Number of Requests for a Second Course of Teprotumumab in the US Over Four Years

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INTRODUCTION

- Thyroid Eye Disease (TED) is a serious and progressive autoimmune disorder that re-models the fat and muscle tissue behind the eye causing debilitating symptoms such as pain, diplopia and proptosis.[1]
- Teprotumumab-trbw (teprotumumab) is a fully human IgG1 monoclonal antibody that inhibits insulin-like growth factor 1 receptor (IGF-1R) which is overexpressed in the orbital fibroblasts of patients with TED.[2] Treatment consists of 8 intravenous infusions over 24 weeks.
- In 2020, teprotumumab became the first and only Food and Drug Administration (FDA)-approved treatment specifically for TED.[3,4]
- Real-world evidence remains limited in patients with TED requiring an additional course of teprotumumab.

OBJECTIVE

This retrospective cohort study assessed the number of requests for a second course of teprotumumab, submitted by physicians and office staff on behalf of patients, in the US over a four-year duration from January 2020 to September 2024.

METHODS

- Deidentified data from patients with TED in the US from January 2020 (US Marketing authorization approval) to September 2024 (n = 29,093) were obtained from an Amgen internal TED database.
- Data were collected through healthcare professionals and infusion centers, including both initial and second course requests for treatment with teprotumumab.
- Treatment requests were submitted via physicians or office staff through a patient enrollment form, which was sent via email, DocuSign or fax to the Amgen By Your Side (ABYS) brand mailbox. However, treatment with teprotumumab was only administered after patients successfully progressed through the required insurance approval steps.
- The proportion of physician and office staff requests for a second course was calculated among patients who completed all 8 infusions at first course between 2020 and 2024 without a COVID related supply disruption between December 2020 and April 2021.
- Descriptive statistics were used to report the data.

RESULTS

- Of the 14,294 patients who completed all 8 consecutive teprotumumab infusions at first course, a second course was requested for 1,546 patients (10.8%).
- Patients for whom physicians or office staff requested a second course of teprotumumab had baseline characteristics comparable to those of patients who completed the first course (**Table 1**).
- Approximately 65% of requests incurred between 5 and 16 months after first course completion, with a median time from first course completion to second course request of 13.5 months (**Figure 1**).
- Of the 1,546 patients with second course requests, 96.6% had completed their first course within a mean duration of 5.1 months.
- Among cohorts with longer follow-up (2020–2022), second course requests ranged from 10% to 18%, while overall re-treatment rates remained stable over time (7–12%;**Table 2**).
- Overall, 7.2% of patients were re-treated with teprotumumab, defined as initiation of a second course among those who had completed all 8 consecutive infusions in the first course.
- Among the patients for whom a second course was requested but not initiated,138 (26%) remained in pending status and were still progressing through the treatment journey, while 13 (2%) were on hold (≥4 weeks in the same status). The majority of patients (n = 372 [71%]) were classified as inactive pre-IV, which encompasses patients unable to advance to infusion due to factors such as physician decision, payer restrictions, comorbidities, patient concerns, or loss to follow-up.

Table 1. Baseline Characteristics of Patients Completing First Course and Second Course Requests for Teprotumumab

	Patients completing first course of treatment N = 14,294	Patients with physician/office staff requests for a second course of treatment n = 1,546
Age in years (mean ± SD)	58 ± 14	59 ± 13
Weight in kg (mean ± SD)	80 ± 23	78 ± 21
Sex - female (%)	76	75

SD - standard deviation

Figure 1. Proportion of Patients With Physician/Office Staff Requests for a Second Course of Teprotumumab, by Months From Completion of First Course

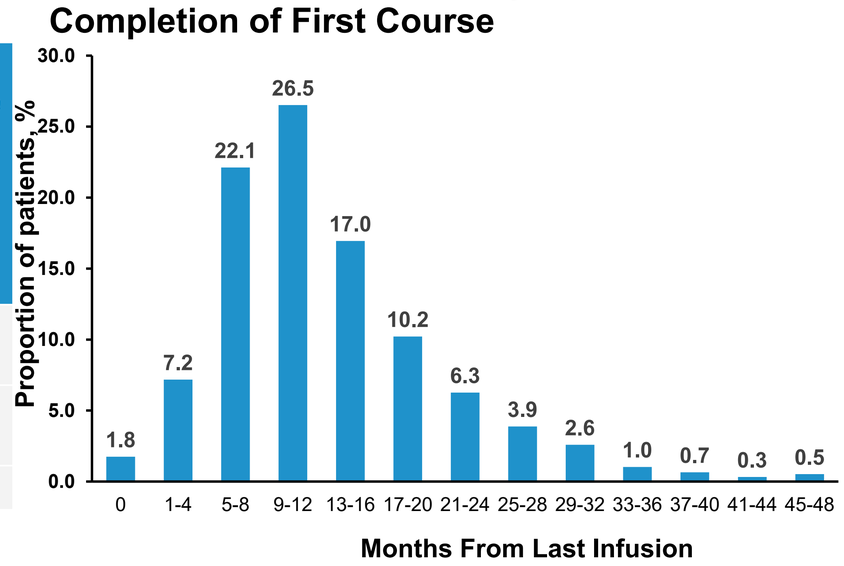

Table 2. Retreatment by Year Among Patients Completing All 8 Infusions During the First Course

First Course Enrollment Year	2020	2021	2022	2023	2024
First Course Completed (N = 14,294)	2,325	4,203	3,743	3,468	555
Second Course Requests (N = 1,546)	410	617	390	125	4
Second Course Requests (%)	18%	15%	10%	4%	1%
Second Course Starts, Total	275	429	249	69	1
Retreatment Percentage	12%	10%	7%	2%	0%

LIMITATIONS

- This study examines only the proportion of patients for whom physicians or office staff submitted requests for a second course of treatment, not those who experienced a flare and subsequently enrolled in a different treatment.
- The dataset does not capture the rationale underlying these requests for a second course of treatment with teprotumumab; therefore, the specific drivers such as physician recommendation, symptom recurrence, or patient preference cannot be determined.

CONCLUSIONS

- Using the largest real-world TED dataset available, this study provides the most comprehensive assessment to date of requests for a second course of teprotumumab.
- Results indicate that among patients with TED who completed 8 consecutive infusions in the first course without disruption over 4 years, physician or office staff submitted requests for a second course of teprotumumab on behalf of 10.8% of patients, and 7.2% were subsequently re-treated with teprotumumab.

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DISCLOSURES

G. Spicer was an employee and held stock at the time of this work. All other authors are employees and stockholders of Amgen Inc.

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