

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	<p>Rituxan Hycela is a monoclonal antibody that induces apoptosis in DHL 4 human B cell lymphoma cells and inhibits rheumatoid factor production, antigen presentation, T-cell activation and proinflammatory cytokine production in rheumatoid arthritis. Hyaluronidase is an enzyme that serves to promote rituximab delivery under the skin so that rituximab can be given subcutaneously (versus intravenously).</p> <p>Rituxan was the original rituximab product launched, but many biosimilars have since come to market including Riabni, Ruxience, Truxima, and Rituxan Hycela.</p>						
<b>Exclusion Criteria</b>	None.						
<b>Required Medical Information</b>	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.						
<b>Other Criteria</b>	<p>Must follow LCD L35026: Rituximab.  <a href="https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35026">https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35026</a></p>						
<b>Age Restriction</b>	None.						
<b>Prescriber Restrictions</b>	None.						
<b>Coverage Duration</b>	Up to two years. Dose will be approved according to the FDA-approved labeling or within 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>J9311</td> <td>Rituxan Hycela (rituximab / hyaluronidase)</td> <td> <p><b>Billing unit: 10 mg</b></p> <p>1400 mg-23400 units/11.7 mL, 1600 mg-26800 units/13.4 mL SDV</p> </td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J9311	Rituxan Hycela (rituximab / hyaluronidase)	<p><b>Billing unit: 10 mg</b></p> <p>1400 mg-23400 units/11.7 mL, 1600 mg-26800 units/13.4 mL SDV</p>
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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