

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MACs CONTINUE TO USE
DIFFERENT METHODS TO
DETERMINE DRUG COVERAGE**



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EXECUTIVE SUMMARY: MACS CONTINUE TO USE DIFFERENT METHODS TO DETERMINE DRUG COVERAGE

OEI-03-13-00450

WHY WE DID THIS STUDY

Medicare Administrative Contractors (MACs) are responsible for reviewing Part B outpatient drug claims to ensure that Medicare pays for drugs that meet the criteria for coverage. Each MAC determines whether a particular use for a given drug, such as a use not approved by the Food and Drug Administration, is “medically accepted” and therefore, covered in its jurisdiction. If MACs do not have appropriate methods to determine drug coverage, Medicare and its beneficiaries may pay for drug uses that are not medically accepted. Further, beneficiaries’ access to drugs may vary based on the coverage criteria set in their jurisdictions. This study reviewed the methods MACs used to make coverage determinations for Part B drugs, as well as their methods for ensuring that claims were paid according to these coverage determinations.

HOW WE DID THIS STUDY

We sent surveys to the Part B MACs operating in 13 jurisdictions (as of December 2012) to obtain information about their policies and procedures for determining appropriate coverage of Part B drugs in 2012. We asked MACs to describe the methods and sources they used to remain up-to-date about covered uses, and how often they updated their coverage determinations. We also asked MACs to describe any challenges they encountered in determining coverage for Part B drugs. Finally, we asked MACs to provide information about any payment controls they implemented to help ensure that drug claims met the coverage requirements in their jurisdictions.

WHAT WE FOUND

In keeping with the flexibility MACs have to make coverage decisions, MACs reported using a variety of information sources on drug uses to assist in making coverage determinations. MACs also used different methods to obtain notifications when these sources were updated. These differences may contribute to inconsistencies in drug coverage across States. Further, most MACs reported challenges in determining coverage for Part B drugs, including difficulties interpreting CMS policy manuals and remaining up-to-date with sources for covered uses. To help ensure that drug claims were paid in accordance with their coverage policies, MACs implemented payment controls, but to varying degrees. However, some MACs were unable to provide us with the results of their payment control efforts. Without tracking these results, it is difficult to accurately evaluate the effectiveness of these payment controls.

WHAT WE RECOMMEND

We recommend that CMS (1) assign a single entity to assist MACs with making coverage determinations, and (2) evaluate the cost-effectiveness of edits and medical reviews that are designed to ensure appropriate payments for covered uses on Part B drug claims. CMS concurred with our second recommendation but did not concur with our first recommendation.

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OBJECTIVES

- (1) To determine the methods and sources that Part B contractors used to make and update drug coverage determinations in each jurisdiction in 2012;
- (2) To evaluate any challenges Part B contractors encountered in determining Part B drug coverage; and
- (3) To determine the extent to which Part B contractors implemented payment controls designed to ensure that payments were made for covered drug uses in 2012.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) contracts with private companies, known as Medicare Administrative Contractors (MACs), to process and pay Medicare Part B claims for defined geographic areas called jurisdictions. In some cases, MACs have the flexibility to determine whether a specific Part B drug treatment is covered in their jurisdictions.¹ MACs may use a number of sources to make coverage determinations, including prescription drug labels, recommendations of major drug compendia, authoritative medical literature, and/or accepted standards of medical practice.

A 2014 Office of Inspector General (OIG) report analyzed Part B-covered items and services, including drugs, to determine the extent to which coverage varied among States.² This report found that coverage for some procedures—often those using new technology—was limited in certain States but not others. OIG recommended that CMS consider requiring MACs to jointly develop a single set of coverage policies to simplify Medicare coverage, and to prevent beneficiaries' access to items and services from being tied to where they live. CMS concurred with this recommendation but noted obstacles, including administrative challenges, implications for beneficiary appeal rights, and States' scope of practice laws. As of March 2016, MACs continue to implement their own local coverage policies, which can create inconsistencies in beneficiaries' access to Medicare coverage for certain drug uses.

MACs may implement payment controls, e.g., prepayment edits and medical reviews, to help ensure—based on the diagnosis information on

¹ CMS, *Medicare Benefit Policy Manual*, Pub. No. 100-02 (Rev. 221, 03-11-16), ch. 15, § 50.4.2; *Medicare Program Integrity Manual*, Pub. No. 100-08 (Rev. 608, 08-14-15), ch. 13 § 13.1.3.

² OIG, *Local Coverage Determinations Create Inconsistency in Medicare Coverage*, OEI-01-11-00500, January 2014.

claims—that Medicare provides reimbursement for covered drug uses. Without effective controls to review Part B drug claims, Medicare may be vulnerable to making improper payments for drug uses that are not medically necessary.

Medicare Part B Drugs

Medicare Part B covers certain outpatient drugs, including drugs furnished incident to a physician’s service, drugs explicitly covered by statute, and drugs used in conjunction with durable medical equipment (DME). These drugs may be used to treat certain cancers, arthritis, and anemia, among other conditions. Generally, Medicare will pay 80 percent of the cost for a Part B drug; the beneficiary is responsible for the remaining 20 percent in the form of coinsurance. Medicare and its beneficiaries spent almost \$13.5 billion for Part B drugs in 2013.³

To obtain payment for covered outpatient prescription drugs, physicians and suppliers submit claims to MACs. These claims contain information including the beneficiary’s Medicare number, the physician or prescriber identification code, the Healthcare Common Procedure Coding System (HCPCS) code that identifies the prescribed drug, and the code(s) that indicates a patient’s diagnosis.

Covered Uses of Part B Drugs

Generally, Medicare Part B will pay for drugs that are approved by the Food and Drug Administration (FDA) when they are used for indications specified on the drug’s label. Physicians also may prescribe a drug for uses that have not been FDA-approved. This practice, which is not uncommon, often is referred to as off-label use.⁴

FDA-approved drugs utilized for off-label uses may be covered under Part B if the MAC determines that the use is medically accepted, taking into consideration (1) recommendations of major drug compendia, (2) authoritative medical literature, and/or (3) accepted standards of

³ This dollar amount is derived from CMS’s Part B Analytics Report for 2013.

⁴ When a drug is used in a way that differs from the use on the FDA-approved drug label, it is said to be an “off-label” use. This can mean that a drug is used for a different disease or medical condition, given through a different route of administration, or given in a different dose than specified on the drug label. FDA, *Understanding Investigational Drugs and Off Label Use of Approved Drugs*. Accessed at www.fda.gov on April 24, 2016.

medical practice.⁵ Each MAC has the authority to establish off-label drug coverage criteria in its jurisdiction based on these three sources. As a result, one jurisdiction may cover a specific use for a drug that is not covered in other jurisdictions. See Table 1 for a description of sources MACs can use to make off-label coverage determinations for Part B drugs.

Source of Information	FDA-Approved Drug Labels	Drug Compendia	Authoritative Medical Literature	Accepted Standards of Medical Practice
Description of Source	Description of a drug product that includes information on: <ul style="list-style-type: none"> - the condition(s) the drug is used to treat; - who should take the drug; - possible side effects; and - other safety information. 	Comprehensive listings of FDA-approved drugs that provide: <ul style="list-style-type: none"> - information about drugs' pharmacologic characteristics, such as dosages and strengths; and - recommended or endorsed uses in specific diseases. 	Literature, such as journal articles, that: <ul style="list-style-type: none"> - may appear in scientific, medical, and pharmaceutical publications; and - must have been critically reviewed for scientific accuracy, validity, and reliability, by unbiased, independent experts. 	MACs' individual determinations that rely on: <ul style="list-style-type: none"> - local medical societies; - a consensus of expert medical opinion; - consultations with medical staff; and - other relevant sources.

Source: CMS, *Medicare Benefit Policy Manual*, Pub. No. 100-02 (Rev. 221, 03-11-16), ch. 15. §§§ 50.4.1, 50.4.2, 50.4.5 and *Medicare Claims Processing Manual*, Pub. No. 100-04 (Rev. 3187, 02-06-15), ch. 30. § 40.1.3.

Coverage Determinations

CMS can publish National Coverage Determinations (NCDs) that describe the circumstances under which a particular item or service, e.g., a drug, is covered nationally under Medicare.⁶ NCDs apply to all MACs nationwide. If an NCD does not exist or needs to be defined further, MACs may issue a Local Coverage Determination (LCD). An LCD is a coverage policy that represents the MAC's decision to cover or exclude a particular item or service on a jurisdiction-wide basis and is applicable only within that jurisdiction. For example, MACs may develop an LCD when they encounter a problem that demonstrates a significant risk to the Medicare trust fund.⁷

MACs have discretion to develop LCDs and to determine how to implement their coverage decisions. The Medicare Prescription Drug,

⁵ CMS has established more detailed guidelines for off-label coverage of drugs prescribed in anti-cancer chemotherapeutic regimens. Specifically, CMS may cover off-label, medically accepted uses of a Part B drug used in an anti-cancer chemotherapeutic regimen if that use is supported in either (1) one or more of the drug compendia or (2) in peer-reviewed medical literature in a publication specified by CMS. The use of the drug must also be reasonable and necessary in order to be covered. *CMS, Medicare Benefit Policy Manual*, Pub. No. 100-02 (Rev. 221, 03-11-16), ch. 15. §§§ 50.4.1, 50.4.2 and 50.4.5.

⁶ 68 Fed. Reg. 55634, 55635 (Sept. 26, 2003).

⁷ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08 (Rev. 608, 08-14-15), ch. 13. § 13.4.

Improvement, and Modernization Act of 2003 (MMA) included language to promote consistency among coverage determinations. Specifically, the MMA states that the Secretary of Health and Human Services should develop a plan to evaluate new LCDs to determine which should be adopted nationally, and to determine the extent to which greater consistency can be achieved among LCDs across MACs.⁸ To comply with these requirements, CMS reported that it convenes face-to-face meetings with the contractor medical directors multiple times a year to (1) learn about effective approaches to coverage, (2) address at least one coverage decision topic in a unified manner at each meeting, and (3) develop standardized processes and criteria for coverage decisions. However, since the enactment of the MMA, studies have shown that there continue to be considerable inconsistencies in LCDs and differences in implementation of coverage determinations among States and regional jurisdictions.⁹

MACs' Payment Controls

MACs have the authority to review Part B claims and implement payment controls to ensure that claims are paid in accordance with coverage determinations. CMS acknowledges that the volume of Medicare claims does not allow for the review of every claim, and instructs MACs to target their efforts to items and services that pose the greatest financial risk to the Medicare program.¹⁰ However, if MACs do not implement effective payment controls, Medicare may be vulnerable to improperly paying for non-covered drug uses.

Edits. MACs may implement prepayment edits to prevent payment for non-covered, incorrectly coded, or inappropriately billed items or services.¹¹ A prepayment edit can automatically deny all or part of a claim that does not meet the edit's criteria. Prepayment edits also can suspend a claim for manual review by the MAC to make coverage and payment determinations.

In addition to edits that MACs implement to ensure appropriate coverage, CMS implements Medically Unlikely Edits (MUEs). An MUE will

⁸ This provision was included in § 731(a) of the MMA and codified at 42 U.S.C. § 1395y(l).

⁹ See, for example, OIG, *Local Coverage Determinations Create Inconsistency in Medicare Coverage*, OEI-01-11-00500, January 2014; Government Accountability Office (GAO), *Greater Prepayment Control Efforts Could Increase Savings and Better Ensure Proper Payment*, GAO-13-102, November 2012.

¹⁰ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08 (Rev. 634, 01-22-16), ch. 3. § 3.2.1.

¹¹ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08 (Rev. 634, 01-22-16), ch. 3. § 3.4.1.5.

review the number of units billed on a claim, and deny the claim if the units of a drug exceed the maximum number that a provider would reasonably administer to a beneficiary on a single date of service.¹²

MACs are required to evaluate their edits regularly to assess whether the edits are effective in preventing inappropriate payments.¹³ However, CMS does not require MACs to report the number or dollars that were denied based on each individual edit.

Medical reviews. MACs may also ensure that drug claims meet coverage criteria by conducting medical reviews. For these reviews, medical professionals evaluate patient records to ensure that payment is made only for items or services that meet Medicare coverage, coding, and medical necessity requirements.¹⁴ In some cases, Part B drug claims do not include enough information on patient diagnoses to determine whether a drug was prescribed for a covered use. In these situations, a medical review may be the only way to determine if the drug use is covered under Part B.

METHODOLOGY

Data Sources and Data Collection

In August 2013, we sent surveys to the 9 Part B MACs operating in 13 jurisdictions.^{15, 16} We asked the MACs how they made and updated coverage determinations for Part B drugs, and how they reviewed claims to ensure that Part B drug claims met their coverage criteria in 2012. Specifically, we asked MACs to provide information about:

- the methods and sources they used to make coverage determinations in their jurisdictions;

¹² Previously issued OIG reports found that MACs overpaid providers for selected Part B drugs. One of these reports found that MUEs could have prevented almost \$24 million (66 percent) of overpayments if the MUEs had been in effect during OIG's entire audit period. OIG, *Medicare Part B Overpaid Millions for Selected Outpatient Drugs* (A-09-14-02024), July 2015.

¹³ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08 (Rev. 634, 01-22-16), ch. 3. § 3.7.3.1.

¹⁴ CMS, *Medicare Program Integrity Manual*, Pub. No. 100-08 (Rev. 634, 01-22-16), ch. 3. § 3.3.1.1; CMS, *Medical Review and Education*. Accessed at www.cms.gov on July 20, 2015.

¹⁵ We did not include DME MACs in our survey. DME MACs are responsible for processing Part B claims for Medicare Durable Medical Equipment, Orthotics, and Prosthetics.

¹⁶ The surveyed Part B MACs are: Cahaba Government Benefit Administrators, LLC; CGS Administrators, LLC; First Coast Service Options, Inc.; NHIC, Corp; NGS; Noridian Healthcare Solutions, LLC; Novitas Solutions, Inc.; Palmetto GBA; and Wisconsin Physician Service Insurance Corporation.

- the number of updates they made to their coverage determinations because of changes to these sources;
- challenges they encountered when determining Part B drug coverage, as well as how they overcame these challenges; and
- the payment controls they implemented to enforce their coverage determinations.¹⁷

In addition to their survey responses, we asked MACs to provide any policies and procedures (internal or external) related to Part B drug coverage determinations in each jurisdiction.

Data Analysis

Coverage updates. Using MACs' survey responses, we identified the sources that MACs used to make coverage determinations. We also calculated the number of times that MACs updated their coverage determinations based on changes to FDA-approved drug labels and drug compendia in 2012. In addition, we reviewed the MACs' survey responses to determine the frequency with which MACs updated their LCDs, and whether their LCDs for drugs listed covered diagnosis codes.

Challenges. We reviewed the MACs' responses regarding challenges and difficulties they encountered in determining Part B drug coverage, as well as efforts MACs made to overcome these challenges in their jurisdiction(s).

Payment controls. We assessed the payment controls that MACs used to ensure that they made payments in accordance with their coverage determinations. Specifically, we determined whether MACs used edits to ensure that drug claims included diagnosis codes for covered uses (hereinafter referred to as coverage edits) in 2012, and if so, the extent to which edits reviewed drug claims. We also determined whether MACs conducted medical reviews to ensure that the diagnosis codes on Part B claims represented covered uses. If MACs stated that they conducted these medical reviews, we asked how they identified claims requiring a medical review, and the processes used to conduct these reviews. In addition, we used data provided by the MACs to determine the number and dollar amounts of claims reviewed and denied through edits and medical reviews in each jurisdiction.

Limitations

The data in this review include responses from Part B MACs only; we did not survey the DME MACs. We did not validate the accuracy or completeness of the survey responses provided by the Part B MACs. We

¹⁷ We considered payment controls to include any type of claim review the MAC performed, such as edits or medical record reviews.

did not survey MACs regarding their coverage determinations for non-FDA-approved drug uses based on accepted standards of medical practice because these can differ by locality.

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.

FINDINGS

CMS provides MACs with the flexibility to make coverage determinations for Part B drugs based on certain information sources. We found that MACs used a variety of these sources to make drug coverage determinations. MACs used different methods to identify when sources for information on drug uses had been updated, and MACs differed on how often they changed their coverage criteria based on updates to these sources. These differences may contribute to inconsistencies in drug coverage across States. MACs also implemented various payment controls (including prepayment edits and medical reviews) to ensure that they paid drug claims in accordance with their coverage criteria. These controls are important because they reduce Medicare’s vulnerability to making improper payments. However, some MACs were unable to provide us with the results of their edits and medical reviews. Without tracking these results, it would be difficult to evaluate the effectiveness of these payment controls.

MACs used a number of drug information sources to assist in making coverage determinations

FDA-approved drug labels, drug compendia, and medical literature—three common sources for information about drug therapies—are continuously updated with new information about drug uses. MACs used a variety of methods to identify when these sources had been updated. However, in most jurisdictions, MACs obtained information about these changes from the provider community, pharmaceutical representatives or drug manufacturers. See Table 2 for a description of how MACs were notified of changes to information sources they used to make coverage determinations in each jurisdiction.

Table 2: Methods of Receiving Updates Relevant to Coverage Determinations in 2012

Notification Method	FDA-Approved Drug Labels	Drug Compendia	Medical Literature
Provider Community	8 Jurisdictions	7 Jurisdictions	12 Jurisdictions
Pharmaceutical Representatives/ Drug Manufacturers	8 Jurisdictions	3 Jurisdictions	4 Jurisdictions
Automatic Alerts	7 Jurisdictions	3 Jurisdictions	0 Jurisdictions
Contractor-initiated Reviews	4 Jurisdictions	6 Jurisdictions	9 Jurisdictions
Other Contractors	3 Jurisdictions	2 Jurisdictions	2 Jurisdictions

Source: OIG analysis of MACs’ survey responses, 2012.

Note: MACs covering these jurisdictions may have been notified of updates through more than one method.

MACs stated that in addition to receiving notifications from providers, pharmaceutical representatives or drug manufacturers, they identified changes to FDA-approved drug labels through contractor-initiated reviews of these drug labels, automatic alerts from FDA, CMS, or other organizations, and/or other contractors. MACs obtained information about compendia changes through contractor-initiated reviews of drug compendia, automatic alerts from compendia, and/or conversations with other contractors. Almost all MACs used information from medical literature to make coverage determinations. These MACs obtained medical literature from journal subscriptions, libraries, online resources, or other contractors.

Coverage determinations, and the frequency of updates to these determinations, differed among MACs

MACs in all jurisdictions specifically listed covered diagnosis codes in their LCDs for drugs. However, the diagnosis codes that were listed in LCDs differed across jurisdictions. For example, an LCD for pegfilgrastim injection—which can be used to decrease the incidence of infection in beneficiaries being treated for certain cancers—included over 600 covered diagnosis codes in one jurisdiction, while an LCD in another jurisdiction listed only 11 covered diagnosis codes for this drug.¹⁸

The number of updates to LCDs based on an addition or removal of a covered diagnosis code also varied across jurisdictions. Almost all MACs reported updating LCDs when the MAC identified a change to a covered use. However, MACs in three jurisdictions did not make any coverage updates as a result of changes to FDA-approved or compendia-supported uses in 2012. MACs in the remaining jurisdictions reported at least one update based on changes to FDA-approved or compendia-supported uses during the year.

Most MACs reported challenges in determining coverage for Part B drugs

MACs covering 11 of the 13 jurisdictions stated that they had encountered challenges in determining coverage for Part B drugs in 2012. MACs covering two jurisdictions stated that “rapidly evolving science” or ongoing updates to medical literature made it difficult to keep track of covered uses. MACs in two jurisdictions reported that it was difficult or cost-prohibitive to have access to all of the compendia. Some MACs reported that the instructions in CMS manuals are ambiguous.

¹⁸ Although LCDs may include lists of covered diagnosis codes, this does not guarantee coverage of a service for that jurisdiction. The MAC determines whether services are reasonable and necessary in each specific case.

MACs reported taking a number of steps to overcome challenges in making coverage determinations. For example, MACs sought expertise from specialty providers, specialty societies, and advisory committee members; communicated with MACs in other jurisdictions or with CMS policy staff; and/or participated in LCD workgroups.

Some MACs also suggested ways CMS could assist with coverage determinations. Specifically, MACs in four jurisdictions suggested that CMS should provide more national coverage criteria for consistency, or that CMS should have a national contractor to monitor changes in medical literature. A MAC in one of these jurisdictions also stated that CMS should clarify instructions in its manuals. MACs also stated that they would like CMS to provide additional guidance regarding pricing and development of HCPCS codes, applying the self-administered drug policy, and adding modifiers to indicate whether a drug is a primary or secondary treatment.

All MACs reported using edits to implement coverage determinations, but to varying degrees

Although MACs in all 13 jurisdictions reported implementing edits to help ensure that drug claims were paid according to coverage determinations, the number of drugs undergoing this type of review varied significantly among jurisdictions. While Part B covered nearly 600 drug codes in 2012, MACs implemented coverage edits for a range of 8 to 494 drug codes in the 8 jurisdictions that provided information on claims reviewed by edits.

In some jurisdictions, MACs' coverage edits reviewed all claims submitted for a particular drug; in others, the edits reviewed only a sample of such claims. MACs reported that they may decide to implement a coverage edit based on the risk of improper payment, drug cost, potential for abuse, or whether a drug is new to the market.

Coverage edits denied 25 percent of reviewed claim dollars in the 7 MAC jurisdictions that provided financial results

Part B MACs in 5 of the 13 jurisdictions did not provide the total number of Part B drug claims that underwent coverage edit reviews in 2012. In the 8 MAC jurisdictions that provided the number of claims reviewed, coverage edits checked whether 1.6 million drug claims met coverage criteria, and MACs denied 261,790 of these claims in 2012. MACs in the 7 jurisdictions that provided dollar results reported that coverage edits reviewed \$1.2 billion in submitted claims; of which \$300 million (25 percent) were denied. The percentage of drug claims undergoing coverage edit reviews differed among the MACs, from a low of less than 1 percent to a high of 43 percent in 2012. However, in 5 jurisdictions, less

than 3 percent of Part B drug claims underwent coverage edit reviews in 2012.

MACs in half of the jurisdictions conducted medical reviews of drug claims, but most could not provide the savings associated with these reviews

In some cases, Part B MACs may not be able to determine if a drug was prescribed for a covered use by reviewing only the diagnosis codes on a claim. For example, a drug use may be covered only after administration of another treatment; however, this detailed information typically is not included on Part B drug claims. MACs may request that providers submit additional documentation for a medical review by the MAC's clinical staff. In 2012, MACs covering 7 of the 13 jurisdictions reported that they utilized medical reviews to determine whether a drug use was covered.

Among the seven MAC jurisdictions that utilized these medical reviews, four used data analysis to select claims that posed a financial risk, and then referred those claims for a medical review. MACs in the other three jurisdictions said they used edits that could trigger a medical review for high-dollar claims.

Of the jurisdictions where MACs conducted these medical reviews, only one MAC, covering two jurisdictions, reported the number and dollars associated with claims denied as a result of medical reviews.¹⁹ This MAC reported that it denied 46 percent of the nearly 8,000 claims it reviewed, resulting in \$1.4 million in denials for these 2 jurisdictions in 2012. If MACs in all jurisdictions had conducted these medical reviews, savings to the Medicare program could have been greater.

¹⁹ A MAC in one jurisdiction provided the number of claims that underwent a medical review, but it did not provide the dollar amounts and denial rates for these claims.

CONCLUSION AND RECOMMENDATIONS

CMS provides MACs with flexibility to make coverage determinations in their jurisdictions. We found that accordingly, MACs used a variety of sources and notification methods to establish and update their coverage criteria. As a result, a beneficiary in one jurisdiction may have different drug uses covered than a beneficiary in another jurisdiction. OIG recognizes the importance of MACs having the flexibility to set priorities and allocate their resources based on areas of concern within their jurisdictions. However, CMS should ensure that beneficiaries do not have limited access to certain drugs because of the MACs' coverage policies.

MACs also are responsible for determining whether claims for Part B drugs meet coverage criteria. We found that all MACs implemented payment controls, such as edits and medical reviews, which are designed to ensure that claims meet coverage criteria and are paid appropriately. However, the extent to which MACs implemented these payment controls varied across jurisdictions. The limited use of payment controls in some jurisdictions could leave Part B vulnerable to improper drug payments.

Finally, MACs in many jurisdictions could not provide us with the results of their edits or medical reviews. Without information about the number of claims and dollars reviewed and denied, it may be difficult to evaluate the MACs' effectiveness in preventing inappropriate payments for Part B drugs, including payments for drug uses that are not medically acceptable or necessary.

Therefore, we recommend that CMS:

Assign a single entity to assist MACs with making coverage determinations

MACs differed in the methods and sources used to make coverage determinations across jurisdictions. MACs also reported that subscribing to and reviewing drug compendia and medical journals can be costly and time intensive, and MACs often relied on other sources, such as providers and drug manufacturers or their representatives, to notify them of updates relevant to drug coverage determinations.

Therefore, we recommend that CMS assign a single entity (this could be a new contract, a current contract, a point-of-contact in CMS, or other CMS-assigned entity) to act as a resource for MACs in determining which drug uses should be covered under Part B. Having a single reference entity to assist with making coverage determinations may also be more efficient and effective than having multiple contractors make these determinations. In addition, this entity could remain up-to-date on sources of information on drug uses and distribute the information necessary for MACs to make coverage determinations. The entity also could provide

MACs with clarification and guidance related to CMS's manuals and assist MACs in processing and paying claims appropriately. With the additional support, MACs may have more time and resources to devote to reviewing claims and preventing improper payments. While it is important to allow for local standards of medical practice and flexibility among jurisdictions, assigning a single entity may help ensure that Part B drug coverage determinations are objective, based on the most current information, and more consistent across jurisdictions.

Evaluate the cost-effectiveness of edits and medical reviews that are designed to ensure appropriate payments for covered uses on Part B drug claims

MACs reported that their coverage edits did not review claims for all drugs in their jurisdictions, and not all MACs reported utilizing medical reviews as a way to enforce coverage determinations and ensure proper payments in 2012. This suggests that MACs may not be using payment controls to the fullest extent possible. When MACs do not review claims, Medicare may be vulnerable to making payments for non-covered uses and potentially paying for drug uses that have not been studied sufficiently. To address these vulnerabilities, it is important that Part B MACs implement effective mechanisms that ensure appropriate coverage and payment for drug claims. Currently, MACs are required to evaluate their edits regularly to assess whether they are effective in preventing inappropriate payments. However, not all MACs were able to provide us with the number and dollars of drug claims evaluated through their coverage reviews.

We recommend that CMS conduct a study to evaluate the cost-effectiveness of implementing edits and conducting medical reviews to check the coverage of diagnosis codes on drug claims. If CMS finds that these reviews are effective in preventing improper payments, it should advise MACs in all jurisdictions to better utilize these reviews to ensure appropriate payments.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE


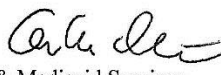
CMS concurred with our recommendation to evaluate the cost-effectiveness of edits and medical reviews designed to ensure appropriate payments for covered uses on Part B drug claims. CMS stated that in calendar year 2017, it will conduct a study to determine if increased monitoring of Part B drug claims results in fewer improper payments.

CMS did not concur with our recommendation to assign a single entity to assist MACs with making coverage determinations. In its response, CMS stated that it does not believe a single entity would capture regional differences, which it considers to be a fundamental characteristic of local coverage. CMS reported that it has taken steps to achieve more consistency among the MACs' coverage determinations. For example, CMS convenes regular meetings with MACs to discuss best practices and effective approaches to coverage determinations. CMS stated that it also has added requirements related to LCD collaboration to the MAC Award Fee metric.

We recognize the importance of the steps that CMS has taken to achieve consistency in coverage determinations among the MACs. However, most MACs reported challenges in determining coverage for Part B drugs. Assigning a single entity to provide guidance on coverage decisions and disseminate information about changes to covered uses may help MACs ensure that claims are paid appropriately. This entity, while providing valuable information to MACs, would not prohibit them from maintaining regional differences in local coverage, where appropriate. Therefore, we continue to recommend that CMS assign a single entity to act as a resource for MACs in determining which drug uses should be covered under Part B. The Appendix contains the full text of CMS's comments.

APPENDIX

Agency Comments

	DEPARTMENT OF HEALTH & HUMAN SERVICES	Centers for Medicare & Medicaid Services
	JUN 24 2016	200 Independence Avenue SW Washington, DC 20201
To:	Daniel R. Levinson Inspector General Office of Inspector General	
From:	Andrew M. Slavitt  Acting Administrator Centers for Medicare & Medicaid Services	
Subject:	MACs Continue to Use Different Methods to Determine Drug Coverage, OEI-03-13-00450	

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 provide Medicare beneficiaries with access to high quality health care while protecting taxpayer dollars.

Medicare Part B includes a limited drug benefit that encompasses certain drugs and biologicals. Currently covered Part B drugs fall into three general categories: drugs furnished incident to a physician's services, drugs administered via a covered item of durable medical equipment (DME), and other drugs specified by statute.

Medicare Administrative Contractors (MACs), who process and pay Part B claims, review claims to ensure that they are paid consistent with coverage policies. MACs may implement prepayment edits to flag claims for further review or prevent payment for non-covered, incorrectly coded, or inappropriately or fraudulently billed items or services and are required to evaluate their edits regularly to assess their effectiveness. MACs may also use prepayment or post-payment medical review to ensure that drug claims meet coverage criteria.

MACs have the authority to make local coverage determinations (LCDs), which may determine whether a particular item or service, including a specific Part B drug is covered in their jurisdiction, as long as such LCDs do not conflict with a national coverage determination (NCD). This authority is intended to allow for geographic differences in practice patterns and to expedite coverage of new technology.

In addition, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) provided the Secretary the authority to develop a plan to evaluate new LCDs to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among LCDs. Since MMA, CMS has implemented initiatives for MACs to achieve greater LCD consistency. CMS convenes regular meetings with the MACs to

discuss best practices and effective approaches to making coverage determinations. Additionally, in order to measure and ensure increased collaboration among the MACs, CMS has added requirements related to LCD collaboration to the MAC Award Fee metric.

OIG Recommendation

OIG recommends that CMS assign a single entity to assist MACs with making coverage determinations.

CMS Response

CMS does not concur with this recommendation. CMS does not believe a single entity would capture the regional differences that is a key fundamental characteristic of local coverage. CMS has taken a number of steps to achieve more consistency among the MACs and the LCDs developed by them. CMS convenes regular meetings with the MACs to discuss best practices and effective approaches to making coverage determinations. Additionally, in order to measure and ensure increased collaboration among the MACs, CMS has added requirements related to LCD collaboration to the MAC Award Fee metric.

OIG Recommendation

OIG recommends that CMS evaluate the cost-effectiveness of edits and medical review that are designed to ensure appropriate payments for covered uses on Part B drug claims.

CMS Response

CMS concurs with this recommendation. As OIG states in their report, there may not be current sufficient data to provide us with results of edits and medical reviews. Without tracking these results, it would be difficult to evaluate the effectiveness of these payment controls. However, in CY 2017 CMS will conduct a study to determine if increased monitoring of Part B drug claims results in fewer improper payments.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

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