

Valoctocogene roxaparvovec-rvox

Goal(s):

- Approve valoctocogene roxaparvovec-rvox (ROCTAVIAN) for conditions supported by evidence of benefit.
- Incorporate 2-step review process for drugs on the high-cost drug carve-out list.

Length of Authorization:

- Once in a lifetime dose.

Requires PA:

- Valoctocogene roxaparvovec (billed as pharmacy or provider administered claim)

Covered Populations:

- FFS and CCO enrolled populations beginning 1/1/26

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is it the FDA approved indication?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is there documentation that the patient has never received another gene therapy for any diagnosis?	Yes: Go to #4	No: Pass to RPh. Deny; medical appropriateness
4. Does the patient have severe Hemophilia A with factor VIII activity of < 1 IU/dL?	Yes: Go to #5	No: Pass to RPh. Deny; medical appropriateness
5. Is there documentation that the patient does not have factor VIII inhibitors?	Yes: Go to #6 Test date _____ Result _____	No: Pass to RPh. Deny; medical appropriateness
6. Is the patient 18 years or older?	Yes: Go to #7	No: Pass to RPh. Deny; medical appropriateness
7. Has the patient tested negative for adeno-associated virus serotype 5 (AAV5) antibodies as measured by an FDA approved test?	Yes: Go to #8 Test date _____ Result _____	No: Pass to RPh. Deny; medical appropriateness

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8. Has this patient had a liver health assessment (ALT, AST, bilirubin, alkaline phosphatase, INR, ultrasound or other radiologic assessment) and were all hepatic enzymes and hepatic radiological tests normal? Note: Mild enzyme elevations which are transient and resolved on repeat testing may answer "Yes" to this question.	Yes: Go to # 11	No: Go to #9
9. Does the patient have a history of severe liver fibrosis or cirrhosis?	Yes: Pass to RPh. Deny; medical appropriateness	No: Go to #10
10. Has the patient been evaluated and cleared for gene therapy treatment by a gastroenterologist or hepatologist?	Yes: Go to #11	No: Pass to RPh. Deny; medical appropriateness
11. Is the patient able and willing to abstain from alcohol for one year following receipt of gene therapy?	Yes: Go to #12	No: Pass to RPh. Deny; medical appropriateness
12. Is there documentation that the patient does not have any active, acute or chronic infections, including HIV, hepatitis B, or hepatitis C?	Yes: Go to #13	No: Pass to RPh. Deny; medical appropriateness
13. Is it anticipated that the patient will be able to safely use corticosteroids or other immunosuppressants for at least 8 weeks if needed?	Yes: Pass to RPh. Pend; Refer to DMAP for secondary review. Duration: Approvals cover one-time infusion for the lifetime of the patient. Approval are valid for 12 months and will be extended if needed to cover treatment journey.	No: Pass to RPh. Deny; medical appropriateness