



## Excluding Noncovered Versions When Setting Payment for Two Part B Drugs Would Have Resulted in Lower Drug Costs for Medicare and its Beneficiaries

### AT A GLANCE

**CMS and a Federal court interpret the law to require the inclusion of noncovered versions of drugs in limited circumstances when setting payment amounts**

**As a result, CMS included noncovered, self-administered versions when calculating payment amounts for two Part B drugs**

**The inclusion of these noncovered versions caused Medicare and its beneficiaries to pay an extra \$366 million from 2014 through 2016**

Medicare coverage for outpatient prescription drugs is primarily provided under the voluntary Part D benefit.<sup>1</sup> However, a limited number of prescription drugs—generally those that are injected or infused in physicians' offices or hospital outpatient settings—are covered under Medicare Part B.<sup>2</sup> With certain exceptions, Part B does not cover drugs that are usually self-administered by patients, including drugs administered by self-injection.<sup>3</sup>

Medicare payment amounts for most Part B drugs are based on manufacturer-reported average sales prices (ASPs).<sup>4</sup> In general, manufacturers must provide the Centers for Medicare & Medicaid Services (CMS) with the ASP and sales volume for each of their Part B national drug codes (NDCs) on a quarterly basis.<sup>5,6</sup> However, Medicare sets payment amounts and reimburses providers for Part B drugs using another type of code, the Healthcare Common Procedure Coding System (HCPCS) code rather than NDCs. Because more than one NDC may meet the definition of a particular HCPCS code, CMS must first "crosswalk" manufacturers' NDCs to their matching HCPCS codes.<sup>7</sup> 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 of the corresponding NDCs.<sup>8</sup> In some cases, "corresponding" NDCs may include versions that, despite containing the same drug/formulation, are not typically used in situations that meet Part B drug coverage criteria. In other words, under certain circumstances, criteria for including drugs in payment amount calculations may differ from criteria for covering a drug under Part B.

Previous OIG work has found that inaccuracies in CMS’s ASP data may have affected Medicare payments for a small number of drugs.<sup>9</sup> This current data brief addresses a similar issue, whereby CMS may be including noncovered, self-administered versions (i.e., NDCs) of certain drugs when calculating Part B payment amounts.

### Exhibit 1: Glossary of Technical Terms Used in This Report

#### Average sales price (ASP)

- Dollar amount of a manufacturer’s sales of a drug to all purchasers (with certain exceptions) in the United States in a quarter divided by the number of units of the drug sold by the manufacturer in that same quarter, net of certain price concessions and discounts.
- Medicare pays for most Part B drug codes at 106 percent of their ASPs.

#### Biological License Application (BLA)

- Essentially, the vehicle by which manufacturers seek approval from the Food and Drug Administration (FDA) to market a biologic.

#### Crosswalk

- Because payments for Part B drugs are based on HCPCS codes rather than on NDCs and because more than one NDC may meet the definition of a particular HCPCS code, CMS must “crosswalk” manufacturers’ NDCs to their matching HCPCS codes.
- Each quarter, CMS publishes a crosswalk file that lists the NDCs matching each Part B drug HCPCS code.

#### Healthcare Common Procedure Coding System (HCPCS) code

- Procedure codes used by providers to submit claims to Medicare and to obtain payment for Part B drugs.
- 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.

#### National drug code (NDC)

- An 11-digit code that is 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 and package type.

#### New Drug Application (NDA)

- Essentially, the vehicle by which manufacturers seek approval from the FDA to market a drug.

## RESULTS

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### CMS and a Federal court interpret the law to require the inclusion of noncovered versions of drugs in limited circumstances when setting payment amounts

In determining which NDCs are crosswalked to a HCPCS code for payment purposes, CMS relies on manufacturer submissions, environmental scanning by contractors, and the clinical expertise of staff. This process is guided by Federal law, regulation, and subregulatory guidance (e.g., FAQs, informational bulletins, etc.).



The Act requires that the payment amount for a single-source (i.e., brand name) drug be determined using all of the NDCs assigned to it.<sup>10</sup> The Act further states that the payment amount for a Part B drug shall be determined “without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.”<sup>11</sup>

In interpreting the statute, CMS staff determined that:

- (1) all versions of a product listed under the same FDA approval number (e.g., NDA or BLA) must be considered the same drug or biological, for payments made under Section 1847A of the Act, and
- (2) for a product marketed under the same approval 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.

To that end, CMS states in its subregulatory guidance that the agency will “ensure that payment will be based on the pricing information for all products produced or distributed under an FDA approval for the drug or biological.”<sup>12</sup> In other words, Part B payments for prescription drugs factor in prices for all versions of a drug, even when certain versions of the drug may be used primarily in situations that are not covered by the program. CMS’s decision is supported by the ruling of the U.S. District Court for the District of Columbia in *Allergan v. Burwell*. The Court 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.<sup>13</sup>

## **The inclusion of noncovered self-administered products when setting payment amounts for two Part B drugs caused Medicare and its beneficiaries to pay an extra \$366 million from 2014 to 2016**

OIG identified two drugs (Orencia and Cimzia) for which CMS includes noncovered self-administered versions when calculating Part B payment amounts, even though Part B generally does not cover drugs that are self-administered. For each drug, the self-administered version(s) was approved by FDA under the same BLA as the physician-administered version, meaning that CMS is following internal policy and case law when setting payment. However, the HCPCS code descriptions (developed by CMS with public input) of both drugs specifically exclude self-administration.

Part B spending for the two drugs would have been reduced by \$366 million (19 percent of expenditures) from 2014 through 2016 if the payment amounts were set using only the physician-administered versions (i.e., had the noncovered self-administered versions not been used in determining payment).<sup>14</sup> Twenty percent of that total (\$73.2 million) would have come directly through reduced coinsurance owed by Medicare beneficiaries.

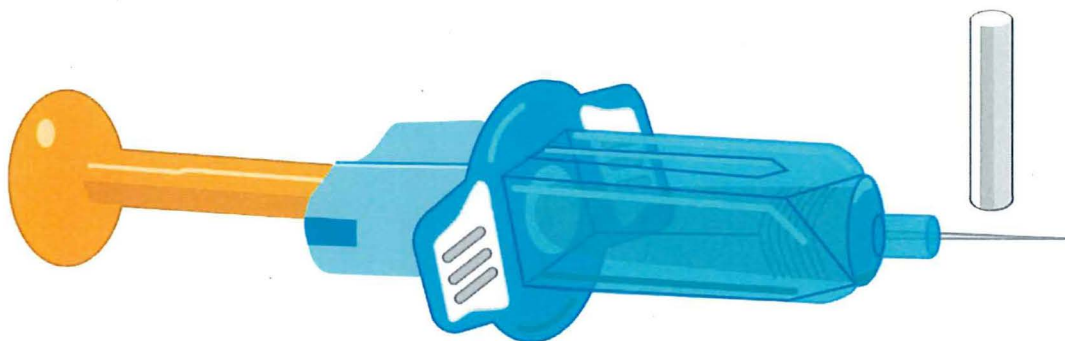
### ***Medicare and its beneficiaries would have saved \$302 million if payment amounts for Orencia had been set using only physician-administered versions.***

Orencia (abatacept) is a prescription drug used to treat moderate to severe rheumatoid arthritis and some other forms of arthritis. Prior to 2014, CMS included ASPs for just a single, intravenous version of

Orencia when calculating the Part B payment amount for the drug. In 2011, a new higher-priced form of Orencia intended primarily for home administration was approved for marketing by FDA (see Exhibit 2) under the same BLA as the original physician-administered version. Orencia's manufacturer began reporting ASP data for an NDC associated with the new form in the first quarter of 2014, and CMS subsequently blended the ASPs for both the physician- and self-administered versions (based on sales volumes) when determining the third-quarter 2014 payment amount for the HCPCS code. In following its pricing policy, CMS made this decision even though the HCPCS code description states that the code "is not for use when drug is self administered."<sup>15</sup>

#### Exhibit 2: Manufacturer Description of Orencia Prefilled Syringe

For home use, ORENCIA<sup>®</sup> comes in a prefilled syringe or prefilled ClickJect autoinjector. After you receive training at your doctor's office, this once-weekly injection can be done in the comfort of your home.

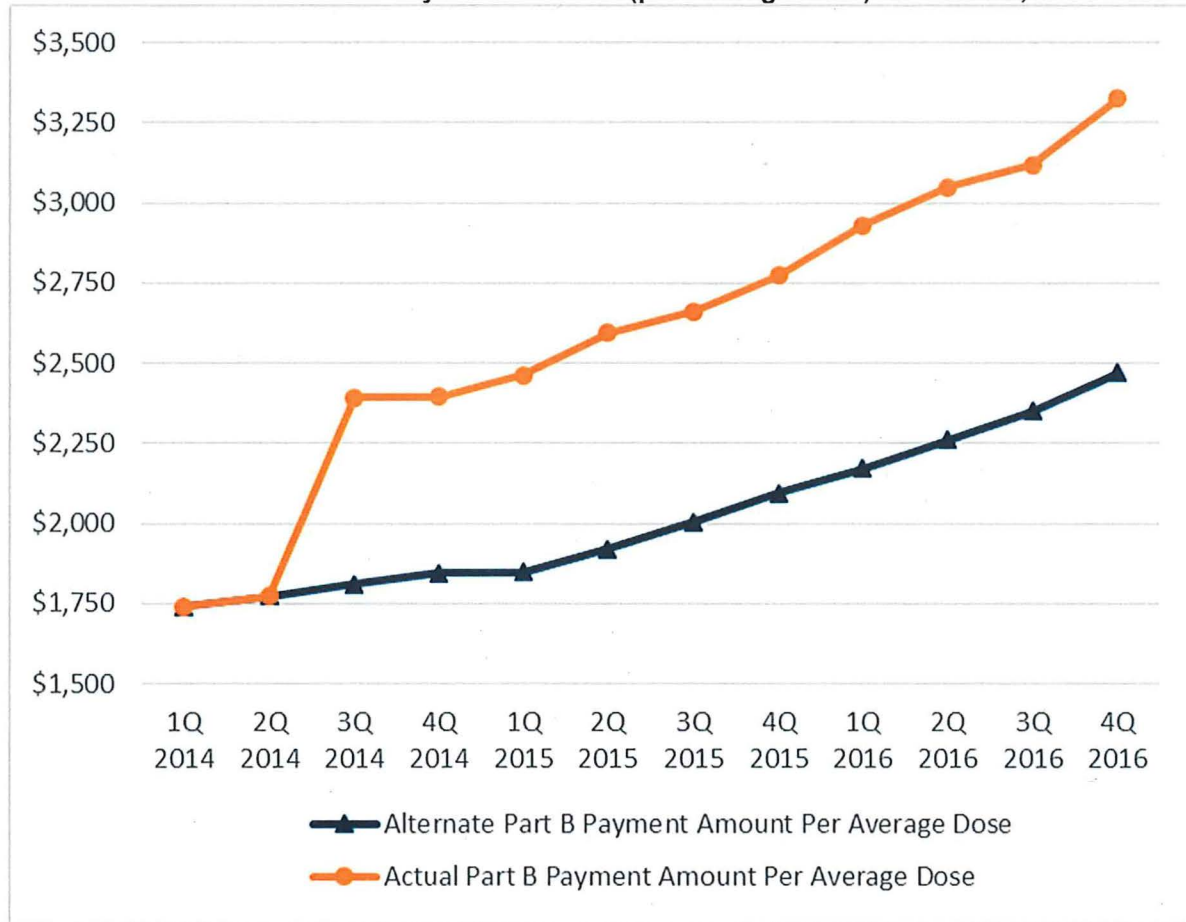


Source: Text from <http://www.orencia.bmscustomerconnect.com/how-to-take-orencia/self-injection-prefilled-syringe>, accessed on February 28, 2017.

When CMS began including the ASPs of self-administered Orencia, the Part B payment amount for a typical monthly dose of the drug immediately jumped from approximately \$1,774 to \$2,394 per month (see Exhibit 3). This increase was not caused by significant growth in the cost of the intravenous version administered by physicians. Rather, it was driven by the introduction of the higher-cost version of Orencia that is primarily intended for self-injection in a patient's home. As a result, Medicare payment amounts for Orencia from the third quarter of 2014 through the fourth quarter of 2016 were 30 percent to 35 percent higher than they could have been. Had CMS not included the self-administered version of Orencia when setting payment, Medicare and beneficiary spending on the drug would have been reduced by \$302 million over 3 years.

To put these numbers in perspective, 23,366 Medicare beneficiaries had at least one claim for Orencia paid under Part B in 2016. On average, beneficiaries owed \$665 in coinsurance per administration, which is generally once per month for the physician-administered version.<sup>16</sup> Had payment been based solely on the physician-administered versions, beneficiaries would have instead owed an average of \$494—i.e., \$171 less—per administration.<sup>17</sup>

**Exhibit 3: Actual vs. Alternate Payment Amounts (per Average Dose) for Orendia, 2014–2016**



Source: OIG analysis of CMS ASP files and Part B claim files.

Note: "Alternate Part B Payment Amount" refers to the payment amount had CMS excluded self-administered versions from its calculations. To calculate actual and alternate payment amounts per average dose, we used the average dose of Orendia in 2016.

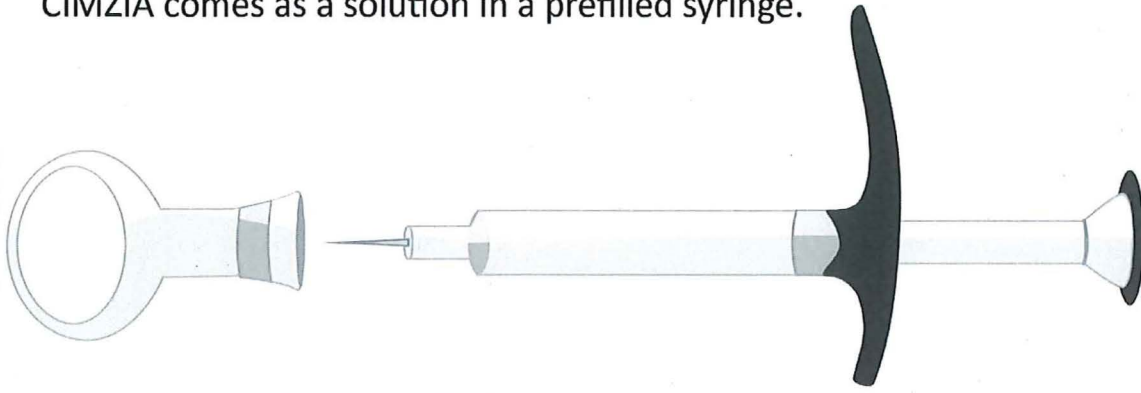
***Medicare and its beneficiaries would have saved \$64 million if payment amounts for Cimzia had been set using only physician-administered versions.***

Cimzia (certolizumab pegol) is a prescription drug used to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and Crohn’s disease. CMS includes the ASPs for three versions of Cimzia when calculating Part B payments amounts for the drug. However, as with Orendia, only one of these versions is primarily for injection by health care professionals, even though all are approved under the same BLA. According to the manufacturer’s Web site, the other two versions are intended to be self-administered by the patient (see Exhibit 4).<sup>18</sup> Similar to Orendia, the HCPCS code definition for Cimzia states that the code is not for use when the drug is self-administered.<sup>19</sup>



#### Exhibit 4: Manufacturer Description of Cimzia Prefilled Syringe

With CIMZIA<sup>®</sup>, your doctor may decide to have you self-inject at home with the prefilled syringe after you receive proper training by your healthcare professional. If you are prescribed at home injections, CIMZIA comes as a solution in a prefilled syringe.

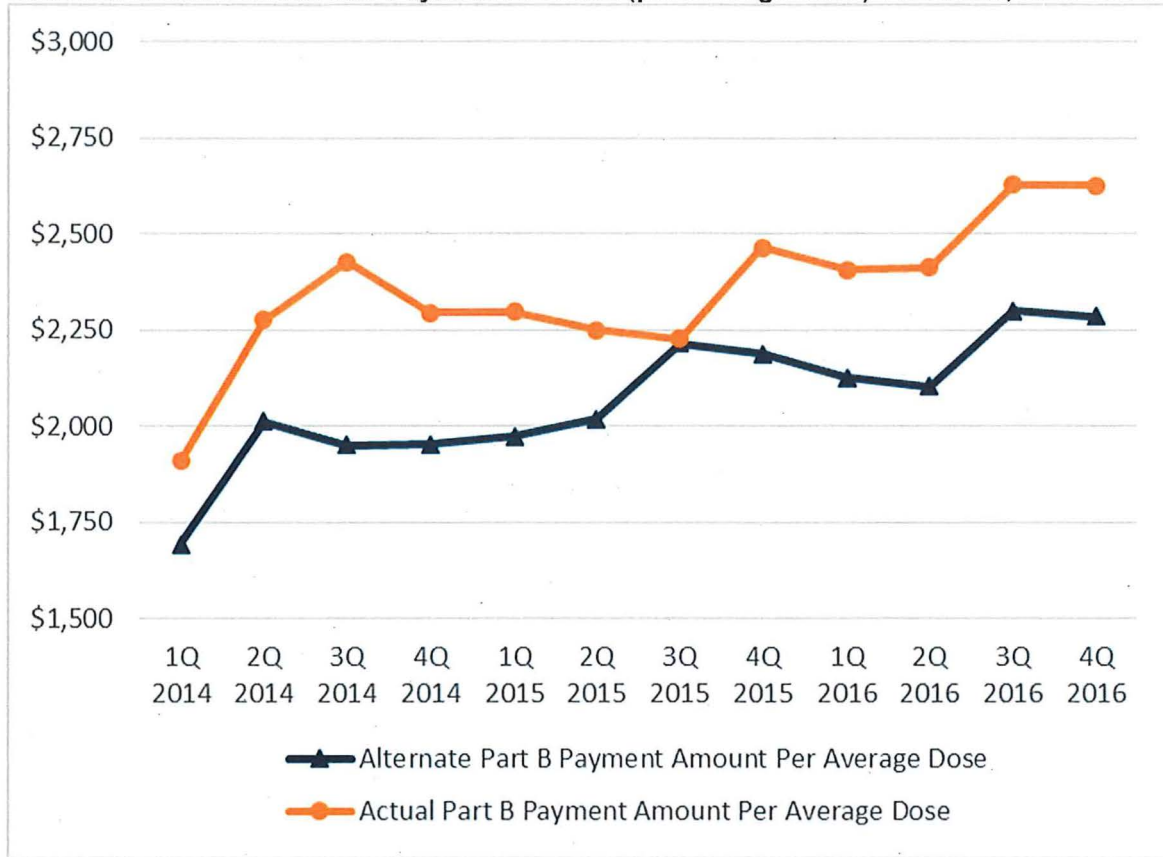


Source: Text from <https://www.cimzia.com/rheumatoid-arthritis/starting-cimzia/injection-training> accessed on February 28, 2017.

As a result of the ASPs for the self-administered versions being used in pricing calculations, Medicare payment amounts for Cimzia from the first quarter of 2014 through the fourth quarter of 2016 were 1 percent to 25 percent higher than they would have been had payment been based solely on the single version of the drug intended to be administered by a physician (see Exhibit 5).<sup>20</sup> Had CMS not included the self-administered version of Cimzia when setting payment, Medicare and beneficiary spending on the drug would have been reduced by \$64 million over 3 years.

In total, 12,050 Medicare beneficiaries had at least one claim for Cimzia paid under Part B in 2016. On average, beneficiaries owed \$525 in coinsurance per drug administration, which can occur as often as twice per month depending on the beneficiary's condition. Had payment been based solely on the physician-administered versions, beneficiaries would have instead owed \$457—i.e., \$68 less—per administration.<sup>21</sup>

**Exhibit 5: Actual vs. Alternate Payment Amounts (per Average Dose) for Cimzia, 2014–2016**



Source: OIG analysis of CMS ASP files and Part B claims files.

Note: "Alternate Part B Payment Amount" refers to the payment amount had CMS excluded self-administered versions from its calculation.

To calculate actual and alternate payment amounts per average dose, we used the average dose of Cimzia in 2016. In the second and third quarters of 2015, CMS substituted the ASP-based payment amount for Cimzia with an amount set at 103 percent of the AMP. See endnote 20.

## RECOMMENDATION

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With certain exceptions, self-administered drugs are typically not covered under Medicare Part B. However, as highlighted in this brief, CMS factors-in the prices for noncovered, self-administered versions when calculating payment amounts for two high-expenditure Part B drugs. As a result, Medicare payment amounts were inflated from 2014 through 2016, causing the program and its beneficiaries to pay an additional \$366 million during this period.

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. We recommend that CMS:

### **Seek a legislative change that would provide the agency flexibility to determine when noncovered versions of a drug should be included in Part B payment amount calculations**

Including prices for higher-cost versions of drugs that are not covered under Medicare Part B when setting Part B payment amounts seems inconsistent with the goal of establishing appropriate payment amounts. A legislative fix should allow CMS to determine—based upon cost implications and other relevant factors—whether the agency will include ASPs for noncovered versions of a drug in Part B payment amounts.

## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

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CMS did not concur with our recommendation. The agency stated that although situations in which a health care professional uses 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. This, in turn, could negatively affect beneficiary access to medically necessary drugs as well as increase the cost of these drugs. The agency also stated that further analysis on the cost, policy, and operational implications would need to be conducted for CMS to determine whether such a change in law would be appropriate.

OIG shares CMS's concern regarding the need to safeguard patient access, and recognizes there may be extremely limited circumstances in which physicians would choose to personally administer a higher-cost version of a drug that is primarily intended for self-injection by the patient. On those occasions, physicians should be reimbursed appropriately for the more expensive drug. However, OIG believes that there are more effective means to address these limited circumstances—means that would not result in Medicare and its beneficiaries paying hundreds of millions of dollars in excess just to accommodate a rare occurrence. For example, if new legislation were to pass providing CMS flexibility to determine when noncovered versions of a drug should be included in Part B payment amount calculations, the agency would be able to implement rules requiring a claims modifier to indicate the use of a typically self-administered version by the physician. This modifier could, in turn, result in an appropriately higher payment amount.

Given the dollars at stake, and the fact that new drugs fitting the criteria identified in this report are entering the market each year, we believe that the benefits of a legislative change warrants further analysis. Therefore, we encourage CMS to study the cost, policy, and operational implications the agency believes are necessary before pursuing such a change.



## METHODOLOGY

*Identifying Drugs.* To identify drugs with payment amounts based in part on ASPs for self-administered versions that typically would not be used in situations that meet Part B coverage criteria, we:

- matched all NDCs listed on CMS’s ASP crosswalk files to current national drug compendia and identified NDCs with routes of administration that are associated with possible self-administration;
- removed from the analysis any NDCs for which self-administration is allowed under Part B coverage criteria (e.g., inhalation drugs, oral anticancer drugs);
- checked related manufacturer websites, as well as FDA listings, for the remaining NDCs to determine whether the associated drugs are primarily recommended for self-administration; and
- selected any associated HCPCS codes that included both (1) NDCs for physician-administered versions and (2) NDCs for self-administered versions that did not meet Part B coverage criteria (see Exhibit 6).

**Exhibit 6: Summary of Part B NDCs Included in Analysis**

Criteria	Number of NDCs Removed	Number of NDCs Remaining
All Part B NDCs	None	4,089
Removed drugs with no route of administration listed*	208	3,881
Removed drugs that would likely only be administered by physicians	3,220	661
Removed non-injectable drugs for which self-administration is covered under Part B (e.g., inhalation, oral anticancer, topical drugs)	582	79
Removed injectable drugs for which self-administration is covered under Part B (i.e., durable medical equipment infusion drugs)	16	63
Removed injectable drugs used for shorter-term conditions that may be either physician- or self-administered	33	30
Removed drugs that only had NDCs for self-administered versions (e.g., insulin)	27	3 (associated with 2 HCPCS codes)

Source: OIG analysis of CMS’s ASP crosswalk files, national drug compendia, Part B coverage criteria, manufacturer websites, and Food & Drug Administration prescribing information.

\*All but eight of these NDCs were for nondrug skin graft products or contrast materials used during medical procedures.

*Determining Alternate Payment Amounts.* For the two HCPCS codes that met all the above criteria, we recalculated the Medicare payment amounts using CMS’s volume-weighted ASP formula in each quarter from 2014–2016 with the self-administered NDCs removed. We calculated the difference between the actual and alternate payment amounts in each quarter.

Savings Calculations. To determine how much Medicare would have spent for each drug had CMS not included self-administered versions, we multiplied the alternate payment amount in each quarter by the total number of units reimbursed by Medicare Part B in that quarter. We then subtracted the results from actual quarterly Part B expenditures for each drug to determine how much less Medicare and its beneficiaries would have saved. In other words, we used the following formula for each quarter:

$$\text{Savings} = \text{Actual expenditures} - (\text{Alternate payment amount} * \text{Number of units reimbursed})$$

**Limitations**

There may be limited occasions when health care professionals could inject what are typically self-administered versions of Orencia or Cimzia. Our analysis did not take into account these circumstances.<sup>22</sup>

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.<sup>23</sup>

**Standards**

This study was conducted 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

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Washington, DC 20201

**DATE:** OCT 13 2017

**TO:** Daniel R. Levinson  
Inspector General

**FROM:** Seema Verma   
Administrator

**SUBJECT:** Office of Inspector General (OIG) Draft Issue Brief: Excluding Non-Covered 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)

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.

Medicare covers many prescription drugs under the Part D benefit. However, some prescription 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 amount for the billing and payment code, or Healthcare Common Procedure Coding System 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 Healthcare Common Procedure Coding System code on the pricing information for products produced or distributed under the applicable Food and Drug Administration 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 injected by a patient at home. Thus, no version of a drug can be excluded from the calculation of the average sales price of a Healthcare Common Procedure Coding System code to which that product is assigned.

OIG's recommendation and CMS' response are below.



**OIG Recommendation**

The OIG recommends that CMS seek legislation that would provide the agency flexibility to determine when non-covered versions of a drug should be included in Part B payment amount calculations.

**CMS Response**

CMS non-concurs with OIG's recommendation. Current legislation permits Part B payment in situations where a health care professional would use a version of a drug that is typically self-administered. While these instances may be rare, modifying the current legislation could limit the flexibility afforded to healthcare professionals which could negatively impact access to medically necessary drugs as well as increase the cost of these drugs. Further analysis on the cost, policy, and operational implications would need to be done in order for CMS to determine whether such a change in law would be appropriate.

## **ACKNOWLEDGMENTS**

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Dave Tawes served as the team leader for this study. Others in the Office of Evaluation and Inspections who conducted the study include Bahar Adili. Office of Evaluation and Inspections staff who provided support include Clarence Arnold and Meghan Kearns.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Lauren McNulty and Jessica Swanstrom.

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

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at [Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).

## ENDNOTES

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<sup>1</sup> Section 1860D-1 et seq. of the Social Security Act (the Act), 42 CFR Part 423.

<sup>2</sup> Hereinafter referred to as physician-administered drugs. 42 CFR § 414.900 and the Medicare Benefit Policy Manual, ch. 15, § 50.

<sup>3</sup> 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. 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.”

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

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

<sup>6</sup> According to previous Office of Inspector General (OIG) work, there is no “master list” of manufacturers that are required to report ASPs. As a result, manufacturers have often reported ASPs for NDCs that CMS does not consider to be associated with a Part B drug. See *Average Sales Prices: Manufacturer Reporting and CMS Oversight*, OEI-03-08-00480, February 2010 and *Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs*, OEI-12-13-00040, July 2014.

<sup>7</sup> Each quarter, CMS publishes a crosswalk file that lists the NDCs matching each Part B drug HCPCS code. CMS also develops a nonpublic quarterly ASP “background” file for internal use, which lists the ASPs and number of units sold for all NDCs that meet the definition of each Part B drug HCPCS code paid under the ASP methodology.

<sup>8</sup> Volume-weighting ensures that ASPs for NDCs with higher sales volumes have greater influence on the payment amount for a HCPCS code than ASPs for NDCs with lower sales volumes.

<sup>9</sup> OIG, *Limitations in Manufacturer Reporting of Average Sales Price Data for Part B Drugs*, OEI-12-13-00040, July 2014.

<sup>10</sup> Section 1847A(b)(4)(A) of the Act.

<sup>11</sup> Section 1847A(b)(5) of the Act.

<sup>12</sup> CMS, 2007 Subregulatory Guidance, May 18, 2007. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>. Accessed online on May 23, 2017.

<sup>13</sup> *Allergan, Inc. v. Sylvia Mathews Burwell*, Case No. 13-00264, 2016 U.S. Dist. LEXIS 43550 (D.D.C. March 30, 2016).

<sup>14</sup> To be clear, we did not find that claims for these two drugs were inappropriately paid under Part B. Rather, the payment amounts under Part B were inflated by the inclusion of versions that are typically self-administered.

<sup>15</sup> 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).

<sup>16</sup> In general, patients are administered initial doses of Orenzia at 2 and 4 weeks, then every 4 weeks thereafter.

<sup>17</sup> We used payment levels from the fourth quarter of 2016 to calculate actual and alternate payment amounts per average dose for Orenzia.

<sup>18</sup> <https://www.cimzia.com/assets/pdf/MedicationGuide.pdf>, accessed on February 28, 2017.

<sup>19</sup> 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).

<sup>20</sup> In the second and third quarters of 2015, CMS substituted the ASP-based payment amount for Cimzia with an amount set at 103 percent of the average manufacturer price (AMP). When Congress established ASPs as the primary basis for Part B reimbursement, it also mandated that OIG compare ASPs to AMPs, and directed CMS to substitute payment amounts for drugs with ASPs that exceeded AMPs by a certain threshold. See Section 1847A(d) of the Act.

<sup>21</sup> We used payment levels from the fourth quarter of 2016 to calculate actual and alternate payment amounts per average dose for Cimzia.

<sup>22</sup> According to the manufacturer of Cimzia, even when the self-administered version is administered in a physician’s office, the beneficiary would obtain the drug from a pharmacy: “If you can self-inject [at home] and your doctor has prescribed the prefilled syringe, your prescription will typically be sent to a specialty pharmacy that specializes in dispensing biologic medications... If self-injecting for the first time, your doctor’s office may ask you to come to their office with your medication so they can provide training and explain important safety



information.” See <https://www.cimzia.com/rheumatoid-arthritis/starting-cimzia/key-steps>, accessed on February 28, 2017. Part B would not cover self-injected versions that a beneficiary purchases from a pharmacy and takes to the physician’s office for training.

<sup>23</sup> CMS Medicare FFS Provider e-News, Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program—“Sequestration,” March 8, 2013, available at <https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf>.