

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY	Thyroid Disorders	P&T DATE:	3/10/2026
THERAPEUTIC CLASS	Endocrine Disorders	REVIEW HISTORY (MONTH/YEAR)	3/25, 3/24, 3/23, 7/22, 12/21, 12/20, 12/19, 12/18, 9/17, 12/16, 11/15
LOB AFFECTED	MCL/Medicare		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the Health Plan of San Joaquin/Mountain Valley Health Plan (Health Plan) Pharmacy and Therapeutic Advisory Committee.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit <https://medi-calrx.dhcs.ca.gov/home/> for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit. All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

This coverage policy is updated on an annual basis. For more recent or up-to-date criteria, reference the Medi-Cal Provider Manual and/or the Medicare National Coverage Determination/Local Coverage Determination (NCD/LCD) for specific criteria. If the Medi-Cal Provider Manual and/or the Medicare NCD/LCD do not have medical necessity criteria, please refer to the "Evaluation Criteria" section in this policy for specific criteria. It is also important to reference the Medicare Benefit Manuals - Chapter 15 and Chapter 16 - when determining benefit coverage and criteria for review of physician administered drugs on the Medicare benefit.

OVERVIEW

Relevant literature used in the creation of this policy include the following: Tepezza (teprotumumab-trbw) is the only FDA approved medication for thyroid eye disease. Recent [FDA labeling](#) includes use regardless of disease activity of duration.⁸ Therefore, criteria were created for Tepezza for both moderate-to-severe active and inactive thyroid eye disease. Requirements and limitations were established using guideline recommendations, clinical trial data, and package insert information.

MEDI-CAL EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).

Thyroid Agents
<i>Teprotumumab-trbw (Tepezza)</i>

- Coverage Criteria:** Tepezza is reserved for all of the following:
 - Either A or B
 - A) Moderate-to-severe active thyroid eye disease with a Clinical Activity Score ≥ 3 with either
 - Failure of a 4-week trial of a systemic corticosteroid (at up to maximally indicated doses), unless clinically significant adverse effects are experienced, or all are contraindicated OR
 - Significant proptosis and/or diplopia.
 - B) Inactive thyroid eye disease with Clinical Activity Score < 3 or no additional inflammation or progression in proptosis/diplopia for ≥ 1 year with
 - Proptosis ≥ 3 mm from before thyroid eye disease and/or from normal.
 - Euthyroid or mild state (free thyroxine and triiodothyronine levels $< 50\%$ +/- normal limits) hypothyroidism or hyperthyroidism AND
 - Patient must not have had optic nerve involvement within the last six months.

- ❑ **Limits:** Up to 10 mg/kg for the first IV infusion, followed by 20 mg/kg IV every 3 weeks for 7 additional infusions. Must be prescribed by an endocrinologist/ophthalmologist.
- ❑ **Required Information for Approval:** N/A
- ❑ **Other Notes:** Patient must not have planned surgical ophthalmological intervention or radiation during Tepezza use. Patients with pre-diabetes/diabetes must be currently managed by an endocrinologist. A history of progression of thyroid eye disease based on worsening of vision, soft tissue inflammation, motility, or proptosis is suggestive of active thyroid eye disease independently of the Clinical Activity Score. Significant proptosis is defined as not just a degree of proptosis ≥ 3 mm above the upper limit for race and sex but also as proptosis that impacts sufficiently on daily life and would justify the risks of treatment.

☒ REFERENCES

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8. TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon.
9. Douglas RS, Couch S, Wester ST, Fowler BT, Liu CY, Subramanian PS, Tang R, Nguyen QT, Maamari RN, Ugradar S, Hsu K, Karon M, Stan MN. Efficacy and Safety of Teprotumumab in Patients With Thyroid Eye Disease of Long Duration and Low Disease Activity. *J Clin Endocrinol Metab.* 2023 Dec 21;109(1):25-35. doi: 10.1210/clinem/dgad637. PMID: 37925673; PMCID: PMC10735297.
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11. Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. *N Engl J Med.* 2020;382(4):341-352. doi:10.1056/NEJMoa1910434
12. THYROGEN (thyrogen alfa) [prescribing information] Genzyme Corporation.
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☒ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	HPSJ Coverage Policy – Endocrine Disorders – Thyroid Disorders 2015-11.docx	11/2015	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Thyroid Disorders 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Endocrine Disorders - Thyroid Disorders 2017-09.docx	09/2017	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy – Endocrine – Thyroid Disorders 2018-12.docx	12/2018	Matthew Garrett, PharmD
Review Policy	Thyroid Disorders	12/2019	Matthew Garrett, PharmD
Review Policy	Thyroid Disorders	12/2020	Matthew Garrett, PharmD
Review Policy	Thyroid Disorders	05/2021	Matthew Garrett, PharmD
Reactivation of Policy	Thyroid Disorders	07/2022	Matthew Garrett, PharmD
Review of Policy	Thyroid Disorders	03/2023	Matthew Garrett, PharmD
Review of Policy	Thyroid Disorders	03/2024	Matthew Garrett, PharmD

Review of Policy	Thyroid Disorders	03/2025	Matthew Garrett, PharmD
Review of Policy	Thyroid Disorders	03/2026	Matthew Garrett, PharmD

Note: All changes are approved by the Health Plan P&T Committee before incorporation into the utilization policy.