Cigna Healthcare Gene Therapy Prior Auth Request Form

This therapy requires supportive documentation (chart notes, genetic test results, etc.).

****Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) fields on this form are completed****

Gene Therapy Prior Authorization

To allow more efficient and accurate processing of your medication request, please complete this form and fax it back along with copies of all supporting clinical documentation. Fax completed form to Fax# 833-910-1625.

Notice: Failure to complete this form in its entirety may result in delayed processing or an adverse determination for insufficient information.

Gene Therapy Product Name **Hemgenix**

Cigna has designated the above product to be a gene therapy product, which is included in the Cigna Gene Therapy Provider Network.

Questions pertaining to gene therapy may be directed to the dedicated Gene Therapy Program team at 855.678.0051 or email to GeneTherapyProgram@Cigna.com

PHYSICIAN INFORMATION			PATIENT INFORMATION		
* Physician Name:			*Due to privacy regulations we will not be able to respond via fax with the outcome of our review unless all asterisked (*) items on this form are completed.*		
Specialty:	* DEA, NPI or TIN:				
Office Contact Person:			* Customer Name:		
Office Phone:			* Cigna ID:	*Customer Date of Birth:	
Office Fax: *Is your fax machine kept in a secure location? ☐ Yes ☐ No *May we fax our response to your office? ☐ Yes ☐ No			* Customer/Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		

Urgency:
☐ Standard ☐ Urgent (In checking this box, I attest to the fact that applying the standard review time frame may seriously jeopardize the customer's life, health, or ability to regain maximum function)

Where will this medication be obtained?
☐ Other (please specify):

ICD10:

Name of Facility administering medication:
Facility Name: State: Tax ID#:
Address (City, State, Zip Code):

Clinical Information – Hemgenix (Ertanacogene dezaparvovec-drlb)

Is your patient a male?
☐ Yes
☐ No

Is your patient 18 years of age or older?
☐ Yes
☐ No

Does your patient have documentation of moderately severe or severe Hemophilia B as evidenced by baseline (without Factor IX replacement therapy) Factor IX level less than or equal to 2% of normal? (Please include copy of clinical to support)
☐ Yes
☐ No

Is there documentation your patient meets **ONE** of the following (i, ii, or iii)? (Please include copy of clinical to support)
i. Your patient meets **BOTH** of the following:
- ☐ Documentation of receiving routine prophylaxis with Factor IX therapy continuously for at least 2 months
- ☐ According to the prescriber, has at least a 150 exposure day history of Factor IX therapy

ii. Your patient meets BOTH of the following:
- ☐ History of life-threatening hemorrhage
- ☐ On-demand use of Factor IX therapy was required for this life-threatening hemorrhage

iii. Your patient meets BOTH of the following:
- ☐ History of repeated, serious spontaneous bleeding episodes
- ☐ On-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes

Is there documentation of BOTH of the following?
☐ Factor IX inhibitor titer testing performed within 30 days before receiving Hemgenix
☐ No current, or history of, Factor IX inhibitors

Is there documentation of **ALL** of the following? (Please include copy of these results)
☐ Alanine aminotransferase is less or equal to 2 times the upper limit of normal
☐ Aspartate aminotransferase is less or equal to 2 times the upper limit of normal
☐ Total bilirubin levels are less or equal to 2 times the upper limit of normal
☐ Alkaline phosphatase levels are less or equal to 2 times the upper limit of normal
☐ No evidence of advanced liver impairment and/or advanced fibrosis
☐ Estimated creatinine clearance of at least 30ml/min
☐ Creatinine level that is less than or equal to 2 times the upper limit of normal
☐ Platelet count of at least 50 x 10^9/L within the last 30 days
☐ Prior to receiving Hemgenix screening for Hepatitis B is negative
☐ Prior to receiving Hemgenix screening for Hepatitis C is negative
☐ Your patient is not currently receiving antiviral therapy for prior Hepatitis B virus or C virus exposure
☐ If your patient is positive for human immunodeficiency virus, documentation that customer is controlled on antiviral therapy as evidence by adequate CD4+ counts of at least 200/uL or by viral load of less than or equal to 200 copies/mL

According to the prescriber, the patient has no other coagulation disorders, besides hemophilia B?
☐ Yes
☐ No
☐ Unknown

Does the patient have a prior history of gene therapy?
☐ Yes
☐ No
☐ Unknown

According to the prescriber prophylactic therapy with Factor IX will **NOT** be given once adequate Factor IX levels have been achieved. (Use of episodic Factor IX therapy is acceptable for the treatment of bleeds and for surgery/procedures if needed as determined by the hemophilia specialist physician).
☐ Yes
☐ No
☐ Unknown

According to prescriber following Hemgenix infusion **ALL** of the following will be performed:
☐ Liver enzyme testing to monitor for liver enzyme elevations will be done at least weekly for the first 3 months and periodically thereafter.
☐ Implementing a course of corticosteroids will be considered if clinically relevant increases in alanine aminotransferase levels.
☐ Will undergo monitoring for Factor IX activity at least weekly for the first 3 months and periodically thereafter.
☐ If patient has a preexisting risk factor for hepatocellular carcinoma, they will receive abdominal ultrasound screening and be monitored at least annually with alpha fetoprotein elevations in the 5 years following receipt of Hemgenix. (Risk factors include a patient with prior history of hepatitis B and/or C, non-alcoholic fatty liver disease, chronic alcohol consumption, non-alcoholic steatohepatitis, and advanced age).

Hemgenix is prescribed by a physician who specializes in hemophillia?
☐ Yes
☐ No
☐ Unknown

If any of the requirements listed above are not met and provider feels administration of Hemgenix is medically necessary please provide clinical support and rationale for the use of Hemgenix.

Additional pertinent information: *(including disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently)*

Additional CPT and Administration Codes for Consideration Following Medical Necessity Determination

Please indicate any other CPT codes that will be billed for administration
☐ Other

Additional Attestation required for Embarc Benefit Protection* Criteria when applicable

Has your patient received Hemgenix in the past?
☐ Yes
☐ No
☐ Unknown

Patient does not currently have an inhibitor to Factor IV
☐ Yes
☐ No
☐ Unknown

Please provide documentation of the following:
☐ Aspartate aminotransferase is less or equal to 2 times the upper limit of normal within the last 30 days
☐ Total bilirubin levels are less or equal to 2 times the upper limit of normal within the last 30 days
☐ Alkaline phosphatase levels are less or equal to 2 times the upper limit of normal within the last 30 days

**For additional information on Embarc Benefit Protection refer to the Cigna Reference Guide of physicians, physicians, hospitals, ancillaries, and other health care providers. This guide is available at CignaforHCP.com > Resources > Reference Guides > Medical Reference Guides: View Documents > Health Care Professional Reference Guides. Providers must log in to access.*

Agreement and Attestation

Do you and your patient agree to share any required plan specific outcome measures?
☐ Yes
☐ No

Attestation: I attest the information provided is true and accurate to the best of my knowledge. I understand that the Health Plan or insurer its designees may perform a routine audit and request the medical information necessary to verify the accuracy of the information reported on this form.

Prescriber Signature:_____ **Date:**_____

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