

Approved by: Optum Medical and Pharmacy Subcommittee	Effective Date: 10/01/2026
Clinical Policy Document: Teprotumumab-trbw (Tepezza)	Date Approved: 10/01/2026
Reference #: MC/PC003	Replaces Effective Clinical Policy Dated: N/A

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PLANS IN SCOPE

Aspirus Health Plan

BACKGROUND & PURPOSE

Background

Thyroid Eye Disease (TED), also referred to as Graves' orbitopathy or thyroid-associated ophthalmopathy, is an autoimmune inflammatory disorder of the orbit characterized by expansion of extraocular muscles and orbital adipose tissue. Clinical manifestations include proptosis, diplopia, eyelid retraction, soft-tissue inflammation, and, in severe cases, vision-threatening complications.

TED is categorized by severity (mild, moderate-to-severe, or sight-threatening) and by disease activity (active or inactive). Although treatment paradigms historically emphasized disease activity, contemporary evidence demonstrates that clinically meaningful proptosis and diplopia may persist in patients with chronic or low-activity disease.

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Systemic glucocorticoids have long been considered first-line therapy for moderate-to-severe TED, particularly in active disease. However, their effects on proptosis are limited, and use may be constrained by toxicity, intolerance, contraindications, or inadequate response.

Teprotumumab-trbw is a fully human monoclonal antibody that inhibits IGF-1R signaling, a key pathogenic pathway in TED. Peer-reviewed randomized controlled trials and meta-analyses demonstrate that teprotumumab improves proptosis, diplopia, disease activity measures, and disease-specific quality of life in adults with moderate-to-severe TED, including those with long-standing or low-activity disease.

Purpose

The purpose of this policy is to support consistent, evidence-based coverage determinations for teprotumumab in alignment with FDA labeling, peer-reviewed clinical evidence, and commercial utilization-management standards.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

COVERAGE INDICATIONS:

Tepezza is prescribed by or in consultation with an ophthalmologist and/or an endocrinologist experienced in TED management.

Tepezza is considered medically necessary when the following criteria are met:

- a) Documented diagnosis of Thyroid Eye Disease (TED).
- b) The member has moderate-to-severe TED, demonstrated by at least one of the following:
 - i) Proptosis ≥ 3 mm above normal for race and sex
 - ii) Lid retraction ≥ 2 mm
 - iii) Inconstant or constant diplopia
 - iv) Moderate or severe soft-tissue involvement (e.g., periorbital edema, conjunctival injection, chemosis)
- c) Member is 18 years of age or older
- d) The member is euthyroid, or, if hyperthyroid or hypothyroid, the underlying thyroid dysfunction is being actively treated and managed toward achievement and maintenance of a euthyroid state. Treatment with Tepezza does not require achievement of a specific free T3 or free T4 threshold before initiation when the treating clinician determines that therapy is otherwise clinically appropriate.

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- e) Member has had an inadequate response to an appropriate trial of systemic glucocorticoids or
- i) Has demonstrated intolerance or clinically significant adverse effects to systemic glucocorticoids
 - ii) Has a contraindication to systemic glucocorticoids
 - iii) Has a clinical determination that glucocorticoids are not appropriate or unlikely to be effective based on patient-specific factors or disease characteristics.

Note: Initial authorization is for one treatment course consisting of 8 intravenous infusions administered per FDA-approved dosing. Routine maintenance therapy or automatically repeated treatment courses are not covered. A repeat course may be considered on individual clinical review for documented recurrence/reactivation following an initial response, or for persistent clinically significant TED after the initial course, when the treating TED specialist documents objective disease findings, prior response and tolerability, and a clinical rationale that the expected benefit outweighs the risks. Continuation of treatment requires adherence to required monitoring and absence of unacceptable toxicity.

Dosing

Due to the risk of hypersensitivity reactions, Tepezza is to be administered under the supervision of a physician by a trained healthcare professional in a location where appropriate medical support is readily available.

The dose for Tepezza

- 10 mg/kg IV for the initial infusion
- 20 mg/kg IV every 3 weeks for 7 additional infusions
- Volume/infusion recommendations: Administer by intravenous infusion over 60–90 minutes in an appropriate clinical setting.

Safety Monitoring and Requirements

Required monitoring includes:

- Blood glucose monitoring at baseline and throughout therapy
- Hearing assessment before, during, and after treatment due to risk of hearing impairment, which may be severe or permanent
- Monitoring for infusion reactions
- Monitoring for signs and symptoms of inflammatory bowel disease, including in patients without prior history; discontinue therapy if IBD exacerbation is suspected

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- Ongoing thyroid disease management

Exclusions

Coverage is not provided for members with sight-threatening Thyroid Eye Disease, including dysthyroid optic neuropathy or severe corneal compromise requiring urgent intervention.

Rationale: Patients with sight-threatening TED were excluded from pivotal clinical trials, and the safety and effectiveness of teprotumumab have not been established in this setting.

Other exclusions include:

- Pregnancy: Tepezza should not be used during pregnancy. For females of reproductive potential, documentation of a negative pregnancy test prior to treatment is required. Effective contraception should be used prior to initiation, during treatment, and for 6 months following the last dose.
- Lactation: Human data regarding teprotumumab exposure during breastfeeding are not available. Lactation alone is not an FDA-labeled contraindication. For a breastfeeding member, the prescriber should document an individualized maternal-infant benefit-risk assessment prior to treatment.
- Pediatric Patients under the age of 18 years, as safety and effectiveness in this age group have not been proven.
- Concomitant use with other biologic immunomodulatory therapies is not covered.

Emerging Therapies

Alternative routes of administration for teprotumumab are under investigation. At this time, no peer-reviewed evidence supporting non-intravenous administration has been published, and such formulations are considered investigational for coverage purposes.

Medical Records Documentation

Benefit coverage is determined by review of member-specific benefit plan information and all applicable laws. Medical records documentation may be required to assess if the member meets criteria; however, provision of records does not guarantee coverage.

APPLICABLE CODES

Note: The code list below is provided for guidance. Code coverage will depend on the coverage guidelines above.

Code Type	Code	Description
HCPCS	J3241	Teprotumumab-trbw 10 mg

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POLICY/REVISION HISTORY

Date	Summary of Changes	Approval By
10/01/2026	Initial Policy Development	Optum Coverage Policy Committee

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Burch, H. B., Perros, P., Bednarczuk, T., Cooper, D. S., Dolman, P. J., Leung, A. M., Mombaerts, I., Salvi, M., & Stan, M. N. (2022). Management of thyroid eye disease: A consensus statement by the American Thyroid Association and the European Thyroid Association. *Thyroid*, 32(12), 1439–1470. <https://doi.org/10.1089/thy.2022.0251>

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U.S. Food and Drug Administration. (2025). *TEPEZZA® (teprotumumab-trbw) prescribing information*. Amgen Inc. Accessed 06/04/2026.
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Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن أعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: यान द : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deutsch (Pennsylvania German / Dutch) schwetzscht, kannst du mitaue Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາໂດຍບໍ່ເສັຽຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-800-332-6501 (TTY: 711).