

| PA Criteria                                   | Criteria Details   |  |             |                            |       |  |  |
|---|--|--|-------------|----------------------------|-------|--|--|
| <b>Covered Uses (FDA approved indication)</b> | Hercessi is a biosimilar to Herceptin.<br><br>Hercessi is a monoclonal antibody that targets HER2 receptors on tumor cells that overexpress the protein, preventing further cell growth, ultimately leading to programmed cell death.  |  |             |                            |       |  |  |
| <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>                         | Must follow LCD L37205: Chemotherapy Drugs and their Adjuncts.<br><a href="https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdld=37205&amp;ver=15">https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdld=37205&amp;ver=15</a>  |  |             |                            |       |  |  |
| <b>Age Restriction</b>                        | None.  |  |             |                            |       |  |  |
| <b>Prescriber Restrictions</b>                | None.  |  |             |                            |       |  |  |
| <b>Coverage Duration</b>                      | One year. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.   |  |             |                            |       |  |  |
| <b>Other Criteria/Information</b>             | Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.<br><table border="1" data-bbox="496 1060 1513 1203"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>Q5146</td> <td>Hercessi (trastuzumab-strf) biosimilar</td> <td><b>Billing unit: 10 mg</b><br/><br/>150 mg, 420 mg SDV</td> </tr> </tbody> </table> | HCPCS  | Description | Billing Units/How Supplied | Q5146 | Hercessi (trastuzumab-strf) biosimilar | <b>Billing unit: 10 mg</b><br><br>150 mg, 420 mg SDV |
| HCPCS   | Description  | Billing Units/How Supplied                           |             |                            |       |  |  |
| Q5146   | Hercessi (trastuzumab-strf) biosimilar   | <b>Billing unit: 10 mg</b><br><br>150 mg, 420 mg SDV |             |                            |       |  |  |

| 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      |
|          |              |             |   |                |
|          |              |             |   |                |