Jivi®

antihemophilic factor
(recombinant) PEGylated-aucl

YOUR GUIDE TO JIVI BILLING AND CODING

A comprehensive resource for
billing and coding 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

- Jivi® antihemophilic factor (recombinant), PEGylated-aucl, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for:
  - On-demand treatment and control of bleeding episodes
  - Perioperative management of bleeding
  - Routine prophylaxis to reduce the frequency of bleeding episodes
- Limitations of use:
  - Jivi® is not indicated for use in children less than 12 years of age due to a greater risk for hypersensitivity reactions.
  - Jivi® is not indicated for use in previously untreated patients (PUPs).
  - Jivi® is not indicated for the treatment of von Willebrand disease.

SELECTED IMPORTANT SAFETY INFORMATION

- Jivi is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.

Please see both the Jivi® full Prescribing Information and full Important Safety Information on page 15.

HELPFUL TOOLS TO ACCESS JIVI®, antihemophilic factor (recombinant), PEGylated-aucl

Bayer is committed to providing coverage and reimbursement support so your patients can access Jivi®

This guide contains resources needed to support healthcare providers and office staff with coding, billing, and obtaining reimbursement for Jivi®.

WHAT IS IN THIS GUIDE?

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- Hypersensitivity reactions, including severe allergic reactions, have occurred with Jivi®. Monitor patients for hypersensitivity symptoms. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. If hypersensitivity reactions occur, immediately discontinue administration and initiate appropriate treatment.

The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to health plans and for compliance with any obligations required by law, contract, or otherwise.

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antihemophilic factor (recombinant) PEGylated-aucl

STEPS TO ACCESSING JIVI®, antihemophilic factor (recombinant), PEGylated-aucl

To access Jivi® for your patients, just follow these simple steps. You can find more details about each step within this guide.

1 Check your contracted rates

2 Verify the patient's benefits to determine:

- How Jivi® will be covered
- Patient cost-sharing responsibilities

3 File a claim for reimbursement

4 Review the patient's Explanation of Benefits (EOB)

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- Jivi® may contain trace amounts of mouse and hamster proteins. Patients treated with this product may develop hypersensitivity to these non-human mammalian proteins.
- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).

Please see both the Jivi® full Prescribing Information and full Important Safety Information on page 15.

For more information about accessing Jivi®, contact Access Services by Bayer:

1-800-288-8374 www.hcp.jivi.com

Jivi®
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Access Services by Bayer™ ACCESS SERVICES BY BAYER

Patient support, financial and affordability solutions

Access Services by Bayer offers Jivi®, antihemophilic factor (recombinant), PEGylated-aucl patients, prescribers and their office staff various resources and practical suggestions for their coding, billing, and reimbursement questions.

It includes several programs and services, such as the:

$0 Co-pay Program*†

- Eligible commercially insured patients can pay as low as $0 per prescription, regardless of income. **(Up to program maximum for eligible patients.)**

Free Trial Program‡§

- Talk to your patients about requesting a free trial of Jivi® with vial adapter

Patient Loyalty Program†§

- Eligible patients can receive Jivi® **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

Live Helpline Support – 1-800-288-8374

- You or your patients can call for answers to any insurance coverage questions. Multiple languages available.

Access Services by Bayer Provides:

- Product coding
- Patient-specific benefits verification
- Prior authorization and appeals assistance
- Patient support including Free Trial Offers, the $0 Co-pay Program and the Loyalty Program for eligible patients
- Additional financial assistance – BUSPAF and Charitable Foundations.

*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. See https://copaysupport.bayer.com for full program details. Eligible patients will be auto-enrolled every January.

†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 Jivi® Free Trial Program is limited to 1 time only per product (patients currently using Jivi® 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. The Free Trial Program for Jivi® is available to patients 12 years of age and older. 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.

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- Neutralizing antibody (inhibitor) formation can occur following administration of Jivi®. 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 (neutralizing antibody).

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CHECK YOUR CONTRACTED RATES

Prior to prescribing Jivi®, antihemophilic factor (recombinant), PEGylated-aucl, you should check your current allowable rates for the product per your individual health insurance contracts.

Please note that your office will have to contact the health insurance company directly to obtain this information.

VERIFY THE PATIENT'S BENEFITS

It is important to verify each patient's benefits to determine coverage and billing requirements.

- Coverage should be checked for Jivi®
- Access Services by Bayer can also provide support with benefits investigations
- This can be done by your own office personnel, a specialty pharmacy, or occasionally by the patient

What you can expect from Access Services by Bayer

Access Services by Bayer can provide support with:

- Determining whether Jivi® is covered under the medical or pharmacy benefit
- Identifying utilization restrictions such as prior authorizations
- Confirming patient cost-share information

To request support with obtaining a benefits investigation from Access Services by Bayer, call 1-800-288-8374 or complete and submit the Patient Support Service Request Form.

The Patient Support Service Request Form can be found online at: https://www.jivihcp.com/en/copay-support

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- A clinical immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has been observed primarily in patients < 6 years of age. The symptoms of the clinical immune response were transient. Anti-PEG IgM titers decreased over time to undetectable levels. No immunoglobulin class switching was observed.

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For more information about accessing Jivi®, contact Access Services by Bayer:

 1-800-288-8374  www.hcp.jivi.com

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VERIFY THE PATIENT'S BENEFITS (cont'd)

Benefits investigation

Office personnel may verify a patient's Jivi®, antihemophilic factor (recombinant), PEGylated-aucl coverage by contacting the patient's health insurance company directly. The phone number can usually be found on the patient's insurance card. It may be helpful to record the following information when verifying benefits from the payer:

- The reference number of the call
- The full name of the individual quoting the benefits
- The date and time of the call
- Other important details

Questions to ask during a benefits investigation

- Can you check coverage for Jivi® under both the medical and pharmacy benefits?
- What is the patient's financial responsibility, including co-payment, co-insurance, and/or deductible? If the patient has a high deductible, how much has been met and does the cost of Jivi® apply to the deductible?
- What code should be used when billing Jivi®? What are the coverage and payment levels for all codes that will be billed?
- Is a prior authorization required?

Prior authorization

- Access Services by Bayer can also provide support with identifying when a health insurance plan requires a prior authorization.

If a patient does not have coverage or does not have insurance, the patient may be eligible for patient assistance. Access Services by Bayer can provide useful information about available options.

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- In case of clinical suspicion of loss of drug effect, conduct testing for Factor VIII inhibitors and Factor VIII recovery. A low post-infusion Factor VIII level in the absence of detectable Factor VIII inhibitors indicates that loss of drug effect is likely due to anti-PEG antibodies. Discontinue Jivi® and switch patients to a previously effective Factor VIII product.

The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to health plans and for compliance with any obligations required by law, contract, or otherwise.

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DRUG ADMINISTRATION CODES

Coding information for Jivi®

Healthcare providers are responsible for selecting appropriate codes used to file a claim. Codes should be based on the patient's diagnosis and the items and services furnished by the provider.

All codes listed in this guide 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.

HCPCS CODE

Healthcare Common Procedure Coding System (HCPCS) Code[1]	Description
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.

NOTE:
The HCPCS code, J7208, replaces the miscellaneous HCPCS codes that some providers have used to bill for Jivi® such as J7199 Hemophilia clotting factor, not otherwise classified.[1,6]

To learn more, see the pocket of this guide for the:

- Annotated CMS-1450/UB-04 claim form
- Annotated CMS-1500 claim form

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- The most frequently (≥5%) reported adverse reactions in clinical trials in previously treated patients (PTPs) ≥12 years of age were headache, cough, nausea, and fever.

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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 Jivi®, antihemophilic factor (recombinant), PEGylated-aucl, and the associated procedures. Providers should verify Medicaid coding guidelines on a state-specific basis.

JIVI® NATIONAL DRUG CODES (NDCs)[3]

Vial strength	500 IU	1000 IU	2000 IU	3000 IU
NDC	0026-3942-25	0026-3944-25	0026-3946-25	0026-3948-25

NDCs are universal product identifiers assigned to drugs upon FDA approval

Some health insurance plans, including Medicaid and TRICARE, require the 11-digit NDC format when billing for Jivi®. For Jivi®, 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.

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- Jivi is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.

The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to health plans and for compliance with any obligations required by law, contract, or otherwise.

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DRUG ADMINISTRATION CODES (cont'd)

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[4]	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[5]	Description
0636	Pharmacy, drugs requiring detailed coding

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- Hypersensitivity reactions, including severe allergic reactions, have occurred with Jivi®. Monitor patients for hypersensitivity symptoms. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. If hypersensitivity reactions occur, immediately discontinue administration and initiate appropriate treatment.

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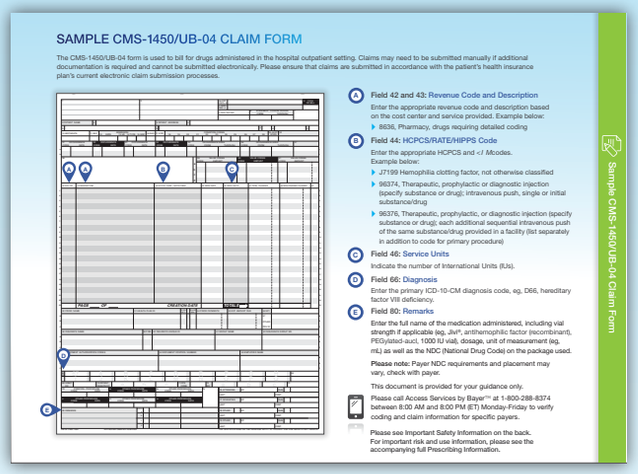
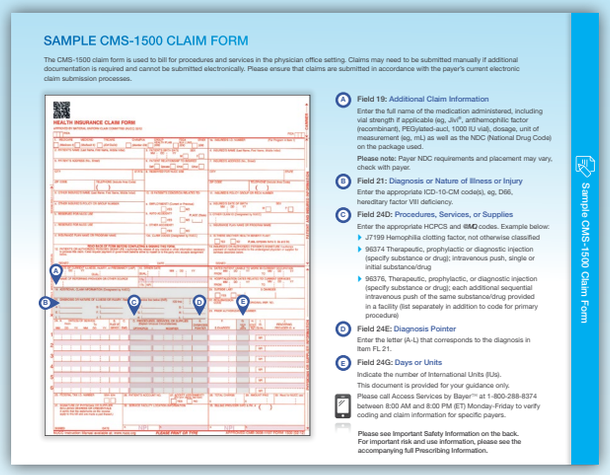
Completing the CMS-1450/UB-04 and CMS-1500 claim forms





The **CMS-1450/UB-04 claim form** is used by health insurance companies to bill for procedures and services in the hospital outpatient setting.

The **CMS-1500 claim form** is used by health insurance companies 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 patient's health insurance plan's current electronic claim submission processes.

The Annotated CMS-1450/UB-04 and CMS-1500 claim forms can be found:

- On pages 13 and 14 of this guide
- Online at www.hcp.jivi.com

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

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

The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to health plans and for compliance with any obligations required by law, contract, or otherwise.

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CLAIM TIPS

1 Use correct coding

- Accurate codes are essential to ensure prompt claim processing and reimbursement
- The health insurance company may provide preferred codes during the benefits investigation process

2 Ensure all necessary prior authorizations are obtained

3 Ensure adequate documentation supports the claim process

- Health insurance companies may request additional documentation to be submitted with the claim
- Additional documentation may include:
  - Letter of Medical Necessity
  - Invoice for purchase of Jivi®, antihemophilic factor (recombinant), PEGylated-aucl
  - Jivi® Prescribing Information
  - Jivi® FDA approval letter
- Doctor's notes

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).

Please see both the Jivi® full Prescribing Information and full Important Safety Information on page 15.

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REVIEW PATIENT'S EXPLANATION OF BENEFITS (EOB)

When your office receives a copy of the EOB, it is critical to thoroughly review the EOB to ensure that it has been processed correctly, any patient cost share has been collected, and the appropriate reimbursement is received for Jivi®, antihemophilic factor (recombinant), PEGylated-aucl.

About claim denials

A claim denial can happen for a variety of reasons, including:

- Inaccurate or incomplete information
- Health insurance plan error
- Specific restriction in a patient's policy

What you can expect from Access Services by Bayer

In the event of a denied claim, Access Services by Bayer can educate your office staff about the appeals process.

Access Services by Bayer™

Access Services by Bayer's Live Helpline Support can help you and your patients with questions regarding reimbursement, financial support or insurance coverage.

Call 1-800-288-8374 **NOW!**
Multiple languages available, including Spanish.

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- Neutralizing antibody (inhibitor) formation can occur following administration of Jivi®. 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 (neutralizing antibody).

The information in this guide is for informational purposes and does not guarantee payment or coverage. Offices should research coding, coverage, and payment for individual patients prior to initiating treatment since policies and guidelines vary by payer and health plan. Offices are responsible for submitting accurate, complete, and appropriate claims to health plans and for compliance with any obligations required by law, contract, or otherwise.

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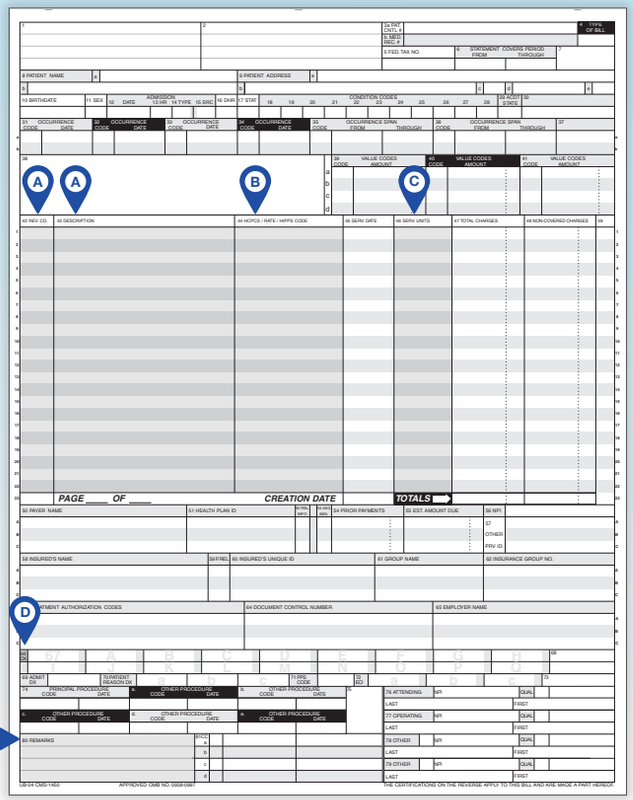
SAMPLE CMS-1450/UB-04 CLAIM FORM

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.



This document is provided for your guidance only.

Please call Access Services by Bayer™ at 1-800-288-8374 to verify coding and claim information for specific payers.

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:

- 8636, Pharmacy, drugs requiring detailed coding

B **Field 44: HCPCS/RATE/HIPPS Code**

Enter the appropriate HCPCS and *CPT* codes.
Example below:

- J7208 Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.
- 96374, Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
- 96376, 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)

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.

E **Field 80: Remarks**

Enter the full name of the medication administered, including vial strength if applicable (eg, Jivi®, antihemophilic factor (recombinant), PEGylated-aucl, 1000 IU vial), dosage, unit of measurement (eg, mL) as well as the NDC (National Drug Code) on the package used.

Please note: Payer NDC requirements and placement may vary, check with payer.

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- A clinical immune response associated with IgM anti-PEG antibodies, manifested as symptoms of acute hypersensitivity and/or loss of drug effect, has been observed primarily in patients < 6 years of age. The symptoms of the clinical immune response were transient. Anti-PEG IgM titers decreased over time to undetectable levels. No immunoglobulin class switching was observed.

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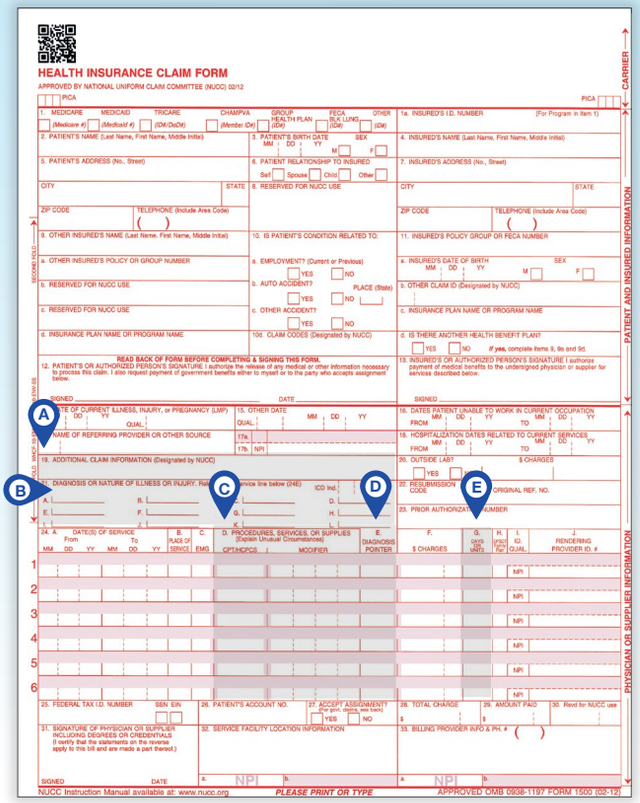
SAMPLE CMS-1500 CLAIM FORM

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.



This document is provided for your guidance only.

Please call Access Services by Bayer™ at 1-800-288-8374 to verify coding and claim information for specific payers.

A **Field 19: Additional Claim Information**

Enter the full name of the medication administered, including vial strength if applicable (eg, Jivi®, antihemophilic factor (recombinant), PEGylated-aucl, 1000 IU vial), dosage, unit of measurement (eg, mL) as well as the NDC (National Drug Code) on the package used.

Please note: Payer NDC requirements and placement may vary, check with payer.

B **Field 21: Diagnosis or Nature of Illness or Injury**

Enter the appropriate ICD-10-CM code(s), eg, D66, hereditary factor VIII deficiency.

C **Field 24D: Procedures, Services, or Supplies**

Enter the appropriate HCPCS and **CPT** codes. Example below:

- J7208 Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.
- 96374 Therapeutic, prophylactic or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
- 96376, 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)

D **Field 24E: Diagnosis Pointer**

Enter the letter (A-L) that corresponds to the diagnosis in Item FL 21.

E **Field 24G: Days or Units**

Indicate the number of International Units (IUs).

SELECTED IMPORTANT SAFETY INFORMATION (cont'd)

- In case of clinical suspicion of loss of drug effect, conduct testing for Factor VIII inhibitors and Factor VIII recovery. A low post-infusion Factor VIII level in the absence of detectable Factor VIII inhibitors indicates that loss of drug effect is likely due to anti-PEG antibodies. Discontinue Jivi® and switch patients to a previously effective Factor VIII product.

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INDICATIONS

- Jivi® antihemophilic factor (recombinant), PEGylated-aucl, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for:
  - On-demand treatment and control of bleeding episodes
  - Perioperative management of bleeding
  - Routine prophylaxis to reduce the frequency of bleeding episodes
- Limitations of use:
  - Jivi® is not indicated for use in children less than 12 years of age due to a greater risk for hypersensitivity reactions.
  - Jivi® is not indicated for use in previously untreated patients (PUPs).
  - Jivi® is not indicated for the treatment of von Willebrand disease.

IMPORTANT SAFETY INFORMATION

- Jivi® is contraindicated in patients who have a history of hypersensitivity reactions to the active substance, polyethylene glycol (PEG), mouse or hamster proteins, or other constituents of the product.
- Hypersensitivity reactions, including severe allergic reactions, have occurred with Jivi®. Monitor patients for hypersensitivity symptoms. Early signs of hypersensitivity reactions, which can progress to anaphylaxis, may include chest or throat tightness, dizziness, mild hypotension and nausea. If hypersensitivity reactions occur, immediately discontinue administration and initiate appropriate treatment.
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- Hypersensitivity reactions may also be related to antibodies against polyethylene glycol (PEG).
- Neutralizing antibody (inhibitor) formation can occur following administration of Jivi®. 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 (neutralizing antibody).
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- In case of clinical suspicion of loss of drug effect, conduct testing for Factor VIII inhibitors and Factor VIII recovery. A low post-infusion Factor VIII level in the absence of detectable Factor VIII inhibitors indicates that loss of drug effect is likely due to anti-PEG antibodies. Discontinue Jivi® and switch patients to a previously effective Factor VIII product.
- The most frequently (≥5%) reported adverse reactions in clinical trials in previously treated patients (PTPs) ≥12 years of age were headache, cough, nausea, and fever.

You are encouraged to report side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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For more information about accessing Jivi®, contact Access Services by Bayer:

1-800-288-8374 www.hcp.jivi.com

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For more information about submitting claims for Jivi®, antihemophilic factor (recombinant), PEGylated-aucl, see sample CMS-1450/UB-04 and CMS-1500 forms on pages 13 and 14.

References

1. American Medical Association. *2018 HCPCS Level II.* Professional ed. Chicago, IL: American Medical Association; 2018.
2. American Medical Association. *2018 ICD-10-CM: The Complete Official Codebook*. Chicago, IL: American Medical Association; 2017.
3. Jivi [package insert]. Whippany, NJ: Bayer; August, 2018.
4. American Medical Association. *Current Procedural Terminology 2018*. Professional ed. Chicago, IL: American Medical Association; 2017.
5. Centers for Medicare & Medicaid Services website. Medicare Claims Processing Manual. Chapter 18 - Preventive and Screening Services. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c18.pdf. Accessed August 3, 2018.
6. Centers for Medicare & Medicaid Services website. 2019 HCPCS Quarterly Update, Revised Other New Codes HCPCS File. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update.html Accessed May 30, 2019.

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