Hemophilia Products – Anti-Inhibitor Coagulant Complex: Feiba NF/Feiba VF (Intravenous)

Effective date: 01/01/2020

Review date: 10/02/2019, 12/18/19, 1/22/20, 06/24/2021

Revision date: 12/18/19, 1/22/20, 06/24/2021

Scope: Medicaid*, Commercial*, Medicare-Medicaid Plan (MMP)

*(Medication only available on the Medical Benefit)

I. Length of Authorization

Unless otherwise specified**, the initial authorization will be provided for 3 months and may be renewed every 12 months thereafter.

*Note: The cumulative amount of medication the patient has on-hand will be taken into account for authorizations.

** Initial and renewal authorization periods may vary by specific covered indication

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

II. Dosing Limits

A. Quantity Limit (max daily dose):
   - Feiba 500 IU (Orange) vial: 293 vials per 30-day supply
   - Feiba 1000 IU (Green) vial: 147 vials per 30-day supply
   - Feiba 2500 IU (Purple) vial: 59 vials per 30-day supply

B. Max Units (per dose and over time) [Medical Benefit]:
   146,625 billable units per 30 day supply

III. Initial Approval Criteria

- MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

Hemophilia A (congenital factor VIII deficiency) † Φ

- Diagnosis of congenital factor VIII deficiency has been confirmed by blood coagulation testing; **AND**
- Confirmation the patient has inhibitors to Factor VIII; **AND**
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); **OR**
Perioperative management *(Authorizations valid for 1 month)*; OR
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
  - Patient has at least two documented episodes of spontaneous bleeding into joints; OR
  - Patient has a documented trial and failure of Immune Tolerance Induction (ITI); AND
    - Patient has a documented trial and failure or contraindication to emicizumab-kxwh therapy.

**Hemophilia B (congenital factor IX deficiency aka Christmas disease) † Φ**
- Diagnosis of congenital factor IX deficiency has been confirmed by blood coagulation testing; AND
- Confirmation the patient has inhibitors to Factor IX; AND
- Used as treatment in at least one of the following:
  - Control and prevention of acute bleeding episodes (episodic treatment of acute hemorrhage); OR
  - Perioperative management *(Authorizations valid for 1 month)*; OR
  - Routine prophylaxis to prevent or reduce the frequency of bleeding episodes; AND
    - Patient has at least two documented episodes of spontaneous bleeding into joints; OR
  - Patient has documented trial and failure of Immune Tolerance Induction (ITI)

† FDA Approved Indication(s); Φ Orphan Drug

### IV. Dispensing Requirements for Rendering Providers (Hemophilia Management Program)

- Prescriptions cannot be filled without an expressed need from the patient, caregiver or prescribing practitioner. Auto-filling is not allowed.
- Monthly, rendering provider must submit for authorization of dispensing quantity before delivering factor product. Information submitted must include:
  - Original prescription information, requested amount to be dispensed, vial sizes available to be ordered from the manufacturer, and patient clinical history (including patient product inventory and bleed history)
  - Factor dose should not exceed +1% of the prescribed dose and a maximum of three vials may be dispensed per dose. If unable to provide factor dosing within the required threshold, below the required threshold, the lowest possible dose able to be achieved above +1% should be dispensed. Prescribed dose should not be increased to meet assay management requirements.
- The cumulative amount of medication(s) the patient has on-hand should be taken into account when dispensing factor product. Patients should not have more than 5 extra doses on-hand for the treatment of acute bleeding episodes.
- Dispensing requirements for renderings providers are a part of the hemophilia management program. This information is not meant to replace clinical decision making when initiating or modifying medication therapy and should only be used as a guide.
V. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified in section III; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: symptoms of allergic-anaphylactic reactions (anaphylaxis, dyspnea, rash, etc.); thromboembolic events (venous thrombosis, pulmonary embolism, myocardial infarction, stroke, etc.), development of neutralizing antibodies (inhibitors), etc.; AND
- Any increases in dose must be supported by an acceptable clinical rationale (i.e. weight gain, half-life study results, increase in breakthrough bleeding when patient is fully adherent to therapy, etc.); AND
- The cumulative amount of medication(s) the patient has on-hand will be taken into account when authorizing. The authorization will allow up to 5 doses on-hand for the treatment of acute bleeding episodes as needed for the duration of the authorization; AND

Treatment of acute bleeding episodes/Treatment of Spontaneous and trauma-induced bleeding episodes/On-demand treatment of bleeding episodes

- Renewals will be approved for a 6 month authorization period

Prevention of acute bleeding episodes/Routine prophylaxis to prevent or reduce the frequency of bleeding episode

- Renewals will be approved for a 12 month authorization period; AND
- Patient has demonstrated a beneficial response to therapy (i.e., the frequency of bleeding episodes has decreased from pre-treatment baseline)

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control and prevention of bleeding Congenital Hemophilia A / Hemophilia B with inhibitors</td>
<td><strong>Joint hemorrhage</strong>&lt;br&gt;50—100 units/kg IV every 12 hours until pain and acute disabilities are improved&lt;br&gt;<strong>Mucous Membrane Bleeding</strong>&lt;br&gt;50—100 units/kg IV every 6 hours for at least 1 day or until bleeding is resolved&lt;br&gt;<strong>Soft tissue hemorrhage</strong>&lt;br&gt;100 units/kg IV every 12 hours until resolution of bleeding&lt;br&gt;<strong>Other severe hemorrhage</strong>&lt;br&gt;100 units/kg IV every 6—12 hours until resolution of bleed</td>
</tr>
<tr>
<td>Routine Prophylaxis Congenital Hemophilia A / Hemophilia B with inhibitors</td>
<td>85 units/kg IV every other day</td>
</tr>
</tbody>
</table>
### Indication Dose

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perioperative management Congenital Hemophilia A / Hemophilia B with inhibitors</td>
<td>50—100 units/kg IV administered as a 1 time dose immediately prior to surgery OR 50 – 100 units/kg IV administered every 6 – 12 hours postoperatively until resolution of bleed and healing is achieved</td>
</tr>
</tbody>
</table>

### VI. Billing Code/Availability Information

**HCPCS Code & NDC:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Manufacturer</th>
<th>J-Code</th>
<th>1 Billable Unit Equiv.</th>
<th>Vial Size</th>
<th>NDC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feiba NF</td>
<td>Baxalta US Inc</td>
<td>J7198</td>
<td>1 IU</td>
<td>500 units</td>
<td>64193-0426-xx</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1000 units</td>
<td>64193-0424-xx</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2500 units</td>
<td>64193-0425-xx</td>
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</table>

### VII. References


Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D66</td>
<td>Hereditary factor VIII deficiency</td>
</tr>
<tr>
<td>D67</td>
<td>Hereditary factor IX deficiency</td>
</tr>
</tbody>
</table>

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): H,L
NCD/LCD Document (s): L35111

Jurisdiction(s): N
NCD/LCD Document (s): L33684

Medicare Part B Administrative Contractor (MAC) Jurisdictions

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>Jurisdiction</td>
<td>Applicable State/US Territory</td>
<td>Contractor</td>
</tr>
<tr>
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</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
</tr>
<tr>
<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>L (12)</td>
<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
<td>NY, CT, MA, RI, VT, ME, NH</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
</tr>
</tbody>
</table>