Medical Policy

BlueCross BlueShield Kansas
An Independent licensee of the Blue Cross Blue Shield Association

Title: Hemgenix

Professional / Institutional
Original Effective Date: January 8, 2026
Latest Review Date: July 23, 2026
Current Effective Date: July 23, 2026

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

Indication	Dose
Hemophilia B (Congenital Factor IX Deficiency)	The recommended dose of Hemgenix is 2 x 10^{13} genome copies (gc) per kilogram (kg) of body weight (or 2 mL/kg body weight) administered as an intravenous infusion. Calculate the dose as follows: – Hemgenix dose (in mL) = patient body weight (in kilogram) x 2 *The multiplication factor 2 represents the per kilogram dose (2 × 10^{13} gc/kg) divided by the amount of genome copies per mL of the Hemgenix solution (1 × 10^{13} gc/mL).* – Number of Hemgenix vials needed = Hemgenix dose (in mL) divided by 10 (round up to next whole number of vials).

	The division factor 10 represents the extractable volume of Hemgenix from each vial (10 mL).
• Prepare Hemgenix using sterile technique under aseptic conditions, proper engineering controls (e.g., biological safety cabinet or isolator) and according to institutional policies. • Do not expose Hemgenix to the light of an ultraviolet radiation disinfection lamp. • Confirm that the patient's identity matches with the patient-specific identifier number on the outer carton. • Verify the required dose of Hemgenix based on the patient's body weight. • Confirm that the carton contains sufficient number of vials to prepare the diluted Hemgenix patient-specific infusion bag. • Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. • For single-dose intravenous infusion only. • DO NOT administer Hemgenix as an intravenous push or bolus. • DO NOT infuse the diluted Hemgenix solution in the same intravenous line with any other products. • DO NOT use a central line or port.	

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for one dose.
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 1 billable unit for one dose

III. Initial Approval Criteria [1-13]

Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines

Prior authorization validity is provided in the following conditions:

Hemophilia B (Congenital Factor IX Deficiency) † Φ

- Patient is at least 18 years of age; **AND**
- Patient has a diagnosis of moderately severe or severe congenital factor IX deficiency (i.e., ≤2% of normal circulating factor IX), as confirmed by blood coagulation testing, for

which the subject is on continuous routine factor IX prophylaxis, unless there is a contraindication or intolerance *(Note: Continuous routine prophylaxis is defined as the intent of treating with an a priori defined frequency of infusions (e.g., twice weekly, once every two weeks, etc.) as documented in the medical records)*; **AND**

- Patient has not received prior hemophilia AAV-vector–based gene therapy **AND**
- Patient has one or more of the following:
    - Currently use Factor IX prophylaxis therapy (e.g., AlphaNine SD, Alprolix, BeneFIX, Idelvion, Ixinity, Mononine, Profilnine, Rebinyn, Rixubis, etc.); **OR**
    - Have current or historical life-threatening hemorrhage; **OR**
    - Have repeated, serious spontaneous bleeding episodes (e.g., intramuscular hematomas requiring hospitalization, hemarthrosis, central nervous system (CNS) bleeding (including intracranial hemorrhage), pulmonary hemorrhage, life-threatening gastrointestinal (GI) hemorrhage and umbilical cord bleeding); **AND**
- Patient has been tested and found negative for Factor IX inhibitor titers (i.e., <0.6 Bethesda Units) and does not have a prior history of inhibitors (if test result is positive, re-test within approximately 2 weeks. If re-test is also positive, Hemgenix should not be given); **AND**
- Patient Factor IX activity will be monitored periodically (e.g., weekly for 3 months) as well as presence of inhibitors if bleeding is not controlled *(Note: patients will continue to require exogenous Factor IX until response to Hemgenix occurs);* **AND**
- Patient will discontinue Factor IX prophylaxis therapy upon achieving FIX levels of 5% from etranacogene dezaparvovec treatment; **AND**
- Patient has a baseline anti-AAV5 antibody titer within acceptable limits as defined by one of the following when measure by the luciferase-based Neutralizing Antibody (Nab) assay:
    - <=1:678 when using the 7-point assay; **OR**
    - <=1:898 when using the 9-point assay; **AND**
- Patient will have baseline liver function assessed prior to and after therapy according to the monitoring schedule outlined in the product labeling with corticosteroids administered in response to elevations; **AND**
- Patients with preexisting risk factors for hepatocellular carcinoma (e.g., patients with cirrhosis, advanced hepatic fibrosis, hepatitis C or B, non-alcoholic fatty liver disease (NAFLD), chronic alcohol consumption, non-alcoholic steatohepatitis (NASH), and advanced age) will have abdominal ultrasound screenings and be monitored regularly (e.g., annually) for alpha-fetoprotein (AFP) elevations following administration

Notes:

- It may take several weeks before improved hemostatic control becomes apparent after etranacogene dezaparvovec infusion; therefore, continued hemostatic support with exogenous human Factor IX may be needed during the first weeks after etranacogene dezaparvovec infusion.
- Use of exogenous Factor IX concentrates before and after etranacogene dezaparvovec administration may impede assessment of endogenous, etranacogene dezaparvovec-derived Factor IX activity.

† FDA Approved Indication(s); ǂ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria

- Duration of authorization has not been exceeded (refer to Section I)

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CLINICAL RATIONALE

See package insert for FDA preshttps://dailymed.nlm.nih.gov/dailymed/index.cfm

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

HCPCS code:

- J1411 – Injection, etranacogene dezaparvovec-drlb, per therapeutic dose; 1 billable unit = 1 kit (based on weight chart below)

NDC(s):

Hemgenix kit sizes:

Total number of vials	Patient Weight (kg)	Total Volume (mL)	NDC
10	46-50	100	00053-0100-10
11	51-55	110	00053-0110-11
12	56-60	120	00053-0120-12
13	61-65	130	00053-0130-13
14	66-70	140	00053-0140-14
15	71-75	150	00053-0150-15
16	76-80	160	00053-0160-16
17	81-85	170	00053-0170-17
18	86-90	180	00053-0180-18
19	91-95	190	00053-0190-19
20	96-100	200	00053-0200-20
21	101-105	210	00053-0210-21
22	106-110	220	00053-0220-22
23	111-115	230	00053-0230-23
24	116-120	240	00053-0240-24
25	121-125	250	00053-0250-25
26	126-130	260	00053-0260-26
27	131-135	270	00053-0270-27
28	136-140	280	00053-0280-28
29	141-145	290	00053-0290-29
30	146-150	300	00053-0300-30
31	151-155	310	00053-0310-31

Total number of vials	Patient Weight (kg)	Total Volume (mL)	NDC
32	156-160	320	00053-0320-32
33	161-165	330	00053-0330-33
34	166-170	340	00053-0340-34
35	171-175	350	00053-0350-35
36	176-180	360	00053-0360-36
37	181-185	370	00053-0370-37
38	186-190	380	00053-0380-38
39	191-195	390	00053-0390-39
40	196-200	400	00053-0400-40
41	201-205	410	00053-0410-41
42	206-210	420	00053-0420-42
43	211-215	430	00053-0430-43
44	216-220	440	00053-0440-44
45	221-225	450	00053-0450-45
46	226-230	460	00053-0460-46
47	231-235	470	00053-0470-47
48	236-240	480	00053-0480-48

REVISIONS	
Posted: 12-09-2025 Effective: 01-08-2026	New medical policy added to the bcbsks.com web site. Policy is maintained by Prime Therapeutics LLC.
Posted: 06-23-2026 Effective: 07-23-2026	Updated Length of Authorization: • Removed: "Coverage will be provided for one does and may not be renewed" • Added: "Initial: Prior authorization validity will be provided initially for one dose." And "Renewal: Prior authorization validity may NOT be renewed." Initial Approval Criteria • Added: ○ Submission of supporting clinical documentation (including but not limited to medical records, chart notes, lab results, and confirmatory diagnostics) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission as part of the evaluation of this request. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic, and mutational testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. Failure to submit the medical records may result in the denial of the request due to inability to establish medical necessity in accordance with policy guidelines • Removed: ○ Submission of medical records (chart notes) related to the medical necessity criteria is REQUIRED on all requests for authorizations. Records will be reviewed at the time of submission. Please provide documentation related to diagnosis, step therapy, and clinical markers (i.e., genetic and mutational

REVISIONS	
	testing) supporting initiation when applicable. Please provide documentation via direct upload through the PA web portal or by fax. • Prior authorization coverage changed to Prior authorization validity Hemophilia B (Congenital Factor IX Deficiency) ○ Changed: "Patient has a diagnosis of moderately severe or severe congenital factor IX deficiency bleeding phenotype (i.e., ≤2% of normal circulating factor IX), as attested by the managing physician, …" to Patient has a diagnosis of moderately severe or severe congenital factor IX deficiency (i.e., ≤2% of normal circulating factor IX), as confirmed by blood coagulation testing," ○ Removed: "(e.g. fidanacogene elaparvovec)" from Patient has not received prior hemophilia AAV-vector–based gene therapy ○ Removed: "Patient's baseline anti-AAV5 antibody titer is used as part of the evaluation process by the managing physician; AND" ○ Added: "Patient has a baseline anti-AAV5 antibody titer within acceptable limits as defined by one of the following when measure by the luciferase-based Neutralizing Antibody (Nab) assay: ▪ <=1:678 when using the 7-point assay; OR ▪ <=1:898 when using the 9-point assay; AND" Updated Reference Section
	Policy is maintained by Prime Therapeutics LLC.

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