



HEMGENIX REIMBURSEMENT GUIDE FOR TREATMENT CENTERS

HEMGENIX is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who:

- Currently use Factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes.

Patients must be over the age of 18 years with no Factor IX inhibitors.

CSL Behring is committed to working with you and providing detailed information to assist in reimbursement for HEMGENIX and related support services.

This resource provides information 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 listed in this guide 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 (e.g., CPT Coding). Because government and other third-party payor coding requirements change periodically, please verify current coding requirements directly with the payer being billed.

Important Safety Information**Warning and Precautions****Infusion Reactions**

Infusion reactions, including hypersensitivity reactions and anaphylaxis, may occur. Monitor during administration and for at least 3 hours after end of infusion. If symptoms occur, slow or interrupt administration. Re-start administration at a slower infusion once resolved.

Hepatotoxicity/Hepatocellular Carcinoma

Post-dose, monitor for elevated transaminase levels. Consider corticosteroid treatment should elevations occur. The integration of liver-targeting AAV vector DNA into the genome may carry the theoretical risk of hepatocellular carcinoma development. For patients with preexisting risk factors for hepatocellular carcinogenicity, perform regular (eg, annual) abdominal ultrasound and alpha-fetoprotein testing following administration.

Immune-mediated neutralization of the AAV5 vector capsid

Preexisting neutralizing anti-AAV antibodies may impede transgene expression at desired levels.

Monitoring Laboratory Tests

In addition to monitoring liver function, monitor for Factor IX activity and Factor IX inhibitors after administration.

Adverse Reactions

The most common adverse reactions (incidence $\geq 5\%$) were elevated ALT, headache, blood creatine kinase elevations, flu-like symptoms, infusion-related reactions, fatigue, nausea, malaise, and elevated AST.

Indication

HEMGENIX is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who:

- Currently use Factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes.

HEMGENIX is for single use intravenous infusion only.

Contraindications: None.

Please see full prescribing information for HEMGENIX.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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CODING AND CLAIMS FOR HEMGENIX

CODING AND CLAIMS FOR HEMGENIX

HEMGENIX is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who:

- Currently use Factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes.

ICD-10-CM DIAGNOSIS CODE FOR HEMOPHILIA B¹

ICD-10-CM CODE	DESCRIPTION
D67	Hereditary Factor IX Deficiency

HCPCS CODES² FOR CONSIDERATION OF HEMGENIX PRIOR TO THE ASSIGNMENT OF A UNIQUE AND BRANDED CODE FOR HEMGENIX

HCPCS	CODE DESCRIPTOR
J7199	Not otherwise classified Hemophilia Clotting Factor
J3590	Not otherwise classified Biologic
C9399	Unclassified Drugs or Biologics - Hospital Outpatient Setting

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HOSPITAL REVENUE CODES³ THAT MAY APPLY TO HEMGENIX IN THE INPATIENT AND OUTPATIENT SETTINGS. REVENUE CODES ARE USED IN CONJUNCTION WITH DRUG HCPCS CODES

CATEGORY	CODE SERIES	DEFINITION
Pharmacy	025X	Pharmacy
Hospital Blood Service	038x	Blood and Blood derivatives
Drugs that require specific identification	0636	Revenue code 636 is necessary for submitting Medicare claims for blood clotting factors provided in a hospital.

HEMGENIX National Drug Code (NDC) 0XXXX-XXXX-XX

Certain payers may require NDC #s on claims. Providers are advised to verify requirements with the payer. In the absence of a branded HCPCS code, when using a not otherwise classified (NOC) code the inclusion of the appropriate HEMGENIX NDC is required. For billing purposes an 11th digit is required. There are 39 unique NDCs associated with HEMGENIX kits. The 11th digit placement is in the labeler code portion of the NDC. For example 0XXXX-XXXX-XX

CPT ADMINISTRATION CODES⁴

When the provider performs administration services in conjunction with HEMGENIX infusion, the following administration codes may be billed for this service. Providers are advised to verify correct code(s) with the payer:

CPT CODE	CODE DESCRIPTOR
96365	Infusion first hour
96366	Infusion each additional hour

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**LABORATORY TEST CONSIDERATIONS
 (PRE AND POST ADMINISTRATION OF HEMGENIX)**

PRE-ADMINISTRATION TESTING	CPT CODE
Factor IX (PTC or Christmas)	85250
Factor inhibitor test	85335
Thromboplastin time (PTT); plasma or whole blood	85730
Thromboplastin time (PTT); substitution, plasma fractions, each	85732
Liver elastography, without imaging, with interpretation and report	91200
Abdominal ultrasound	76700, 76705
POST ADMINISTRATION TESTING	CPT CODE
Factor IX Activity (monitored weekly for 3 months)	85250
Liver Function Panel AST, ALP, ALT, Bilirubin, Albumin, prothrombin time	80076
Bilirubin, total	82447
CBC test	85025
Prothrombin time (PTT)	85610

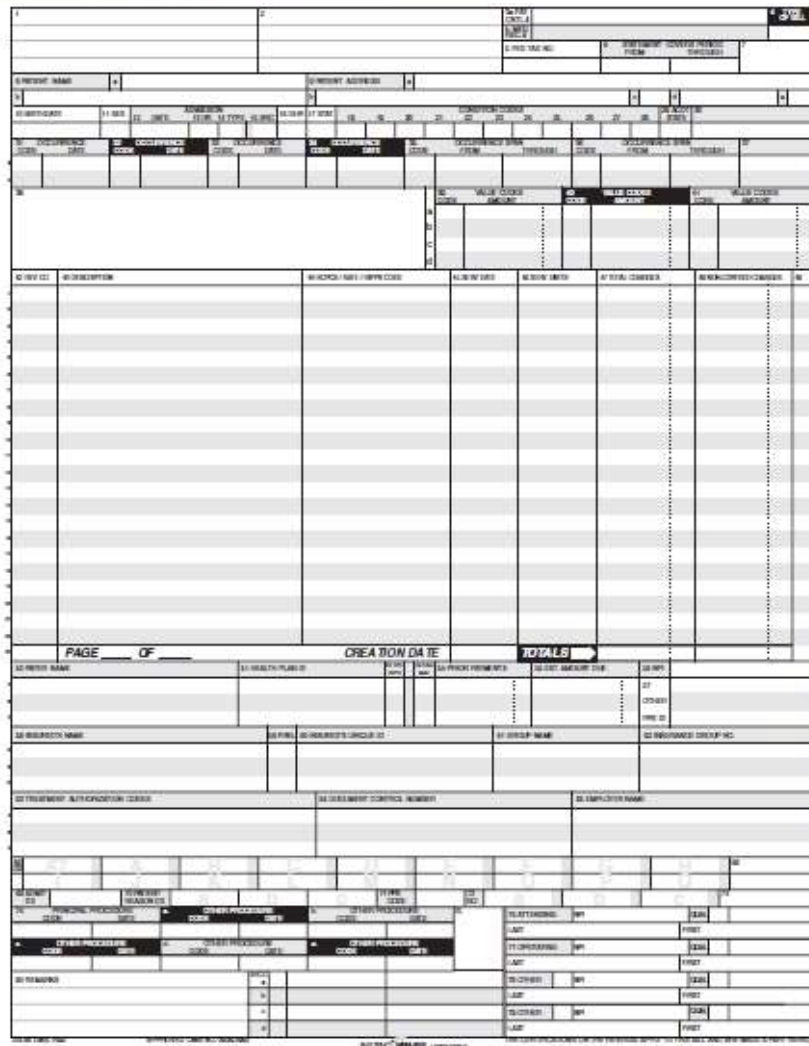
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CMS 1450 (UB-04)

Claim Form Example for HEMGENIX Claims using the CMS 1450 (UB-04) form

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CMS 1450 INSTITUTIONAL CLAIM FORM



The image shows a blank CMS 1450 Institutional Claim Form. The form is divided into several sections:

- Header Section:** Includes fields for Patient Name, Patient Address, and Patient Date of Birth.
- Provider Information Section:** Includes fields for Provider Name, Address, and NPI.
- Insurance Information Section:** Includes fields for Health Plan ID, Group Name, and Insurance Company.
- Service Table:** A large table with columns for ICD-10-CM codes, ICD-10-PCS codes, CPT codes, HCPCS codes, and units. It also includes a 'TOTALS' row at the bottom of the table.
- Footer Section:** Includes fields for Page Number, Creation Date, and Billing Party Name.

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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 HEMGENIX is typically "0636" (drugs requiring detailed coding). However, the revenue code selected is often facility-dependent, taking into consideration various payer requirements.

B FIELD 44 (HCPCS / RATE / HIPPS CODE)

If the payer accepts or expects line-item reporting for HEMGENIX, HCPCS NOC coding options are:

- J3590 (unclassified biologics)
- J7199 (Hemophilia clotting factor, Not otherwise specified)
- C3999 - Unclassified Drugs or Biologics - Outpatient Setting - Hospital Outpatient Drugs

C FIELD 46 (SERVICE UNITS):

When HCPCS codes J3590 or J7199 are reported in Field 44, a unit code must be reported in Field 46. Requirements for Field 46 vary by payer. For example, some payers rely on the information in Field 80 or 43 for this data and request a placeholder of "1" in Field 46.

D FIELD 67 (DIAGNOSTIC CODE):

Enter the primary ICD-10-CM diagnosis code in Field 67. Conditions that co-exist with the primary diagnosis or develop during treatment can be entered in Fields 67A - 67Q.

E FIELD 80 (REMARKS) AND/OR FIELD 43 (DESCRIPTION)

If the payer accepts or expects HCPCS code J3590 or J7199 or C9399 for HEMGENIX, the institution must provide additional information about HEMGENIX in a free-text field, such as Field 80 or its electronic equivalent. Payers typically require the name of the drug, its NDC, the route of administration, and the amount of HEMGENIX used to care for the patient.

Some payers 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 is highly variable by payer. (The formatting shown in Field 43 in the sample UB-04 is only one example.) Formatting should be verified with the payer to which the claim will be filed.

NDC Code: Note that the 10-digit NDC code for HEMGENIX is converted to an 11-digit billing format by inserting a zero in the first segment. The NDC code on the package is 0053-XXXX-XX; the 11-digit billing format is **00053-XXXX-XX**

Amount of HEMGENIX Used to Care for the Patient: This includes the unique kit NDC # on the outer carton of the HEMGENIX kit) administered to the patient.

CMS-1500 Claim Form Example for HEMGENIX Claims

This resource provides information 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 listed in this guide 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 (e.g., CPT Coding). Because government and other third-party payor coding requirements change periodically, please verify current coding requirements directly with the payer being billed.


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**This example illustrates the types of information generally required by health plans that accept CMS-1500 billing from facilities and is for reference only. Facilities filing claims electronically must cross-walk the paper CMS-1500 data elements to a format compatible with their individual billing software packages in compliance with health plan electronic transaction requirements. This example is NOT intended to illustrate billing for physicians' professional services in an outpatient hospital setting.*

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HEALTH INSURANCE CLAIM FORM
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/82

1. MEDICARE (Medicare) MEDICAID (Medicaid) TRICARE (TRICARE) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA (FECA) SELF-INSURED (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE (MM | DD | YY) SEX (M | F)

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED (Self | Spouse | Child | Other)

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment.)

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize payment of medical benefits to the undersigned physician or supplier for services described below.)

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP) (MM | DD | YY) QJAL

15. OTHER DATE (MM | DD | YY) QJAL

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION (FROM | TO) (MM | DD | YY)

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE (17a) NPI (17b)

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES (FROM | TO) (MM | DD | YY)

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? (YES | NO) \$ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Provide A-L to six rows below (24E)) (ICD 10#)

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE (From | To) (MM | DD | YY | MM | DD | YY) B. RACE OF SERVICE C. EMG D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) (CPT/HCPCS) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OF UNITS H. HI COST PAID I. ID# J. RENDERING PROVIDER ID #

25. FEDERAL TAX I.D. NUMBER SSN/ EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For gov. plans, see back) (YES | NO)

28. TOTAL CHARGE \$

29. AMOUNT PAID \$

30. Pmt. for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER (INCLUDING DEGREE OR CREDENTIALS) (Only if the statements on the reverse apply to this bill and are made a part thereof.)

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH# ()

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED UMB-0938-1197 FORM 1500 (02-12)

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 HEMGENIX in a free-text field, such as Field 19 or its electronic equivalent. Payers typically require the name of the drug, its NDC, the route of administration, and the amount used to care for the treatment. For example:

HEMGENIX NDC 00053-XXXX-XX IV infusion; 1 (per each kit)

NDC Code: Note that the 10-digit NDC code for HEMGENIX is converted to an 11-digit billing format by inserting a zero in the first segment. The NDC code on the package is 0053-XXXX-XX; the 11-digit billing format is 00053-XXXX-XX

Amount of HEMGENIX Used to Care for the Patient: This includes the number of units [1 each] administered to the patient.

B FIELD 21 (DIAGNOSIS OR NATURE OF ILLNESS B 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, the NDC information in a specific format is required in the shaded area above the line on which HEMGENIX 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 11-digit format preceded by the modifier N4 (N4XXXXX-0XXX-XX). This is typically followed by the NDC unit of measure UN (units) [for each Kit] and the numeric quantity of the NDC that was dispensed.

Other payors may require similar information. (The formatting shown in Field 24 in the sample CMS-1500 is only one example.) Check with the payor for specific requirements.

D FIELD 24.D: CPT/HCPCS

HCPCS coding options for HEMGENIX are:

- J3590 (unclassified biologics)
- J7199 (Hemophilia clotting factor, not otherwise classified)

CPT coding options for the IV infusion of HEMGENIX are:

- 93635 (Intravenous infusion for therapy, prophylaxis or diagnosis; initial, up to 1 hour
- CPT 93666 infusion, each additional hour

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

E FIELD 24.E (DIAGNOSIS POINTER):

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

F FIELD 24.G (DAYS OR UNITS):

Requirements for Field 24G vary by payor. For example, some payors rely on the information in Field 19 for this data and request a placeholder of "1" in Field 24G.



ORDERING HEMGENIX

ORDERING HEMGENIX

Please note: Prior to placing an order, please ensure that your institution has completed the CSL Behring-offered clinical training. The following provides general guidance around what is required to place an order for HEMGENIX.

FOR ALL ORDERS, PLEASE ENSURE THE FOLLOWING IS SUBMITTED TO HEMGENIX CONNECTSM:

- Purchase Order
 - Contact name and alternative contact name for purchase order
- HEMGENIX Prescription Form

IF YOU ARE AN EXISTING CSL BEHRING CUSTOMER, THE FOLLOWING IS REQUIRED ON THE PURCHASE ORDER:

- NDC
- Delivery Address
- Contact/Receiving Name, Role and Phone Number
- Billing Address
- Customer Reference/Purchase Order Number
- Contact Name, Role and Phone Number if there are questions related to the purchase order
- Requested Delivery Date
- Administering Physician Name
- Expected Infusion Date and Time
- Expected Infusion Location

IF THIS IS YOUR FIRST TIME ORDERING PRODUCT FROM CSL BEHRING, THE FOLLOWING IS REQUIRED IN ADDITION TO THE ABOVE:

- Complete Credit Application
- State Pharmacy License/DEA License
 - Please note: The pharmacy license must match the delivery address
- 340B ID and verification (if applicable)
- Letter of Affiliation

**To place an order, please fax all paperwork to 1-844-727-2757.
For any questions, call HEMGENIX ConnectSM at 1-833-436-0021.**



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DEDICATED SUPPORT THAT'S CUSTOMIZED FOR YOU AND YOUR PATIENTS

HEMGENIX Connect can help enrolled patients and their caregivers understand the coverage process, perform benefits investigations, access financial assistance, and receive resources and support as needed. HEMGENIX Connect can also provide you with answers to product-related questions and access to a dedicated CSL Behring representative.

HEMGENIX Connect offers you and your healthcare team support, including:



A dedicated reimbursement team to answer any of your financial support questions



Answers to your clinical questions from a medical information team



Assistance with identifying centers trained and approved to administer HEMGENIX



Submitting a prescription to order HEMGENIX

Elevate your expectations for patient support with HEMGENIX Connect, including:



A dedicated team, including a dedicated Patient Resource Navigator and a CSL Case Manager for your patients



Insurance assessment to investigate coverage and explain benefits to your patient



Determining patient eligibility for financial assistance programs



Logistics and travel support



Ongoing commitment to providing additional support and resources to your patients

If you have questions throughout the HEMGENIX treatment journey, or would like to locate a treatment center that can administer HEMGENIX, call **1-833-436-0021, Mon-Fri, 8 am-8 pm ET.**