



KOVALTRY® Antihemophilic Factor (Recombinant)
HPCS code J7211¹

YOUR GUIDE TO KOVALTRY® BILLING AND CODING

**Informative coding and reimbursement
information for your office**

Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. This resource is not intended as legal advice or as a substitute for a provider's independent professional judgment.

INDICATIONS

- ▶ KOVALTRY® Antihemophilic Factor (Recombinant) is a recombinant human DNA sequence derived, full length Factor VIII concentrate indicated for use in adults and children with hemophilia A for:
 - ▶ On-demand treatment and control of bleeding episodes
 - ▶ Perioperative management of bleeding
 - ▶ Routine prophylaxis to reduce the frequency of bleeding episodes
- ▶ KOVALTRY® is not indicated for the treatment of von Willebrand disease.

SELECTED IMPORTANT SAFETY INFORMATION

- ▶ KOVALTRY® is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, to any of the excipients, or to mouse or hamster proteins.

Please see additional Important Safety Information throughout and the accompanying full [Prescribing Information](#).



Antihemophilic Factor (Recombinant)

CODING INFORMATION FOR KOVALTRY®

Antihemophilic Factor (Recombinant)

All codes are for informational purposes and are not an exhaustive list. The billing party is solely responsible for coding of services, and all codes should be verified between the provider and payer.

Diagnosis Code

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes ²	Description
D66	Hereditary Factor VIII deficiency

Some state Medicaid programs may require the use of local coding for KOVALTRY® and the associated procedures. Providers should verify Medicaid coding guidelines on a state-specific basis.

HCPCS Code

Healthcare Common Procedure Coding System (HCPCS) Code ¹	Description
J7211 Injection, Kovaltry®, 1 IU	Injection, Factor VIII, (Antihemophilic Factor, Recombinant), (Kovaltry®), 1 IU

The HCPCS code, J7211, replaces the miscellaneous HCPCS codes that some providers have used to bill for KOVALTRY®, such as J7192 Factor VIII (antihemophilic factor, recombinant) per IU, not otherwise specified and J7199 Hemophilia clotting factor, not otherwise classified.^{1,3}

KOVALTRY® National Drug Codes (NDCs)⁴



250IU*
Billing NDC#
0026-3821-25
Diluent (mL)
2.5



500IU*
Billing NDC#
0026-3822-25
Diluent (mL)
2.5



1000IU*
Billing NDC#
0026-3824-25
Diluent (mL)
2.5



2000IU*
Billing NDC#
0026-3826-50
Diluent (mL)
5.0



3000IU*
Billing NDC#
0026-3828-50
Diluent (mL)
5.0

Some health insurance plans, including Medicaid and TRICARE, require the 11-digit NDC format when billing for KOVALTRY®. For KOVALTRY®, the 10-digit NDC code is converted to an 11-digit billing format by inserting a zero in the first segment. If the NDC code on the package is XXXX-XXXX-XX, the 11-digit billing format is 0XXXX-XXXX-XX. Confirm NDC billing instructions with each health insurance company, as requirements may vary.

*Report the total number of Factor VIII units printed on the label of the KOVALTRY® vial.

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- Hypersensitivity reactions, including anaphylaxis, are possible with KOVALTRY®. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. Discontinue KOVALTRY® if symptoms occur and seek immediate emergency treatment.

DRUG ADMINISTRATION CODES

Current Procedural Terminology (CPT) codes

Note that health insurance companies may not cover all of the procedures listed here. Always check coverage prior to scheduling any procedure.

CPT Code ^{5,6}	Setting	Description
96374	Physician/ outpatient	Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96376	Physician/ outpatient	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of the same substance/drug provided in a facility (list separately in addition to code for primary procedure)

Product Code

Hospital Revenue Code ⁷	Description
0636	Pharmacy, drugs requiring detailed coding

SELECTED IMPORTANT SAFETY INFORMATION

- KOVALTRY® may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.

Reimbursement Support, Coverage, Financial and Affordability Solutions

Call 1-800-288-8374 NOW!

9:00 AM–6:00 PM (ET) Monday-Friday.

Multiple languages available, including Spanish.

Access Services by Bayer Provides:

- Product coding
- Information on appealing claim denials
- Payer-specific coverage policy knowledge
- Referrals for additional financial assistance
- Patient-specific benefits verification and prior authorization support

\$0 Co-pay Program*†

Eligible commercially insured patients can pay as low as \$0 per prescription, regardless of income. **(Up to \$20,000 in co-pay assistance per year.)**

Patient Loyalty Program†§

Eligible patients can receive KOVALTRY® Antihemophilic Factor (Recombinant) at no cost if they experience gaps or changes with insurance coverage.

Bayer is committed to helping your patients start and stay on therapy regardless of changes in their commercial health insurance coverage status

Free Trial Program†§

Talk to your patients about requesting a Free Trial of KOVALTRY® with vial adapter

Live Helpline Support

You or your patients can call for answers to any insurance coverage questions

*Co-pay program support is available for up to 1 year. Can include any out-of-pocket prescription costs, such as co-pay and co-insurance.

†Patients who are enrolled in any type of government insurance are not eligible. Bayer reserves the right to rescind, revoke, or amend this offer without notice at any time.

‡Participation in the Kovaltry® Free Trial Program is limited to 1 time only per product (patients currently using Kovaltry® are not eligible for a Free Trial of their current product). The Free Trial Program includes a 1 month supply up to a maximum of 40,000 IU. Bayer reserves the right to rescind, revoke, or amend this offer without notice at any time.

§The medication provided through this program is at no cost to the patient and is not contingent on future use of this medication. Reselling or billing any third party for free product provided by this program is prohibited by law.

Sample CMS-1450/UB-04 Claim Form

The CMS-1450/UB-04 form is used to bill for drugs administered in the hospital outpatient setting. Claims may need to be submitted manually if additional documentation is required and cannot be submitted electronically. Please ensure that claims are submitted in accordance with the patient's health insurance plan's current electronic claim submission processes.

The image shows a sample CMS-1450/UB-04 Claim Form. Callout A points to the Revenue Code and Description fields (42 and 43). Callout B points to the HCPCS/RATE/Health Insurance Prospective Payment System (HIPPS) Code field (44). Callout C points to the Service Units field (46). Callout D points to the Diagnosis field (66).

- A Field 42 and 43 Revenue Code and Description**
Enter the appropriate revenue code and description based on the cost center and service provided. Example below:
 - ▶ 0636, Drugs requiring detailed coding
- B Field 44 HCPCS/RATE/Health Insurance Prospective Payment System (HIPPS) Code**
Enter the appropriate HCPCS and CPT codes. Examples below:
 - ▶ J7211 Injection, Kovaltry® Antihemophilic Factor (Recombinant)®, 1 IU
 - ▶ 96374, Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
- C Field 46 Service Units**
Indicate the number of International Units (IUs).
- D Field 66 Diagnosis**
Enter the primary ICD-10-CM diagnosis code, eg, D66, hereditary factor VIII deficiency.



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Sample CMS-1500 Claim Form

The CMS-1500 claim form is used to bill for procedures and services in the physician office setting. Claims may need to be submitted manually if additional documentation is required and cannot be submitted electronically. Please ensure that claims are submitted in accordance with the payer's current electronic claim submission processes.

HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

Field 21 (A): DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. ICD-10-CM code: D66.

Field 24D (B): PROCEDURES, SERVICES, OR SUPPLIES. HCPCS code: J7211; CPT code: 96374.

Field 24E (C): DIAGNOSIS POINTER. Letter: A.

Field 24G (D): DAYS OR UNITS. Value: 1.

A Field 21 Diagnosis or Nature of Illness or Injury
Enter the appropriate ICD-10-CM code(s), eg, D66, hereditary factor VIII deficiency.

B Field 24D Procedures, Services, or Supplies
Enter the appropriate HCPCS and CPT codes. Examples below:

- J7211 Injection, Kovaltry® Antihemophilic Factor (Recombinant), 1 IU
- 96374 Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug

C Field 24E Diagnosis Pointer
Enter the letter (A-L) that corresponds to the diagnosis in Item FL 21.

D Field 24G Days or Units
Indicate the number of International Units (IUs).



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- ▶ KOVALTRY® may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.
- ▶ Neutralizing antibody (inhibitor) formation has occurred following administration of KOVALTRY®. Previously untreated patients (PUPs) are at greatest risk for inhibitor development with all Factor VIII products. Carefully monitor patients for the development of Factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma Factor VIII activity levels are not attained or if bleeding is not controlled as expected with administered dose, suspect the presence of an inhibitor.
- ▶ Hemophilic patients with cardiovascular risk factors or diseases may be at the same risk to develop cardiovascular events as non-hemophilic patients when clotting has been normalized by treatment with Factor VIII.
- ▶ Catheter-related infections may occur when KOVALTRY® is administered via central venous access devices (CVADs). These infections have not been associated with the product itself.
- ▶ The most frequently reported adverse reactions in clinical trials ($\geq 5\%$) were inhibitors in previously untreated patients (PUPs)/minimally treated patients (MTPs), and pyrexia, headache, and rash.

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Antihemophilic Factor (Recombinant)

For more information about submitting claims for KOVALTRY® Antihemophilic Factor (Recombinant), please see pages 5 and 6.

References:

1. Centers for Medicare & Medicaid Services. 2019 Alpha-Numeric HCPCS File. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2019-Alpha-Numeric-HCPCS-File.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>. Accessed May 8, 2019.
2. ICD10Data website. <https://www.icd10data.com/ICD10CM/Codes/D50-D89/D65-D69/D66-/D66>. Accessed May 8, 2019.
3. Centers for Medicare & Medicaid Services. Local coverage determination coding guidelines. https://downloads.cms.gov/medicare-coverage-database/lcd_attachments/31078_9/131078_inj003_cbg_070111.pdf. Accessed May 8, 2019.
4. KOVALTRY® Ordering Information. <https://www.kovaltryhcp.com/?url=ordering-information>. Accessed May 8, 2019.
5. UnitedHealthcare Provider website. Injection and infusion services policy. <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/medadv-reimbursement/MEDADV-Non-Chemotherapy-Injection-Infusion-Services-Policy.pdf>. Accessed October 24, 2023.
6. UnitedHealthcare Provider website. Injection and infusion services policy. <https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-Outpatient-Hospital-Add-On-Codes-Policy-Facility.pdf>. Accessed October 24, 2023.
7. CMS website. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf>. Accessed May 8, 2019.



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