Anti-Inhibitor Coagulant Complex (AICC) (NCD 110.3)

Guideline Number: MPG014.06
Approval Date: September 9, 2020

Overview
Anti-inhibitor coagulant complex (AICC) is a drug used to treat hemophilia in patients with factor VIII inhibitor antibodies. Hemophilia is a blood disease characterized by greatly prolonged coagulation time. The blood fails to clot and abnormal bleeding occurs. Hemophilia is usually inherited. It is a sex-linked hereditary trait transmitted by normal heterozygous females who carry the recessive gene. It occurs almost exclusively in males.

In rare cases, hemophilia can develop after birth, which is called acquired hemophilia caused by the development of antibodies (immune system proteins) directed against the body’s own VIII or IX blood clotting factors. Unlike inherited hemophilia, acquired hemophilia A is not a genetic disorder and affects both males and females. The development of acquired hemophilia A has been related to other medical conditions or health states, such as pregnancy, cancer, or the use of certain medications. However, in about half of the cases, no underlying cause can be found.

Guidelines
AICC has been shown to be safe and effective and has Medicare coverage when furnished to patients with hemophilia A and inhibitor antibodies to factor VIII who have major bleeding episodes and who fail to respond to other, less expensive therapies.

Medicare provides coverage of self-administered blood clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision. Medicare covers blood clotting factors for the following conditions:
- Factor VIII deficiency (classic hemophilia, hemophilia A)
- Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component)
- Von Willebrand’s disease
- Acquired hemophilia (acquired Factor VIII autoantibodies most frequently) and other coagulation factor deficiencies, intrinsic circulating anticoagulants, antibodies or inhibitors.
- Congenital deficiencies of other clotting factors (such as congenital afibrinogenemia and others).
Applicable Codes

The following list(s) of procedure and/or diagnosis 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.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J7198</td>
<td>Anti-inhibitor, per IU</td>
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<thead>
<tr>
<th>Diagnosis Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>D66</td>
<td>Hereditary factor VIII deficiency</td>
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<td>D67</td>
<td>Hereditary factor IX deficiency</td>
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<td>D68.0</td>
<td>Von Willebrand's disease</td>
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<td>D68.1</td>
<td>Hereditary factor XI deficiency</td>
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<td>D68.2</td>
<td>Hereditary deficiency of other clotting factors</td>
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<tr>
<td>D68.311</td>
<td>Acquired hemophilia</td>
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<tr>
<td>D68.312</td>
<td>Antiphospholipid antibody with hemorrhagic disorder</td>
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<tr>
<td>D68.318</td>
<td>Other hemorrhagic disorder due to intrinsic circulating anticoagulants, antibodies, or inhibitors</td>
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<tr>
<td>D68.4</td>
<td>Acquired coagulation factor deficiency</td>
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References

CMS National Coverage Determinations (NCDs)

NCD 110.3 Anti-Inhibitor Coagulant Complex (AICC)

CMS Local Coverage Determinations (LCDs) and Articles

<table>
<thead>
<tr>
<th>LCD</th>
<th>Article</th>
<th>Contractor</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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<tbody>
<tr>
<td>L33684 Hemophilia Clotting Factors</td>
<td>A56482 Billing and Coding: Hemophilia Clotting Factors</td>
<td>First Coast</td>
<td>FL, PR, VI</td>
<td>FL, PR, VI</td>
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<td>L35111 Hemophilia Factor Products</td>
<td>A56433 Billing and Coding: Hemophilia Factor Products</td>
<td>Novitas</td>
<td>AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX</td>
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<td>N/A</td>
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CMS Benefit Policy Manual

Chapter 6; § 30 Drugs and Biologicals
Chapter 15; § 50.5.5 Hemophilia Clotting Factors
CMS Claims Processing Manual
Chapter 17; § 40 Discarded Drugs and Biologicals, § 80.4-80.4.1 Billing for Hemophilia Clotting Factors/Clotting Factor Furnishing Fee, § 90.2 Drugs, Biologicals, and Radiopharmaceuticals

MLN Matters
Article MM9759, Annual Clotting Factor Furnishing Fee Update 2017
Article MM10254, Annual Clotting Factor Furnishing Fee Update 2018
Article MM10918, Annual Clotting Factor Furnishing Fee Update 2019
Article MM11435, Annual Clotting Factor Furnishing Fee Update 2020

UnitedHealthcare Commercial Policy
Clotting Factors, Coagulant Blood Products & Other Hemostatics

Other(s)
Medicare Annual Blood Clotting Factor Furnishing Fee Schedules
Palmetto GBA Jurisdiction J, Part B, Hemophilia Clotting Factors: Submitting the Number of Units
Palmetto GBA Jurisdiction M Part B, Hemophilia Clotting Factors: Submitting the Number of Units
Noridian Healthcare Solutions Jurisdiction E Part B, Hemophilia Clotting Factor Billing
Noridian Healthcare Solutions Jurisdiction F Part B Hemophilia Clotting Factor Billing

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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
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<tbody>
<tr>
<td>04/01/2021</td>
<td>Template Update</td>
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<tr>
<td></td>
<td>● Reformatted policy; transferred content to new template</td>
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<tr>
<td>09/09/2020</td>
<td>Related Policies</td>
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<tr>
<td></td>
<td>● Added reference link to the Medicare Advantage Reimbursement Policy titled Medically Unlikely Edits Policy, Professional</td>
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<tr>
<td></td>
<td>Supporting Information</td>
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<tr>
<td></td>
<td>● Updated References section to reflect the most current information</td>
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<td></td>
<td>● Archived previous policy version MPG014.05</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.
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.