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?
☐ Buy and Bill / Office Stock
☐
☐ Other (please specify):

Where will this medication be administered?
Facility Name:
Address: State:
Tax ID#:

What location will this medication be administered?

☐ Outpatient Hospital ☐ Inpatient Hospital ☐ MD Office / Clinic
☐ Home ☐ Other

ICD 10 Associated with the Indication of this request:

Hemgenix is considered medically necessary when the following criteria are met, check all that apply:

Documentation: Documentation is required for use of Hemgenix as noted in the criteria as [documentation required]. Documentation may include, but is not limited to chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information.

☐ Patient is male*

☐ Patient is ≥ 18 years of age

☐ Patient has not received a gene therapy for hemophilia B in the past [verification in claims history required]
Note: If no claim for Hemgenix or Beqvez (fidanacogene elaparvovec-dzkt intravenous infusion) is present (or if claims history is not available), the prescribing physician confirms that the patient has not previously received Hemgenix or Beqvez.

☐ Patient has moderately severe or severe hemophilia B as evidenced by a baseline (without Factor IX replacement therapy) Factor IX level ≤ 2% of normal [documentation required]

☐ Patient meets ONE of the following (i, ii, or iii):
- ☐ i. According to the prescribing physician, the patient has a history of use of Factor IX therapy for ≥ 150 exposure days; OR
- ☐ ii. Patient meets BOTH of the following (a and b):
  - ☐ a. Patient has a history of life-threatening hemorrhage; AND
  - ☐ b. On-demand use of Factor IX therapy was required for this life-threatening hemorrhage; OR
- ☐ iii. Patient meets BOTH of the following (a and b):
  - ☐ a. Patient has a history of repeated, serious spontaneous bleeding episodes; AND
  - ☐ b. On-demand use of Factor IX therapy was required for these serious spontaneous bleeding episodes; AND

☐ Patient meets BOTH of the following (i and ii):
- ☐ i. Factor IX inhibitor titer testing has been performed within the past 30 days [documentation required]; AND
- ☐ ii. Patient is negative for Factor IX inhibitors [documentation required]

☐ Patient meets BOTH of the following (i and ii):
- ☐ i. Patient does not have an active infection with hepatitis B virus or hepatitis C virus [documentation required]; AND
- ☐ ii. Patient is not currently receiving antiviral therapy for a prior hepatitis B virus or hepatitis C virus exposure [documentation required]

☐ According to the prescribing physician, the patient does not have uncontrolled human immunodeficiency virus infection

☐ Patient has undergone liver function testing within the past 30 days and meets ALL of the following (i, ii, iii, and iv):
- ☐ i. Alanine aminotransferase level is ≤ two times the upper limit of normal [documentation required]; AND
- ☐ ii. Aspartate aminotransferase level is ≤ two times the upper limit of normal [documentation required]; AND
- ☐ iii. Total bilirubin level is ≤ two times the upper limit of normal [documentation required]; AND
- ☐ iv. Alkaline phosphatase level is ≤ two times the upper limit of normal [documentation required]

☐ Patient does not have evidence of advanced liver impairment and/or advanced fibrosis

☐ Within the past 30 days, the platelet count was ≥ 50 x 109/L [documentation required]

☐ Within the past 30 days, patient meets ONE of the following (i or ii):
- ☐ i. Patient has an estimated creatinine clearance ≥ 30 mL/minute [documentation required]; OR
- ☐ ii. Creatinine level is ≤ two times the upper limit of normal [documentation required]

☐ The medication is prescribed by a hemophilia specialist physician

☐ Current body weight has been obtained within the past 30 days [documentation required]

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 recent history and physical, recent lab work, disease stage, prior therapy, performance status, and names/doses/admin schedule of any agents to be used concurrently)*

Any other use is considered experimental, investigational, or unproven, including the following, check all that apply:

☐ **Prior Receipt of Gene Therapy.** Prior receipt of gene therapy was a reason for patient exclusion in the pivotal study.

☐ **Patient with a History of Factor IX Inhibitors.** A history of Factor IX inhibitors was a reason for patient exclusion in the pivotal trial.

If any of above apply to your customer, please provide clinical support and rationale for the use of this gene therapy.

Additional CPT and Administration Codes for Consideration Following Medical Necessity Determination

Provide all associated CPT codes for administration of Hemgenix

Agreement and Attestation

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

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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