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Congressional Mandate:

Part B Payment Amounts for Two Drugs Included Noncovered Self-Administered Versions in 2022

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Key Results

The Centers for Medicare & Medicaid Services (CMS) correctly removed noncovered self-administered versions of Orencia and Cimzia when calculating 2022 payment amounts, as required by law.

Payment amounts for both Fasenra and Xolair included noncovered self-administered versions in 2022. However, including the self-administered versions did not substantially affect per-injection payment amounts.

Required Action

In accordance with regulations, CMS is required to remove self-administered versions of Fasenra and Xolair 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 in limited circumstances—i.e., 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]

In two earlier reports, the Office of Inspector General (OIG) evaluated the financial impact of including the prices of noncovered self-administered versions when setting the Part B payment amounts for the provider-administered versions of these drugs. OIG found that the inclusion of the noncovered versions of two drugs—Orencia and Cimzia—caused Medicare and its enrollees to pay an extra $863 million from 2014 through 2018.[4]

Although Congress did not change the way CMS sets Part B payment amounts for *all* drugs with noncovered versions, the OIG reports contributed to Congress enacting provisions requiring CMS to remove noncovered self-administered versions of Cimzia and Orencia from payment amount calculations for their billing codes beginning in July 2021 if the exclusions would result in lower payment amounts.[5] In that same legislation, Congress required OIG to conduct periodic studies to identify additional 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.[6] 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.[7]

This review fulfills OIG's statutory responsibility to periodically identify additional billing codes for which both noncovered self-administered versions and covered provider-administered versions are used to set Part B payment amounts. In addition, we assessed whether CMS had correctly removed higher-cost, self-administered versions of Orencia and Cimzia when calculating 2022 payment amounts for those two drugs, as required by law.

FINDINGS

CMS correctly removed noncovered self-administered versions of Orencia and Cimzia when calculating 2022 payment amounts

In accordance with statute, CMS correctly removed higher-cost, self-administered versions of Orencia and Cimzia from payment determinations, resulting in substantially lower payment amounts for both drugs in 2022. For example, the fourth-quarter payment amount for a typical 750 mg injection of Orencia was reduced from $4,337 to $3,243 (25 percent).[8] The payment amount that quarter for a typical 400 mg injection of Cimzia was reduced from $3,138 to $2,164 (31 percent).[9] As a result, Medicare Part B and its enrollees saved a total of $480 million in 2022 for the two drugs.

OIG identified two drugs—Fasenra and Xolair—for which Part B payment amounts included noncovered self-administered versions in 2022

As previously mentioned, the noncovered versions provisions enacted by Congress did not prospectively alter the way CMS sets payment amounts for *all* Part B drugs; rather, the provisions require OIG to identify any additional billing codes (i.e., other than those representing Orencia and Cimzia) for which both noncovered self-administered versions and covered provider-administered versions are used to set Part B payment amounts, and to determine whether the self-administered versions should be excluded from payment amount calculations. Among Part B drugs paid for in 2022, we identified two—Fasenra and Xolair—for which CMS included noncovered self-administered versions in setting the payment amounts. Both drugs are administered via an injection under the skin (i.e., subcutaneous administration) every few weeks.

Fasenra and Xolair each have a version that is approved and marketed for self-administration and another version that is intended to be administered by a provider in an office or outpatient setting. For each drug, the self-administered version was approved by FDA under the same application number as was the provider-administered version, meaning that CMS was following policy when setting 2022 payment amounts.

CMS included self-administered versions in payment amounts for two high-expenditure drugs in 2022.

J0517	Fasenra	$227 million	Severe eosinophilic asthma	Every 4 weeks for the first 3 doses, followed by every 8 weeks	Prefilled syringe	Provider-administered
					Autoinjector pen	Self-administered
J2357	Xolair	$442 million	Allergic asthma; chronic hives; and chronic rhinosinusitis with nasal polyps	Every 2 or 4 weeks	Vial	Provider-administered
					Prefilled syringe (2 dosage sizes)	Self-administered

Source: OIG analysis of CMS average sales price (ASP) files, drug product data, and Part B expenditure data.
Note: The manufacturer of Xolair began marketing a single-dose prefilled autoinjector version (3 dosage sizes) in August 2023—i.e., after the time period covered by this report. The autoinjector version can be self-administered.

Fasenra is a brand-name drug indicated for the add-on maintenance treatment of patients with severe eosinophilic asthma.[10] It is administered as a subcutaneous injection once every 4 weeks for the first three doses, followed by once every 8 weeks. Fasenra is available as (1) a single-dose prefilled syringe intended for provider-administration, and (2) a single-dose autoinjector pen marketed for self-administration. In total, Medicare Part B and its enrollees paid $227 million for Fasenra in 2022.

Xolair is a brand-name drug indicated for allergic asthma, chronic hives, and chronic rhinosinusitis with nasal polyps.[11] It is administered as a subcutaneous injection every 2 or 4 weeks. At the time of our review, Xolair was available only as (1) a single-dose prefilled syringe that can be self-administered, and (2) a single-dose vial containing powder for reconstitution that is intended only for provider administration. Two dosage sizes were available for the self-administered version. In total, Medicare Part B and its enrollees paid $442 million for Xolair in 2022. In August 2023, the manufacturer of Xolair released an additional formulation of the drug (a single-dose prefilled autoinjector) that also can be self-administered.[12] In subsequent quarters, the prefilled autoinjector version should also be excluded from calculations if doing so would result in lower payment amounts.[13]

Including the self-administered versions did not substantially affect quarterly per-injection payment amounts for Fasenra and Xolair

CMS calculated 2022 payment amounts for Fasenra and Xolair in accordance with statute and policy. As previously mentioned, when OIG (1) identifies Part B drug billing codes for which both noncovered self-administered versions and covered provider-administered versions were

used to set payment amounts and (2) determines that the self-administered versions should be excluded, CMS is generally required to remove these versions from calculations in subsequent quarters only if the exclusions would result in lower payment amounts.[14] To demonstrate potential savings, we recalculated quarterly 2022 payment amounts with the self-administered versions of Fasenra and Xolair removed.

In the first and second quarters of 2022, removing the self-administered version of Fasenra would not have reduced payments. In the third and fourth quarters, excluding the self-administered version of Fasenra would have decreased Medicare payment amounts by $5.22 and $25.11 per dose, respectively (.1 percent and .5 percent).[15] For example, the payment amount for a typical 30 mg injection in the fourth quarter of 2022 would have decreased from $5,084 to $5,059.

For Xolair, excluding the self-administered versions from payment amount calculations would have reduced payment amounts in each quarter, with decreases ranging from $0.84 to $7.41 per dose (.1 percent to .6 percent, respectively).[16] For example, the payment amount per 150 mg injection in the fourth quarter of 2022 would have decreased from $1,160 to $1,152.[17]

Two additional codes may warrant further review from CMS

OIG identified two additional drugs—heparin injection and Granix—for which versions that *can* be self-administered and versions that are administered by providers were included in payment amounts. However, we could not determine whether the versions that can be self-administered would meet CMS's definition of "usually self-administered" set forth by the Medicare Benefit Policy Manual and applied by CMS's contractors.[18] Specifically, CMS states in its guidance to contractors that, in general, drugs used for acute conditions are less likely to be self-administered by patients.[19] CMS defines an acute condition as one that begins over a short time period; is likely to be of short duration; and/or requires a course of treatment lasting less than 2 weeks regardless of frequency or route of administration. Determining whether heparin injection and Granix are used for acute or chronic conditions would require information beyond the scope of our study.

Heparin Injection

Heparin is a blood thinner (i.e., anticoagulant) used to prevent blood clots from forming in patients.[20] Most indications for heparin injection are for the treatment of acute conditions, such as blood clots associated with surgery and other procedures. For each quarter under review, manufacturers reported pricing data for around 70 national drug codes (NDCs) representing heparin. Product information for only one NDC, representing a prefilled syringe, explicitly mentions that patients can self-administer the product.[21] It may be unlikely that providers would prescribe injectable heparin for self-administration long-term, because oral formulations of blood thinners are widely available and tend to be used for chronic conditions.

Granix

Granix is used during chemotherapy to support the production of white blood cells.[22] In general, it is intended to be used daily during the duration of chemotherapy until the patient's white blood cell count returns to normal levels. Marketing and product information indicate that some prefilled syringe formulations of Granix are appropriate for self-administration.[23] However, because a course of treatment may vary considerably among patients, it is unclear whether Granix meets the definition of "usually self-administered" set forth by the Medicare Benefit Policy Manual and applied by CMS's contractors.[24]

CONCLUSION

Congress requires OIG to conduct periodic studies to identify billing codes for which both noncovered self-administered versions and covered provider-administered versions of drugs are used to set Part B payment amounts, and to determine whether the self-administered versions should be excluded from Part B payment amount calculations.[25, 26] OIG found that CMS included noncovered self-administered versions of Fasenra and Xolair when calculating 2022 Part B payment amounts (in accordance with payment policies). However, including the self-administered versions did not substantially affect payment amounts that year.

REQUIRED ACTION

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

OIG identified two additional drugs that have one or more versions that may be considered noncovered self-administered drugs; however, we do not have sufficient data to make a definitive determination as to whether these are "usually self-administered" and therefore not covered by Part B. CMS and its contractors may wish to further examine the characteristics of these drugs to determine whether certain versions of heparin injection and Granix meet agency criteria for being considered "usually self-administered."

OIG will periodically conduct similar studies identifying additional drug billing codes for which self-administered versions and provider-administered versions are used in Part B payment amount calculations, and that subsequently should be considered for exclusion from payment amount calculations. If and when we identify such self-administered versions, we will notify CMS of our findings.

METHODOLOGY

Medicare sets payment amounts for Part B drugs using HCPCS codes. Because more than one NDC may meet the definition of a HCPCS code, CMS must first "crosswalk" manufacturers' NDCs to their corresponding HCPCS codes. We used CMS's ASP files to identify all NDCs used to set Part B 2022 ASP-based payment amounts.

Using drug compendia data; prescription drug packaging and labeling information from FDA; and manufacturer resources, we determined whether each NDC represents a product that is typically self-administered. We based our definition of "self-administered" on CMS's guidance.[27]

We then identified the HCPCS codes to which each self-administered NDC is crosswalked. We removed HCPCS codes that were not also crosswalked to a provider-administered product, and we removed HCPCS codes for which self-administration is allowed under Part B coverage criteria (e.g., HCPCS codes representing blood clotting factors).

For the remaining HCPCS codes, we recalculated Part B payment amounts using CMS's volume-weighted ASP formula in each quarter of 2022 with the self-administered NDCs removed.[28] We calculated the difference between the actual and alternate payment amounts in each quarter. We also calculated total 2022 expenditures.

Limitations

There may be limited circumstances in which providers could administer typically self-administered versions of drugs, such as when a patient is not able or willing to self-inject. Our analysis did not take into account these circumstances.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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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] OIG, *Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and Its Beneficiaries*, OEI-12-17-00260, November 2017. OIG, *Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars*, OEI-BL-20-00100, July 2020. CMS did not concur with our recommendation to seek legislative change that would provide the agency with flexibility to determine when noncovered versions should be included in the calculation of the Part B payment amount.

[5] Section 1847A(g)(3) of the Act as amended by Section 405 of Division CC, Title IV, of the Consolidated Appropriations Act, 2021 (Section 405 of CAA 2021). Under Section 1847A(g)(3), Part B payment for Cimzia and Orencia must be the lesser of (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.

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

[7] If and when OIG identifies a noncovered self-administered NDC, OIG shall inform the Secretary of the U.S. Department of Health and Human Services (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).

[8] A typical dose of Orencia is determined on the basis of the condition for which Orencia is being administered and, in some cases, the patient's body weight. Prior OIG work found that most Part B claims for Orencia were for 750 mg. To maintain

consistency with prior OIG work, we calculated the actual payment amount and potential payment amount based on a dose of 750 mg.

[9] A typical dose of Cimzia is determined on the basis of the condition and the patient. Prior OIG work found that most Part B claims for Cimzia were for 400 mg. To maintain consistency with prior OIG work, we calculated the actual payment amount and potential payment amount based on a dose of 400 mg.

[10] Fasenra package insert, http://www.azpicentral.com/pi.html?product=fasenra, accessed on July 20, 2023.

[11] Xolair package insert, https://www.gene.com/download/pdf/xolair_prescribing.pdf, accessed on July 20, 2023.

[12] FDA, *National Drug Code Directory*, https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm, accessed on October 4, 2023. Three dosage sizes are available for the single-dose prefilled autoinjector version. Because the autoinjector was released after CY 2022, ASP data for the autoinjector were not included in 2022 payment amount calculations.

[13] 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).

[14] 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).

[15] A typical dose of Fasenra is a single 30 mg/mL subcutaneous injection.

[16] A typical dose of Xolair is determined on the basis of the condition for which Xolair is being administered and, in some cases, the patient's body weight as well as blood antibody levels. A single dose of Xolair ranges from 75 mg to 600 mg. We calculated the actual payment amount and potential payment amount based on a dose of 150 mg (i.e., one provider-administered vial or one 150 mg size prefilled syringe).

[17] For Xolair, excluding the self-administered versions from payment amount calculations would have decreased fourth-quarter payment amounts per injection by $7.41 from $1,159.56 to $1,152.15.

[18] CMS provides its contractors with instructions for determining whether drugs are usually self-administered by the patients. See *Medicare Benefit Policy Manual*, ch. 15 § 50.2. Each contractor makes its own individual determination for each drug. CMS recently issued a request for information regarding drugs and biologicals which are not usually self-administered by the patient. See 88 Fed. Reg. 52387 (August 7, 2023).

[19] *Medicare Benefit Policy Manual*, ch. 15 § 50.2.

[20] MedlinePlus, *Heparin Injection*, https://medlineplus.gov/druginfo/meds/a682826.html, accessed on July 20, 2023.

[21] NDC 00264-5705-10 represents a self-administered version of heparin sodium injection.

[22] Granix package insert, https://www.granixhcp.com/globalassets/granix-hcp/prescribing-information.pdf, accessed on July 20, 2023.

[23] For example, see https://www.granixrx.com/about-granix, accessed on July 31, 2023; Granix package insert, https://www.granixhcp.com/globalassets/granix-hcp/prescribing-information.pdf, accessed on July 20, 2023. The following NDCs represent self-administered versions of Granix: 63459-0910-17, 63459-0910-36, 63459-0912-17, and 63459-0912-36.

[24] CMS provides its contractors with instructions for determining whether drugs are usually self-administered by the patient. See *Medicare Benefit Policy Manual*, ch. 15 § 50.2. Each contractor makes its own individual determination for each drug.

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

[26] 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).

[27] For example, *Medicare Benefit Policy Manual*, ch. 15 § 50.2.

[28] 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).