

# PHARMACOLOGIC REIMBURSEMENT AND PHYSICIANS



Studies shed light on CMS practices.

BY FRANCIS PRICE JR, MD

## TEPROTUMUMAB-RELATED ADVERSE EVENTS IN THYROID EYE DISEASE: A MULTICENTER STUDY

Shah SA, Amarikwa L, Sears CM, et al<sup>1</sup>  
*Industry support: Most of the authors disclosed a financial relationship with Horizon Therapeutics and other companies*

### ABSTRACT SUMMARY

A multicenter, retrospective, observational cohort study assessed adverse events (AEs) in patients with thyroid eye disease (TED) who were treated with teprotumumab-trbw (Tepezza, Horizon Therapeutics). This monoclonal antibody binds to the insulin-like growth factor-1 (IGF-1) receptor and blocks its activation and signaling.

Proptosis improved by 2 mm or more in 101 (77%) of the 131 patients evaluated. AEs occurred in 107 (81.7%) of the treated individuals. Patients experienced a median of four AEs, most (74%) of which were mild. The average resolved AE duration was 17.6 weeks. Mean follow-up was 70.2 ± 38.5 weeks after the first infusion, and 60 (46%) patients had at least one persistent AE at the last follow-up visit. The most common type of AEs was musculoskeletal (58%), followed by gastrointestinal (38.2%),

## STUDY IN BRIEF

- ▶ A multicenter, retrospective, observational cohort study assessed adverse events (AEs) in patients with thyroid eye disease who were treated with teprotumumab-trbw (Tepezza, Horizon Therapeutics). Proptosis improved by 2 mm or more in 77% of the patients, AEs occurred in 81.7% of the treated individuals, 35% of AEs were unresolved 70 weeks after the first infusion, and 12% of patients discontinued treatment owing to AEs.

## WHY IT MATTERS

CMS pays a high amount for this treatment that has a high complication rate.

ear and labyrinth (30.5%), nervous system (20.6%), metabolic (15.3%), and reproductive system (12.2%).

### DISCUSSION

IGF-1 is overexpressed by orbital fibroblasts in patients with TED, a condition that affects about 50% of individuals with Graves disease and 2% of those with Hashimoto disease. IGF-1 affects the cochleovestibular ganglions, the growth of gastrointestinal mucosa, glucose metabolism, and the skeletal muscles. Inhibiting the natural effects of IGF-1 can therefore cause problems, including hearing loss, inflammatory bowel disease, diabetes, alopecia, cramps, and fatigue.

Although most of the AEs in this study were mild and reversible, 37 (28.2%) and 11 (8.4%) patients experienced moderate and severe AEs, respectively. Sixteen (12.2%) patients discontinued treatment because of AEs.

Medicare reimbursement for the course of eight teprotumumab-trbw infusions can be greater than \$500,000 (a J-code is used for billing). The average commercial reimbursement is a reported \$823,000.<sup>2</sup> The potential financial impact if teprotumumab-trbw were used to treat all TED patients could be staggering because the incidence is 16/100,000 in women and 2.9/100,000 in men.<sup>3</sup>

## DRUG SAVINGS FOR MEDICARE PART D BENEFICIARIES USING A DIRECT-TO-CONSUMER MODEL

Berkowitz ST, Groth S, Sternberg P Jr, Patel S<sup>4</sup>

*Industry support: None*

### ABSTRACT SUMMARY

This study compared the aggregate cost of patient payments, third-party

payments, and CMS expenditures to what the cost would be if CMS purchased the drugs in bulk from Mark Cuban's Cost-Plus Drug Company (MCCPDC). MCCPDC sells drugs at a fixed margin of 15% above cost, a fixed dispensing fee (\$3), and a shipping fee (\$5). The three generic glaucoma drugs included in the study were brimonidine tartrate, dorzolamide hydrochloride, and a fixed combination of dorzolamide hydrochloride and timolol. The three drugs' aggregate cost in 2021 under Medicare Part D was \$210,505,750. The estimated potential savings if MCCPDC had been used was between 34% and 58% or \$71,000,000 and \$122,000,000.

As of May 2023, MCCPDC listed more than 1,000 generic drugs. Berkowitz and colleagues estimated that Medicare Part D could have saved \$3.3 billion in 2020 for 77 generic drugs. They speculated that inefficiency in the pharmaceutical marketplace contributes to increased spending for both Medicare and beneficiaries.

## DISCUSSION

US health care costs, including the expense of new biologics and older generics, are a major concern. One strategy to address health care costs has been for CMS to use budget neutrality for calculating a conversion factor to determine physician reimbursement, leading to reductions in payments to physicians. There does not appear to be a similar effort by CMS either to base the fees of new biologics or brand-name drugs on the potential financial risk to Medicare or the country as a whole or to control drug costs with budget neutrality. Nor does there seem to be a program that promotes cost containment and quality outcome measures for brand-name drugs and biologics, whereas the US government established the Merit-Based Incentive Payment System for clinicians.

A recent report by the Association of American Medical Colleges projected that the United States will have a physician shortage of as many as 86,000 physicians by

2036.<sup>5</sup> Additionally, a study using data from the National Center for Health Workforce Analysis identified ophthalmology as among the medical specialties with the lowest rate of workforce adequacy by 2035.<sup>6</sup>

The study by Berkowitz et al shows that CMS could save Medicare Part D billions of dollars by adopting a direct-to-consumer model for generic drugs.<sup>4</sup> In light of this finding and the predicted doctor shortage, it seems reasonable to suggest that the agency prioritize strategies for reducing drug costs rather than further cuts to physician reimbursement. ■

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## STUDY IN BRIEF

- A study analyzed potential cost savings if Medicare Part D bought three generic glaucoma drugs through a direct-to-consumer model for generic drugs instead of the current system that makes purchases through carriers and retail stores. In 2021, 34% to 58% or \$71,000,000 to \$122,000,000 would have been saved on these three drugs. The authors further estimated that Medicare part D could have saved \$3.3 billion on 77 generic drugs in 2020.

## WHY IT MATTERS

US health care costs are a major concern. In response, CMS has implemented strategies such as establishing the Merit-Based Incentive Payment System and decreasing the physician fee schedule conversion factor. In light of this study's findings and a projected shortage of physicians in general<sup>5</sup> and ophthalmologists in particular,<sup>6</sup> it seems reasonable to suggest that the agency prioritize strategies for reducing generic drug costs.

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