

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	<p>Herceptin (trastuzumab) is the reference product for multiple trastuzumab biosimilars. Trastuzumab biosimilars include, but may not be limited to Ontruzant (trastuzumab-dttb), Ogivri (trastuzumab-dkst), Herzuma (trastuzumab-pkrb), and Trazimera (trastuzumab-qyyp).</p> <p>Herceptin is a HER2/neu receptor antagonist indicated in adults for:</p> <p>The treatment of HER2-overexpressing breast cancer.</p> <p>The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.</p>						
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?lcdId=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	<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>J9355</td> <td>Herceptin (trastuzumab)</td> <td>Billing unit: 10 mg 150 mg SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J9355	Herceptin (trastuzumab)	Billing unit: 10 mg 150 mg 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