

Local Coverage Article: Parenteral Iron Administration Coverage in Non-Dialysis Usage (A55653)

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern American Samoa
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	Guam Hawaii Northern Mariana Islands American Samoa
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada American Samoa California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	Guam Hawaii Nevada Northern Mariana Islands

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Article Information

General Information

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Article Title

Parenteral Iron Administration Coverage in Non-Dialysis Usage

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Article Guidance

Article Text:

Summary of Coverage

Noridian will cover the medically necessary and reasonable use of parenteral iron preparations in the following non-dialysis related clinical presentations. This coverage article is separate from and does not address or apply to the use of parenteral iron preparations in the beneficiary with end stage renal disease on hemodialysis.

Coverage for parenteral iron in iron deficiency anemia (IDA):

1. When oral supplementation has been tried and the patient has demonstrated significant gastrointestinal distress whereas compliance with an oral regimen is no longer feasible. This includes patients with chronic kidney disease who are not yet requiring dialysis;
2. In beneficiaries who have a pathological or anatomical presentation where oral iron is unlikely to be absorbed or may further cause exacerbation of the underlying gastrointestinal disorder. This primarily includes use in patients with proven inflammatory bowel disease, short bowel/short gut syndrome and following gastric bypass surgery. This includes patients with a known abnormally high hepcidin level and those with iron refractory iron deficiency anemia;
3. Beneficiaries with chemotherapy induced anemia when an erythropoietin stimulating agent is being used in accordance with Medicare guidelines and where oral supplementation is unlikely to be sufficient or the anemia is so severe as to require more urgent iron supplementation. If treating anemia exacerbated cardiac disease one should give precedence to transfusions in the acute setting;

4. In a beneficiary who has ongoing iron losses (such as severe menorrhagia, Rendu-Osler-Weber disease) where oral iron replenishment is inadequate or contraindicated only until definitive intervention, when available, is successfully undertaken.

5. Use in the pregnant beneficiary when iron stores are depleted such that the mother and/or the fetus are at risk of adverse outcomes and oral iron replenishment is either not tolerated or the anemia is of such severity as to require more immediate replenishment. Additionally, use in the peripartum period may be indicated when intra/post-partum hemorrhage is severe and by administering parenteral iron a transfusion may be avoided. This indication does not replace the strong consideration for transfusions when the hemorrhage is potentially life threatening.

Summary of Evidence

Medicare policy for the use of parenteral iron preparations in the beneficiary with Chronic Kidney Disease (CKD) on hemodialysis (HD) who is receiving supplemental erythropoietin therapy is addressed in National Coverage Determination 110.10. This article does not address care of the beneficiary with Chronic Kidney Disease (CKD) on hemodialysis (HD) who is receiving supplemental erythropoietin therapy

Medicare is a defined benefit program. One of the rules that impacts coverage of the injectable iron preparations is from the Internet Only Manual 100-02 (Benefit Policy), Chapter 15 (Covered Services), Section 50.4.3 that defines "reasonable and necessary" with respect to drugs:

2. Injection Method Not Indicated

"Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration."

The usual method for administering iron preparations is by the oral route, except in dialysis patients in whom vascular access is already present. Medicare does not cover intravenous iron outside of dialysis patients unless there is a medical reason that precludes oral administration.

The Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee states that common indications for intravenous iron use include:

- Iron deficiency anaemia with intolerance of oral iron, especially in inflammatory bowel disease, or where oral iron is ineffective.
- To support the use of erythropoiesis stimulating agents (including patients on renal dialysis).
- As an alternative to blood transfusion when a rapid increase in hemoglobin is required (e.g. perioperative anaemia, severe anaemia in late pregnancy or postpartum anaemia).¹

James Harper, MD et al in Medscape article "Iron Deficiency Treatment & Management" state:

Reserve parenteral iron for patients who are either unable to absorb oral iron or who have increasing anemia despite adequate doses of oral iron. It is expensive and has greater morbidity than oral preparations of iron. Parenteral iron has been used safely and effectively in patients with inflammatory bowel disease (e.g., ulcerative colitis, Crohn disease), as the ferrous sulfate preparations may aggravate the intestinal inflammation.²

Matthew Short, MD et al in Am Fam Physician state:

Parenteral therapy may be used in patients who cannot tolerate or absorb oral preparations, such as those who have undergone gastrectomy, gastrojejunostomy, bariatric surgery, or other small bowel surgeries. The most common indications for intravenous therapy include GI effects, worsening symptoms of inflammatory bowel disease, unresolved bleeding, renal failure-induced anemia treated with erythropoietin, and insufficient absorption in patients with celiac disease.³

Other authors have indicated that such use may be appropriate in the patient who is pooling blood for future auto transfusion.

Clara Camaschella M.D. in a NEJM article states:

The benefit of treating iron deficiency before the development of anemia remains uncertain. A few small studies show that the administration of intravenous iron improves fatigue in women without anemia whose ferritin levels are in the iron-deficient range. Some studies have also suggested that oral iron supplementation benefits physical performance in women of reproductive age,⁶¹ but such studies have included a limited number of participants and are strikingly heterogeneous.

Patients with severe iron-deficiency anemia that causes cardiovascular symptoms, such as heart failure or angina, should receive red-cell transfusions. This approach rapidly corrects not only hypoxia but also iron deficiency, since one unit of packed red cells provides approximately 200 mg of iron.

Further in the article:

Patients with malabsorption and genetic iron refractory iron deficiency anemia (IRIDA) may require intravenous iron. Intravenous administration is also preferred when a rapid increase in hemoglobin level is required or when iron-deficiency anemia caused by chronic blood loss cannot be controlled with the use of oral iron, as is the case in patients with hereditary hemorrhagic telangiectasia. Active inflammatory bowel disease is an emerging indication for the use of intravenous iron; oral iron is not only ineffective but may also increase local inflammation.

Continuing in the article:

Studies of the use of parenteral iron therapy for conditions other than those mentioned are either limited or not controlled.

In concluding she writes:

Well-designed, randomized, controlled trials are needed to verify the long-term effects of intravenous iron supplementation. In the interim, intravenous iron should be used only when the benefits outweigh the risks.⁴

Auerbach et al in the American Journal of Hematology (2015) summarized as follows:

For uncomplicated ID without comorbidity, oral iron is readily available, inexpensive, effective, safe, and convenient. For those patients intolerant of oral iron or with conditions where oral iron is likely to be ineffective or harmful, the IV route is preferred. Except for patients with ID associated with chemotherapy administration or dialysis, a single infusion of a replacement dose offers convenience and cost benefit. The preponderance of published credible evidence suggests IV iron is safe and effective, and should be moved forward in the treatment paradigm. Given poorer outcomes in neonates born iron deficient, failure to address IV iron in pregnancy may represent an unmet clinical need.⁵

Powers et al in Hematology/Oncology Clinics of North America (2014) state as two of their main points in the treatment of IDA

- Initial therapy for IDA is an oral iron medication for a minimum of 3 months, while attempting to identify and correct the underlying cause. Nevertheless, firm data regarding optimal dose, duration of therapy, and monitoring of the hematologic response are unavailable.

- The administration of intravenous iron to patients who fail oral iron treatment warrants further investigation and strong consideration as a potentially safe and effective option to oral iron dosing.⁶

Sources:

Internet Only Manual (IOM) Medicare Benefit Policy Manual, Publication 100-02, Chapter 15, Section 50.4.3.

1. Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee Transfusion Guidebook Section 6.4 Parenteral Iron (updated 2014-02-04)

2. Harper, James L; Besa, Emmanuel; Iron Deficiency Anemia & Management, Medscape Nov 14, 2016 <http://emedicine.medscape.com/article/202333-treatment#d7>

3. Short, Matthew W.; Domagalski, Jason E. Iron Deficiency Anemia: Evaluation and Management Am Fam Physician 2013 Jan 15;87(2): 98-104
4. Camaschella; Iron Deficiency Anemia, N Engl J Med 2015;372:1832-43
5. Auerbach, Michael; Adamson, John Am J Hematology 2016 Jan;91(1);31-38
6. Powers, Jacquelyn M.; Buchanan, George R.; Hematology/Oncology Clinics of North America, 2014 Aug; 28(4);729-745

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Bill Type Code Bill Type Description

013x	Hospital Outpatient
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N/A

CPT/HCPCS Codes N/A

ICD-10 Codes that are Covered N/A

ICD-10 Codes that are Not Covered N/A

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[Revision History Information](#)

N/A [Back to Top](#) **Related Local Coverage Document(s)** N/A

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

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- CKD
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