

GCHP Medi-Cal Clinical Guidelines Teprotumumab (Tepezza™)

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



	<ul style="list-style-type: none">• Must have well controlled diabetes if the member has diabetes (defined as HgbA1C < 9 at most recent clinic visit).• Contraindication, intolerance, or lack of response to glucocorticoids or a documented justification why the use of glucocorticoids is not appropriate.		
Age Restriction	18 years of age and older. 18-21 years of age – check CCS.		
Prescriber Restrictions	Prescribed by or in consultation with an ophthalmologist, endocrinologist or a physician who specializes in treatment of thyroid eye disease.		
Coverage Duration	12 months (maximum of eight doses) per lifetime.		
Other Criteria/Information	Criteria adapted from DHCS February 2025.		
	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.

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