Intravenous Iron Therapy (NCD 110.10)

Guideline Number: MPG178.04

Overview
Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) which transport oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBCs that improve hematocrit levels. Iron deficiency is a common condition in end stage renal disease (ESRD) patients undergoing hemodialysis. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis. The available evidence suggests that the mode of intravenous administration is perhaps the most effective treatment for iron deficiency in hemodialysis patients. Unlike oral iron products, which must be absorbed through the GI tract, IV iron products are infused directly into the bloodstream in a form that is readily available to the bone marrow for RBC synthesis, resulting in an earlier correction of iron deficiency and anemia.

Coverage also includes the medically necessary and reasonable use of parenteral iron preparations in non-dialysis related clinical conditions.

Guidelines
Medicare covers Sodium Ferric Gluconate Complex in Sucrose Injection as a first line treatment of Iron Deficiency Anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy.

Medicare also covers Iron Sucrose Injection as a first line treatment of Iron Deficiency Anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy.

Coverage also includes for parenteral iron in iron deficiency anemia:
For patients with iron deficiency anemia who do not respond to oral iron supplementation due to malabsorption disorders or patients who have documented intolerance to oral iron supplementation.

For anemia related to chronic kidney disease.

Initial treatment of absolute iron deficiency in patients receiving myelosuppressive chemotherapy who have asymptomatic anemia and risk factors for the development of symptomatic anemia requiring transfusion.

For 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.

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UnitedHealthcare Medicare Advantage Policy Guideline

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### APPLICABLE CODES

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 imply 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. Other Policies and Guidelines may apply.

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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>J1439</td>
<td>Injection, Ferric Carboxymaltose, 1 mg</td>
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<tr>
<td>J1750</td>
<td>Injection, Iron Dextran, 50 mg</td>
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<tr>
<td>J1756</td>
<td>Injection, Iron Sucrose, 1 mg (Venofer®)</td>
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<td>J2916</td>
<td>Injection, Sodium Ferric Gluconate Complex in Sucrose Injection, 12.5 mg (Ferrlecit®)</td>
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<td>Q0138</td>
<td>Injection, Ferumoxytol, for treatment of Iron Deficiency Anemia, 1 mg (Non-ESRD use)</td>
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<td>Q0139</td>
<td>Injection, Ferumoxytol, for treatment of Iron Deficiency Anemia, 1 mg (For ESRD on dialysis)</td>
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### PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

### REFERENCES

**CMS National Coverage Determinations (NCDs)**

**NCD 110.10 Intravenous Iron Therapy**

**CMS Local Coverage Determinations (LCDs)**

<table>
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<th>LCD</th>
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<tr>
<td>L34093 (Chemotherapy and Biologicals) CGS</td>
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**CMS Articles**

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<tr>
<td>A52427 (Iron Sucrose, Iron Dextran and Ferumoxytol Therapy) CGS</td>
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<td>A52429 (Sodium Ferric Gluconate. (Intravenous Iron Therapy)) CGS</td>
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<td>A55653 (Parenteral Iron Administration Coverage in Non-Dialysis Usage) Noridian</td>
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<td>A54583 (Parenteral Iron Administration in Beneficiaries with Chronic Kidney Disease (CKD) with Iron Deficiency Anemia (IDA) or Reduced Iron Stores) Noridian</td>
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Intravenous Iron Therapy (NCD 110.10)

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Approved 09/12/2018

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**CMS Benefit Policy Manual**

Chapter 11; § 30.4.2.1 Intravenous Iron Therapy

Chapter 15; § 50 Drugs and Biologicals

**CMS Claims Processing Manual**

Chapter 8; § 60.2.4 Intravenous Iron Therapy, § 60.2.4.2 Physician Billing Requirements to the Carrier

**CMS Transmittals**

Transmittal 1122, Change Request 7818, Dated 09/14/2012 (International Classification of Diseases (ICD)-10 Conversion from ICD-9 and Related Code Infrastructure of the Medicare Shared Systems as They Relate to CMS National Coverage Determinations (NCDs) (CR 1 of 3) (ICD-10)

Transmittal 1388, Change Request 8691, Dated 05/23/2014 (ICD-10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to National Coverage Determinations (NCDs)-Maintenance CR)

Transmittal 1537, Change Request 9252, Dated 08/21/2015 (ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)-3rd Maintenance CR)

Transmittal 1580, Change Request 9252, Dated 12/03/2015 (ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)-3rd Maintenance CR)

**MLN Matters**

Article MM8786, July 2014 Update of the Ambulatory Surgical Center (ASC) Payment System

Article MM9014, January 2015 Update of the Hospital Outpatient Prospective Payment System (OPPS)

Article MM9087, ICD-10 Conversion/Coding Infrastructure Revisions/ICD-9 Updates to National Coverage Determinations (NCDs)-2nd Maintenance CR

Article MM9252 Revised, ICD-10 Conversion/Coding Infrastructure Revisions to National Coverage Determinations (NCDs)-3rd Maintenance CR

**Other**

Chemotherapy and Biological Chart 07/11/2017, CGS Administrators

Chemotherapy and Biological Chart 07/10/2018, CGS Administrators

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**GUIDELINE HISTORY/REVISION INFORMATION**

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
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<tr>
<td>09/12/2018</td>
<td>• Annual review</td>
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<td></td>
<td>• Added additional clinical indications for which iron therapy can be given and corresponding HCPCS codes</td>
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TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

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 member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.