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Trends in Teprotumumab Insurance Authorization and Socioeconomic Determinants of Teprotumumab Access

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Abstract

Background: Teprotumumab is a novel biologic Food and Drug Administration (FDA)-approved medication for thyroid eye disease (TED). Cost remains a significant barrier to medication access. The present study analyzed the contribution of patient socioeconomic and clinical factors on access and eligibility for TED treatment with teprotumumab.

Methods: This study is a retrospective chart review of 93 TED patients receiving care at a tertiary care academic hospital between December 2019 and December 2023, for whom a prior authorization (PA) for teprotumumab treatment was submitted. We collected sociodemographic data, smoking status, insurance type, clinical activity score (CAS), and prior attempted treatments, as well as PA approval status and reason for denial, if applicable. Data were compared between patients approved or denied PA at the first request using a *t*-test, Fisher's exact test, and descriptive analysis, as appropriate.

Results: PA was denied for 13 patients (14%). PA was significantly more likely to be approved for patients with Medicare coverage and denied for those Medi-Cal coverage and geographically further away from the hospital. Five PAs were denied in 2020 (38%), five in 2021 (38%), two in 2022 (15%), and one in 2023 (8%). Common reasons for denial included collection of thyroid labs over 30 days prior to the request (n = 4, 31%), lack of prior oral corticosteroid trial (n = 3, 23%), and administrative error (n = 3, 23%). Ten (77%) patients received subsequent approval.

Conclusions: Insurance type, geographic location, and socioeconomic status are important factors that may affect teprotumumab authorization. PA denials decreased after 2022, likely secondary to updated TED guidelines and drug availability. Compliance with insurance requirements may streamline the authorization process and increase PA approval rates.

Keywords: Teprotumumab; Thyroid eye disease; Prior authorization; Healthcare access; Treatment access

Introduction

Thyroid-associated orbitopathy, or thyroid eye disease (TED), is a rare but significant manifestation of Graves' disease that can lead to significant debilitation and vision compromise in patients [1]. Symptoms vary significantly, ranging from easily treatable sequelae, such as dry eyes, mild lagophthalmos to more severe sequelae including exophthalmos, diplopia and compressive optic neuropathy (CON) [1]. The pathophysiology of TED is complex and driven by the activation of thyrotropin receptors, which facilitate overproduction of the thyroid hormones and overexpression of the insulin-like growth factor receptor (IGF-1R) antibodies that ultimately drive cytokine production and extracellular matrix deposition [2-4]. These processes result in further inflammation, enlargement of extraocular muscles, and increased orbital fat [5, 6].

The treatment of TED has been aimed at decreasing intraorbital inflammation [7]. Corticosteroids, potent immunosuppressors, especially in higher doses, have been used for the treatment of TED for decades and remain a mainstay for management for patients in the active state [8]. Other biological agents, including tocilizumab, a monoclonal antibody targeting interleukin (IL)-6, and rituximab, a monoclonal antibody targeting B cells expressing CD-20, have been utilized as second-line treatments for patients who do not respond to corticosteroids as expected [9]. Decompression of the orbit during the active disease phase is generally reserved for patients with CON [10]. However, the effects of these treatments on some sequelae, such as exophthalmos, remain limited.

Teprotumumab, a humanized monoclonal antibody that blocks IGF-1R, is the first and only Food and Drug Administration (FDA)-approved medication for the treatment of TED [11]. The novel biologic has become the most commonly recommended treatment agent in the United States [12]. However, high cost, especially for uninsured patients, remains a

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significant socioeconomic barrier to access [13]. A single vial of teprotumumab costs approximately $14,900 [14], and the cost of treatment can range from $200,000 to $480,000 depending on the patient's weight. In this study, we analyzed the association between socioeconomic factors and access to teprotumumab in a cohort of TED patients, for whom a prior authorization (PA) request was submitted.

Materials and Methods

This is a retrospective cohort study of TED patients receiving care at the Department of Ophthalmic Plastic and Orbital Surgery at the University of California, Davis, between December 2019 and December 2023. The Institutional Review Board approval was obtained at the University of California, Davis, and the study was conducted in accordance with the Declaration of Helsinki and Health Insurance Portability and Accountability Act (HIPAA) compliance.

Eligibility criteria included patients with TED, for whom an insurance authorization for teprotumumab was requested. Patients were excluded if teprotumumab was recommended, but the authorization request was not placed. We conducted a retrospective chart review and collected the following information: 1) sociodemographic history, including age at the visit prior to teprotumumab request, race, biological sex, distance from clinic patients' zip code and distance to clinic, education level, employment status, primary insurance type and availability of secondary insurance; 2) relevant medical history, including current smoking status, TED phase (active/stable), and clinical activity score (CAS) at the visit prior to teprotumumab request, as well as prior treatments tried for TED. We also obtained PA details, including the date of request and the date and reason for denial, if applicable. Patients were divided into two groups based on insurance authorization approval or denial for treatment with teprotumumab at the first request. The data between the two cohorts were compared and analyzed with the *t*-test and Fisher's exact tests, as appropriate, using Prism software (San Diego, CA, version 10.2.0). We also performed a descriptive analysis of insurance denial reasons and compared the denial rate across each year. A P value less than 0.05 was considered significant.

Results

We reviewed 108 patient charts, of which 93 were eligible and included in the final study cohort. Two patients were excluded due to the pending insurance authorization at the time of data collection, two patients requested and/or received teprotumumab at another treatment center, and 11 patients were recommended teprotumumab but did not proceed with the insurance request.

Sociodemographic characteristics

Patients' sociodemographic characteristics, stratified by teprotumumab approval status, are summarized in Table 1. The average age at the visit prior to the teprotumumab request was 56.5 years old (range 21 - 82). Twenty patients (22%) were male, and 73 (78%) were female. Sixty-two (67%) patients were White, 10 (11%) Hispanic or Latino, eight (9%) Asian, and seven (8%) Black or African American. Twenty-eight (30%) patients were employed or full-time students at the time of the clinic visit, and 37 were unemployed (40%), of which seven (8%) did not have a current job, seven (8%) were disabled, and 23 (25%) were retired. On average, patients lived 47 miles away from the hospital (range 2 - 377). The average median income by zip code of residence was $59,041 ($27,379 to $117,700) among all patients. Thirty patients (32%) were insured through Medicare, 36 (39%) had private insurance, 24 (26%) had Medi-Cal, three (3%) had federal insurance. Twenty-six patients (28%) had secondary coverage.

Fisher's exact test showed a significant association between teprotumumab approval rates with geographic location (P = 0.02) and insurance coverage (P = 0.003). On average, patients that were denied the initial teprotumumab request lived significantly further away from the hospital. Kruskal-Wallis analysis showed that there was no significant association between patient's geographic location and insurance status (P = 0.18). Patients who received PA approval on the first request were significantly more likely to have Medicare coverage (P = 0.008), and those denied were significantly more likely to have Medi-Cal coverage (P = 0.004). Fischer's exact test showed no significant association between teprotumumab approval and age (P = 0.26), biological sex (P = 0.47), employment status (P = 0.22), or median income (P = 0.72).

Treatment-related data

Medical history and treatment-related statistics, stratified by teprotumumab approval status, are summarized in Table 2. Overall, the average CAS score prior to the teprotumumab request was 5.5 (1 to 10). Eighteen (19%) patients were active smokers. Seventy-three (78%) patients had active disease, and 14 (15%) had stable disease. Thirty-seven (40%) patients had already tried another TED treatment. Prior TED treatments included radiotherapy (n = 3, 3%), pulse steroids (n = 10, 11%), oral steroids (n = 16, 17%), decompression (n = 13, 14%), strabismus (n = 3, 3%), or eyelid surgery (n = 5, 5%). There were no significant associations between PA approval and CAS score (P = 0.68), disease phase (P = 0.51), smoking status (P = 0.27), or attempting prior TED treatment (P > 0.99).

PA was denied for 13 patients (14%): five patients were denied in 2020 (38%), five in 2021 (38%), two in 2022 (15%), and one in 2023 (8%). The reasons for denial included: thyroid laboratory tests obtained more than 30 days prior to request (n = 4, 31%), administrative error (n = 3, 23%), absence of oral corticosteroids trial (n = 3, 23%), requested facility being out of network (n = 2, 15%), patient being an active smoker (n = 2, 15%), not euthyroid (n = 2, 15%) or low CAS score (n = 2, 15%), no endocrinology evaluation (n = 1, 8%), limited vision potential (n = 1, 8%), or teprotumumab deemed not medically necessary (n = 1, 8%). Ten out of 13 patients (77%) received

Table 1. Socioeconomic Characteristics of the Study Population

	PA approved (N = 80)	PA not approved (N = 13)	P value
Age at visit prior to teprotumumab request (mean, median (range))	57, 60.5 (21 - 82)	52, 52 (32 - 70)	0.26
Biologic sex			0.47
Male	64 (80%)	9 (69%)	
Female	16 (20%)	4 (31%)	
Race/ethnicity			
White	52 (65%)	10 (77%)	
Asian	8 (10%)	0	
African American	7 (9%)	0	
Hispanic/Latino	9 (10%)	2 (15%)	
Other	2 (3%)	0	
Unknown	2 (3%)	1 (8%)	
Employment status			0.22
Employed or student	23 (29%)	5 (38%)	
Unemployed	35 (44%)	2 (16%)	
Unemployed	6 (8%)	1 (8%)	
Disabled	7 (9%)	0	
Retired	22 (28%)	1 (8%)	
Unknown	22 (28%)	6 (46%)	
Distance to clinic (miles) (mean, median (range))	41, 23 (2 - 377)	83, 44 (15 - 263)	0.02*
Median income by zip code ($) (median (range))	58,738 (27,379 - 117,700)	60,884 (28,963 - 100,308)	0.72
Insurance type			0.003*
Medicare	30 (38%)	0	
Private	31 (39%)	5 (38%)	
Medi-Cal	16 (20%)	8 (62%)	
Federal	3 (4%)	0	
Secondary insurance			0.1
Yes	25 (31%)	1 (8%)	
No	55 (69%)	12 (92%)	

*P < 0.05. PA: prior authorization.

subsequent approval on average 138 (1 to 476) days after the initial PA was submitted.

Discussion

Our study highlights several socioeconomic factors associated with teprotumumab approval on the first insurance request. Our findings show that teprotumumab PA was significantly more likely to be denied for patients who resided further away from the clinic and those with Medi-Cal coverage. Medicare members were significantly more likely to be approved for treatment. Most PA denials were issued in 2020 and 2021, likely due to the novelty of the drug, lack of updated treatment guidelines, and pandemic-associated delays.

Geographic location is a significant barrier to accessing care [15] and may be associated with worse health outcomes. In our cohort, PA for teprotumumab was more likely to be denied for patients who were located further from the hospital, regardless of patients' insurance status. Coincidentally, the majority of the patients in the denied group received Medi-Cal-managed care, indicative of a lower socioeconomic status despite this group having a slightly higher average median income by zip code. Although the median income by zip code was similar between the two groups, lower-income patients with Medi-Cal coverage experienced the greatest proportion of PA denials. Employment was not associated with PA status, although the employment status for numerous patients was not known, which limited our analysis. These findings suggest that geographic location and lower socioeconomic status may pose a barrier to teprotumumab approval and access. Additionally, median income by zip code may not be a reliable metric to gauge socioeconomic status and type of insurance coverage. However, it remains unclear if geographic location further in-

Table 2. Clinical Characteristics of the Study Population

	PA approved (N = 80)	PA not approved (N = 13)	P value
Average CAS (mean, median (range))	5.5, 5 (1 - 10)	5.7, 6 (2 - 8)	0.68
Current smoker			0.27
Yes	14 (18%)	4 (31%)	
No	66 (83%)	9 (69%)	
Disease phase			0.51
Active	68 (85%)	11 (85%)	
Stable	15 (15%)	2 (15%)	
Prior treatment tried			> 0.99
Yes	32 (40%)	5 (38%)	
No	48 (60%)	8 (52%)	
If prior treatment tried, type	Of 32 patients	Of 5 patients	
Radiotherapy	3 (9%)	0	
Pulse steroids	7 (22%)	3 (60%)	
Oral steroids	13 (41%)	3 (60%)	
Decompression surgery	11 (34%)	2 (40%)	
Strabismus surgery	3 (9%)	0	
Lid surgery	5 (16%)	0	
Other	1 (3%)	0	
Year of approval/denial	Approval	Denial	
2019	2 (3%)	-	
2020	33 (41%)	5 (38%)	
2021	14 (18%)	5 (38%)	
2022	14 (18%)	2 (15%)	
2023	17 (21%)	1 (8%)	
If denied, reason for denial			
Thyroid Labs > 30 days ago	-	4 (31%)	
Administrative error	-	3 (23%)	
No oral steroids trial	-	3 (23%)	
Facility out of network	-	2 (15%)	
Patient not euthyroid	-	2 (15%)	
CAS too low	-	2 (15%)	
Smoking status	-	2 (15%)	
No endocrinology evaluation	-	1 (8%)	
Limited visual potential	-	1 (8%)	
Not medically necessary	-	1 (8%)	
If denied, subsequent approval?			
Yes	-	10 (77%)	
Days to approval (mean, median (range))	-	138, 57 (1 - 476)	
No	-	2 (15%)	
Unknown	-	1 (8%)	

CAS: clinical activity score; PA: prior authorization.

fluences access to in-network infusion facilities as only two patients in our cohort were denied due to recommended facilities being out of network, rendering analysis unsuitable due to low numbers. Anecdotally, one patient was located 32 miles and the second 171 miles away from the medical center. Additionally, patients located further away from the clinic tended to have less reliable continuity of primary care, as some patients were seen by providers in walk-in clinics, and timely completion of thyroid labs was further complicated for patients, whose primary care providers or endocrinologists were outside

of hospital system. These factors could have potentially contributed to PA denials for patients located further away.

Insurance coverage was also found to be a significant factor for insurance authorization. Specifically, Medicare and non-Medi-Cal insurance (private or federal) status were significantly associated with being approved on the first PA request. No patient with Medicare coverage was denied teprotumumab authorization. According to the US Department of Health Office of Inspector General investigation, Medi-Cal denies twice as many PA requests compared to Medicare (12.5% versus 5.7%, respectively) [16]. Out of 24 patients with Medi-Cal coverage in our cohort, 33% were denied compared to 14% of those with private insurance (five out of 36) and none with Medicare coverage. Following the initial denial, appeals were submitted for seven out of eight Medi-Cal patients, and five (71%) received a subsequent approval on average 247 days after the initial request (median 57, range 2 to 476). The success rate of the first-level appeal for teprotumumab is comparatively higher than the nationally reported successful first-level PA appeal rate for Medi-Cal (36%) [16]. These findings suggest that patients with Medi-Cal may be at greater risk to be denied teprotumumab authorization and experience delays in accessing treatment. Considering the unpredictable length of the delay, patients with Medi-Cal may be offered to explore an alternative TED treatment modality while awaiting appeal results.

Publicly available teprotumumab insurance approval criteria necessitate all of the following requirements to be met for teprotumumab to be considered medically necessary: prescription written by an ophthalmologist and/or endocrinologist, age greater than 18, moderate-to-severe TED with at least one ocular complication, minimum CAS score requirement (varies depending on the carrier), patient is euthyroid, prior failure or contraindication to corticosteroid trial, and other criteria depending on the insurance provider [17-19]. In our cohort, the most frequent reasons for PA denial included thyroid labs completed more than 30 days before PA, administrative error, lack of corticosteroid trial, low CAS score or not euthyroid labs, and active smoking status. Providers prescribing teprotumumab should consider addressing these requirements before placing a PA, especially for patients with Medi-Cal-managed care, to streamline medication access. Additionally, this may further help avoid the need to consult drug representatives to secure teprotumumab approval. The authorization process for teprotumumab is unique compared to other medications as the drug manufacturer offers a considerable number of resources and drug coordinators to facilitate the PA process, considering the company's financial stake in the process.

Most PA denials were issued in 2020 and 2021. The denial rates may be in part due to the lack of uniform guidelines on teprotumumab shortly after its launch. The biologic was granted FDA approval on January 21, 2020 [20], and naturally not included in the latest American Thyroid Association guidelines on hyperthyroidism management from 2016 [21]. In December 2022, the American and European Thyroid Associations released a consensus endorsing teprotumumab as the preferred treatment modality for moderato-to-severe TED with significant proptosis and/or diplopia [22]. This likely facilitated PA approval rates; in our cohort, only three patients in our cohort were denied teprotumumab after 2022. It is also worth noting that the coronavirus disease 2019 (COVID-19) pandemic also led to widespread disruption in health care delivery, staffing shortages, and supply chain disruption [23-25]. Teprotumumab availability was limited between March 2020 and April 2021 due to government mandates prioritizing the production of the COVID-19 vaccine [26]. Additionally, the burden of PA persisted through the pandemic. Although some PA requirements were transiently relaxed, over 90% of practicing physicians reported delays in PA processing and access to vital treatment for their patients [27]. These effects likely contributed to the higher teprotumumab denial rates observed among our patients who were treated during the pandemic.

To our knowledge, this is the first study to explore the association between teprotumumab insurance approval rates and socioeconomic and clinical disease factors. Limitations of our study include the retrospective nature of the study design. Additionally, our findings are limited to patients evaluated at a tertiary academic setting, which may not be representative of teprotumumab authorization among federally qualified health centers or private practice patients. Our findings were also limited by the small number of patients who were denied teprotumumab and a substantial number of PAs submitted both during the pandemic and before the updated FDA guidelines regarding teprotumumab. Thus, future studies capturing a larger number of patients and PAs submitted post-pandemic may reveal more insight and significant associations that were not captured in this study due to above-mentioned limitations. Future studies should also explore PA approval rates among non-academic centers without trained insurance coordinator staff and investigate the approval rates for instances of reauthorization for the duration of approval or a second round of infusions.

In summary, geographic location, socioeconomic status, and insurance type may significantly impact teprotumumab PA rates. Patients located further away from the academic treatment center and those with Medi-Cal or non-Medicare managed care patients are at greater risk for teprotumumab PA denial. The adoption of uniform guidelines likely streamlined the approval rates. Clinicians should consult insurance guidelines and address common reasons for denials, such as the lack of recent thyroid labs or non-euthyroid status, prior to submitting a PA.

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None to declare.

Financial Disclosure

None to declare.

Conflict of Interest

The study was presented, in part, at the American Society of Ophthalmic Plastic Reconstructive Surgeons (ASOPRS) Annual Fall Scientific Symposium on November 2, 2023.

Informed Consent

The study received a HIPAA waiver of authorization from the Institutional Review Board, which approved access to the electronic medical records to collect the minimum necessary protected health information (PHI) about participants for this research.

Author Contributions

PC recorded data, conducted analyses, drafted the manuscript, and critically revised the manuscript. AN recorded data, conducted analyses, and drafted the manuscript. SC recorded data and critically revised the manuscript. LKL was the primary investigator and guided analysis, helped draft the tables, manuscript, and critically revised the manuscript.

Data Availability

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Abbreviations

CAS: clinical activity scores; CON: compressive optic neuropathy; IGF-1R: insulin-like growth factor receptor; FDA: Food and Drug Administration; PA: prior authorization; TED: thyroid eye disease

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