

## Gold Coast Health Plan (GCHP) Medi-Cal Clinical Guidelines Tislelizumab-jsgr (Tevimbra™)

| PA Criteria                               | Criteria Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                                                                      |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|---------------|-------|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------------------|--|
| Covered Uses<br>(FDA approved indication) | <p>Programmed death receptor-1 (PD-1)-blocking antibody indicated for:</p> <p>Esophageal Cancer</p> <ul style="list-style-type: none"><li>In combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1.</li><li>As a single agent in adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor.</li></ul> <p>Gastric Cancer in combination with platinum and fluoropyrimidine-based chemotherapy in adults for the first line treatment of unresectable or metastatic HER2- negative gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1.</p> |                                                                                                                                                                                                                                                                                                                                                      |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
| Exclusion Criteria                        | None                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                      |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
| Required Medical Information              | <p><u>Initial – Must meet ALL of the following:</u></p> <ul style="list-style-type: none"><li>Tumor progress during or after prior systemic chemotherapy that did not include a PD-(L)1 inhibitor for advances unresectable/metastatic ESCC.</li><li>Inadequate response, intolerance, or contraindication to nivolumab or pembrolizumab.</li><li>Baseline liver enzymes, creatinine, and thyroid function.</li><li>Pregnancy testing and advice on contraception are provided to patients of reproductive potential prior to initiating treatment.</li></ul> <p>Renewal:</p> <ul style="list-style-type: none"><li>Continues to meet initial approval criteria</li></ul> <p>Absence of unacceptable toxicities or side effects, including immune-mediated adverse reactions, severe infusion reactions</p>    |                                                                                                                                                                                                                                                                                                                                                      |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
| Age Restriction                           | 18 years and older. 18 to 21 years of age – check CCS eligibility                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                      |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
| Prescriber Restrictions                   | Oncologist or hematologist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                      |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
| Coverage Duration                         | Initial – 6 months; Renewal – 12 months                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                      |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
| Other Criteria/Information                | <p>Criteria adapted from DHCS Oct. 2025</p> <table><tr><th>HCPCS</th><th>Description</th><th>Dosing, Units</th></tr><tr><td>J9329</td><td>Injection, tislelizumab-jsgr, 1mg (Tevimbra)</td><td><ul style="list-style-type: none"><li>150 mg every 2 weeks or 200 mg every 3 weeks or 300 mg every 4 weeks or 400 mg every 6 weeks Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle.</li></ul><p><u>FL:</u> 12mg/kg IV infusion</p><ul style="list-style-type: none"><li>Cycles 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle</li></ul></td></tr><tr><td></td><td>100mg/10ml single dose vial</td><td></td></tr></table>                                                                                                                                                                             | HCPCS                                                                                                                                                                                                                                                                                                                                                | Description | Dosing, Units | J9329 | Injection, tislelizumab-jsgr, 1mg (Tevimbra) | <ul style="list-style-type: none"><li>150 mg every 2 weeks or 200 mg every 3 weeks or 300 mg every 4 weeks or 400 mg every 6 weeks Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle.</li></ul> <p><u>FL:</u> 12mg/kg IV infusion</p> <ul style="list-style-type: none"><li>Cycles 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle</li></ul> |  | 100mg/10ml single dose vial |  |
| HCPCS                                     | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Dosing, Units                                                                                                                                                                                                                                                                                                                                        |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
| J9329                                     | Injection, tislelizumab-jsgr, 1mg (Tevimbra)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"><li>150 mg every 2 weeks or 200 mg every 3 weeks or 300 mg every 4 weeks or 400 mg every 6 weeks Cycle 4 and beyond: Days 1 and 15 of each 28-day cycle.</li></ul> <p><u>FL:</u> 12mg/kg IV infusion</p> <ul style="list-style-type: none"><li>Cycles 1 to 3: Days 1, 8, 15, and 22 of each 28-day cycle</li></ul> |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |
|                                           | 100mg/10ml single dose vial                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                      |             |               |       |                                              |                                                                                                                                                                                                                                                                                                                                                      |  |                             |  |



|  |  |                              |                                                                                                     |  |
|--|--|------------------------------|-----------------------------------------------------------------------------------------------------|--|
|  |  | 200mg<br>single dose<br>vial | <ul style="list-style-type: none"><li>Cycles 4 to 12: Days 1 and 15 of each 28-day cycle.</li></ul> |  |
|--|--|------------------------------|-----------------------------------------------------------------------------------------------------|--|

| STATUS  | DATE<br>REVISED | REVIEW DATE | APPROVED/REVIEWED BY                       | EFFECTIVE<br>DATE |
|---------|-----------------|-------------|--------------------------------------------|-------------------|
| Created | Jan. 15, 2026   | N/A         | Yoonhee Kim, Senior Clinical<br>Pharmacist | N/A               |