



## Centers for Medicare & Medicaid Services (CMS) Issues Permanent J-Code for TEPEZZA® (teprotumumab-trbw) Effective Oct. 1, 2020

July 9, 2020

DUBLIN--(BUSINESS WIRE)--Jul. 9, 2020-- Horizon Therapeutics plc (Nasdaq: HZNP) today announced that the U.S. Centers for Medicare and Medicaid Services (CMS) has assigned a permanent, product-specific Healthcare Common Procedure Coding System (HCPCS) J-code (J3241) for TEPEZZA® (teprotumumab-trbw), the first and only FDA-approved medicine for the treatment of Thyroid Eye Disease (TED).

The permanent J-code, which enables reimbursement in all outpatient treatment settings, will go into effect on Oct. 1, 2020. In the interim, between July 1 and October 1, a temporary C-code (C9061) has been established for TEPEZZA to support Medicare Fee-for-Service pass-through payment in the hospital outpatient department. Other payers, such as commercial insurers, may also use C9061 in the interim.

J-codes are used by commercial insurers and government payers to standardize claims submissions and reimbursements for medicines, such as TEPEZZA, that are administered by a healthcare professional. While not a guarantee of payment, these codes enable timely claims adjudication and processing.

“Given the significant burden of TED on patients’ physical and emotional well-being, as well as the lack of other approved treatment options for this chronic and disabling disease, it is important that patients are able to access TEPEZZA in a timely manner,” said Keli Walbert, senior vice president, integrated marketing, commercial operations and general manager, ophthalmology, Horizon. “The permanent J-code for TEPEZZA will help streamline and simplify the billing and reimbursement process for providers and payers, enabling improved access to this first of its kind, breakthrough treatment.”

### About Thyroid Eye Disease

TED is a serious, progressive and vision-threatening rare autoimmune disease.<sup>1</sup> TED often occurs in people living with hyperthyroidism or Graves’ disease; however, it is a distinct disease that is caused by autoantibodies activating an IGF-1R-mediated signaling complex on cells within the retro-orbital space.<sup>2,3</sup> This leads to a cascade of negative effects, which may cause long-term, irreversible damage. As TED progresses, the serious damage it can cause includes proptosis (eye bulging), strabismus (misalignment of the eyes) and diplopia (double vision) – and in some cases can lead to blindness.<sup>4,5</sup>

### About TEPEZZA

#### INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

#### IMPORTANT SAFETY INFORMATION

##### Warnings and Precautions

**Infusion Reactions:** TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic, or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

**Preexisting Inflammatory Bowel Disease:** TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

**Hyperglycemia:** Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be managed with medications for glycemic control, if necessary. Monitor patients for elevated blood glucose and symptoms of hyperglycemia while on treatment with TEPEZZA. Patients with preexisting diabetes should be under appropriate glycemic control before receiving TEPEZZA.

##### Adverse Reactions

The most common adverse reactions (incidence  $\geq$ 5% and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache and dry skin.

For additional information on TEPEZZA, please see [Full Prescribing Information](#) at [TEPEZZAhcp.com](#).

##### About Horizon

Horizon is focused on researching, developing and commercializing medicines that address critical needs for people impacted by rare and rheumatic diseases. Our pipeline is purposeful: we apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science

and compassion must work together to transform lives. For more information on how we go to incredible lengths to impact lives, please visit [www.horizontherapeutics.com](http://www.horizontherapeutics.com) and follow us on [Twitter](#), [LinkedIn](#), [Instagram](#) and [Facebook](#).

### Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding the timing and impact of the J-code for TEPEZZA. These forward-looking statements are based on management expectations and assumptions as of the date of this press release, and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include whether TEPEZZA is successfully commercialized and adopted by physicians and patients, the risk that a J-code for TEPEZZA may not have the anticipated benefits in the billing and reimbursement process or enabling improved access to TEPEZZA, as well as those described in Horizon's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this press release and Horizon does not undertake any obligation to update or revise these statements, except as may be required by law.

### References

1. Barrio-Barrio J, et al. Graves' Ophthalmopathy: VISA versus EUGOGO Classification, Assessment, and Management. *Journal of Ophthalmopathy*. 2015;2015:1-16.
2. Weightman DR, et al. Autoantibodies to IGF-1 Binding Sites in Thyroid Associated Ophthalmopathy. *Autoimmunity*. 1993;16(4):251-257.
3. Pritchard J, et al. Immunoglobulin Activation of T Cell Chemoattractant Expression in Fibroblasts from Patients with Graves' Disease Is Mediated Through the Insulin-Like Growth Factor 1 Receptor Pathway. *J Immunol*. 2003;170:6348-6354.
4. Ross DS, et al. The 2016 European Thyroid Association /European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy. *Eur Thyroid J*. 2016;5(1):9-26.
5. McKeag D, et al. Clinical features of dysthyroid optic neuropathy: a European Group on Graves' Orbitopathy (EUGOGO ) survey. *Br J Ophthalmol*. 2007;91:455-458.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20200709005304/en/): <https://www.businesswire.com/news/home/20200709005304/en/>

#### Tina Ventura

Senior Vice President, Investor Relations

[Investor-relations@horizontherapeutics.com](mailto:Investor-relations@horizontherapeutics.com)

#### Ruth Venning

Executive Director, Investor Relations

[Investor-relations@horizontherapeutics.com](mailto:Investor-relations@horizontherapeutics.com)

#### U.S. Media Contacts:

##### Matt Flesch

Vice President, Communications and Patient Advocacy

[media@horizontherapeutics.com](mailto:media@horizontherapeutics.com)

##### Rachel Vann

Associate Director, Product Communications

[media@horizontherapeutics.com](mailto:media@horizontherapeutics.com)

#### Ireland Media Contact:

##### Gordon MRM

Ray Gordon

[ray@gordonmrm.ie](mailto:ray@gordonmrm.ie)

Source: Horizon Therapeutics plc