemia from chronic kidney disease, hemodialysis, or chemotherapy. CCA may also cover intravenous iron therapy for members who have laboratory studies showing anemia, symptoms of anemia, AND have already taken oral iron therapy daily for three months without improvement in their labs or symptoms.

Normally one dose of intravenous iron corrects anemia in most individuals for a period of months to years depending on their underlying disease processes.

DECISION GUIDELINES:

Clinical Coverage Criteria:

CCA will cover up to six (6) doses per authorization of intravenous iron therapy according to the following decision guidelines:

a. Member has a clinically significant iron deficiency anemia[1] AND
b. Member has active symptoms[2] consistent with anemia which impair their ADL and IADL function; AND
c. Member has taken oral iron therapy daily or more frequently for three months without improvement; AND
d. Member has not had an adverse reaction to a prior therapeutic iron infusion.

Members may have other medical conditions which produce an anemia similar to the anemia of chemotherapy or chronic kidney disease. It is the responsibility of the ordering clinician to document how this anemia is not from one of the following anemias where iron infusion remains an experimental and investigational treatment which is not covered.

[1] clinically significant iron deficiency anemia shall be defined as an absolute or functional iron deficiency. An absolute iron deficiency is defined as a serum ferritin < 30 ng/mL or transferrin saturation (TSAT) < 15% (obtained within the last 30 days). A functional iron deficiency is defined as a serum ferritin < 100 ng/mL and TSAT < 20% (obtained within the last 30 days) with symptoms clearly related to this measurement.

[2] symptoms consistent with anemia include measurable and observable dyspnea, fatigue, fainting or weakness

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Exclusions:

CCA will consider intravenous iron therapy to be experimental and investigational and NOT a covered service for all other indications because its clinical value in these situations has not been established including the (not all inclusive) following list:

a. Acute mountain sickness
b. Anemia of inflammation
c. Anemia of pregnancy that does not meet criteria above
d. Post-partum anemia
e. Prophylactic use to improve function in non-anemic persons undergoing orthopedic surgery (e.g., hip fracture)
f. Prophylactic use to prevent postoperative anemia in persons undergoing bariatric surgery
g. Restless legs syndrome
h. Post-operative anemia following major surgery (e.g., cardiothoracic surgery, colorectal cancer surgery, other)
i. Hemodialysis – please note that IV iron therapy is bundled into hemodialysis care and is NOT covered as a separately identified and billable service

Note that for all above criteria that specify a specialty, the PCP may prescribe the agent AS LONG AS there is documentation of the active, regular involvement of the appropriate specialist, as documented by up to date office notes or equivalent.

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 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:

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6142502/
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6437426/
3. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4518169/
4. https://pubmed.ncbi.nlm.nih.gov/21239816/

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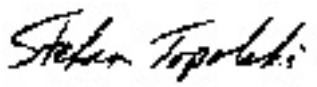
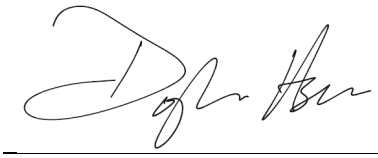
ATTACHMENTS:

EXHIBIT A:	
EXHIBIT B	

REVISION LOG:

REVISION DATE	DESCRIPTION

APPROVALS:

Stefan Topolski	Medical Director
CCA Senior Clinical Lead [Print]	**Title [Print]**
	08/05/2020
Signature	**Date**
Doug Hsu, MD	VP, Medical Policy & Utilization Review
CCA Senior Operational Lead [Print]	**Title [Print]**
	08/05/2020
Signature	**Date**
Lori Tishler, MD	SVP, Medical Services
CCA CMO or Designee [Print]	**Title [Print]**
	08/05/2020
Signature	**Date**