Local Coverage Determination (LCD): Hemophilia Factor Products (L33658)

Contractor Information

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Novitas Solutions, Inc.

Contract Number
04412

Contract Type
A and B MAC

LCD Information

Document Information

LCD ID
L33658

LCD Title
Hemophilia Factor Products

Revision Effective Date
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Revision Ending Date
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Jurisdiction
Texas

Original Effective Date
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Retirement Date
N/A

Notice Period End Date
04/08/2015

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determination(s) or payment policy rules and regulations for blood-clotting factors for hemophilia. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for blood-clotting factors for hemophilia and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies regarding blood-clotting factors for hemophilia are found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

- Medicare Benefit Policy Manual, Pub. 100-02
  - Chapter 6, Section 30 - Drugs and Biologicals
  - Chapter 15 - Covered Medical and Other Health Services, Section 50.5.5 - Hemophilia Clotting Factors (Rev. 1, 10-01-03); A3-3112.4.B.2, HO-230.4.B.2.

- Medicare National Coverage Determinations Manual, Pub. 100-03, Chapter 1, Part 2, Section 110.3.- Anti-Inhibitor Coagulant Complex (AICC) (formerly CIM 45-24).
- Medicare Claims Processing Manual, Pub. 100-04:
  - Chapter 3, Section 20.7.3 - Payment for Blood Clotting Factor Administered to Hemophilia Inpatients
  - Chapter 17 - Drugs and Biologicals, Section 80.4 - Billing for Hemophilia Clotting Factors.


- Correct Coding Initiative - Medicare Contractor Beneficiary and Provider Communications Manual - Pub. 100-09, Chapter 5.
  Formerly: MCM 2050.5, 5245 CIM 45-24 PM AB-98-3, 01-29-98; PM AB-99-75, 10-99.

Social Security Act (Title XVIII) Standard References

- Title XVIII of the Social Security Act (the Act), Section 1852(a)(1)(A) - This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.
- Title XVIII of the Social Security Act, Section 1852(a)(1)(D) Investigational or Experimental.
- Title XVIII of the Social Security Act, Section 1852(a)(7). This section excludes routine physical examinations.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

42 CFR 410.10(q) - Hemophilia clotting factors (the limitation contained in 42 CFR 410.10(q) states that this applies to hemophilia patients competent to use these factors without supervision).

Section 1881(e)(2)(I) of the Act provides Medicare coverage of blood-clotting factors for hemophilia patients competent to use such factors to control bleeding with medical supervision, and items related to the administration of such factors. The Medicare Modernization Act, Section 3023(e)(1) added Section 1842(o)(5)(C) of the Social Security Act, which requires that, beginning January 1, 2005, a furnishing fee will be paid for items and services associated with clotting factor. The Centers for Medicare & Medicaid Services (CMS) includes the clotting factor furnishing fee in the published national payment limits for clotting factor billing codes. When the national payment limit for a clotting factor is not included on the Average Sales Price (ASP) Medicare Part B Drug Pricing File or the Not Otherwise Classified (NOC) Pricing File, the contractor must make payment for the clotting factor as well as make payment for the furnishing fee.

Payment for Blood Clotting Factor Administered to Hemophilia Inpatients, 20.7.3 - Section 6011 of Public Law (PL) 101-239 amended Section 1886(a)(4) of the Act to provide that Prospective Payment System (PPS) hospitals receive an additional payment for the costs of administering blood-clotting factor to Medicare hemophiliacs who are hospital inpatients. Section 6011(d) of PL 101-239 specified that the payment be based on a predetermined price per unit of clotting factor multiplied by the number of units provided. This add-on payment originally was effective for blood-clotting factors furnished on or after June 19, 1990, and before December 19, 1991. Section 13505 of PL 103-66 amended Section 6011(d) of PL 101-239 to extend the period covered by the add-on payment for blood-clotting factors administered to Medicare inpatients with hemophilia through September 30, 1994. Section 4452 of PL 105-33 amended Section 6011(d) of PL 101-239 to reinstate the add-on payment for the costs of administering blood-clotting factor to Medicare beneficiaries who have hemophilia and who are hospital inpatients for discharges occurring on or after October 1, 1998.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity
Notice: It is not appropriate to bill Medicare for services that are not covered (as described by this entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.

Hemophilia is a blood disease characterized by greatly prolonged coagulation time. The blood fails to clot, due to inadequate factor levels, 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. Hemophilia can also be acquired. For purposes of Medicare coverage, hemophilia encompasses Factor VIII deficiency (classic hemophilia, hemophilia A), Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component), von Willebrand's disease, autoimmune-related acquired hemophilia (acquired Factor VIIIc inhibitor) and Factor XIII deficiency (congenital afibrinogenemia). Approximately 80 percent of those with hemophilia have type A.

The frequency and severity of hemorrhagic events induced by hemophilia are related to the amount of coagulation factor in the blood. Those with mild hemophilia (defined as having from 5 to 40 percent of normal coagulation factor activity) experience complications only after having undergone surgery or experiencing a major physical trauma. Those with moderate hemophilia (from 1 to 5 percent of coagulation factor activity) experience some spontaneous hemorrhage but normally exhibit bleeding provoked by trauma. Those with severe hemophilia (less than 1 percent of coagulation factor activity) exhibit spontaneous hemorrhasis and bleeding. Short-term prophylactic treatment is given to patients before they undergo surgical procedures or engage in activities that carry a high risk of provoking a bleed. It may also be given to break the cycle of frequent bleeding into specific joints (target joints). Treatment for these patients is dependent on the severity of the disease and may include the administration of blood-clotting factors such as Factor VIII, Factor IX, Factor VIIa and anti-inhibitors to control the bleeding. Medicare provides coverage of these factor products through Part A and B coverage. In Part B, Medicare provides coverage in two manners, one of an ‘incident to’ event where the provider has a cost of the factor and administers, whereby the claim will demonstrate the factor product code and administration codes. Medicare also 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).
- Factor XIII deficiency (congenital afibrinogenemia).

Antihemophilic Factor

Antihemophilic factor is usually indicated for hemophilia when a bleeding episode arises (demand treatment) or when bleeding is anticipated or likely (prophylactic treatment). Primary prophylactic therapy may be indicated for patients with severe hemophilia A or B who have less than 1 percent of normal factor (less than 0.01 IU/mL (National Hemophilia Foundation, 2001). Primary prophylactic therapy should be instituted early, prior to the onset of frequent bleeding, with the aim of keeping the trough factor or Factor VIII or Factor IX level above 1 percent between doses (National Hemophilia Foundation, 2001). In some cases, continuous prophylactic therapy may be indicated in persons with hemophilia A or hemophilia B that is not severe (i.e., hemophiliacs with more than 1 percent of normal factor levels) who have repeated episodes of spontaneous bleeding. Inhibitors are antibodies that neutralize Factor VIII and can render replacement therapy ineffective. They are found more commonly in patients with moderate to severe hemophilia (up to 30 percent of those with severe disease) who have received significant amounts of replacement therapy. Immune tolerance strategies in those with identified inhibitors also have been successful. Assuming no anamnestic response, low-titer inhibitors occasionally can be overcome with high doses of Factor VIII. Recombinant human coagulation Factor VIIa (rFVIIa) is indicated for the treatment of patients with bleeding episodes and for the prevention of bleeding in surgical interventions or invasive procedures in patients with hemophilia A or B with inhibitors to Factor VIII or Factor IX. High-titer inhibitors have been treated with variable success using porcine Factor VIII, Factor IX complex concentrates, recombinant Factor VIII, and exchange plasma pheresis. Anti-Inhibitor Coagulant Complex (AICC) is a drug used to treat hemophilia in patients with Factor VIII inhibitor antibodies. AICC has been shown to be safe and effective and is covered by Medicare 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.

Immune Tolerance Induction

Immune tolerance induction is designed to overcome the effects of antihemophilic factor or Factor IX inhibitors in certain hemophiliac patients, thus restoring effectiveness of antihemophilic factor or Factor IX therapy to resolve active bleeding in these patients. It consists of administration of very high doses of anti-hemophilic factor or Factor IX over an extended period of time.

Self-Administered Drugs

Self-administered blood-clotting factors for hemophilia patients and items related to the administration of such factors are covered under Part B when all the following criteria exist:

- The factor is used to control bleeding associated with hemophilia.
- The patient is competent to use such factors without medical or other supervision.
- The amount of clotting factors determined to be necessary to have on hand and thus covered under this provision will be based on the historical utilization pattern or profile developed by the carrier for each patient. Changes in a patient's medical needs over a period of time may require adjustments in the profile. It is expected that the treating source, e.g., a family physician or Comprehensive Hemophilia Diagnostic and Treatment Center, will have such information.

Anti-Inhibitor Products

The drugs listed below are presently listed as available for Anti-inhibitor needs. Additional drugs may be subsequently available but not necessarily listed. Providers are responsible to use FDA labels for this treatment.

Anti-Inhibitor Coagulation Complex (AICC)
Anti-Inhibitor Coagulation Complex (AICC) (billed as J7298 and listed as Feiba, VH Immuno, Autoplex or Hemophilia clotting factor) is a drug used to treat hemophilia in patients with Factor VIII inhibitor antibodies. AICC has been shown to be safe and effective and is covered when furnished to patients with hemophilia A or B and inhibitor antibodies to Factor VIII who have major bleeding episodes and who fail to respond to other less-expensive therapies.

NovoSeven

Factor VIII (anti-hemophilic factor, recombinant) (billed as J7298 and listed as a specific drug) is indicated for the treatment of bleeding episodes in hemophilia A or B patients or with acquired hemophilia. NovoSeven, as noted in the Prescribing Information for the product, should be administered to patients only under the supervision of a physician experienced in the treatment of hemophilia. Novitas notes this product would not be appropriate to be used in a self-administration situation and the supervision should be "direct" as in incident to in an office under Part B Medicare.

Note: This LCD does NOT describe drug and biological coverage under the Medicare Part D benefit.

Limitations:

This LCD imposes diagnosis limitations that support diagnosis-to-procedure code automated denials. However, services performed for any given diagnosis must meet all of the indications and limitations stated in this policy, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS National Coverage Determinations (NCDs), and all Medicare payment rules.

As published in CMS IOM Pub. 100-08, Chapter 13, Section 13.5.1, in order to be covered under Medicare, a service shall be reasonable and necessary. When appropriate, contractors shall describe the circumstances under which the proposed LCD for the service is considered reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member.
  - Furnished in a setting appropriate to the patient’s medical needs and condition.
  - Ordered and furnished by qualified personnel.
  - One that meets, but does not exceed, the patient’s medical needs.
  - At least as beneficial as an existing and available medically appropriate alternative.

Drug Wasteage

Medicare provides payment for the discarded drug/biological remaining in a single-use drug product after administering what is reasonable and necessary for the patient’s condition. If the physician has made good faith efforts to minimize the unused portion of the drug/biological in how patients are scheduled and how he/she ordered, accepted, stored and used the drug and made good faith efforts to minimize the unused portion of the drug in how it is supplied, then the program will cover the amount of drug discarded along with the amount administered. Documentation requirements are given below. Reference to national policy: Medicare Claims Processing Manual, Pub. 100-04, Chapter 17, Section 40.

Bill Type and Revenue Codes DO NOT apply to Part B.

Coding Information

Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

<table>
<thead>
<tr>
<th>Bill Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>12x</td>
<td>Hospital Inpatient (Medicare Part B only)</td>
</tr>
<tr>
<td>13x</td>
<td>Hospital Outpatient</td>
</tr>
<tr>
<td>18x</td>
<td>Hospital - Swing Beds</td>
</tr>
<tr>
<td>21x</td>
<td>Skilled Nursing - Inpatient (Including Medicare Part A)</td>
</tr>
<tr>
<td>22x</td>
<td>Skilled Nursing - Inpatient (Medicare Part B only)</td>
</tr>
<tr>
<td>23x</td>
<td>Skilled Nursing - Outpatient</td>
</tr>
<tr>
<td>71x</td>
<td>Clinic - Rural Health</td>
</tr>
<tr>
<td>72x</td>
<td>Clinic - Hospital Based or Independent Renal Dialysis Center</td>
</tr>
<tr>
<td>73x</td>
<td>Clinic - Freestanding</td>
</tr>
<tr>
<td>74x</td>
<td>Clinic - Outpatient Rehabilitation Facility (CORF)</td>
</tr>
<tr>
<td>75x</td>
<td>Clinic - Comprehensive Outpatient Rehabilitation Facility (CORF)</td>
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<tr>
<td>77x</td>
<td>Clinic - Federally Qualified Health Center (FQHC)</td>
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<tr>
<td>83x</td>
<td>Ambulatory Surgery Center</td>
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<tr>
<td>85x</td>
<td>Critical Access Hospital</td>
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</table>

Revenue Codes


Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

**Note:** The contractor has identified the Bill Type and Revenue Codes applicable for use with the CPT/HCPCS codes included in this LCD. Providers are reminded that not all CPT/HCPCS codes listed can be billed with all Bill Type and/or Revenue Codes listed. CPT/HCPCS codes are required to be billed with specific Bill Type and Revenue Codes. Providers are encouraged to refer to the CMS Internet-Only Manual Publication 100-04, Claims Processing Manual, for further guidance.

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0250</td>
<td>Pharmacy - General Classification</td>
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<tr>
<td>0636</td>
<td>Pharmacy - Drugs Requiring Detailed Coding</td>
</tr>
</tbody>
</table>

**CPT/HCPCS Codes**

**Group 1 Paragraph**

**Note:** Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

**Group 1 Codes**

- J7180: Factor XIII anti-hem factor
- J7181: Factor XIII recombinant subunit
- J7182: Factor VIII recombinant
- J7183: Wilate injection
- J7185: Xyntha inj
- J7186: Antihemophilic factor/vWF comp
- J7187: Humate-P, inj
- J7189: Factor VIII
- J7190: Factor IX
- J7191: Factor VIII (porcine)
- J7192: Factor IX recombinant NOS
- J7193: Factor IX non-recombinant
- J7194: Factor IX complex
- J7195: Factor IX recombinant NOS
- J7198: Anti-inhibitor
- J7200: Factor IX recombinant rixubis
- J7201: Factor IX fusion recombi

**ICD-9 Codes that Support Medical Necessity**

**Group 1 Paragraph:** It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

**Note:** Providers should continue to submit ICD-9-CM diagnosis codes without decimals on their claim forms and electronic claims.

The CPT/HCPCS codes included in this LCD will be subjected to "procedure to diagnosis" editing. The following lists include only those diagnoses for which the identified CPT/HCPCS procedures are covered. If a covered diagnosis is not on the claim, the edit will automatically deny the service as not medically necessary.

Medicare is establishing the following limited coverage for CPT/HCPCS code J7180:

**Covered for:**

**Group 1 Codes**

- 286.3: CONGENITAL DEFICIENCY OF OTHER CLOTTING FACTORS

Medicare is establishing the following limited coverage for CPT/HCPCS code J7183:

**Covered for:**

**Group 2 Paragraph:** Medicare is establishing the following limited coverage for CPT/HCPCS code J7183.

**Covered for:**

**Group 2 Codes**

- 286.4: VON WILLEBRAND'S DISEASE

Medicare is establishing the following limited coverage for CPT/HCPCS codes J7182 and J7189:

**Covered for:**

**Group 3 Paragraph:** Medicare is establishing the following limited coverage for CPT/HCPCS codes J7182 and J7189.

**Covered for:**

**Group 3 Codes**

- 286.0: CONGENITAL FACTOR VIII DISORDER

Medicare is establishing the following limited coverage for CPT/HCPCS code J7186:

**Covered for:**

**Group 4 Paragraph:** Medicare is establishing the following limited coverage for CPT/HCPCS code J7186.

**Covered for:**
<table>
<thead>
<tr>
<th>Group 4 Codes</th>
<th>ICD-9 Codes</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>286.0</td>
<td>286.0 CONGENITAL FACTOR VIII DISORDER</td>
<td></td>
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<tr>
<td>286.4</td>
<td>286.4 VON WILLEBRAND'S DISEASE</td>
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<tr>
<td>286.52</td>
<td>286.52 ACQUIRED HEMOPHILIA</td>
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<tr>
<td>286.53</td>
<td>286.53 ANTI-PHOSPHOLIPID ANTIBODY WITH HEMORRHAGIC DISORDER</td>
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<tr>
<td>286.59</td>
<td>286.59 OTHER HEMORRHAGIC DISORDER DUE TO INTRINSIC CIRCULATING ANTICOAGULANTS, ANTIBODIES, OR INHIBITORS</td>
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<tr>
<th>Group 5 Codes</th>
<th>ICD-9 Codes</th>
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<tr>
<td>286.0</td>
<td>286.0 CONGENITAL FACTOR VIII DISORDER</td>
<td></td>
</tr>
<tr>
<td>286.4</td>
<td>286.4 VON WILLEBRAND'S DISEASE</td>
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**Group 5 Paragraph:** Medicare is establishing the following limited coverage for CPT/HCPCS code J7187:
Covered for:

<table>
<thead>
<tr>
<th>Group 6 Codes</th>
<th>ICD-9 Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>286.0*</td>
<td>286.0* CONGENITAL FACTOR VIII DISORDER</td>
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<tr>
<td>286.1*</td>
<td>286.1* CONGENITAL FACTOR IX DISORDER</td>
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<tr>
<td>286.3</td>
<td>286.3 CONGENITAL DEFICIENCY OF OTHER CLOTTING FACTORS</td>
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<tr>
<td>286.52</td>
<td>286.52 ACQUIRED HEMOPHILIA</td>
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<td>286.53</td>
<td>286.53 ANTI-PHOSPHOLIPID ANTIBODY WITH HEMORRHAGIC DISORDER</td>
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<tr>
<td>286.59</td>
<td>286.59 OTHER HEMORRHAGIC DISORDER DUE TO INTRINSIC CIRCULATING ANTICOAGULANTS, ANTIBODIES, OR INHIBITORS</td>
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**Note:** 286.0* and 286.1* requires documentation that patient has ongoing bleeding in Factor VIII and IX deficiencies.

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<thead>
<tr>
<th>Group 7 Codes</th>
<th>ICD-9 Codes</th>
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<tbody>
<tr>
<td>286.0</td>
<td>286.0 CONGENITAL FACTOR VIII DISORDER</td>
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**Group 7 Paragraph:** Medicare is establishing the following limited coverage for CPT/HCPCS Factor VIIa code J7189:
Covered for:

<table>
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<tr>
<th>Group 8 Codes</th>
<th>ICD-9 Codes</th>
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<tr>
<td>286.0</td>
<td>286.0 CONGENITAL FACTOR VIII DISORDER</td>
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**Group 8 Paragraph:** Medicare is establishing the following limited coverage for CPT/HCPCS Factor VIII codes J7190, J7191 and J7192:
Covered for:

<table>
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<tr>
<th>Group 9 Codes</th>
<th>ICD-9 Codes</th>
<th>Description</th>
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<tbody>
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<td>286.0</td>
<td>286.0 CONGENITAL FACTOR VIII DISORDER</td>
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<tr>
<td>286.1</td>
<td>286.1 CONGENITAL FACTOR IX DISORDER</td>
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**Group 9 Paragraph:** Medicare is establishing the following limited coverage for CPT/HCPCS code J7198:
Covered for:

<table>
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<tr>
<th>Group 10 Codes</th>
<th>ICD-9 Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>286.1</td>
<td>286.1 CONGENITAL FACTOR IX DISORDER</td>
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**Group 10 Paragraph:** Medicare is establishing the following limited coverage for CPT/HCPCS code J7200 and J7201:
Covered for:

<table>
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<tr>
<th>Group 11 Codes</th>
<th>ICD-9 Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>286.3*</td>
<td>286.3* CONGENITAL DEFICIENCY OF OTHER CLOTTING FACTORS</td>
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**Explanation:** 286.3* documentation should show this is a congenital Factor VIII subunit A deficiency.

<table>
<thead>
<tr>
<th>ICD-9 Codes that DO NOT Support Medical Necessity</th>
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</table>
All those not listed under the "ICD-9 Codes that Support Medical Necessity" section of this policy.

General Information

Associated Information

Documentation Requirements

- All documentation must be maintained in the patient’s medical record and made available to the contractor upon request.
- Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
- The submitted medical record must support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
- The medical record documentation must support the medical necessity of the services as directed in this policy.
- A profile of the patient’s use and a prescription for supplies should be submitted with a beneficiary new to the Contractor or a newly enrolled beneficiary. This should be submitted with the first claim to the Contractor or if the beneficiary has not previously been enrolled in this program with the Contractor.

Drug Wastage Documentation Requirements

Any amount wasted must be clearly documented in the medical record, regardless of whether the JW modifier will be used in billing for the drug/biological, with:

- Date and time.
- Amount of medication wasted.
- Reason for the wastage.

Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Claims for blood-clotting factors for hemophilia patients with these diagnoses may be covered if the patient is competent to use such factors without medical supervision. The amount of clotting factors determined to be necessary to have on hand and thus covered under this provision is based on the historical utilization pattern or profile developed by the contractor for each patient. It is expected that the treating source, e.g., a family physician or comprehensive hemophilia diagnostic and treatment center, has such information. From this data, the contractor is able to anticipate and make reasonable projections concerning the quantity of clotting factors the patient will need over a specific period of time. Unanticipated occurrences involving extraordinary events, such as automobile accidents or inpatient hospital stays, will change this baseline data and should be appropriately considered. In addition, changes in a patient’s medical needs over a period of time require adjustments in the profile. (Reference: Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, Section 50.5.5 – Hemophilia Clotting Factors).

Notice: This LCD imposes utilization guideline limitations. Despite Medicare allowing up to these maximums, each patient’s condition and response to treatment must medically warrant the number of services reported for payment. Medicare requires the medical necessity for each service reported to be clearly demonstrated in the patient’s medical record. Medicare expects that patients will not routinely require the maximum allowable number of services.

Sources of Information and Basis for Decision

Contractor is not responsible for the continued viability of websites listed.


Prescribing information for various factor products discussed.

Studies on Emerging (Still Non-Covered) Indications


Other Contractor Policies
Contractor Medical Directors

Other Contractor Local Coverage Determinations

"Hemophilia Clotting Factors," Arkansas BlueCross BlueShield (Pinnacle) LCD, (NM, OK) L16113.


Novitas Solutions, Inc. - JH Local Coverage Determination (LCD) Consolidation Narrative Justification - Most Clinically Appropriate LCD

LCDs Compared:
L31431, Hemophilia Factor Products, TrailBlazer (A/B) - CO, NM, OK, TX
L16113, Hemophilia Clotting Factors, PBSI (B) - AR, LA
L31022, Hemophilia Clotting Factors PBSI (A) - LA, MS
L24722, Hemophilia Clotting Factors PBSI (A) - AR

CMD Rationale:

First, using an assessment of whether apparent edits (including frequency limits) are more likely to promote clinically appropriate use of such LCD services, the following comparisons are noted:

TrailBlazer LCD #1 does a good job with somewhat more well-articulated coding structure than PBSI LCDs #2-4 (duplicates).

Second, with respect to the text in the Indications...Section being well-corralted with those separately-listed procedure-to-diagnosis code pairings, the following findings are noted:

TrailBlazer does a good job, with superior clinical detail. PBSI does a satisfactory job.

Third, none of the LCDs have literature-based summaries, such that this is not a discriminating factor between the three LCDs.

Fourth, TrailBlazer and PBSI are likely amenable to MR activities, but TrailBlazer likely more helpful per more extensive clinical detail noted above.

Overall choice is TrailBlazer LCD #1, L31431, based upon a combination of all of the above discussion factors. L31431 is the most clinically appropriate LCD.

Revision History Information

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<tr>
<td><strong>Revision Number</strong></td>
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Link to this LCD on the MCD:

Looking for more detail? View this policy at the CNS Medicare Coverage Database (MCD) for your state by choosing the appropriate link:

Arkansas | Louisiana | Mississippi | Colorado | Texas | Oklahoma | New Mexico

Associated Documents

Attachments
N/A

Related Local Coverage Documents
N/A

Related National Coverage Documents
N/A

Keywords
N/A