

# Product fact sheet

## 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.

Please see **Important Safety Information** on page 6 and accompanying full **Prescribing Information** for HEMGENIX.

# Product information

<b>Brand name</b>	HEMGENIX
<b>Generic name</b>	Etranacogene dezaparvovec-drlb
<b>WAC price (per IU)</b>	\$3.5 million
<b>Product J-code (HCPCS)</b>	J1411
<b>NDCs/list numbers</b>	See table on page 3
<b>Storage and handling</b>	<ul style="list-style-type: none"><li>• HEMGENIX is shipped at 2 °C to 8 °C (36 °F to 46 °F)</li><li>• Upon receipt, store HEMGENIX vials in a refrigerator at 2 °C to 8 °C (36 °F to 46 °F)</li><li>• Store HEMGENIX in the original carton until use</li><li>• Protect HEMGENIX from light until time of dilution and administration</li><li>• Do NOT FREEZE</li></ul> <p><b>After dilution</b></p> <ul style="list-style-type: none"><li>• Once diluted, store HEMGENIX in the infusion bag protected from light</li><li>• Store diluted HEMGENIX in the infusion bag at 15 °C to 25 °C (59 °F to 77 °F)</li><li>• Infuse the diluted product within 24 hours after the dose preparation</li></ul>
<b>Administration centers</b>	HEMGENIX is administered at trained hemophilia treatment centers. Call <b>HEMGENIX Connect<sup>SM</sup></b> at <b>1-833-436-0021</b> for details.
<b>How supplied</b>	<p>HEMGENIX is supplied as a sterile, preservative-free, clear, and colorless suspension.</p> <p>HEMGENIX has a nominal concentration of <math>1 \times 10^{13}</math> gc/mL.</p> <p>HEMGENIX is provided as a customized kit to meet dosing requirements for each patient, with each kit containing 10 to 48 single-use vials (NDC 0053-0099-01), each with an extractable volume of no less than 10 mL of HEMGENIX (see table on page 3). The total number of vials in each kit corresponds to the dosing requirement for the individual patient depending on the patient's body weight. The customized kit is accompanied by the patient's specific identifier number (lot) on the outer carton. Each HEMGENIX kit may contain different drug product lots.</p>

Abbreviations: HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; WAC, wholesale acquisition cost.

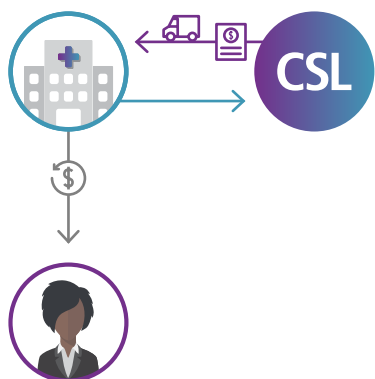
# HEMGENIX multi-vial kits

Total number of vials per kit	Patient body weight (kg)	Total volume per kit (mL)	NDC number
10	46-50	100	0053-0100-10
11	51-55	110	0053-0110-11
12	56-60	120	0053-0120-12
13	61-65	130	0053-0130-13
14	66-70	140	0053-0140-14
15	71-75	150	0053-0150-15
16	76-80	160	0053-0160-16
17	81-85	170	0053-0170-17
18	86-90	180	0053-0180-18
19	91-95	190	0053-0190-19
20	96-100	200	0053-0200-20
21	101-105	210	0053-0210-21
22	106-110	220	0053-0220-22
23	111-115	230	0053-0230-23
24	116-120	240	0053-0240-24
25	121-125	250	0053-0250-25
26	126-130	260	0053-0260-26
27	131-135	270	0053-0270-27
28	136-140	280	0053-0280-28
29	141-145	290	0053-0290-29
30	146-150	300	0053-0300-30
31	151-155	310	0053-0310-31
32	156-160	320	0053-0320-32
33	161-165	330	0053-0330-33
34	166-170	340	0053-0340-34
35	171-175	350	0053-0350-35
36	176-180	360	0053-0360-36
37	181-185	370	0053-0370-37
38	186-190	380	0053-0380-38
39	191-195	390	0053-0390-39
40	196-200	400	0053-0400-40
41	201-205	410	0053-0410-41
42	206-210	420	0053-0420-42
43	211-215	430	0053-0430-43
44	216-220	440	0053-0440-44
45	221-225	450	0053-0450-45
46	226-230	460	0053-0460-46
47	231-235	470	0053-0470-47
48	236-240	480	0053-0480-48

# Purchase options

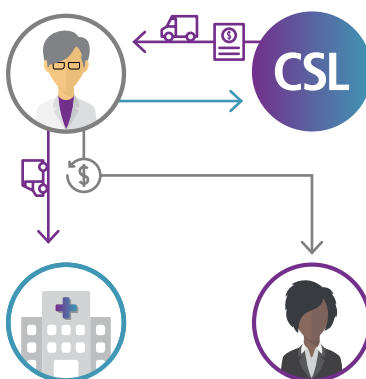
HEMGENIX is available for purchase directly from CSL Behring or through a limited distribution network of specialty pharmacies.

## Direct purchase option



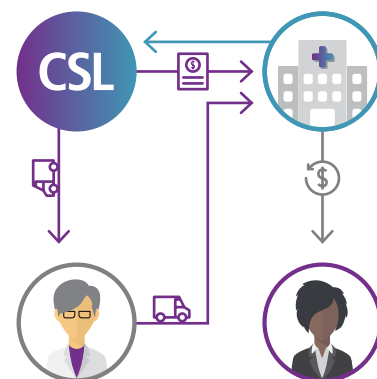
- Provider orders HEMGENIX directly from CSL Behring
- CSL Behring ships HEMGENIX directly to the provider and invoices the provider
- Provider seeks reimbursement from the payer

## Specialty pharmacy limited distribution network



- SP orders HEMGENIX directly from CSL Behring
- CSL Behring ships HEMGENIX to the SP and invoices the SP
- SP ships HEMGENIX to the provider
- SP seeks reimbursement from the commercial payer

## Contract 340B specialty pharmacy



- Provider orders HEMGENIX directly from CSL Behring
- CSL Behring ships HEMGENIX to the SP and invoices the provider
- SP ships HEMGENIX to the provider
- Provider seeks reimbursement from the payer



- Call **1-833-436-0021**  
Monday through Friday, 8 AM to 8 PM ET
- Email [CSLPatientservices@cslbehring.com](mailto:CSLPatientservices@cslbehring.com)
- Fax 1-844-727-2757

Abbreviation: SP, specialty pharmacy.

# How to submit a direct purchase order to CSL Behring

## For direct orders, please ensure the following is submitted to HEMGENIX Connect:

- Purchase order
- HEMGENIX prescription form

## If you are an existing CSL Behring customer, the following is required on the purchase order:

- NDC number
- Delivery address
- Three (3) contacts/receiving names with roles and phone numbers for day of delivery
- 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
- Patient weight and date weighed (date weighed must be within 30 days of expected infusion date)

## If this is your first time ordering from CSL Behring, the following additional information is required:

- Complete credit application
- State pharmacy license/DEA license
  - Please note: The pharmacy license must match the delivery address
- 340B ID and verification (if applicable)



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## 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.

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- Have repeated, serious spontaneous bleeding episodes.

HEMGENIX is for single use intravenous infusion only.

**Contraindications:** None.

**Please see accompanying 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](http://www.fda.gov/medwatch).