

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	Herceptin Hylecta is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase, indicated in adults for the treatment of HER2-overexpressing breast cancer.						
Exclusion Criteria	None.						
Required Medical Information	Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment.						
Other Criteria	Must follow Local Coverage Determination (LCD) L37205: Chemotherapy Drugs and their Adjuncts. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdld=37205&ver=15						
Age Restriction	None.						
Prescriber Restrictions	None.						
Coverage Duration	One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.						
Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document. <table border="1" data-bbox="496 995 1511 1140"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J9356</td> <td>Herceptin Hylecta (trastuzumab and hyaluronidase)</td> <td>Billing unit: 10 mg 600 mg-10000 unit/5 mL SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J9356	Herceptin Hylecta (trastuzumab and hyaluronidase)	Billing unit: 10 mg 600 mg-10000 unit/5 mL SDV
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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