

Cigna Healthcare Beqvez Gene Therapy Prior Auth
This therapy requires supportive documentation (chart notes, genetic test results, etc.).

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: **Beqvez**

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: <input type="checkbox"/> Yes <input type="checkbox"/> No *May we fax our response to your office? <input type="checkbox"/> Yes <input type="checkbox"/> No			*Customer / Patient Street Address:		
Office Street Address:			City:	State:	Zip:
City:	State:	Zip:	Patient Phone:		
Urgency: <input type="checkbox"/> Standard <input type="checkbox"/> 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? <input type="checkbox"/> Buy and Bill / Office Stock <input type="checkbox"/> Accredo Specialty Pharmacy <input type="checkbox"/> Other					

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:

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

Patient is male*; AND

Note: the specified gender is defined as follows: males are defined as individuals with the biological traits of a man, regardless of the individual's gender identity or gender expression.

Patient is ≥ 18 years of age; AND

Patient has not received a gene therapy for hemophilia B in the past **[verification in claims history required]**; AND

Note: If no claim for Beqvez or Hemgenix (etranacogene dezaparvovec-drlb intravenous infusion) is present (or if claims history is not available), the prescribing physician confirms that the patient has not previously received Beqvez or Hemgenix.

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]**; AND

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

ii. 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 does not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid by an approved test **[documentation required]**; AND

Patient meets **ALL** the following (i, ii, and iii):

i. Factor IX inhibitor titer testing has been performed within 30 days **[documentation required]**; AND

ii. Patient is negative for Factor IX inhibitors **[documentation required]**; AND

iii. Patient does not have a history of Factor IX inhibitors **[documentation required]**; AND

Prophylactic therapy with Factor IX will not be given after Beqvez administration once adequate Factor IX levels have been achieved; AND

Note: 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.

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]**; AND

- According to the prescribing physician, the patient does not have uncontrolled human immunodeficiency virus infection; AND
- Patient has undergone liver function testing within 30 days and meets **ALL** the following (i, ii, iii, and iv):
 - i. Alanine aminotransferase level is \leq two times the upper limit of normal **[documentation required]**; AND
 - ii. Aspartate aminotransferase level is \leq two times the upper limit of normal **[documentation required]**; AND
 - iii. Total bilirubin level is \leq 1.5 times the upper limit of normal **[documentation required]**; AND
 - iv. Alkaline phosphatase level is \leq two times the upper limit of normal **[documentation required]**; AND
- Patient does not have evidence of advanced liver impairment and/or advanced fibrosis; AND
Note: For example, liver elastography (e.g., \geq 9 kPA) suggestive of or equal to METAVIR Stage 3 disease.
- Within the past 30 days, the platelet count was $\geq 100 \times 10^9/L$ **[documentation required]**; AND
- Within the past 30 days, creatinine was ≤ 2.0 mg/dL **[documentation required]**; AND
- The medication is prescribed by a hemophilia specialist physician; AND
- Current patient body weight has been obtained within 30 days **[documentation required]**;

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

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.

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

Provide all associated CPT codes for administration of Beqvez

Additional Attestation required for Embarc Benefit Protection*:

The prescribing physician confirms that the patient has not previously received Beqvez?

- Yes
- No
- Unknown

**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

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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