Cigna Healthcare Roctavian Gene Therapy Prior Auth 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: Roctavian

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?
☐ Accredo
☐ Other (please specify):

ICD10:

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

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:

Clinical Information

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

☐ Patient is male*; AND

☐ Patient is ≥ 18 years of age; AND

☐ Patient has not received Roctavian in the past [verification in claims history required];
AND
Note: If no claim for Roctavian is present (or if claims history is not available), the prescribing physician confirms that the patient has not previously received Roctavian.

☐ Patient has severe hemophilia A as evidence by a baseline (without Factor VIII replacement therapy) Factor VIII level of < 1 IU/dL [documentation required]; AND

☐ Patient does not have detectable pre-existing antibodies to adeno-associated virus 5 (AAV5) by an FDA-approved test [documentation required]; AND

☐ According to the prescribing physician, the patient has a history of use of Factor VIII therapy for at least 150 exposure days; AND

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

- ☐ i. Factor VIII inhibitor titer testing has been performed within the past 30 days [documentation required]; AND
- ☐ ii. Patient does not currently have an inhibitor to Factor VIII [documentation required]; AND
- ☐ iii. Patient does not have a history of Factor VIII inhibitors [documentation required]; AND

☐ Prophylactic therapy with Factor VIII will not be given after Roctavian administration once adequate Factor VIII levels have been achieved; AND
Note: Use of episodic Factor VIII therapy is acceptable for the treatment of bleeds and for surgery/procedures if needed as determined by the hemophilia specialist physician.

☐ Patient does not have a known hypersensitivity to mannitol; AND

☐ Patient does not have chronic or active hepatitis B [documentation required]; AND

☐ Patient does not have active hepatitis C [documentation required]; AND

☐ Patient is not human immunodeficiency virus positive [documentation required]; AND

☐ Patient does not have evidence of significant hepatic fibrosis or cirrhosis; AND

☐ Patient meets ONE of the following (i or ii):

- ☐ i. Patient has undergone liver function testing within the past 30 days and meets ALL of the following (a, b, c, d, e, and f):
  - ☐ a) Alanine aminotransferase levels are ≤ 1.25 times the upper limit of normal [documentation required]; AND
  - ☐ b) Aspartate aminotransferase levels are ≤ 1.25 times the upper limit of normal [documentation required]; AND
  - ☐ c) Total bilirubin levels are ≤ 1.25 times the upper limit of normal [documentation required]; AND
  - ☐ d) Alkaline phosphatase levels are ≤ 1.25 times the upper limit of normal [documentation required]; AND
  - ☐ e) Gamma-glutamyl transferase levels are ≤ 1.25 times the upper limit of normal [documentation required]; AND
  - ☐ The International Normalized Ratio is < 1.4 [documentation required]; OR
- ☐ ii. If the patient had one or more of the laboratory values listed in Criteria a-f above that was not at the value specified in Criteria a-f above, then a hepatologist has evaluated the patient and has determined that use of Roctavian is clinically appropriate [documentation required]; AND

☐ Within the past 30 days, the platelet count was ≥ 100 x 109/L [documentation required]; AND

☐ Within the past 30 days, the creatinine level was < 1.4 mg/dL [documentation required]; AND

☐ Medication is prescribed by a hemophilia specialist physician; AND

☐ Current patient 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 Roctavian is medically necessary, please provide clinical support and rationale for the use of Roctavian

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 this gene therapy.

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*.

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

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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