

## GCHP Medi-Cal Clinical Guidelines

### Teprotumumab (Tepezza<sup>TM</sup>)

PA Criteria	Criteria Details
<b>Covered Uses (FDA Approved Indication)</b>	Treatment of thyroid eye disease (TED) regardless of thyroid eye disease activity or duration.
<b>Exclusion Criteria</b>	Pregnancy or lactating female.
<b>Required Medical Information</b>	<ul style="list-style-type: none"> <li>• Documentation of the following:           <ul style="list-style-type: none"> <li>○ Symptomatic, active disease TED               <ul style="list-style-type: none"> <li>▪ Clinical diagnosis of Graves' disease associated with active TED</li> <li>▪ Onset of active TED symptoms within nine months prior to Baseline</li> <li>▪ Clinical Activity Score (CAS) greater than or equal to four for the most severely affected eye at Screening and Baseline</li> <li>▪ Presence of moderately to severely active TED, associated with at least one of the following:                   <ul style="list-style-type: none"> <li>✓ Lid retraction greater than or equal to two (2mm) millimeters</li> <li>✓ Moderate or severe soft tissue involvement</li> <li>✓ Proptosis greater than or equal to three (3mm) millimeters above normal for race and gender</li> <li>✓ Inconstant or constant diplopia (presence of diplopia)</li> </ul> </li> <li>○ Stable, chronic (inactive) TED               <ul style="list-style-type: none"> <li>▪ Clinical diagnosis of Grave's disease associated stable, chronic (inactive) TED</li> <li>▪ TED duration of 2 – 10 years</li> <li>▪ Clinical Activity Score (CAS) less than or equal to one in both eyes before screening for at least one year; or</li> <li>▪ Has all of the following for at least one year before screening:                   <ul style="list-style-type: none"> <li>✓ No proptosis progression</li> <li>✓ No diplopia progression in patients with history of diplopia</li> <li>✓ No new inflammatory TED symptoms</li> </ul> </li> <li>▪ Must have had greater than or equal to three (3mm) millimeters increase in proptosis from before diagnosis of TED and/or proptosis greater than or equal to three (3mm) millimeters above normal values for race and gender</li> </ul> </li> <li>• Euthyroid or with mild hypo- or hyperthyroidism defined as free thyroxine and free triiodothyronine levels less than 50 percent above or below the normal limits.</li> <li>• Does not require surgical ophthalmological intervention.</li> </ul> </li> </ul> </li></ul>

	<ul style="list-style-type: none"> <li>Must have well controlled diabetes if the member has diabetes (defined as HgbA1C &lt; 9 at most recent clinic visit).</li> <li>Contraindication, intolerance, or lack of response to glucocorticoids or a documented justification why the use of glucocorticoids is not appropriate.</li> </ul>						
<b>Age Restriction</b>	18 years of age and older. 18-21 years of age – check CCS.						
<b>Prescriber Restrictions</b>	Prescribed by or in consultation with an ophthalmologist, endocrinologist or a physician who specializes in treatment of thyroid eye disease.						
<b>Coverage Duration</b>	12 months (maximum of eight doses) per lifetime.						
<b>Other Criteria/Information</b>	<p>Criteria adapted from DHCS February 2025.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Dosing, Units</th> </tr> </thead> <tbody> <tr> <td>J3241</td> <td>Injection, teprotumumab-trbw, 10mg (Tepezza™)</td> <td>10mg/kg IV as a single dose followed by 20mg/kg IV every three weeks for seven additional doses.</td> </tr> </tbody> </table>	HCPCS	Description	Dosing, Units	J3241	Injection, teprotumumab-trbw, 10mg (Tepezza™)	10mg/kg IV as a single dose followed by 20mg/kg IV every three weeks for seven additional doses.
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	5/01/2024	5/01/2024	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	5/15/2024	Pharmacy & Therapeutics (P&T) Committee	3/1/2025
Approved	N/A	7/18/2024	Medical Advisory Committee (MAC)	3/1/2025
Updated	10/09/2025	N/A	Yoonhee Kim, Clinical Program Pharmacist	N/A
Approved	N/A	11/13/2025	Pharmacy & Therapeutics Committee	12/1/2025