

Valoctocogene roxaparvovec-rvox

Goal(s):

- Approve valoctocogene roxaparvovec-rvox (ROCTAVIAN) for conditions supported by evidence of benefit.

Length of Authorization:

- Once in a lifetime dose.

Requires PA:

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

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

Approval Criteria

<p>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?</p> <p>Note: Mild enzyme elevations which are transient and resolved on repeat testing may answer “Yes” to this question.</p>	<p>Yes: Go to # 11</p>	<p>No: Go to #9</p>
<p>9. Does the patient have a history of severe liver fibrosis or cirrhosis?</p>	<p>Yes: Pass to RPh. Deny; medical appropriateness</p>	<p>No: Go to #10</p>
<p>10. Has the patient been evaluated and cleared for gene therapy treatment by a gastroenterologist or hepatologist?</p>	<p>Yes: Go to #11</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>11. Is the patient able and willing to abstain from alcohol for one year following receipt of gene therapy?</p>	<p>Yes: Go to #12</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>12. Is there documentation that the patient does not have any active, acute or chronic infections, including HIV, hepatitis B, or hepatitis C?</p>	<p>Yes: Go to #13</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>13. Is it anticipated that the patient will be able to safely use corticosteroids or other immunosuppressants for at least 8 weeks if needed?</p>	<p>Yes: Approve one lifetime does.</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>

P&T/DUR Review: 10/23 (SF)
Implementation: 11/1/23