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):
I

Clinical Information

Does your patient have a diagnosis of Hemophilia A?
☐ Yes
☐ No

Is your patient male?
☐ Yes
☐ No

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

Does your patient have documentation of severe hemophilia A as evidenced by a base line (without Factor VIII replacement therapy) Factor VIII level of less that 1IU/dL?
☐ Yes
☐ No

Does your patient have documentation by an FDA-approved test showing NO detectable pre-existing antibodies to adeno-associated virus 5 (AAV5)?
☐ Yes
☐ No

Does your patient have a history of Factor VIII therapy for at least 150 exposure days?
☐ Yes
☐ No

Does your patient have documentation of the following:
☐ Factor VIII inhibitor titer testing has been performed within 30 days before intended receipt of Roctavian
☐ Does NOT currently have an inhibitor to Factor VIII.
☐ Does NOT have a history of Factor VIII inhibitors.

Do you attest that prophylactic therapy with Factor VIII will NOT be given once adequate Factor VIII levels have been achieved? (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)
☐ Yes
☐ No

Do you attest that below apply to your patient:
☐ Has not received Roctavian in the past.
☐ Does not have a known hypersensitivity to mannitol.
☐ Does not have an active acute or uncontrolled chronic infection.
☐ Does not have chronic or active hepatitis B.
☐ Does not have active hepatitis C.
☐ Does not have evidence of significant hepatic fibrosis or cirrhosis.

Does your patient have documentation of one the following (i.or ii.)
i. Has your patient undergone a liver health assessment within 30 days before intended receipt of Roctavian and meets all the following?
☐ Alanine aminotransferase levels are less than or equal to 1.25 times the upper limit of normal.
☐ Aspartate aminotransferase levels are less than or equal 1.25 times the upper limit of normal.
☐ Total bilirubin levels are less than or equal 1.25 times the upper limit of normal.
☐ Alkaline phosphatase levels are less than or equal 1.25 times the upper limit of normal.
☐ Gamma-glutamyl transferase levels are less than or equal 1.25 times the upper limit of normal.
☐ The International Normalized Ratio is less than 1.4.
ii. If your patient has had one or more of the laboratory values listed in criteria above that was not at the value specified, then a hepatologist has evaluated the individual and has determined that use of Roctavian is clinically appropriate.
☐ Yes
☐ No

Does your patient have documentation that within 30 days before intended receipt of Roctavian of the following:
☐ Platelet count was at least 100 x 10^9/L?
☐ Creatnine level was less that 1.4mg/dL?

Do you attest that your patient has NOT used a systemic immunosuppressive agent. (Corticosteroids are NOT included as systemic immunosuppressive agents)
☐ Yes
☐ No

Do you attest that the below apply to your patient:
☐ Does NOT have any disease or condition that would interfere with the compliance requirements that involve the use of systemic corticosteroid therapy or systemic alternative immunosuppressive medications.
☐ Does NOT have an immunosuppressive disorder.
☐ Documentation showing negative for human immunodeficiency virus.
☐ Does not have any other bleeding disorder, besides hemophilia A
☐ Does not have a history of thrombosis or thrombophilia.
☐ Does not have current active malignancy (Current active malignancy does NOT include non-melanoma skin cancer)
☐ Does not have a history of hepatic malignancy.
☐ Has not received a live vaccine within 30 days before intended receipt of Roctavian
☐ A hemophilia specialist physician has discussed with your patient that for a period of up to 6 months after administration of Roctavian that the male of reproductive potential (and his female partner) should prevent or postpone pregnancy by utilizing and effective form of contraception.
☐ A hemophilia specialist physician has discussed with your patient that for a period of up to 6 months after administration of Roctavian that the male should not donate sperm.

Do you attest that the medication is prescribed by a hemophilia specialist physician?
☐ Yes
☐ No

Does your patient have documentation of their current body weight obtained within 30 days before intended receipt of Roctavian?
☐ Yes
☐ No
Date obtained:____/____/____

If any of the requirements listed above are not met and provider feels administration of Roctanian 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).

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:_____

[redacted]

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 Address: Cigna Pharmacy Services, PO Box 42005, Phoenix AZ 85080-2005