



MASSACHUSETTS

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## Gene Therapies for Hemophilia A – Prior Authorization Request Form for Roctavian® (Valoctocogene roxaparvovec-rvox), #166

### Medical Policy #168 Gene Therapies for Hemophilia A or B

#### CLINICAL DOCUMENTATION

- Clinical documentation that supports the medical necessity criteria for **Roctavian** must be submitted.
- If the patient does not meet all the criteria listed below, please submit a letter of medical necessity with a request for [Clinical Exception \(Individual Consideration\)](#) explaining why an exception is justified.

#### Requesting Prior Authorization Using Authorization Manager

Providers will need to use [Authorization Manager](#) to submit initial authorization requests for services. Authorization Manager, available 24/7, is the quickest way to review authorization requirements, request authorizations, submit clinical documentation, check existing case status, and view/print the decision letter. For commercial members, the requests must meet medical policy guidelines.

To ensure the request is processed accurately and quickly:

- Enter the facility's NPI or provider ID for where services are being performed.
- Enter the appropriate surgeon's NPI or provider ID as the servicing provider, *not* the billing group.

#### Authorization Manager Resources

- Refer to our [Authorization Manager](#) page for tips, guides, and video demonstrations.

**For out of network providers:** Requests should still be faxed to 888-973-0726.

Patient Information	
Patient Name:	Today's Date:
BCBSMA ID#:	Date of Treatment:
Date of Birth:	Place of Service: Outpatient <input type="checkbox"/> Inpatient <input type="checkbox"/>
	Distributor:

Physician Information	Facility Information
Name:	Name:
Address:	Address:
Phone #:	Phone #:
Fax#:	Fax#:
NPI#:	NPI#:

Please check off if the patient has the following diagnosis:	
Congenital Hemophilia A	<input type="checkbox"/>

Please check off that the patient meets ALL the following criteria:	
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1. Individual is 18 years of age or older; <b>AND</b>	<input type="checkbox"/>
2. Assigned male at birth; <b>AND</b>	<input type="checkbox"/>
3. Diagnosis of severe or moderately severe hemophilia A as defined by residual Factor VIII (FVIII) levels $\leq$ 1 IU/dL; <b>AND</b>	<input type="checkbox"/>
4. Currently receiving FVIII prophylaxis; <b>AND</b>	<input type="checkbox"/>
5. No history of FVIII inhibitors or a positive screen results of $\geq$ 0.6 BU using the Nijmegen-Bethesda assay; <b>AND</b>	<input type="checkbox"/>
6. No detectable pre-existing antibodies to the adeno-associated virus serotype 5 (AAV5) capsid; <b>AND</b>	<input type="checkbox"/>
7. No history of receiving gene therapy or under consideration for treatment for another gene therapy for hemophilia A; <b>AND</b>	<input type="checkbox"/>
8. Medications is being prescribed by or in consultation with a hematologist or a prescriber who specializes in hemophilia A; <b>AND</b>	<input type="checkbox"/>
9. A baseline liver health assessment including but not limited to ALT; <b>AND</b>	<input type="checkbox"/>
10. Educated regarding alcohol abstinence and concomitant use of certain medications (e.g., isotretinoin, efavirenz); <b>AND</b>	
11. HIV negative; <b>AND</b>	
12. No active hepatitis B and/or hepatitis C infection.	

<b>HCPCS Code Description Codes</b>	
C9399	Unclassified drugs or biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics

Providers should enter the relevant diagnosis code(s) below:

<b>Code</b>	<b>Description</b>	
		<input type="checkbox"/>
		<input type="checkbox"/>

Providers should enter other relevant code(s) below:

<b>Code</b>	<b>Description</b>	
		<input type="checkbox"/>
		<input type="checkbox"/>