

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Roctavian is an adeno-associated virus (AAV) vector-based gene therapy product indicated for the treatment of adults with severe hemophilia A without antibodies to adeno-associated virus serotype 5 (AAV5).						
<b>Exclusion Criteria</b>	<ol style="list-style-type: none"> <li>1. Patient must not have any detectable antibodies to adeno-associated virus serotype 5 (AAV5) – AND –</li> <li>2. Patient must not have any FVIII inhibitors.</li> </ol>						
<b>Required Medical Information</b>	<p>Medical records supporting the request must be provided and include documentation of the following:</p> <ol style="list-style-type: none"> <li>1. Patient’s current weight.</li> <li>2. Confirmatory diagnosis of severe hemophilia A with a factor VIII activity level showing &lt; 1 IU/dL.</li> </ol>						
<b>Age Restriction</b>	Must be 18 years of age or older.						
<b>Prescriber Restrictions</b>	None.						
<b>Coverage Duration</b>	One lifetime dose in accordance with the FDA-approved labeling or accepted standards of medical practice.						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J1412</td> <td>Roctavian (valoctocogene roxaparvovec-rvox)</td> <td><b>Billing unit: 1 mL</b>  2 x 10<sup>13</sup> vector genomes/mL SD infusion bag</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J1412	Roctavian (valoctocogene roxaparvovec-rvox)	<b>Billing unit: 1 mL</b>  2 x 10 <sup>13</sup> vector genomes/mL SD infusion bag
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025