# 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 provider 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<br>Test date_____<br>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<br>Test date_____<br>Result_____ | **No:** Pass to RPh. Deny; medical appropriateness |

| Approval Criteria | | |
|---|---|---|
| 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?<br><br>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**: Approve one lifetime does. | **No:** Pass to RPh. Deny; medical appropriateness |

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