

PA Criteria	Criteria Details						
Covered Uses (FDA approved indication)	<p>Ontruzant is a trastuzumab biosimilar.</p> <p>Ontruzant is indicated for adjuvant treatment of HER2-overexpressing node-positive or node-negative (ER/PR-negative or with one high-risk feature) breast cancer:</p> <ul style="list-style-type: none"> As part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel. As part of a treatment regimen with docetaxel and carboplatin. As a single agent following multi-modality anthracycline-based therapy. 						
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	<p>Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts.</p> <p>https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37205&ver=15</p>						
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>Q5112</td> <td>Ontruzant (trastuzumab-dttb) biosimilar</td> <td>Billing unit: 10 mg 150 mg, 420 mg SDV</td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	Q5112	Ontruzant (trastuzumab-dttb) biosimilar	Billing unit: 10 mg 150 mg, 420 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