



DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



July 2, 2020

TO: Seema Verma, M.P.H
Administrator
Centers for Medicare & Medicaid Services

FROM: Suzanne Murrin
Deputy Inspector General
for Evaluation and Inspections

SUZANNE MURRIN Digitally signed by
SUZANNE MURRIN
Date: 2020.07.01
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SUBJECT: OIG Final Recommendation Followup Report: *Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars*, OEI-BL-20-00100

Attached is our final recommendation followup report entitled *Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollar*. This report contains no new recommendations.

If you have any questions about this recommendation followup report, please do not hesitate to call me, or one of your staff may contact Joe Chiarenzelli at (202) 836-1073 or Joe.Chiarenzelli@oig.hhs.gov. To facilitate identification, please refer to report number OEI-BL-20-00100 in all correspondence.

Attachment



HHS OIG Recommendation Followup • July 2020 • OEI-BL-20-00100

Loophole in Drug Payment Rule Continues To Cost Medicare and Beneficiaries Hundreds of Millions of Dollars

AT A GLANCE

Closing the payment loophole for self-administered drugs would have saved Medicare and its beneficiaries half a billion dollars on Orencia and Cimzia in 2017 and 2018.

Physicians almost never administered the self-injected version of Orencia to patients in their offices.

The payment loophole may provide physicians with substantial incentives to administer Orencia and Cimzia instead of other drugs.

Certain operational issues would need to be addressed if CMS and Congress were to exclude noncovered self-administered versions from payment amount calculations.

With certain exceptions, self-administered drugs are typically not covered under Medicare Part B.¹ However, as described in earlier Office of Inspector General (OIG) work and highlighted in this report, the Centers for Medicare & Medicaid Services (CMS) continues to factor in the prices for noncovered self-administered versions when it calculates the payment amounts for certain Part B drugs.

In general, Medicare coverage for outpatient prescription drugs is provided primarily under the Part D benefit.² However, a limited number of drugs—largely, those that are injected or infused in physicians' offices or hospital outpatient settings—are covered under Medicare Part B.³

Medicare payments for most Part B drugs are based on average sales prices (ASPs).⁴ In general, manufacturers must provide CMS with the ASP and sales volume for each of their Part B national drug codes (NDCs) on a quarterly basis.^{5, 6} However, Medicare sets payment amounts for Part B drugs using a different type of code—Healthcare Common Procedure Coding System (HCPCS) codes—rather than NDCs.⁷ Because more than one NDC may meet the definition of a HCPCS code, CMS must first “crosswalk” manufacturers' NDCs to their corresponding HCPCS codes.⁸ To determine the quarterly Part B payment amount for a HCPCS code, CMS calculates a volume-weighted ASP using the ASPs and sales volumes for each corresponding NDC.

In a November 2017 report, the Office of Inspector General (OIG) found that “corresponding” NDCs may sometimes represent versions of drugs that do not meet Part B drug coverage criteria.⁹ Specifically, CMS and a Federal court

interpret relevant statute to require the inclusion of versions of drugs not generally covered under Part B in limited circumstances when setting Medicare payment amounts. As a result, CMS included noncovered, self-administered versions of Orencia and Cimzia when determining payments for those two drugs. The inclusion of these noncovered versions caused Medicare and its beneficiaries to pay an extra \$366 million from 2014 through 2016. Twenty percent of that total (\$73.2 million) stemmed directly from additional coinsurance owed by Medicare beneficiaries.

OIG recommended that CMS seek a 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. CMS did not concur, citing concerns related to beneficiary access and operational implications, and noting that further analysis is necessary to determine whether such a change in law would be appropriate. OIG responded that it shares CMS’s concern regarding the need to safeguard patient access but believes that there are more effective measures to address this issue—measures that would not result in Medicare and its beneficiaries paying hundreds of millions of dollars in excess.

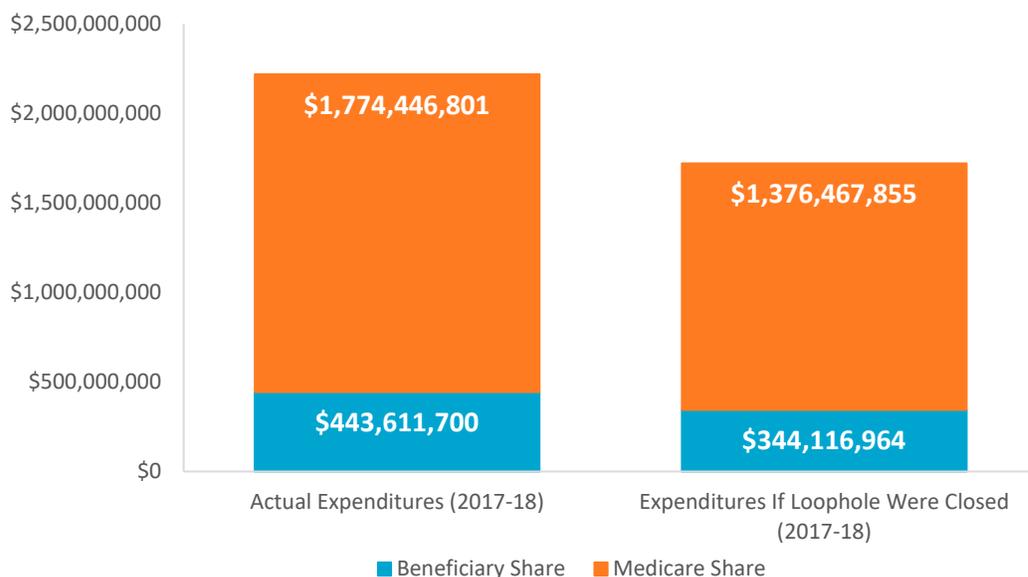
RESULTS

Closing the payment loophole for self-administered drugs would have saved Medicare and its beneficiaries nearly half a billion dollars in 2017 and 2018

As of December 2019, CMS continued to include noncovered, self-administered versions when calculating Part B payment amounts for Orencia and Cimzia, the same two drugs identified in OIG’s November 2017 report. In both cases, the HCPCS code descriptions associated with Part B coverage of the drugs specifically *exclude* self-administration.^{10, 11} From our analysis, these two drugs were the only ones for which noncovered, self-administered versions were used to set Part B payment amounts in 2017 or 2018 (i.e., CMS did not include in payment amount calculations any new NDCs that fit this criteria since the time we conducted analysis for our previous report).

Part B spending for Orencia and Cimzia would have been reduced by \$497 million (22 percent of expenditures for the two drugs) from 2017 through 2018 if their payment amounts had been set using only the physician-administered versions (i.e., if the self-administered versions had not been used in determining payment). (See Exhibit 1.) Twenty percent (\$99.5 million) of the total savings would have come directly through reduced coinsurance owed by Medicare beneficiaries.

Exhibit 1: Medicare and Its Beneficiaries Would Have Saved \$497 Million on Orencia and Cimzia Over 2 Years If the Payment Loophole Had Been Closed



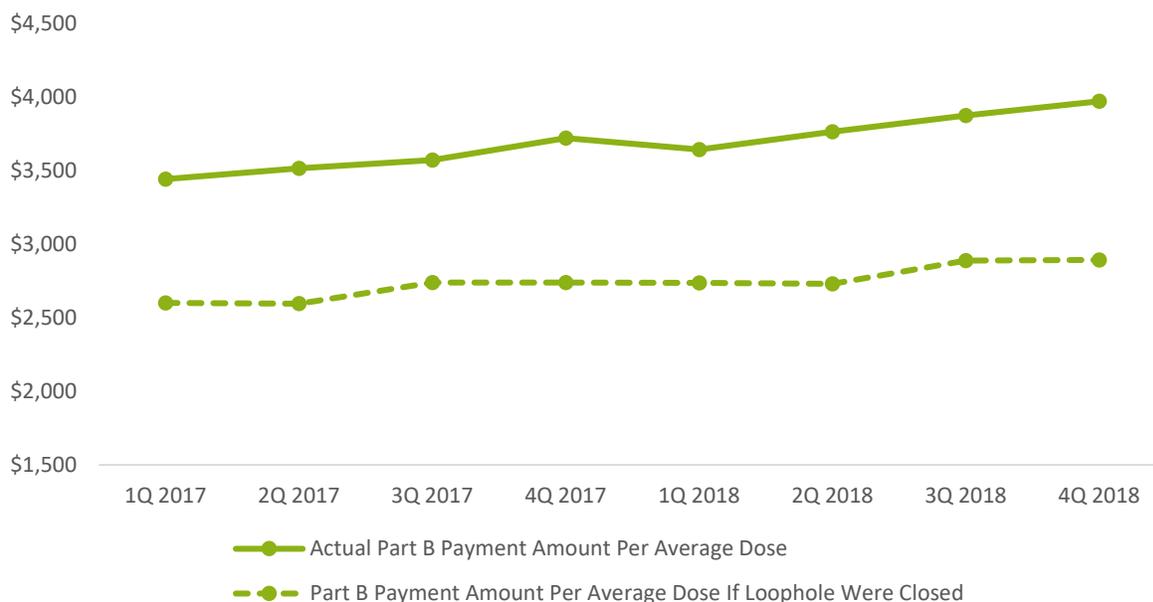
Source: OIG analysis of Part B payments and expenditures for Orencia and Cimzia, November 2019.

Medicare and its beneficiaries would have saved \$394 million over 2 years if payment amounts for Orenzia had been set using only physician-administered versions.

The inclusion of self-administered versions of Orenzia continues to artificially drive up the Medicare Part B payment amount. Orenzia (abatacept) is a prescription drug approved to treat arthritis. Prior to 2014, CMS included pricing for just a single, infused (i.e., physician-administered) version of Orenzia when calculating the Part B payment amount for the drug. In 2011, a new, higher-priced version of Orenzia intended primarily for self-administration at home—a prefilled syringe¹²—was approved for marketing by the U.S. Food and Drug Administration. Orenzia’s manufacturer began reporting pricing data for the new version in the first quarter of 2014, and CMS subsequently blended the prices for both the physician- and self-administered versions (based on their respective sales volumes) when determining the third-quarter 2014 payment amount. Because the self-administered version cost substantially more than the original, physician-administered form, Medicare’s payment amount for Orenzia immediately jumped by 35 percent.

If CMS had excluded self-administered versions of Orenzia (i.e., prefilled syringes and subsequently approved autoinjectors) when setting payment, the quarterly Medicare payment amount would have been between 23 percent to 27 percent lower from January 2017 through December 2018 (see Exhibit 2). As a result, Medicare and beneficiary spending would have been reduced by \$394 million, or roughly 26 percent of the \$1.5 billion spent on the drug during those 2 years.

Exhibit 2: Orenzia Cost Approximately \$800 to \$1,100 More Per Dose Because of Payment Loophole



Source: OIG analysis of Part B payments and expenditures for Orenzia, November 2019.

The payment loophole for Orenzia could cost a typical beneficiary almost \$3,000 per year.

Approximately 27,000 Medicare beneficiaries had at least 1 claim for Orenzia paid under Part B in 2018. For the most common infused dose (750 milligrams (mg)), current payment rules resulted in Medicare and these beneficiaries paying close to \$4,000 per infusion instead of \$2,900 (using fourth-quarter 2018 numbers).¹³ Given the 20-percent coinsurance under Part B, beneficiaries were therefore responsible for more than \$200 in additional cost-sharing per treatment (i.e., almost \$800 rather than

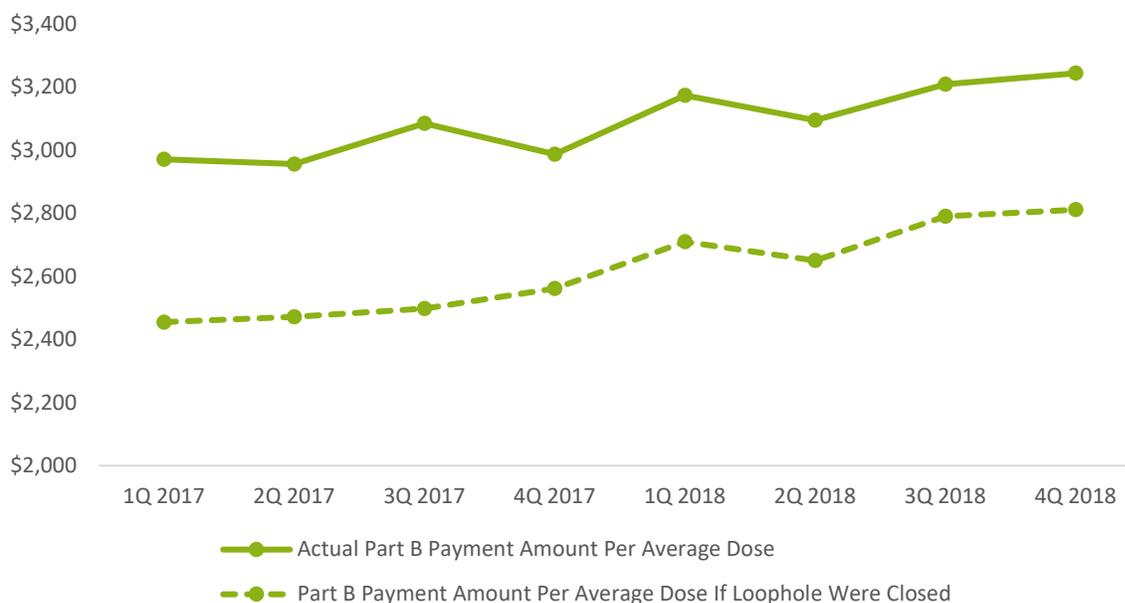
approximately \$580). The dosing schedule for Orencia recommends an infusion every 4 weeks, meaning that a typical beneficiary faced approximately \$2,800 per year in additional out-of-pocket spending simply because of a payment loophole.

Medicare and its beneficiaries would have saved \$104 million over 2 years if payment amounts for Cimzia had been set using only physician-administered versions.

As with Orencia, self-administered versions of Cimzia artificially drive up the drug’s Medicare Part B payment amount. Cimzia (certolizumab pegol) is a prescription drug used to treat certain forms of arthritis, plaque psoriasis, and Crohn’s disease. CMS includes the prices for three versions of Cimzia when calculating Part B payment amounts for the drug. However, as with Orencia, only one of these versions is intended primarily for administration by physicians. According to the manufacturer, the other two versions are typically intended to be self-administered by the patient.¹⁴

If CMS had based payment solely on the version of Cimzia intended to be administered by physicians, Medicare quarterly payment amounts for the drug would have been 13 percent to 19 percent lower in 2017 and 2018 (see Exhibit 3). In turn, Medicare and beneficiary spending on Cimzia would have been reduced by \$104 million, or 15 percent of the \$684 million spent on the drug during that period.

Exhibit 3: Cimzia Cost Approximately \$400 to \$600 More Per Dose Because of Payment Loophole



Source: OIG analysis of Part B payments and expenditures for Cimzia, November 2019.

The payment loophole for Cimzia could cost a typical beneficiary more than \$1,000 per year. Nearly 16,000 Medicare beneficiaries had at least one claim for Cimzia paid under Part B in 2018. For the standard physician-administered dose (400 mg), current payment rules resulted in Medicare and these beneficiaries paying close to \$3,250 per injection instead of roughly \$2,800 (using fourth-quarter 2018 numbers).¹⁵ Given the 20-percent coinsurance under Part B, beneficiaries were therefore responsible for almost \$90 in additional cost-sharing per treatment (i.e., approximately \$650 rather than \$560). The usual dosing schedule includes a 200-mg injection every 2 weeks or a 400-mg injection every 4 weeks, meaning that a typical beneficiary faced an additional \$1,100 per year in out-of-pocket spending simply because of a payment loophole (see Exhibit 4).

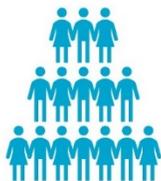
Exhibit 4: Drug Payment Loophole Continues To Have Significant Costs for Medicare Beneficiaries

Orencia

Approximately

27,000

beneficiaries
affected



Medicare and its
beneficiaries could
have saved

\$394 million

in 2017-18



A typical beneficiary
could have saved

\$2,800

annually through
reduced coinsurance



Cimzia

Approximately

16,000

beneficiaries
affected

Medicare and its
beneficiaries could
have saved

\$104 million

in 2017-18

A typical beneficiary
could have saved

\$1,100

annually through
reduced coinsurance

Source: OIG analysis of Part B payments and expenditures for Orencia and Cimzia, November 2019.

Physicians almost never administered the self-injected versions of Orencia to patients in their offices

In CMS's response to OIG's earlier report, the agency cited concerns related to beneficiary access as a reason for not concurring with our recommendation. Specifically, CMS stated that although situations in which a physician administers a version of a drug that is typically self-administered may be rare, modifying current law could limit the flexibility afforded to physicians to do so.

However, current payment levels *already* limit physician flexibility by presenting significant financial disincentives for physicians to provide self-administered versions of Orencia in their offices. In the fourth quarter of 2018, a physician who administered the 125-mg prefilled syringe of Orencia (the standard dosage of the subcutaneous form of the drug) would have received approximately \$660 in reimbursement for the drug under Part B. However, the average cost of that same syringe approached

\$1,000, meaning the physician would face a loss of more than \$300 every time he or she elected to administer this version.

Furthermore, an analysis of claims data from 2018 shows just how rarely beneficiaries receive injections of the typically self-administered versions of Orencia in their doctors' offices or hospital outpatient departments. In 2018, just 1.6 percent of the injection codes listed on claims for Orencia (3,449 out of 222,200) were for subcutaneous administrations (i.e., the only approved route for self-administered formulations). Moreover, nearly 2,700 of those claims listed an *additional* infusion/intravenous injection as also having been administered during the same visit, raising the possibility that the subcutaneous injection was not related to Orencia at all, but instead to another drug. In fact, just 150 claims for Orencia in 2018 (0.07 percent) listed billing units that reflected a dosage amount (125 mg) associated with the subcutaneous version—i.e., the self-administered version—of Orencia.

(Note: For Cimzia, because the recommended dosages and route of administration of the drug are identical across all three versions, OIG could not distinguish which version of the drug was billed. However, as with Orencia, the Part B reimbursement amount for Cimzia creates a financial disincentive for physicians to administer the prefilled Cimzia syringes (intended for self-administration) in their offices and outpatient settings.)

The payment loophole may give physicians substantial incentives to administer Orencia and Cimzia instead of other drugs for the same conditions

Because of the payment loophole, physicians who administered Orencia to Medicare beneficiaries in their offices received an average of 40 percent above their cost for the drug in 2018, compared to an estimated 6 percent for any competitor drug paid for under Part B.¹⁶ To put this into perspective, for each Medicare beneficiary who received a typical dose of Orencia in the final quarter of 2018, physicians netted almost \$1,300 every 4 weeks. If these physicians had instead administered one of several other Part B drugs for the same condition—drugs with payment amounts that are not subject to the loophole—they would have netted roughly \$75 to \$250 over a 4-week period (i.e., at least \$1,000 less per beneficiary per month).

Similarly, because of the loophole, physicians who administered Cimzia received an average of 23 percent above their cost for the drug that year. In the fourth quarter of 2018, these physicians netted almost \$690 every 4 weeks for each beneficiary, compared to between \$75 and \$375 for administering one of several other competitor drugs not affected by the loophole.

Previous OIG work has shown that financial incentives may affect prescribing behavior in Medicare.¹⁷ Given that the incentives cited in those reports were far smaller than the ones that currently exist for Orencia and Cimzia, OIG has serious concerns that the loophole could affect prescribing decisions.

To give an extreme example of the potential incentives associated with the loophole, a rheumatologist in Florida administered more than 1,000 infusions of Orencia to 118 Medicare beneficiaries in 2018. (We identified no obvious signs of inappropriate billing related to this provider.¹⁸) That year, Medicare reimbursed this physician almost \$3.8 million for Orencia. Assuming the drug was purchased at its ASP, the physician would have netted an estimated \$1.5 million for Orencia in 2018, compared to approximately \$130,000 if the loophole had been closed.

Certain operational issues would need to be addressed if CMS and Congress were to exclude noncovered self-administered versions from payment amount calculations

In our November 2017 report, OIG recommended that CMS seek a legislative change that would allow the agency to exclude noncovered versions of a drug when calculating Part B payment amounts. Given the complexities inherent in identifying noncovered versions and the goal of treating such versions consistently, it is critical that any legislation address the sources and evidence that CMS may use to determine self-administration.

In general, manufacturers report ASPs – including ASPs for any new NDCs associated with a particular Part B drug – each quarter. Therefore, to ensure all noncovered self-administered versions are excluded when setting payment, CMS would need to update OIG’s analysis on a quarterly basis.¹⁹ The vast majority of new NDCs listed on CMS’s Part B files will be associated with routes of administration that require the presence of healthcare professionals (e.g., intravenous infusions and intramuscular injections). Further, some self-administered drugs (e.g., oral anti-cancer drugs and certain inhalation drugs) are covered under Part B by statute. CMS could readily determine that any NDCs fitting the above criteria are considered to be covered and therefore do not fit the loophole criteria. In contrast, the NDCs requiring the closest scrutiny are those associated with subcutaneous injections.

The *Medicare Benefit Policy Manual* explains that a drug injected subcutaneously is presumably intended for self-administration, but clarifies that this likely is not the case if the drug is used to treat an acute condition or is administered less frequently.²⁰ Therefore, for any new NDCs that list a subcutaneous route of administration (around four NDCs per quarter during the period covered by this review), CMS will need to examine manufacturer labeling information for details regarding the drugs’ indications and uses. If a label indicates that the drug is for an acute condition or the label does not discuss the appropriateness of self-administration, CMS may reasonably conclude that the drug should be covered under Part B and does not fit the loophole criteria.^{21, 22}

However, simply because a drug treats a chronic condition and its label permits self-administration does not mean that it should definitively be considered noncovered. In addition, FDA-approved labels may change over time or may not contain all the necessary information CMS needs to make a fully informed decision regarding payment. Therefore, legislation would likely need to cite other resources that CMS may use in making a payment determination. For example, the manufacturer Web site for Orencia specifically refers to the pre-filled syringes and auto-injectors as “self-injection Orencia,” which clearly indicates that those versions should not be included when setting Part B payment. Further, manufacturer Web sites for both Orencia and Cimzia provide explicit instructions, including videos, on how to self-administer.

CONCLUSION

With certain exceptions, self-administered drugs are typically not covered under Medicare Part B. However, as described in earlier OIG work and highlighted in this report, CMS continues to factor in the prices for noncovered self-administered versions when calculating payment amounts for two high-expenditure Part B drugs: Orencia and Cimzia. As a result of this loophole, Medicare payment amounts remained inflated in 2017 and 2018, causing the program and its beneficiaries to pay an additional \$497 million during this period. Since 2014, current rules have resulted in an additional \$173 million in Medicare beneficiary coinsurance for Orencia and Cimzia.

CMS interprets the applicable law to require such an inclusion of noncovered versions of drugs, and a Federal district court reached the same conclusion. Accordingly, a legislative change may be required to address this matter. To that end, OIG previously recommended that CMS seek a legislative change that would provide the agency with flexibility to determine when noncovered versions of a drug should be included in calculations of Part B payment amounts. CMS did not concur with our prior recommendation, citing concerns related to beneficiary access and operational implications.

OIG shares CMS's concern regarding the need to safeguard patient access. However, OIG believes that there are more effective measures to address this issue—measures that would not (1) result in Medicare and its beneficiaries paying hundreds of millions of dollars in excess simply to account for exceedingly rare treatment instances; and (2) provide substantial financial incentives for physicians to administer a certain drug instead of others. Therefore, OIG continues to recommend that CMS:

Seek a legislative change requiring that noncovered, self-administered versions of drugs be excluded in the calculation of Part B payment amounts

Given the complexities inherent in identifying such noncovered versions, it is critical that any legislation address various decision points in the process, particularly the sources and evidence that CMS may use to determine self-administration for drugs injected subcutaneously.

AGENCY COMMENTS AND OIG RESPONSE

Consistent with its response to our earlier report on this issue, CMS did not concur with OIG's recommendation. CMS stated that it remains concerned with a number of complexities in identifying any noncovered versions included in Part B payment amount calculations.

Primarily, CMS states that because FDA does not identify an NDC on the basis of where it is likely to be administered, the manufacturer's label would not necessarily provide the level of detail needed to make an appropriate determination regarding self-administration. Further, CMS believes that it is not clear what sources and evidence would be appropriate to ensure that these determinations are made accurately and consistently. As a result, CMS notes that the analysis required to address the issues identified in this report would be difficult and time consuming, and that any consideration of potential legislation would need to account for the time and resource requirements involved.

CMS then reiterated its concern that, in some cases, the changes recommended by OIG could result in price increases or even affect access to Part B drugs. The agency closes by noting that OIG's analysis identified only two drugs for which noncovered, self-administered versions were used to set Part B payment amounts in 2017 and 2018 and that the projected savings based on OIG's findings represent less than 1 percent of the total spending for Part B drugs during this period.

OIG recognizes the potential complexities inherent in addressing the issues identified in this report, and as stated in our recommendation, we believe that it is critical for any legislation to address the sources and evidence that CMS may use to determine self-administration. However, the evidence from relevant sources is abundantly clear for the two drugs identified by OIG, both of which have FDA-approved labels, product inserts, and advertising touting the ease and benefits of self-administration. Simply put, the time and difficulty that CMS may encounter in assessing more complex examples should not mean that the agency does not take action on the obviously noncovered, self-administered versions of drugs like Orencia and Cimzia. Although \$500 million over 2 years reflects a small percentage of all Part B drug payments, it is not an insignificant sum, especially when considering that individual beneficiaries may be paying thousands extra every year simply due to a policy loophole.

Further, CMS states that any potential fixes need to consider agency time and resources. As OIG notes in the report, an average of 107 new NDCs were added to CMS's Part B drug payment files each quarter and 103 of them could be immediately excluded from any analysis due to their routes of administration and the rules for Part B coverage. In other words, the agency would typically need to make determinations for just four NDCs each quarter. On the basis of OIG's own experience conducting this analysis, the benefits of ensuring that Part B drugs are reimbursed appropriately far outweighs the small amount of resources used to conduct a more in-depth examination of how four drugs are typically administered.

Finally, CMS is correct that implementing the policy recommended by OIG could potentially lead to payment increases in certain circumstances. However, OIG has always maintained the importance of accurate payment amounts. In fact, a drug being under-reimbursed by Medicare is much more likely to lead to the types of access issues raised by CMS, and provides further support that payment amounts should be set using only versions that are actually covered under Part B.

METHODOLOGY

Data Collection and Analysis

Determining Whether Additional Drugs Met Noncovered-Versions Criteria. To determine whether there were any additional drugs (beyond the two identified in our previous report) for which noncovered versions were being used to set Part B payment amounts in 2017 or 2018, we:

- identified all NDCs listed on the file used by CMS to set fourth-quarter 2018 Part B payment amounts that were not on a similar file for mid-2016;
- determined whether any of the new NDCs represented subcutaneous injections (i.e., a route of administration more likely to be self-administered);
- removed any new subcutaneous injections that were already included on Part B contractor-developed lists of self-administered drugs to be excluded from payment (and therefore were not eligible to be paid under Part B) or were approved only for administration by health care professionals; and
- determined whether the associated billing code for any remaining injections also included versions that were not self-administered.

Determining Payment Amounts If Loophole Had Been Closed. For the HCPCS codes representing Orenzia and Cimzia, we recalculated the Medicare payment amounts using CMS's volume-weighted ASP formula in each quarter of 2017 and 2018 with the self-administered versions removed. In each quarter, we calculated the difference between the actual payment amounts and the payment amounts that would have been in effect if the loophole had been closed.

Calculating Savings. To determine how much Medicare would have spent for each drug if CMS had not included self-administered versions, we multiplied the total Part B expenditures for the drug each quarter by the percentage reduction that would have been achieved if the payment loophole had been closed.²³

Determining Provider Payments for Orenzia and Cimzia. We summarized 2018 payments in physicians' offices for Orenzia and Cimzia by the national provider identifier of the rendering provider (i.e., the provider who administered the injection or infusion). For hospital outpatient departments, we summarized 2018 payments by the national provider identifier of the billing provider because no information on the rendering provider was available.

Identifying Part B Claims for Self-Administered Versions of Orenzia. For each Orenzia claim in 2018, we identified the method of administration by referring to the drug administration code(s)—e.g., for intravenous infusion or for subcutaneous injection—listed on the same claim. Further, according to the U.S. Food and Drug Administration label and manufacturer instructions, patients who receive Orenzia via infusion (i.e., via physician administration) would receive 500 mg, 750 mg, or 1,000 mg, depending on their weight. The recommended dosage for the prefilled syringe and autoinjector (typically for self-administration) is 125 mg. For any Orenzia claims with an associated subcutaneous injection, we determined whether the amount of Orenzia for which the physician billed actually reflected the approved subcutaneous dose.

Limitations

Our analysis did not take into account the effects of sequestration on Medicare payment amounts and expenditures. Part B claims dated on or after April 1, 2013, incur a 2-percent reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (i.e., sequestration). This mandatory payment reduction is applied after the beneficiary's coinsurance has been determined.²⁴

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.

AGENCY COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: June 24, 2020

TO: Christi Grimm
Principal Deputy Inspector General
Office of Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services



SUBJECT: Office of Inspector General (OIG) Draft Issue Brief: Loophole in Drug Payment Rule Continues to Cost Medicare and Beneficiaries Hundreds of Millions of Dollars (OEI-BL-20-00100)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS strives to maximize the affordability and availability of drugs for Medicare beneficiaries while protecting taxpayer dollars. For example, Fiscal Year 2020 President's Budget includes proposals to address drug pricing in Medicare, including establishing an inflation limit for Medicare payment of Part B drugs.

Medicare covers many prescription drugs under the Part D benefit. However, some prescription drugs and biologicals (hereinafter referred to as drugs), typically those that are injected or infused in physicians' offices or hospital outpatient settings, are covered under the Part B benefit.

Drugs covered under the Part B benefit are generally priced using the average sales price payment methodology outlined in Section 1847A of the Social Security Act (the "Act"), which requires that the payment limit for the billing and payment code, or Healthcare Common Procedure Coding System (HCPCS) code, for a drug or biological be determined using all of the National Drug Codes assigned to the code regardless of how the drug is packaged.

For Part B drug payments made under the average sales price payment methodology in section 1847A of the Act, CMS bases the payment limit for a biological product or single source drug assigned to a HCPCS code on the pricing information for products produced or distributed under the applicable Food and Drug Administration (FDA) approval. The average sales price payment methodology factors in prices for all versions of a drug, including versions of a drug that may primarily be used in situations that are not covered under Part B, such as versions of drugs that are self-administered by a patient at home. Thus, no version of a drug is excluded from the calculation of the average sales price of a HCPCS code to which that product is assigned.

OIG's recommendation and CMS' response are below.

OIG Recommendation

The OIG continues to recommend that CMS seek a legislative change requiring that noncovered, self-administered versions of drugs be excluded in the calculation of Part B payment amounts. Given the complexities inherent in identifying such noncovered versions, it is critical that any legislation address various decisions points in the process, particularly the sources and evidence that CMS may use to determine self-administration for drugs injected subcutaneously.

CMS Response

CMS follows current law in calculating payments for Part B drugs. While the Fiscal Year 2020 President's Budget includes proposals to address drug pricing in Medicare, including establishing an inflation limit for Medicare payment of Part B drugs, CMS continues to non-concur with the OIG's recommendation, for the reasons laid out below.

We believe that the OIG's perspective on these issues is important and we appreciate the additional detail that the OIG provided in this follow up report. However, we remain concerned that there are a number of complexities associated with identifying a drug's noncovered versions, including self-administered versions, for the purpose of excluding them from the calculation of payment allowances under section 1847A of the Social Security Act. The FDA does not identify a National Drug Code (NDC) based on whether it is self-administered or administered in a physician's office. The manufacturer's label would not necessarily indicate which NDC is self-administered, or indicate the frequency of use in a given setting for products that may be used in multiple settings. It is not clear what sources and evidence would be appropriate to be used to assist with making these determinations accurately and consistently. Therefore, the analysis to determine whether a particular NDC of a product is self-administered and noncovered by Medicare and should be excluded from the calculation of the average sales price based payment allowance for a HCPCS code would be difficult and require time and resources. Any potential legislation would need to balance the time and resource requirements for this policy compared to the resource requirements that would involve CMS implementation of other new legislative provisions as well as existing law and policies on Part B payment for drugs. Finally, as with other policies impacting Part B payment for drugs, there is a concern about whether excluding a specific type of NDC from HCPCS payment allowance calculations could potentially result in price increases for particular Part B NDCs or have other distortions in pricing which could result in drug price increase and affect access to Part B drugs.

CMS notes that the OIG has identified only two drugs for which noncovered, self-administered versions were used to set Part B payment amounts in 2017 and 2018. The projected savings based on OIG's findings represent less than one percent of the total spending for Part B drugs during this time.

ACKNOWLEDGMENTS

This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore regional office; Heather Barton, Deputy Regional Inspector General; and Louise Schoggen, Assistant Regional Inspector General.

Dave Tawes also served as the team leader for this study. Other OIG staff who provided support include Bahar Adili, Joe Chiarenzelli, Adam Freeman, Christine Moritz, and Jessica Swanstrom.

ENDNOTES

¹ Medicare Part B does cover a small number of self-administered drugs, including certain oral anticancer drugs; blood clotting factors; and inhalation and infusion drugs used with durable medical equipment. 42 CFR § 414.900(b) and the *Medicare Benefit Policy Manual*, ch. 15 § 50. At 50.2 of the same manual, CMS describes how contractors can determine whether a drug is “usually self-administered.”

² Section 1860D-1 et seq. of the Social Security Act (the Act).

³ Hereinafter referred to as physician-administered drugs. 42 CFR § 414.900 and the *Medicare Benefit Policy Manual*, ch. 15, § 50.

⁴ Section 1847A(a) of the Act (requiring use of ASP payment methodology), 42 CFR § 414.904(a).

⁵ Section 1847A(f) (requiring quarterly reporting of ASP using the reporting requirements located at section 1927(b)(3) of the Act).

⁶ An NDC is an 11-digit code divided into three segments identifying (1) the firm that manufactures, distributes, or repackages the drug product; (2) the strength, dosage form, and formulation of the product; and (3) the product’s package size.

⁷ In the case of prescription drugs, each HCPCS code defines the drug’s name and the amount of drug represented by one unit of the HCPCS code but does not specify manufacturer or package size information.

⁸ Each quarter, CMS publishes a crosswalk file that lists the NDCs matching each Part B drug HCPCS code.

⁹ 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. Please see this report for a full explanation of CMS’s reasoning for including noncovered versions in these calculations in certain circumstances.

¹⁰ J0129: Injection, abatacept, 10 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered).

¹¹ J0717: Injection, certolizumab pegol, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self administered).

¹² Orenzia, “How to Take or Administer Orenzia,” <https://www.orenzia.com/about-orenzia/how-to-take-orenzia>. Accessed on December 3, 2019.

¹³ According to Orenzia’s label, dosing is generally based on the patient’s weight. In 2018, 65 percent of paid claims for Orenzia were for 750 mg (3 vials) of the drug, 19 percent were for 1,000 mg (4 vials), and 15 percent were for 500 mg (2 vials). The remaining 1 percent reflected nonstandard dosing.

¹⁴ Cimzia, “Cimzia Medication Guide,” <https://www.cimzia.com/assets/pdf/MedicationGuide.pdf>. Accessed on September 24, 2019.

¹⁵ According to Cimzia’s label, the recommended dosing is an initial 400-mg injection followed by 200-mg or 400-mg injections every 2 or 4 weeks depending on the condition and the patient. In 2018, 90 percent of paid claims for Cimzia were for 400 mg (2 vials) of the drug and 9 percent were for 200 mg (1 vial). The remaining 1 percent reflected nonstandard dosing.

¹⁶ Assuming the typically physician-administered version of Orenzia was provided and that the physician purchased the drug at its ASP. Medicare typically reimburses providers 106 percent of the ASP for Part B drugs. The provider would also receive an additional payment for administering the drug.

¹⁷ For example, see OIG, *Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B*, <https://oig.hhs.gov/oei/reports/oei-12-12-00210.pdf>; and OIG, *Beneficiary Utilization of Albuterol and Levalbuterol Under Medicare Part B*, <https://oig.hhs.gov/oei/reports/oei-03-07-00440.pdf>.

¹⁸ For example, the physician’s patients were not receiving Orenzia infusions more frequently than recommended, and the number of units billed for each patient visit were in line with national averages.

¹⁹ On average, 107 unique NDCs per quarter were added to CMS’s ASP files during the period covered by this review.

²⁰ *Medicare Benefit Policy Manual*, ch. 15 § 50.2.

²¹ CMS may also remove from their analysis any self-administered NDCs for which the related HCPCS codes are not associated with any physician-administered versions. Although Part B coverage of these HCPCS codes may warrant

its own examination (i.e., because all versions of the drug are self-administered), they do not fit the payment loophole criteria.

²² Solely relying on FDA labels to determine self-administration would be complicated for a drug that is frequently used for off-label indications. This illustrates additional complexities that could be faced by CMS and potentially addressed in any legislation.

²³ The method for determining savings differs from that in our prior report because of changes made to how Medicare reimburses hospitals that purchase drugs under the 340B drug discount program. We do not believe that this change would make a material difference in our calculations.

²⁴ CMS Medicare FFS Provider e-News, “Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program—'Sequestration,'" March 8, 2013. Accessed at <https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf> on December 3, 2019.