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Early Alert: Part B Payment Amount for Tezspire Included a Noncovered Self-Administered Version in 2023

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Early Alert Brief
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Key Results

The payment amount for Tezspire in the third and fourth quarters of 2023 included a noncovered self-administered version of the drug.

Including the self-administered version led to a small increase in the per-injection payment amount for those quarters.

Required Action

In accordance with regulations, the Centers for Medicare & Medicaid Services (CMS) is required to remove the self-administered version of Tezspire from payment amount calculations in subsequent quarters if the exclusion would result in lower payment amounts.

With certain exceptions, self-administered drugs are not covered under Medicare Part B.[1] However, the billing codes used in setting payments for Part B drugs often include multiple versions of the same drug and, in a small number of cases, some of those versions may be self-administered. Specifically, CMS interprets a relevant statute to require the inclusion of prices for noncovered self-administered versions when the agency calculates the payment amount for a billing code if both the covered and noncovered versions of a product are approved by the U.S. Food & Drug Administration (FDA) under the same application number.[2, 3]

The Office of Inspector General (OIG) is required to conduct periodic studies to identify billing codes for which both noncovered self-administered versions and covered provider-administered versions of a drug are used to set Part B payment amounts, and to subsequently determine whether those self-administered versions should be excluded.[4] In general, for the drugs that OIG identifies, CMS is required to remove noncovered self-administered versions from payment amount calculations in subsequent quarters if the exclusions would result in lower payment amounts; however, the statute provides CMS with some discretion in addressing the requirement.[5] In a recent report, OIG identified two drugs—Fasenra and Xolair—for which Part B payment amounts included both noncovered self-administered versions and covered provider-administered versions in 2022.

In conducting other work, OIG determined that the Part B payment amount for the drug Tezspire included a noncovered self-administered version and a covered provider-administered version beginning in July 2023. OIG is issuing this early alert brief so that CMS can remove the self-administered version of Tezspire from payment amount calculations in subsequent quarters if the exclusion would result in lower payment amounts. OIG will follow this early alert brief with a full assessment of billing codes in 2023 to determine if there are any additional codes for which self-administered versions and provider-administered versions were used to set payment amounts that year.

The payment amount for Tezspire in the third and fourth quarters of 2023 included a noncovered self-administered version of the drug

OIG found that CMS had included a higher-cost, self-administered version of Tezspire in its payment amount calculations for both the third and fourth quarters of 2023. The self-administered version of

Tezspire was approved by FDA under the same application number as was the provider-administered version, meaning that CMS was following policy when setting the payment amounts.

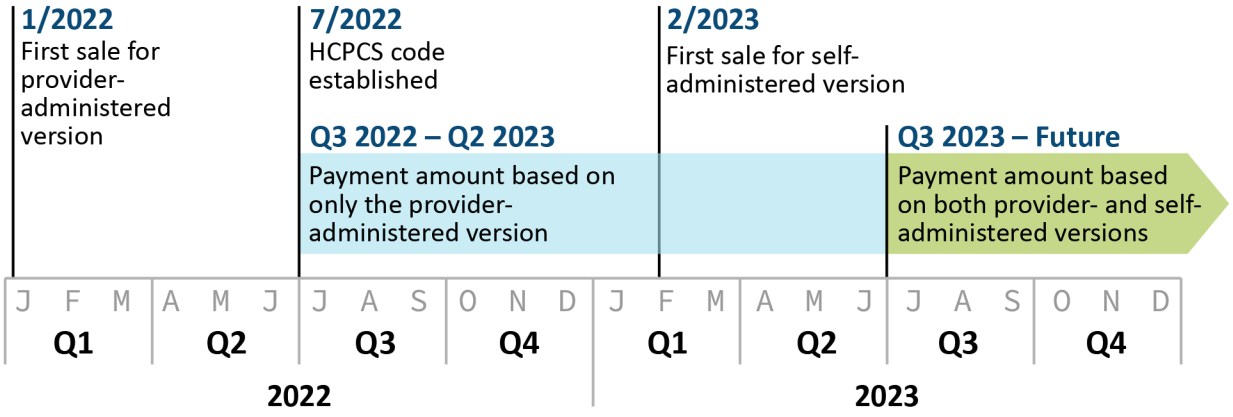
Tezspire is a brand-name drug indicated for the add-on maintenance treatment of patients with severe asthma.[6] It is administered as an injection under the skin (i.e., subcutaneous administration) once every 4 weeks. Tezspire is available as (1) a single-dose prefilled syringe intended for provider administration and (2) a single-dose prefilled pen intended for self-administration.[7, 8]

Including the self-administered version led to a small increase in the per-injection payment amount

When calculating payment amounts in the initial quarters after the billing code (i.e., Healthcare Common Procedure Coding System (HCPCS) code) representing Tezspire was established, CMS included sales data for only the prefilled syringe version intended for provider administration as it was the sole version available for sale.[9] However, in early 2023, the manufacturer of Tezspire began selling the newly approved self-administered version and subsequently reported sales data to CMS. In accordance with statute and policy, beginning in the third quarter of 2023, CMS used sales data for both versions when calculating payment amounts for Tezspire.

In the third and fourth quarters of 2023, excluding the self-administered version of Tezspire would have decreased Medicare payment amounts by $12 and $71 per dose, respectively (.3 percent and 1.8 percent).[10] For example, the payment amount in the fourth quarter of 2023 would have decreased from $3,901.80 to $3,830.40 per injection.

Sales data for both the provider-administered and self-administered versions of Tezspire were used to set payment amounts beginning in third-quarter 2023.



Source: OIG analysis of CMS average sales price (ASP) files and HCPCS Application Summary documents.

REQUIRED ACTION

In accordance with regulations, CMS must remove the self-administered version of Tezspire from payment amount calculations in subsequent quarters if the exclusion would result in lower payment amounts.

Endnotes

[1] Medicare Part B does cover a small number of self-administered drugs, including certain oral anti-cancer drugs; blood clotting factors; and inhalation and infusion drugs used with durable medical equipment. See Section 1861(s)(2) of the Social Security Act (the Act) regarding coverage of drugs and biologicals that are "not usually self-administered." Also, see 42 CFR § 414.900(b) and the *Medicare Benefit Policy Manual*, ch. 15 § 50. At Section 50.2 of the same manual, CMS describes how contractors can determine whether a drug is "usually self-administered."

[2] Medicare sets payment amounts for Part B drugs using Healthcare Common Procedure Coding System (HCPCS) codes. Because more than one national drug code (NDC) may meet the definition of a HCPCS code, CMS must first "crosswalk" manufacturers' NDCs to their corresponding HCPCS codes. In interpreting the Act, CMS staff determined that (1) all versions of a product listed under the same U.S. Food & Drug Administration (FDA) application number must be considered the same drug or biological, for payments made under Part B, and (2) for a product marketed under the same application number, labeling that indicates that a version may be used primarily when the drug is not covered under Part B (e.g., the version is for self-administration only) cannot be used as a basis to exclude that version from a payment amount calculation. See Sections 1847A(b)(4)(A) and 1847A(b)(5) of the Act. Also, see CMS, *Update to Information Regarding Medicare Payment and Coding for Drugs and Biologics*, May 18, 2007, https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf, accessed on July 27, 2023.

[3] CMS's interpretation is supported by *Allergan, Inc. v. Sylvia Mathews Burwell*, Case No. 13-00264, 2016 U.S. Dist. LEXIS 43550 (D.D.C. March 30, 2016). The U.S. District Court for the District of Columbia considered whether the manufacturer of a biological marketed as BOTOX for therapeutic use (i.e., the covered version) and as BOTOX Cosmetic (i.e., the noncovered version) was required to report ASP data for the noncovered version to CMS.

[4] Section 1847A(g)(1) of the Act as amended by Section 405 of CAA 2021.

[5] If and when OIG identifies a noncovered self-administered NDC, OIG shall inform the Secretary and the Secretary shall, to the extent the Secretary deems appropriate, apply a "lesser of" payment amount for the HCPCS code, as follows: (A) the amount of payment that would result if the self-administered drug were excluded from the determination of the payment amount, or (B) the amount of payment determined without that exclusion. CMS is required to exclude the NDC from payment amount calculations if the exclusion would result in a lower payment amount. CMS regulations require that the agency exclude such an NDC from payment amount calculations beginning on the first day of the second quarter following the publication of the corresponding OIG report. Regulations provide an exception to not lower payment amounts if the drug is in short supply, as identified by FDA, for that quarter. See Section 1847A(g)(2) of the Act and 42 CFR § 414.904(d)(4)(i)–(ii) & (iv).

[6] Tezspire package insert, https://www.azpicentral.com/pi.html?product=tezspire, accessed on August 24, 2023.

[7] FDA approved an additional version (single-dose vial) of Tezspire. However, the manufacturer does not include this version on its website, and no sales were reported to CMS for the product.

[8] In total, Medicare Part B and its enrollees paid $59 million for Tezspire in the first six months of 2023. At the time of our analysis, Part B expenditure data for third-quarter 2023 were not available.

[9] To calculate HCPCS code payment amounts, CMS averages pricing data by sales volume for all NDCs crosswalked to a HCPCS code. Medicare pays for most Part B drugs at 106 percent of the volume-weighted average sales prices. 42 U.S.C. §1395w-3a(b)(1).

[10] A typical dose of Tezspire is a single 210 mg/1.91 mL injection.