Coding and Reimbursement Guide

Diagnosis, NDC, and ICD-10-CM* billing codes for Antihemophilic Factor (Recombinant), Single Chain

Effective June 2017
# AFSTYLA Coding Information

## Diagnosis and billing codes for Antihemophilic Factor (Recombinant), Single Chain

Disclaimer: The codes being provided are from a complex and evolving medical coding system. The treating physician is solely responsible for diagnosis coding and determination of the appropriate ICD-10-CM codes that describe the patient’s condition and are supported by the medical record. All codes are for informational purposes and are not an exhaustive list. The CPT®, HCPCS, ICD-10-CM, and ICD-10-PCS codes provided are based on AMA or CMS guidelines. The billing party is solely responsible for coding of services (eg, CPT® coding). Because government and other third-party payor coding requirements change periodically, please verify current coding requirements directly with the payor being billed.

### ICD-10-CM Diagnosis Code

The following ICD-10-CM code may be used to identify patient medical conditions typically associated with hemophilia A.

<table>
<thead>
<tr>
<th>ICD-10-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D66</td>
<td>Hereditary Factor VIII deficiency</td>
</tr>
</tbody>
</table>

### HCPCS Codes

The following represents possible drug codes for AFSTYLA (Antihemophilic Factor [Recombinant], Single Chain). The prescriber is advised to verify with the payor or Medicare fiscal intermediary to determine the correct code(s).

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
</tr>
<tr>
<td>J7199</td>
<td>Hemophilia clotting factor, not otherwise classified</td>
</tr>
<tr>
<td>C9140</td>
<td>Injection, Factor VIII (antihemophilic factor, recombinant) (AFSTYLA), 1 IU</td>
</tr>
</tbody>
</table>

When using not otherwise classified codes, be sure to include the drug NDCs for AFSTYLA and the total number of Factor VIII units printed on the carton.

### AFSTYLA National Drug Codes (NDCs)

The bolded “0” below represents the additional digit required for 11-digit formatting, which must be used for claims filing.

<table>
<thead>
<tr>
<th>NDC</th>
<th>Fill Size Color Indicator</th>
<th>Nominal Strength* International Units (IU)</th>
<th>NDC</th>
<th>Fill Size Color Indicator</th>
<th>Nominal Strength* International Units (IU)</th>
</tr>
</thead>
<tbody>
<tr>
<td>69911-0474-02</td>
<td>Orange</td>
<td>250 IU of coagulation Factor VIII</td>
<td>69911-0477-02</td>
<td>Purple</td>
<td>2000 IU of coagulation Factor VIII</td>
</tr>
<tr>
<td>69911-0475-02</td>
<td>Blue</td>
<td>500 IU of coagulation Factor VIII</td>
<td>69911-0481-02</td>
<td>Gray</td>
<td>2500 IU of coagulation Factor VIII</td>
</tr>
<tr>
<td>69911-0476-02</td>
<td>Green</td>
<td>1000 IU of coagulation Factor VIII</td>
<td>69911-0478-02</td>
<td>Yellow</td>
<td>3000 IU of coagulation Factor VIII</td>
</tr>
<tr>
<td>69911-0480-02</td>
<td>Turquoise</td>
<td>1500 IU of coagulation Factor VIII</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Report the actual number of Factor VIII units printed on the vial or carton.

Please see Important Safety Information on page 10 and accompanying full prescribing information.
AFSTYLA Drug Administration Codes

CPT® administration codes: outpatient facilities or physician’s office

The following CPT® codes describe the procedure of AFSTYLA administration and will vary depending on the length of the infusion.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96374</td>
<td>Intravenous push, single or initial substance/drug—report for infusion of 15 minutes or less</td>
</tr>
<tr>
<td>96376</td>
<td>Each additional sequential intravenous push of the same substance/drug provided in a facility (Facility use only—list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>96365</td>
<td>Intravenous infusion, for therapy, prophylaxis, or diagnosis, initial, up to 1 hour</td>
</tr>
</tbody>
</table>

Images are a representation, not actual depiction of vials.
AFSTYLA CMS-1500 Claim Form

Claim form example

Please see Important Safety Information on page 10 and accompanying full prescribing information.
AFSTYLA CMS-1500 Claim Form Details

A Field 19: Additional Claim Information

When one of the unclassified drug HCPCS codes (J3590, J7199) is used, the provider must include additional information about AFSTYLA in a free-text field, such as Field 19 or its electronic equivalent. Payors typically require the name of the drug, its NDC, the route of administration, and the amount used to care for the treatment. For example:

AFSTYLA NDC 69911-0477-02; IV infusion; 2000 units

NDC Code: Note that the 10-digit NDC code for AFSTYLA is converted to an 11-digit billing format by inserting a zero in the second segment. The NDC code format on the package is XXXXX-XXX-XX; the 11-digit billing format is XXXXX-0XXX-XX.

Amount of AFSTYLA Used to Care for the Patient: This includes the number of units administered to the patient plus any units in a single-use vial that are documented as discarded. Although wastage is typically included in total units reported, some payors may require that wastage be reported separately with modifier “JW.” Effective January 1, 2017, Medicare claims for discarded drugs or biologicals amount not administered to any patient shall be submitted using the JW modifier.

B Field 21: Diagnosis or Nature of Illness of Injury

Enter the ICD-10-CM diagnosis code(s) that best describe the reason the patient is receiving care.

C Field 24: Shaded Area

For Medicaid claims, and for Medicare claims that will cross over to Medicaid as the secondary payor, NDC information in a specific format is required in the shaded area above the line on which AFSTYLA is reported in Field 24D. The various Medicaid plans and Medicare have different reporting formats for this information. In general, the provider will need to supply the NDC in an 11-digit format preceded by the modifier N4 (N4XXXXX-0XXX-XX). This is typically followed by the NDC unit of measure (F2 [International Units]) and the numeric quantity of the NDC that was dispensed.

Other payors may require similar information. Check with the payor for specific requirements.

D Field 24D: CPT/HCPCS

HCPCS coding options for AFSTYLA are:
- J3590 (Unclassified biologics)
- J7199 (Hemophilia clotting factor, not otherwise classified)

CPT® coding options for the IV infusion/IV push of AFSTYLA are:
- 96365 (Intravenous infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour)
- 96374 (Therapeutic, prophylactic, or diagnostic injection; intravenous push, single or initial substance/drug). Report 96374 for infusion of 15 minutes or less

The code selected is based on the documented service provided to the patient.

E Field 24E: Diagnosis Pointer

Enter the line number(s) from Field 21 that best describes the medical necessity for the service.

F Field 24G: Days or Units

Requirements for Field 24G vary by payor. For example, some payors rely on the information in Field 19 for these data and request a placeholder of “1” in Field 24G. Other payors may require 1 unit per unit of drug used in the care of the patient.

Please see Important Safety Information on page 10 and accompanying full prescribing information.
AFSTYLA Inpatient Codes

ICD-10-PCS (procedure coding system)\textsuperscript{5}

The following codes apply to the hospital inpatient setting.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>ICD-10 Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infusion of Factor VIII</td>
<td>30233V1</td>
<td>Transfusion of Nonautologous Antihemophilic Factors Into Peripheral Vein, Percutaneous Approach</td>
</tr>
<tr>
<td>Infusion of Factor VIII</td>
<td>30243V1</td>
<td>Transfusion of Nonautologous Antihemophilic Factors Into Central Vein, Percutaneous Approach</td>
</tr>
</tbody>
</table>

Please see Important Safety Information on page 10 and accompanying full prescribing information.
**Hospital revenue codes**

Revenue codes may apply to AFSTYLA in the inpatient and outpatient settings and are used in conjunction with drug HCPCS codes.

<table>
<thead>
<tr>
<th>Category</th>
<th>Code Series</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy</td>
<td>025X</td>
<td>Pharmacy</td>
</tr>
<tr>
<td>Hospital blood service</td>
<td>038X</td>
<td>Blood and blood derivatives</td>
</tr>
<tr>
<td>Drugs that require specific identification</td>
<td>0636</td>
<td>Revenue code 0636 is necessary for submitting Medicare claims for blood clotting factors provided in a hospital</td>
</tr>
</tbody>
</table>
AFSTYLA UB-04 Claim Form (CMS 1450)

Claim form example

<table>
<thead>
<tr>
<th>A: PATIENT NAME</th>
<th>B: DATE OF BIRTH</th>
<th>C: SEX</th>
<th>D: INSURED’S UNIQUE ID</th>
<th>E: GROUP NAME</th>
<th>F: EMPLOYER NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td>01/01/2023</td>
<td>M</td>
<td>123456</td>
<td>Acme Corp</td>
<td>Example Corp</td>
</tr>
</tbody>
</table>

Please see Important Safety Information on page 10 and accompanying full prescribing information.
### A Field 42: Revenue Code
Enter a revenue code that corresponds to the item or service reported in Field 43 or Field 44. The revenue code associated with AFSTYLA is typically “0636” (drugs requiring detailed coding). However, the revenue code selected is often facility dependent, taking into consideration various payor requirements.

### B Field 43: Description
If the payor accepts or expects HCPCS code J3590 or J7199 for AFSTYLA, additional information about AFSTYLA must be provided in a free-text field such as Field 80 or its electronic equivalent. Payors typically require the name of the drug, its NDC, the route of administration, and the amount of AFSTYLA used to care for the patient.

Some payors may require this information in Field 43 instead of Field 80. The formatting of the NDC code and the units used to care for the patient are highly variable by payor. Formatting should be verified with the payor to which the claim will be filed.

**NDC Code:** Note that the 10-digit NDC code for AFSTYLA is converted to an 11-digit billing format by inserting a zero in the second segment. The NDC code format on the package is XXXXX-XXX-XX; the 11-digit billing format is XXXXX-0XXX-XX.

**Amount of AFSTYLA Used to Care for the Patient:** This includes the number of units administered to the patient and any units in a single-use vial that the institution documents as discarded. Although wastage is typically included in total units reported, some payors may require that wastage be reported separately with modifier JW.

### C Field 44: HCPCS/Rate/HIPPS Code
If the payor accepts or expects line-item reporting for AFSTYLA, HCPCS coding options are:
- **J3590** (Unclassified biologics)
- **J7199** (Hemophilia clotting factor, not otherwise classified)

For Medicare Hospital Inpatient and Outpatient Claims
- **C9140** Factor VIII (antihemophilic factor, recombinant), AFSTYLA, 1 IU

**Effective January 1, 2017, Medicare claims for discarded drugs or biologicals amount not administered to any patient shall be submitted using the JW modifier.** For AFSTYLA this is captured on a separate line in Field 44, such as C9140JW, plus any units in a single-use vial, that are documented as discarded in Field 46.

When filing an outpatient claim on a separate line, enter the CPT code that represents the administration procedure performed.

### D Field 46: Service Units
When HCPCS code J3590 or J7199 is reported in Field 44, a unit code must be reported in Field 46. Requirements for Field 46 vary by payor. For example, some payors rely on the information in Field 80 or 43 for these data and request a placeholder of “1” in Field 46. Other payors may require 1 unit per unit of drug used in the care of the patient.

**Code C9140:** Enter one billing unit for every international unit (IU) of AFSTYLA printed on the vial or carton.

### E Field 67: Diagnosis
Enter the primary ICD-10-CM diagnosis code in Field 67. Conditions that coexist with the primary diagnosis or develop during treatment can be entered in Fields 67A–67Q.

### F Fields 74: Principal Procedure and 74A–74E
When filing an inpatient claim to Medicare, enter ICD-10-CM procedure code, for example 30233V1 Transfusion of Nonaugotologous Antihemophilic Factors Into Peripheral Vein, Percutaneous.

### G Field 80: Remarks
If the payor accepts or expects HCPCS code J3590 or J7199 for AFSTYLA, additional information about AFSTYLA must be provided in a free-text field, such as Field 80 or its electronic equivalent. Payors typically require the name of the drug, its NDC, the route of administration, and the amount of AFSTYLA used to care for the patient. For example:

**AFSTYLA NDC 69911-0476-02, IV 1000 IUs**

Some payors may require this information in Field 43 instead of Field 80. The formatting of the NDC code and the units used to care for the patient in Field 43 are highly variable by payor. Formatting should be verified with the payor to which the claim will be filed.

**NDC Code:** Note that the 10-digit NDC code for AFSTYLA is converted to an 11-digit billing format by inserting a zero in the second segment. The NDC code format on the package is XXXXX-XXX-XX; the 11-digit billing format is XXXXX-0XXX-XX.

**Amount of AFSTYLA Used to Care for the Patient:** This includes the number of units administered to the patient plus any units in a single-use vial that the hospital documents as discarded. Although wastage is typically included in total units reported, some payors may require that wastage be reported separately with modifier JW.
Call Now for Reimbursement Support

AFSTYLA reimbursement and access support is available free of charge through My SourceSM for AFSTYLA.

Call Monday–Friday 8 AM to 8 PM ET 1-800-676-4266

My Source for AFSTYLA offers services* above and beyond reimbursement support, including:

• AFSTYLA Trial Program — Get your patients a free one-month prescription to see if AFSTYLA is right for them†
• Co-pay savings — The My Access® for AFSTYLA program can cover up to $12,000 of patient out-of-pocket expenses
• CSL Behring AssuranceSM Program — This program can make AFSTYLA available when there is a lapse in insurance coverage

*Terms and conditions apply.
†Because dosing is based on various patient considerations, there may be a cap to the 30-day supply.

Indications and Important Safety Information

AFSTYLA is indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:

• On-demand treatment and control of bleeding episodes
• Routine prophylaxis to reduce frequency of bleeding episodes
• Perioperative management of bleeding

AFSTYLA is not indicated for the treatment of von Willebrand disease.

AFSTYLA is contraindicated in patients who have had life-threatening hypersensitivity reactions to AFSTYLA or its excipients, or to hamster proteins.

AFSTYLA is for intravenous use only. AFSTYLA can be self-administered or administered by a caregiver with training and approval from a healthcare provider or hemophilia treatment center. Higher and/or more frequent dosing may be needed for patients under 12 years of age.

Hypersensitivity reactions, including anaphylaxis, are possible. Advise patients to immediately report symptoms of a hypersensitivity reaction. If symptoms occur, discontinue AFSTYLA and administer appropriate treatment.

Development of Factor VIII (FVIII) neutralizing antibodies (inhibitors) can occur. If expected FVIII activity levels are not attained or bleeding is not controlled with appropriate dose, perform an assay to measure FVIII inhibitor concentration.

Monitor plasma FVIII activity using a chromogenic assay or one-stage clotting assay. If one-stage clotting assay is used, multiply result by a conversion factor of 2 to determine FVIII activity level.

The most common adverse reactions reported in clinical trials (>0.5%) were dizziness and hypersensitivity. Please see accompanying full prescribing information.


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