Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

HOSPITALS DID NOT ALWAYS MEET DIFFERING MEDICARE CONTRACTOR SPECIFICATIONS FOR BARIATRIC SURGERY

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Office of Inspector General

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Report in Brief
Date: February 2022
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U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Hospitals Did Not Always Meet Differing Medicare Contractor Specifications for Bariatric Surgery

Why OIG Did This Audit

Bariatric surgery helps those with morbid obesity to lose weight by making changes to their digestive system. A prior OIG audit found that a hospital's claims for bariatric surgeries performed in 2015 and 2016 did not fully meet a Medicare contractor's eligibility specifications. Because eligibility specifications varied among the Medicare contractors, we conducted this nationwide audit of hospitals' inpatient claims for bariatric surgeries performed from January 2018 through July 2019 (audit period), for which Medicare paid approximately $279 million.

Our objective was to determine whether hospitals' inpatient claims for bariatric surgeries met Medicare national requirements and Medicare contractors' eligibility specifications.

How OIG Did This Audit

Our audit covered $275.2 million in Medicare payments for 24,821 inpatient claims for bariatric surgeries performed during our audit period. We stratified the claims into four strata (which we refer to as "groups") based on the Medicare contractor jurisdictions that had similar eligibility specifications for bariatric surgery. We selected for review a statistical sample of 120 claims to determine whether the claims met Medicare national requirements in the Centers for Medicare & Medicaid Services' (CMS's) national coverage determination (NCD) and eligibility specifications in local coverage determinations (LCDs) or local coverage articles (LCAs).

What OIG Found

Not all hospitals' inpatient claims for bariatric surgeries met Medicare national requirements or Medicare contractors' eligibility specifications. Specifically, of the 120 sampled inpatient claims, 86 met NCD requirements and applicable eligibility specifications for bariatric surgery, and 1 claim was not reviewed but treated as a non-error because it was under review by a CMS contractor. However, of the remaining 33 claims, 32 claims met the NCD requirements but not the eligibility specifications, and 1 claim did not meet the NCD requirements.

Differing eligibility specifications for bariatric surgery contributed to differences in the number of claims that did not meet the specifications among Medicare contractor jurisdiction groups. Jurisdiction groups with more restrictive specifications had more claims that did not meet the eligibility specifications and more specifications that were not met. The Medicare contractors may have issued differing eligibility specifications because CMS's NCD requirements were not specific. On the basis of our sample results, we estimated that Medicare could have saved $47.8 million during our audit period if Medicare contractors had disallowed claims that did not meet Medicare national requirements or Medicare contractor specifications for bariatric surgery.

What OIG Recommends and CMS's Comments

We recommend that CMS: (1) determine whether any eligibility specifications in the Medicare contractors' LCDs and LCAs should be added to the NCD for bariatric surgery and, if so, take the necessary steps to update the NCD; (2) work with the Medicare contractors to review the eligibility specifications in the applicable Medicare contractors' bariatric surgery LCDs and LCAs and determine which, if any, of those additional specifications should be requirements rather than guidance; and (3) educate hospitals on the NCD requirements for bariatric surgeries if the NCD has been updated in response to our first recommendation.

CMS did not concur with our recommendations and stated, among other things, that: (1) CMS will continue monitoring scientific evidence related to bariatric surgery procedures and will evaluate whether an update to the NCD is necessary, and (2) the Social Security Act does not mandate that LCDs be uniform across all jurisdictions and there are valid reasons that variation at the local Medicare contractor level is appropriate. After reviewing CMS's comments, we maintain that our recommendations are valid.

TABLE OF CONTENTS

INTRODUCTION

WHY WE DID THIS AUDIT

Bariatric surgery helps those with morbid obesity to lose weight by making changes to their digestive system, such as reducing the size of the stomach with a gastric band. A prior Office of Inspector General (OIG) audit found that a hospital's claims for bariatric surgeries performed in 2015 and 2016 did not fully meet a Medicare administrative contractor's (Medicare contractor's) eligibility specifications established in the local coverage determinations (LCDs) and local coverage article (LCA).[1, 2] Specifically, for 25 of 62 bariatric surgery claims we reviewed, the hospital did not provide adequate documentation of the beneficiaries' multidisciplinary medical evaluations or participation in a weight management program. Because eligibility specifications for bariatric surgery varied among the Medicare contractors, we conducted this nationwide audit of hospitals' inpatient claims for bariatric surgeries performed from January 1, 2018, through July 31, 2019 (audit period), for which Medicare paid approximately $279 million.[3]

OBJECTIVE

Our objective was to determine whether hospitals' inpatient claims for bariatric surgeries met Medicare national requirements and Medicare contractors' eligibility specifications.

BACKGROUND

The Medicare Program

The Medicare program provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the program. Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge.

Medicare Part A pays inpatient hospital costs at predetermined rates for patient discharges. The rates vary according to the Medicare Severity Diagnosis-Related Group (MS-DRG) to which

[1] An LCD is a decision by a Medicare contractor whether to cover a particular item or service on a contractor-wide basis in accordance with section 1862(a)(1)(A) of the Social Security Act (section 1869(f)(2)(B) of the Social Security Act). Medicare contractors develop and issue LCAs, which generally contain billing, coding, or other guidance that complement LCDs. CMS considers LCAs guidance rather than Medicare requirements.

[2] *Cedars-Sinai Medical Center: Audit of Medicare Payments for Bariatric Surgeries* (A-09-18-03010), issued Oct. 14, 2020.

[3] In this report, the term "eligibility specifications" refers to specifications in LCDs or LCAs issued by the Medicare contractors. CMS considers LCAs guidance rather than requirements.

a beneficiary's stay is assigned. The MS-DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs (e.g., the costs for multiple medical procedures) associated with the beneficiary's stay.

To be paid by Medicare, a service or an item must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (the Social Security Act (the Act) § 1862(a)(1)(A)). In addition, payment must not be made to any provider of services without information necessary to determine the amount due the provider (the Act § 1815(a)). The provider must furnish to the Medicare contractor sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

The Role of the Medicare Contractors

During our audit period, CMS contracted with the following seven Medicare contractors to, among other things, process and pay Medicare Part A claims submitted by hospitals and conduct reviews and audits for defined geographic areas, or jurisdictions:

- Noridian Healthcare Solutions, LLC (Noridian);
- Palmetto GBA, LLC (Palmetto);[4]
- Novitas Solutions, Inc. (Novitas);
- First Coast Service Options, Inc. (First Coast);
- National Government Services, Inc. (NGS);
- Wisconsin Physicians Service Government Health Administrators (WPS); and
- CGS Administrators, LLC (CGS).

Hospitals must submit claims to the Medicare contractor that serves the State or territory in which the hospital is physically located. Medicare contractors are responsible for processing bariatric surgery claims submitted by hospitals within 12 designated jurisdictions of the United States and its territories. Appendix B provides a table that shows the Medicare contractor and geographic composition for each jurisdiction.

[4] Cahaba Government Benefit Administrators, LLC, was the Medicare contractor that processed claims for jurisdiction J (Alabama, Georgia, and Tennessee) until January 28, 2018. Effective January 29, 2018, Palmetto became the Part A Medicare contractor for jurisdiction J. Our audit included jurisdiction J claims processed by only Palmetto.

Medicare Requirements for Coverage of Bariatric Surgery

Bariatric surgery is a procedure that helps beneficiaries with morbid obesity to lose weight by making changes to their digestive system.[5] There are two types of bariatric surgical procedures: Restrictive procedures restrict the amount of food the stomach can hold, and malabsorptive procedures divert food from the stomach to a lower part of the digestive tract, resulting in less absorption of nutrients. Surgery can combine both types of procedures.

Medicare covers approved bariatric surgery procedures that are performed to treat comorbid (i.e., present at the same time) health conditions associated with morbid obesity, such as cardiac and respiratory diseases, diabetes, and hypertension. Treatments for obesity alone are not covered.[6]

According to CMS's *Medicare National Coverage Determinations Manual*, Pub. No. 100-03, chapter 1, part 2, section 100.1, "Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity," Medicare will cover certain specified bariatric surgery procedures[7] if a beneficiary meets all of the following three eligibility requirements: (1) has a body mass index (BMI)[8] greater than or equal to 35, (2) has at least one comorbidity related to obesity, (3) and has previously been unsuccessful with medical treatment for obesity.[9, 10]

Medicare Contractors' Eligibility Specifications for Bariatric Surgery

Four of the seven Medicare contractors that CMS contracted with during our audit period issued LCDs or LCAs that list specifications (eligibility specifications) for documenting that a beneficiary has met CMS's national coverage determination (NCD) requirements (i.e., Medicare

[5] Morbid obesity is "a serious health condition that can interfere with basic physical functions, such as breathing or walking. Those who are morbidly obese are at greater risk for illnesses, including diabetes, high blood pressure, sleep apnea, gastroesophageal reflux disease, gallstones, osteoarthritis, heart disease, and cancer." Available at https://www.urmc.rochester.edu/highland/bariatric-surgery-center/journey/morbid-obesity.aspx. Accessed on June 9, 2021.

[6] CMS's *Medicare National Coverage Determinations Manual,* Pub. No. 100-03, chapter 1, part 2, § 100.1.

[7] CMS's *Medicare National Coverage Determinations Manual,* Pub. No. 100-03, chapter 1, part 2, section 100.1, lists bariatric surgery procedures that are covered and noncovered.

[8] BMI is a person's weight in kilograms divided by the square of the person's height in meters. A high BMI can indicate a high body-fat level.

[9] A national coverage determination (NCD) is a determination by the Secretary regarding whether a particular item or service is covered nationally under Medicare (the Act § 1869(f)(1)(B)).

[10] The NCD also gives Medicare contractors the discretion to cover any other bariatric surgery procedures that are not specifically identified in the NCD as covered or noncovered when all three of these eligibility requirements are met (CMS's *National Medicare National Coverage Determinations Manual,* Pub. No. 100-03, chapter 1, part 2, § 100.1(D)).

national requirements) for bariatric surgery, including specifications for documenting that the beneficiary has been previously unsuccessful with medical treatment for obesity.[11] Three of the four Medicare contractors (Palmetto, Novitas, and First Coast) placed eligibility specifications in their LCDs, and one Medicare contractor (Noridian) placed eligibility specifications in its LCA.[12]

The eligibility specifications for bariatric surgery varied among the four Medicare contractors.[13] In addition, three of these four Medicare contractors issued eligibility specifications that covered all Medicare-approved bariatric surgery procedures, including laparoscopic sleeve gastrectomy (LSG) procedures (Noridian, Novitas, and First Coast), and one Medicare contractor issued eligibility specifications for only LSG procedures (Palmetto).[14]

The remaining three Medicare contractors either had LCAs for bariatric surgery that did not include eligibility specifications (NGS and WPS) or did not issue an LCD or LCA for bariatric surgery (CGS).[15] These contractors relied solely on the eligibility requirements listed in the NCD.

The table in Appendix C provides details on the primary differences in applicable eligibility specifications for bariatric surgery for the seven Medicare contractors.

[11] NCDs are binding on Medicare administrative contractors, Qualified Independent Contractors (QICs), Administrative Law Judges (ALJs) and attorney adjudicators, and the Medicare Appeals Council (42 CFR § 405.1060(a)(4)). In contrast, QICs, ALJs, attorney adjudicators, and the Medicare Appeals Council are not bound by LCDs, but they give LCDs substantial deference (42 CFR §§ 405.968(b)(2) and 405.1062(a)).

[12] Generally, section 1871(a)(2) of the Act requires CMS to use notice-and-comment rulemaking to establish or change a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits. In *Azar v. Allina,* 139 S. Ct. 1804 (2019), the Supreme Court vacated a policy change announced on CMS's website because it violated section 1871(a)(2). We express no opinion on the enforceability of the LCAs under section 1871(a)(2).

[13] Section 1869(f)(2)(B) of the Act does not mandate that LCDs be uniform across Medicare contractor jurisdictions.

[14] This bariatric procedure is performed by vertically removing approximately 70 to 80 percent of the stomach, which decreases the amount of food that can fit in the stomach. As a result, a person feels full after eating a small meal.

[15] NGS and WPS issued LCAs for bariatric surgery that referred to the requirements in the NCD but did not list individual eligibility specifications. (NGS's LCA covered only LSG procedures.) WPS's LCA also included a list of eligible comorbidity codes.

Bariatric Surgery Specifications That Medicare Contractors Considered Most Important for Ensuring Beneficiaries' Health and Safety

Because the eligibility specifications for bariatric surgery varied among the Medicare contractors, we contacted the seven Medicare contractors to determine which eligibility specifications for bariatric surgery they considered most important for ensuring beneficiaries' health and safety. The four contractors that had eligibility specifications for bariatric surgery in their LCDs or LCAs (Noridian, Palmetto, Novitas, and First Coast) ranked the specifications in the order of importance. The three contractors that did not have eligibility specifications for bariatric surgery (NGS, CGS, and WPS) stated that they thought that the NCD requirements were sufficient.

In addition to the Medicare national requirements included in the NCD, the following are the top five eligibility specifications that the four Medicare contractors considered most important for ensuring a beneficiary's health and safety:[16]

- The beneficiary receives a preoperative evaluation by a physician other than a surgeon (Noridian, Palmetto, Novitas, and First Coast).

- The beneficiary participates in a weight management or dietary program (Noridian, Palmetto, Novitas, and First Coast).

- The beneficiary receives a mental health clearance for bariatric surgery, including a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements (Noridian, Palmetto, Novitas, and First Coast).

- The beneficiary does not have any contraindications to bariatric surgery (Palmetto, Novitas, and First Coast).

- The beneficiary receives an evaluation by a bariatric surgeon within 6 months before the bariatric surgery (Noridian, Novitas, and First Coast).

Generally, the four Medicare contractors believed that appropriate evaluations and measures should be taken before bariatric surgery and considered an eligibility specification to be most important for ensuring the beneficiary's health and safety when the specification: (1) prevented unnecessary or unsafe bariatric surgeries, (2) assisted with determining that bariatric surgery is the best treatment option, and (3) contributed to the beneficiary's understanding of the pre- and postsurgery requirements.

[16] We created the list of the top five specifications that are most important for ensuring a beneficiary's health and safety by first considering the specifications that were most frequently mentioned in the Medicare contractors' responses to our survey and then considering the contractors' ranked order for the specifications.

Prior Office of Inspector General Audit

A prior OIG audit of bariatric surgery claims found that a hospital did not fully meet a Medicare contractor's LCDs and LCA eligibility specifications for documenting previously unsuccessful medical treatment for obesity when billing for bariatric surgeries performed in calendar years 2015 and 2016.[17] Specifically, for 25 of the 62 claims we reviewed, the hospital did not provide adequate documentation of the beneficiaries' multidisciplinary medical evaluations or participation in a weight management program. The hospital did not meet the specifications in the LCDs for 12 claims, with payments totaling $154,074, and did not meet the specifications in the LCA for 13 claims, with payments totaling $175,199.

HOW WE CONDUCTED THIS AUDIT

Our audit covered $275.2 million in Medicare Part A payments for 24,821 inpatient claims for bariatric surgeries that hospitals performed from January 1, 2018, through July 31, 2019.

We stratified the 24,821 claims into 4 strata (which we refer to as "groups") based on the Medicare contractor jurisdictions that had similar eligibility specifications for bariatric surgery. The four groups ranged from the Medicare contractor jurisdictions that had the most restrictive eligibility specifications (i.e., had the most eligibility specifications—in LCAs) to those jurisdictions with no eligibility specifications (i.e., relied solely on the NCD requirements).[18] For example, the most restrictive group (group 1) had specifications in LCAs that applied to all Medicare-approved bariatric surgery procedures, including LSG, while the moderately restrictive group (group 2) had specifications in an LCD that applied only to LSG procedures and included slightly fewer specifications than the most restrictive group. From the 24,821 inpatient claims, we selected for review a stratified random sample of 120 inpatient claims (30 claims from each group), for which Medicare paid 105 hospitals $1.3 million.[19]

Table 1 on the following page lists the four groups of Medicare contractors and the associated jurisdictions, the restrictiveness of the eligibility specifications, and the number of sampled claims in each group.

[17] *Cedars-Sinai Medical Center: Audit of Medicare Payments for Bariatric Surgeries* (A-09-18-03010), issued Oct. 14, 2020.

[18] Group 1 included only LCA eligibility specifications, groups 2 and 3 included LCD eligibility specifications, and the Medicare contractors in group 4 did not issue eligibility specifications for bariatric surgery.

[19] In our stratified random sample, 13 hospitals submitted more than 1 claim.

Table 1: The Four Groups of Medicare Contractors and Associated Jurisdictions, Restrictiveness of Eligibility Specifications, and Number of Sampled Claims in Each Group

Group	Medicare Contractor and Jurisdiction (J)	Restrictiveness of Eligibility Specifications	Number of Sampled Claims
1	Noridian (JE and JF)	Most restrictive (LCAs)	30
2	Palmetto (JJ and JM)	Moderately restrictive (LCD for LSG only)	30
3	Novitas (JH and JL) First Coast (JN)	Least restrictive (LCDs)	30
4	NGS (J6 and JK) WPS (J5 and J8) CGS (J15)	No specifications* (NCD only)	30

* Medicare contractors categorized in the fourth group either: (1) did not include eligibility specifications for bariatric surgery in their LCAs (e.g., NGS's and WPS's LCAs referred to the requirements in the NCD, and WPS's LCA also included a list of eligible comorbidity codes) or (2) did not issue an LCD or LCA for bariatric surgery (CGS). Therefore, when reviewing the claims in this group, we applied only the NCD requirements. For claims in groups 1, 2, and 3, we applied the NCD requirements and the applicable Medicare contractor eligibility specifications.

Hospitals provided us with supporting medical record documentation for the sampled claims. We reviewed the documentation to determine whether the claims met Medicare national requirements and applicable Medicare contractor eligibility specifications. We did not use a medical reviewer to determine whether services were medically necessary.

Our audit included findings based on eligibility specifications in the LCAs, which CMS considers guidance rather than requirements. In addition, we did not determine the medical necessity of other procedures that may have been included on the bariatric surgery claims. As a result, to be conservative, we considered all Medicare payments made to hospitals for claims that did not meet Medicare national requirements or Medicare contractor eligibility specifications for bariatric surgery to be costs that Medicare could potentially have avoided rather than improper payments.

We interviewed CMS officials to gain an understanding of Medicare billing requirements for bariatric surgery and to identify any oversight activities performed by CMS or Medicare contractors. We also contacted the seven Medicare contractors to obtain an understanding of their eligibility specifications for bariatric surgeries, controls and system edits for processing bariatric surgery claims, and the specifications that each Medicare contractor considers necessary to ensure beneficiaries' health and safety.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions

based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A describes our audit scope and methodology, Appendix D describes our statistical sampling methodology, and Appendix E contains our sample results and estimates.

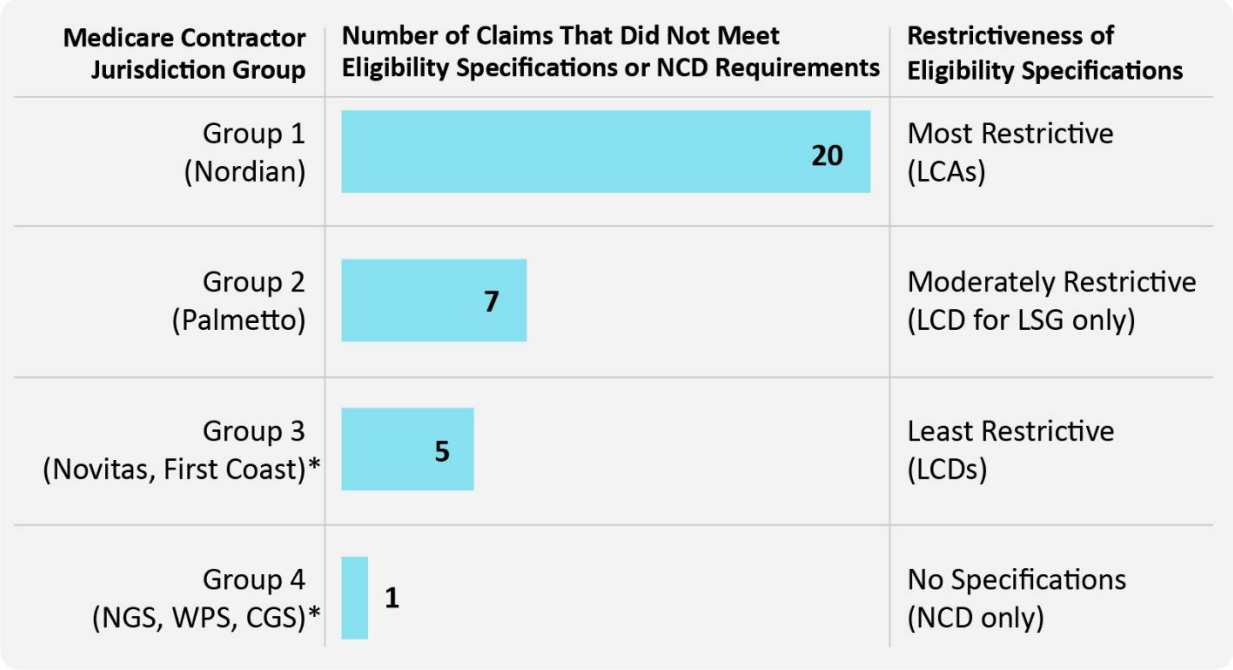
FINDINGS

Not all hospitals' inpatient claims for bariatric surgeries that hospitals performed from January 1, 2018, through July 31, 2019, met Medicare national requirements or Medicare contractors' eligibility specifications. Specifically, of the 120 sampled inpatient claims, 86 met NCD requirements and applicable Medicare contractor eligibility specifications for bariatric surgery, and 1 claim was not reviewed but treated as a non-error because it was under review by a CMS contractor after we had selected our sample. However, of the remaining 33 claims, with payments totaling $351,038, 32 claims met the NCD requirements but not the eligibility specifications, and 1 claim did not meet the NCD requirements.[20]

Differing Medicare contractor eligibility specifications for bariatric surgery contributed to differences in the number of claims that did not meet the specifications among Medicare contractor jurisdiction groups. Jurisdiction groups with more restrictive specifications had more claims that did not meet the eligibility specifications and more specifications that were not met. The Medicare contractors may have issued differing eligibility specifications for bariatric surgery because CMS's NCD requirements were not specific. The figure on the following page shows the number of claims that did not meet the eligibility specifications (groups 1 through 3) or the NCD requirements (group 4) for each Medicare contractor jurisdiction group.

[20] Of the 33 claims, 20 claims (totaling $226,186) did not meet the specifications in the LCAs; 12 claims (totaling $115,032) did not meet the specifications in the LCDs; and 1 claim (totaling $9,820) did not meet the NCD requirements.

Figure: The Number of Claims That Did Not Meet Eligibility Specifications or Medicare National Requirements for Each Medicare Contractor Jurisdiction Group



* First Coast, NGS, and CGS did not process any claims that did not meet eligibility specifications or NCD requirements in our stratified random sample.

For the 33 claims that did not meet the eligibility specifications or NCD requirements, Table 2 on the following page shows by Medicare contractor jurisdiction group and by specification type or NCD requirement the number of specifications or requirements that were not met. The main eligibility specifications that the claims did not meet related to inadequate documentation of the following: (1) participation in a weight management program, (2) mental health evaluation, and (3) evaluation by a physician other than a surgeon. The total number of eligibility specifications or NCD requirements that were not met exceeds 33 because 21 of the 33 claims did not meet more than 1 specification.

Table 2: Number of Eligibility Specifications or NCD Requirements That Were Not Met

Medicare Contractor Eligibility Specifications or NCD Requirements	No. of Eligibility Specifications Not Met at Noridian (Group 1: LCAs)	No. of Eligibility Specifications Not Met at Palmetto (Group 2: LCD for LSG only)	No. of Eligibility Specifications Not Met at Novitas (Group 3: LCD)	No. of NCD Requirements Not Met at WPS (Group 4: NCD Only)	Total No. of Eligibility Specifications and NCD Requirements Not Met
Beneficiary's Participation in a Weight Management Program	19	2			**21**
Mental Health/Psychological Evaluation and Clearance*	10	6	3		**19**
Evaluation by a Physician Other Than a Surgeon/Primary Care Provider Referral	10	5			**15**
Nutritional Evaluation by a Physician or Registered Dietician	1	1			**2**
Documentation That Beneficiary Did Not Have Contraindications			2		**2**
Eligible Comorbidity (NCD requirement)				1	**1**
BMI ≥ 35 at the Time of Surgery			1		**1**
Beneficiary Received Knowledge and Tools for Lifelong Lifestyle Changes			1		**1**
Beneficiary Made a Diligent Effort To Achieve a Healthy Body Weight			1		**1**
Requirements for Beneficiaries Older Than 61		1			**1**
Total No. of Eligibility Specifications and NCD Requirements Not Met	**40**	**15**	**8**	**1**	**64**

* Palmetto's LCD requires an evaluation for bariatric surgery by a mental health provider that includes a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements but does not specifically require clearance for bariatric surgery.

These eligibility specifications and the NCD requirement were mainly not met because the hospitals: (1) did not have effective management oversight to ensure that there was adequate

documentation to support beneficiaries' eligibility for bariatric surgeries and (2) according to officials at some hospitals, the hospitals did not understand or were not aware of the eligibility specifications for bariatric surgery. On the basis of our sample results, we estimated that Medicare could have saved $47.8 million during our audit period if Medicare contractors had disallowed claims that did not meet Medicare national requirements or Medicare contractor eligibility specifications for bariatric surgery.[21]

NOT ALL HOSPITALS' INPATIENT CLAIMS FOR BARIATRIC SURGERIES MET MEDICARE NATIONAL REQUIREMENTS OR MEDICARE CONTRACTORS' ELIGIBILITY SPECIFICATIONS

Twenty Claims Did Not Meet the Most Restrictive Eligibility Specifications

Noridian's LCAs A53026 and A53028 provided the most restrictive eligibility specifications for bariatric surgery, including documentation of: (1) the beneficiary's participation in a weight management program (i.e., monthly documentation of weight and BMI, current dietary regimen, and physical activity) for at least 4 consecutive months within the last 12 months before bariatric surgery and (2) multidisciplinary evaluations, which must have been performed within 6 months of bariatric surgery (i.e., an evaluation by a bariatric surgeon, a recommendation and clearance from a physician other than a surgeon, clearance from a mental health provider that includes a statement regarding a beneficiary's motivation and ability to follow postsurgical requirements, and a nutritional evaluation by a physician or registered dietician).

Of the 30 sampled claims that Noridian processed, 20 claims (submitted by 16 hospitals), with payments totaling $226,186, did not meet the specifications in Noridian's LCAs. Specifically, the beneficiary medical records did not include adequate documentation to support that:[22]

- the beneficiary participated in a weight management program for at least 4 consecutive months within the last 12 months before the bariatric surgery or the weight management documentation included the beneficiary's weight, BMI, current dietary regimen, and physical activity (19 claims);

- the beneficiary received a separate medical evaluation from a physician other than a surgeon, the evaluation was performed within 6 months before the bariatric surgery, the physician recommended the beneficiary for bariatric surgery, or the physician provided a medical clearance for the proposed bariatric surgery (10 claims);

[21] The unrounded amount is $47,787,468. This estimate includes findings related to LCA eligibility specifications, which CMS considers guidance rather than requirements.

[22] The total number of eligibility specifications that were not met exceeds 20 because 14 claims did not meet more than 1 specification.

- the beneficiary received a mental health evaluation, the evaluation was performed within 6 months before the bariatric surgery, or the mental health clearance included a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements (10 claims); and

- the beneficiary received a nutritional evaluation by a physician or registered dietician within 6 months before the bariatric surgery (1 claim).

These claims did not meet the eligibility specifications in the LCAs, which CMS considers guidance rather than requirements.[23]

Seven Claims Did Not Meet the Moderately Restrictive Eligibility Specifications

Palmetto's LCD L34576 provided moderately restrictive eligibility specifications for bariatric surgery because the specifications applied only to LSG procedures and included fewer specifications than the most restrictive group. The LCD required documentation of: (1) the beneficiary's participation in a weight management program within the last 12 months before bariatric surgery (i.e., monthly documentation of weight, current dietary regimen, and physical activity); (2) multidisciplinary evaluations, which must have been performed within 6 months of bariatric surgery (i.e., an evaluation by a bariatric surgeon, a referral from a primary care provider, an evaluation by a mental health provider that includes a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements, and a nutritional evaluation by a physician or registered dietician); and (3) for beneficiaries more than 61 years old, evidence that the patient had the capacity to follow postoperative care and nutritional requirements and an informed consent personally signed by the patient.

Of the 30 sampled claims that Palmetto processed, 7 claims (submitted by 7 hospitals), with payments totaling $67,285, did not meet the eligibility specifications in Palmetto's LCD. Specifically, the beneficiary medical records did not include adequate documentation to support that:[24]

- the beneficiary received a mental health evaluation, the evaluation was performed within 6 months before the bariatric surgery, or the mental health evaluation included a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements (six claims);

- the beneficiary received a referral from a primary care provider or the referral was made within 6 months before the bariatric surgery (five claims);

[23] To be conservative, we considered all Medicare payments made to hospitals for claims that did not meet Medicare national requirements or eligibility specifications for bariatric surgery in the LCDs or LCAs to be costs that Medicare could potentially have avoided rather than improper payments.

[24] The total number of eligibility specifications that were not met exceeds seven because four claims did not meet more than one specification.

- the beneficiary participated in a weight management program within the last 12 months before the bariatric surgery or the weight management documentation included the beneficiary's current dietary regimen and physical activity (two claims);

- the beneficiary received a nutritional evaluation by a physician or registered dietician (one claim); and

- the beneficiary had the capacity to follow the postoperative care and nutritional requirements and personally signed the informed consent (one claim). This beneficiary was more than 61 years old.

Five Claims Did Not Meet the Least Restrictive Eligibility Specifications

Novitas's LCD L35022 and First Coast's LCD L33411 provided the least restrictive eligibility specifications for bariatric surgery and required documentation that the beneficiary: (1) had a BMI greater than or equal to 35 at the time of the bariatric surgery; (2) had been provided with knowledge and tools needed to achieve lifelong lifestyle changes; (3) had made a diligent effort to achieve a healthy body weight, with such efforts described in the medical record and certified by the operating surgeon; (4) had undergone a preoperative psychological evaluation and clearance if the beneficiary had a history of psychiatric or psychological disorders, was under the care of a psychologist or psychiatrist, or was on psychotropic medications; and (5) did not have certain contraindications (e.g., failure to cease tobacco use) to the bariatric surgery.

Of the 30 sampled claims processed by Novitas (27 claims) and First Coast (3 claims), 5 claims (submitted by 5 hospitals to Novitas), with payments totaling $47,747, did not meet the specifications in Novitas's LCD.[25] Specifically, the beneficiary medical records did not have adequate documentation to support that the beneficiary:[26]

- received a psychological evaluation and clearance when the beneficiary had a history of a psychological disorder or was on a psychotropic medication (three claims);

- did not have certain contraindications to bariatric surgery (two claims);

- had a BMI greater than or equal to 35 at the time of surgery (one claim);[27]

[25] The three claims processed by First Coast met the eligibility specifications in First Coast's LCD.

[26] The total number of eligibility specifications that were not met exceeds five because three claims did not meet more than one specification.

[27] Only Novitas's and First Coast's LCDs provided clarification on when the beneficiary's BMI should be measured. Their LCDs require that the beneficiary have a BMI greater than or equal to 35 at the time of surgery. The NCD does not specify when BMI should be measured (e.g., when a beneficiary first enrolled in a weight management program or at the time of surgery).

- was provided with knowledge and tools needed to achieve lifelong lifestyle changes (one claim); and

- had made a diligent effort to achieve a healthy body weight (one claim).

One Claim Did Not Meet Requirements in the Medicare Contractor Jurisdictions That Relied Solely on CMS's National Coverage Determination

For a beneficiary to qualify for bariatric surgery, CMS's NCD requires the beneficiary to have a BMI greater than or equal to 35, have at least one comorbidity related to obesity, and have previously been unsuccessful with medical treatment for obesity (chapter 1, § 100.1).

Of the 30 sampled claims processed by NGS (14 claims), WPS (13 claims), and CGS (3 claims), 1 claim (submitted by 1 hospital to WPS), with payments totaling $9,820, did not meet Medicare national requirements in the NCD.[28] (None of these Medicare contractors had eligibility specifications for bariatric surgery in LCDs or LCAs.) Specifically, the beneficiary's medical record did not include support that the beneficiary had an eligible comorbidity related to obesity.

DIFFERING MEDICARE CONTRACTOR ELIGIBILITY SPECIFICATIONS FOR BARIATRIC SURGERY CONTRIBUTED TO DIFFERENCES IN THE NUMBER OF CLAIMS THAT DID NOT MEET THE SPECIFICATIONS AMONG MEDICARE CONTRACTOR JURISDICTION GROUPS

Differing Medicare contractor eligibility specifications for bariatric surgery contributed to differences in the number of claims that did not meet the specifications among Medicare contractor jurisdiction groups. Of the 33 claims in our sample that did not meet the specifications or NCD requirements, 20 claims did not meet the specifications in the LCAs (group 1); 12 claims did not meet the specifications in the LCDs (groups 2 and 3); and 1 claim did not meet the NCD requirements (group 4). Medicare contractor jurisdiction groups with more restrictive specifications had more claims that did not meet the specifications. The Medicare contractors may have issued differing eligibility specifications for bariatric surgery because CMS's NCD requirements were not specific.

The table in Appendix C highlights the primary differences in the Medicare contractors' eligibility specifications for bariatric surgery.

Medicare Contractors With More Restrictive Eligibility Specifications Had More Claims That Did Not Meet the Specifications

Noridian (group 1) had the most restrictive eligibility specifications, which applied to all Medicare-approved bariatric procedures, including LSG, and had the most claims that did not

[28] The 14 claims processed by NGS and the 3 claims processed by CGS met Medicare national requirements in the NCD.

meet the specifications (20 claims). Noridian's LCAs included specifications for documenting the beneficiary's participation in a weight management program (i.e., monthly documentation of weight and BMI, current dietary regimen, and physical activity) for at least 4 consecutive months within the last 12 months before bariatric surgery and documenting multidisciplinary evaluations (e.g., evaluation by a physician other than a surgeon, including a recommendation and clearance for bariatric surgery). In comparison, the other Medicare contractors' specifications were less restrictive. For example, most of the other Medicare contractors did not require that specific information be included in the weight management program documentation or that the weight management program be documented for a specific number of months. In addition, most of the other Medicare contractors did not require all of the multidisciplinary evaluations that were included in Noridian's LCAs.

Palmetto (group 2) had moderately restrictive eligibility specifications that applied only to LSG procedures and had fewer claims that did not meet the specifications (seven claims) than Noridian (group 1). Palmetto's LCD did not specify the minimum number of months for documenting a weight management program, did not require monthly documentation of a patient's BMI, and required only a referral from a primary care provider instead of an evaluation by a physician other than a surgeon.

In group 3 of our sample, Novitas and First Coast had the least restrictive eligibility specifications (which were in LCDs). Novitas had only five claims that did not meet the eligibility specifications, and First Coast did not have any claims that did not meet the specifications. These two Medicare contractors' LCDs only required documentation that the beneficiary had failed to maintain a healthy weight despite adequate participation in a dietary program and did not require that the dietary program documentation include specific information. In addition, their LCDs did not specify the minimum number of months for documenting a beneficiary's participation in a dietary program and did not require multidisciplinary evaluations for all beneficiaries.

In group 4 of our sample, WPS, NGS, and CGS did not include eligibility specifications for bariatric surgery in either LCDs or LCAs and followed the Medicare national requirements in the NCD, which were more general. WPS had only one claim that did not meet NCD requirements, and NGS and CGS did not have any claims that did not meet NCD requirements.

Eligibility Requirements for Bariatric Surgery in CMS's National Coverage Determination Were Not Specific

The Medicare contractors may have issued differing eligibility specifications for bariatric surgery because CMS's NCD requirements were not specific. We determined that the differences in the specifications may have occurred because CMS's NCD did not specify: (1) when BMI should be measured, (2) the required supporting documentation for demonstrating prior unsuccessful treatment for obesity, and (3) the required presurgical medical evaluations necessary to ensure that beneficiaries are appropriate candidates for bariatric surgery. As a result, some Medicare contractors issued LCDs or LCAs, which included their own specifications for when BMI should

be measured, for documenting prior unsuccessful medical treatment for obesity, and for the necessary presurgical medical evaluations.

CONCLUSION

Adequate eligibility requirements for bariatric surgery, if applied consistently, may improve beneficiaries' health and safety. The Medicare contractors' issuance of differing eligibility specifications may have resulted in beneficiaries in different jurisdictions receiving different preoperative evaluations and participating in weight management programs of different duration before surgery, which may not have always been sufficient to assess that the beneficiaries were physically and psychologically fit to undergo bariatric surgery. To ensure that appropriate preoperative evaluations are given to beneficiaries before bariatric surgery and that beneficiaries participate in an adequate weight management program, CMS could make the NCD more specific by reviewing LCD and LCA eligibility specifications for bariatric surgery and incorporating them as appropriate into the NCD, which may help better safeguard beneficiaries' health and safety.

Participation in a Weight Management Program and Preoperative Evaluations Are Essential for Optimizing a Beneficiary's Health

According to a peer-reviewed article from the National Institutes of Health's website, ". . . upon entrance to a bariatric surgery program and before proceeding with surgery, patients should participate in a guided weight loss program with exercise and lifestyle modifications; this will help ensure that the patient can make the commitment necessary to undergo the postoperative nutritional restrictions of the procedure. . . . The preoperative evaluation should be holistic, integral, and include an assessment by an interprofessional team . . . . Several steps during the pre-op evaluation should take place to ensure a positive outcome after the bariatric surgery procedure. . . . Bariatric surgery is an elective procedure, and it is essential to optimize the patient's functional and health status prior to surgery." ("Obesity Surgery Pre-Op Assessment and Preparation." StatPearls Publishing, Jan. 16, 2021). Available at https://www.ncbi.nlm.nih.gov/books/NBK546667/. Accessed on June 9, 2021.

RECOMMENDATIONS

We recommend that the Centers for Medicare & Medicaid Services do the following, which could have saved Medicare an estimated $47.8 million during our audit period:

- Determine whether any eligibility specifications in the Medicare contractors' LCDs and LCAs should be added to the NCD for bariatric surgery and, if so, take the necessary steps to update the NCD by, for example:
    - specifying when BMI should be measured;

- specifying what constitutes medical treatment for obesity (e.g., by including specific requirements for a beneficiary's participation in a weight management program); and

- including additional requirements needed to ensure that beneficiaries are appropriate candidates for bariatric surgery (e.g., the requirements that a physician other than a surgeon evaluate the beneficiary before surgery and that the beneficiary have a mental health evaluation, which includes a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements).

- Work with the Medicare contractors to review the eligibility specifications in the applicable Medicare contractors' bariatric surgery LCDs and LCAs (i.e., those specifications that were not added to the NCD in response to our first recommendation), and determine which, if any, of those additional specifications should be requirements rather than guidance (i.e., included in LCDs, not LCAs).

- Educate hospitals on the NCD requirements for bariatric surgeries if the NCD has been updated in response to our first recommendation.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, CMS did not concur with our recommendations. CMS provided introductory comments in addition to addressing our recommendations. Summaries of CMS's comments and our responses are provided below. After reviewing CMS's comments, we maintain that our recommendations are valid.

CMS also provided technical comments on our draft report, which we addressed as appropriate. CMS's comments, excluding the technical comments, appear as Appendix F.

INTRODUCTORY COMMENTS

CMS Comments

CMS stated that section 1869(f)(2)(B) of the Act does not mandate that LCDs be uniform across Medicare contractor jurisdictions. In addition, CMS stated that the Medicare contractors were set up to provide flexibility in serving sometimes diverse jurisdictions and that there are many valid reasons why these contractors may have differing LCDs.

CMS asserted that variations between eligibility specifications contained in LCDs are not necessarily an indication of increased risk to beneficiary health or safety and that eliminating these variations cannot ensure the health and safety of beneficiaries. CMS stated that because OIG did not use a medical review contractor to determine whether bariatric surgery procedures were medically necessary or a clinician to evaluate the health benefits or adverse events

associated with these procedures and because OIG found only one claim that did not meet NCD requirements, CMS does not believe that this report supports that lack of specificity within the NCD or variation among LCDs may have affected beneficiaries' health and safety.

With respect to LCAs, CMS stated that it is important to note that LCAs contain coding or other supplemental guidelines that complement an LCD, but LCAs do not establish new coverage criteria or requirements.

Office of Inspector General Response

To clarify, we are not recommending that CMS mandate that LCDs be uniform across all jurisdictions; rather, we are recommending that CMS work with the Medicare contractors to review eligibility specifications and make them binding, if warranted. In addition, although CMS provided reasons why there may be variations among Medicare contractors' LCDs, it is not clear what the evidence-based reasons are for the variations in eligibility specifications for bariatric surgery. CMS should assess the reasons for these variations and take measures as necessary. For example, if some Medicare contractors have evidence that certain specifications (e.g., psychological evaluations) are necessary to ensure positive outcomes after bariatric surgery, we believe that CMS should examine that evidence to determine whether that standard should be considered for inclusion in its NCD.

Although we did not use a medical review contractor to determine whether bariatric surgery procedures were medically necessary or a clinician to evaluate the health benefits or adverse events associated with these procedures, our audit identified issues with the existing bariatric surgery requirements and guidance. We identified that the Medicare contractors' specifications for bariatric surgery varied significantly and may have resulted in beneficiaries in different jurisdictions receiving different preoperative evaluations. Having adequate eligibility requirements for bariatric surgery that are applied consistently may improve beneficiaries' health and safety.

We also identified that the current NCD requirements are not specific. For example, without clarification from LCDs or LCAs on the NCD requirements, it was difficult for us to determine whether a beneficiary met the NCD requirement of having been "previously unsuccessful with medical treatment for obesity." Because the NCD was not specific, we were conservative and allowed claims for which: (1) a physician mentioned in a consultation note that a beneficiary had failed medical management for weight loss but (2) there was no documentation of medical treatment for obesity. Without clarification from an LCD or LCA, providers may also have the same difficulty in determining whether beneficiaries have met the NCD requirements for bariatric surgery. In addition, it may not be clear to providers that CMS considers the LCA eligibility specifications to be guidance; therefore, providers within the same jurisdiction may apply different standards (e.g., providers that follow LCA guidance may require their beneficiaries to meet more eligibility specifications).

Although CMS stated that LCAs do not establish new coverage criteria or requirements, our audit identified that some Medicare contractors included certain eligibility specifications (e.g., regarding weight management programs or preoperative evaluations) in LCDs, while another Medicare contractor included similar specifications in LCAs. In addition, as permitted by the NCD, some Medicare contractors decided to cover LSG procedures and added coverage of these procedures as guidance in an LCA instead of providing the criteria for coverage in an LCD.

COMMENTS ON RECOMMENDATIONS

CMS Comments

CMS did not concur with our three recommendations:

- Regarding our first recommendation, CMS stated that it will continue to monitor the scientific evidence related to bariatric surgery procedures and, based on that evidence, will evaluate whether an update to the NCD is necessary. CMS also stated that if it is determined that an update is necessary, CMS will follow the established process for NCDs.

- Regarding our second recommendation, CMS stated that section 1869(f)(2)(B) of the Act does not mandate that LCDs be uniform across all jurisdictions and that there are valid reasons that variation at the local Medicare contractor level is appropriate. CMS also stated that, based on the information in our report, it believes that there is no conflict with the national policy, the Medicare contractors' LCDs are consistent with their statutory authority, and the Medicare contractors have complied with the scope of their contracts.

- Regarding our third recommendation, CMS stated that, given that it did not concur with our first recommendation to update its NCD, it does not concur with this recommendation. However, CMS stated that it will continue to educate hospitals on proper billing and Medicare requirements for Medicare-covered items and services.

Office of Inspector General Response

Regarding our first and third recommendations, we appreciate that CMS will continue to monitor the scientific evidence related to bariatric surgery procedures (updating the NCD if necessary) and continue to educate hospitals on proper billing and Medicare requirements. However, to increase the likelihood of positive outcomes after bariatric surgery, we suggest that CMS prioritize determining whether an update to the NCD is necessary, using its established process.

Regarding our second recommendation, we understand the roles of and statutory basis for NCDs, LCDs, and LCAs in the Medicare program. We are unaware of any statutory provision that would prohibit CMS from working with Medicare contractors (which they utilize to perform

critical functions in Medicare) to address issues associated with LCDs and LCAs. To clarify, we are not recommending that CMS mandate that LCDs be uniform across all jurisdictions. Rather, we continue to recommend that CMS work with the Medicare contractors to correct the issues identified in this audit, such as the lack of specificity in the NCD requirements.

Based on CMS's nonconcurrence with the three recommendations in this report, it does not appear that CMS will proactively take action to: (1) use its evidence-based process to determine whether any eligibility specifications that clarified the NCD or added requirements beyond the NCD should be added to the bariatric surgery NCD or (2) address Medicare contractors' LCAs that include eligibility specifications and not just coding or other supplemental guidelines that complement an LCD (e.g., if warranted, by recommending that Medicare contractors move LCA language to LCDs using the established process for developing LCDs).

We are concerned that if CMS does not take any corrective action, the eligibility specifications for Medicare beneficiaries may continue to vary significantly among the Medicare contractors without evidence-based reasons for the differences. We believe it is imperative that CMS update the NCD if necessary and work with the Medicare contractors to ensure that any bariatric surgery eligibility specifications that are in LCAs and that the contractors believe should be binding are moved from LCAs to LCDs using CMS's established process for developing LCDs.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered $275,215,570 in Medicare Part A payments for 24,821 inpatient claims for bariatric surgeries performed by hospitals from January 1, 2018, through July 31, 2019. We included claims with: (1) MS-DRG codes 619, 620, or 621 (procedures for obesity); (2) the morbid-obesity diagnosis code E66.01; (3) Medicare-approved bariatric procedure codes listed in CMS's *Medicare Claims Processing Manual* (the Manual), Pub. No. 100-04, chapter 32, section 150; and (4) no previous reviews by CMS contractors or OIG investigators as of the time we created our sampling frame.

We stratified the 24,821 claims into 4 groups based on Medicare contractor jurisdictions that had similar eligibility specifications for bariatric surgery. The four groups ranged from the jurisdictions with the most restrictive eligibility specifications to those with no eligibility specifications. We then selected for review a stratified random sample of 120 inpatient claims (30 claims from each group), for which Medicare paid 105 hospitals $1,309,428.

We did not use a medical reviewer to determine whether services were medically necessary.

We did not perform an overall assessment of CMS's internal control structure. Rather, we limited our review of internal controls to those that were significant to our objective. Specifically, we: (1) interviewed CMS officials to identify any oversight activities they have performed and (2) assessed the Medicare contractors' controls and system edits for processing bariatric surgery claims.

Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History (NCH) file, but we did not assess the completeness of the file.

We conducted our audit from December 2019 to September 2021.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;

- interviewed CMS officials to gain an understanding of Medicare billing requirements for bariatric surgery and to identify any oversight activities that CMS has performed specific to bariatric surgeries, including CMS's or Medicare contractors' reviews of bariatric surgery claims;

- contacted officials from 7 Medicare contractors to obtain an understanding of: (1) the Medicare contractors' eligibility specifications for bariatric surgeries, (2) controls and system edits for processing bariatric surgery claims, and (3) the bariatric surgery specifications that each Medicare contractor considers most important to ensure a beneficiary's health and safety;

- obtained from CMS's NCH file the paid Medicare Part A claims for bariatric surgeries that hospitals provided to Medicare beneficiaries during our audit period;

- created a sampling frame of 24,821 claims for bariatric surgery and selected for review a stratified random sample of 120 claims (Appendix D);

- reviewed data from CMS's Common Working File for the selected claims to determine whether the claims had been canceled or adjusted;

- obtained billing and medical record documentation provided by hospitals as support for the sampled claims and reviewed the documentation to determine whether each claim met Medicare national requirements and the applicable Medicare contractor eligibility specifications;

- requested hospitals to provide a reason for inadequate medical record documentation of the beneficiaries' eligibility for bariatric surgery, for claims that did not meet Medicare national requirements or Medicare contractor eligibility specifications;

- estimated the amount that Medicare could have saved if Medicare contractors had disallowed claims that did not meet Medicare national requirements or Medicare contractor eligibility specifications for bariatric surgery (Appendix E); and

- discussed the results of our audit with CMS officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

APPENDIX B: MEDICARE CONTRACTOR AND GEOGRAPHIC COMPOSITION FOR EACH JURISDICTION

Jurisdiction	Medicare Contractor	States and Territories
5	WPS	Iowa, Kansas, Missouri, Nebraska
6	NGS	Illinois, Minnesota, Wisconsin
8	WPS	Indiana, Michigan
15	CGS	Kentucky, Ohio
E	Noridian	American Samoa, California, Guam, Hawaii, Nevada, Northern Mariana Islands
F	Noridian	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming
H	Novitas	Arkansas, Colorado, Louisiana, Mississippi, New Mexico, Oklahoma, Texas
J	Palmetto	Alabama, Georgia, Tennessee
K	NGS	Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont
L	Novitas	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania
M	Palmetto	North Carolina, South Carolina, Virginia, West Virginia
N	First Coast	Florida, Puerto Rico, U.S. Virgin Islands

APPENDIX C: PRIMARY DIFFERENCES IN MEDICARE CONTRACTORS' ELIGIBILITY SPECIFICATIONS FOR BARIATRIC SURGERY

Medicare Contractor Eligibility Specifications for Bariatric Surgery		Most Restrictive Specifications	Moderately Restrictive Specifications	Least Restrictive Specifications		No Specifications (NCD Only)		
		Noridian LCAs	Palmetto LCD (for LSG only)	Novitas LCD	First Coast LCD	NGS LCA (for LSG only)	WPS LCA	CGS No LCD or LCA
Weight Management Program	Participation in a Weight Management or Structured Dietary Program	X	X	X	X			
	Within 12 Months of Bariatric Surgery	X	X					
	Four Consecutive Months of Weight Management Evaluations	X						
	Monthly Documentation of Patient's Weight, Current Dietary Regimen, and Physical Activity	X	X					
	Monthly Documentation of Patient's BMI	X						
Medical Evaluations	Evaluation by a Bariatric Surgeon Within 6 Months of Bariatric Surgery	X	X					
	Evaluation by a Physician Other Than a Surgeon That Includes Recommendation and Clearance Within 6 Months of Bariatric Surgery	X						
	Primary Care Provider Referral Within 6 Months of Bariatric Surgery		X					
	Nutritional Evaluation by a Physician or Registered Dietician Within 6 Months of Bariatric Surgery	X	X					
	Mental Health Evaluation and Clearance Within 6 Months of Bariatric Surgery*	X	X					
	Psychological Evaluation and Clearance for Beneficiaries With History of Psychiatric or Psychological Disorder			X	X			
Additional Requirements	BMI ≥ 35 at the Time of Bariatric Surgery			X	X			
	Beneficiary Received Knowledge and Tools for Lifestyle Changes, Exhibits Understanding of the Needed Changes, Demonstrated Capability and Willingness To Undergo the Changes, and Has Made a Diligent Effort To Achieve Healthy Body Weight			X	X			
	Beneficiary > 61 Years Old Must: Understand Potential Complications, Be Capable To Follow Postoperative Requirements, Sign Informed Consent, Have a Listed Comorbidity, and Not Have Contraindications		X					
	Contraindications to Bariatric Surgery for All Beneficiaries			X	X			

* Palmetto's LCD requires an evaluation for bariatric surgery by a mental health provider that includes a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements but does not specifically require clearance for bariatric surgery.

APPENDIX D: STATISTICAL SAMPLING METHODOLOGY

SAMPLING FRAME

Our sampling frame consisted of 24,821 Medicare Part A paid claims from CMS's NCH file for which hospitals received payments of $275,215,570 for bariatric surgeries performed from January 1, 2018, through July 31, 2019.

The frame included claims with: (1) MS-DRG codes 619, 620, or 621 (procedures for obesity); (2) the morbid-obesity diagnosis code E66.01; (3) Medicare-approved bariatric procedure codes listed in the Manual (chapter 32, § 150); and (4) no previous reviews by CMS contractors or OIG investigators as of the time we created our sampling frame.

SAMPLE UNIT

The sample unit was a Medicare Part A paid claim for a bariatric surgery.

SAMPLE DESIGN AND SAMPLE SIZE

We used a stratified random sample. To accomplish this, we separated the sampling frame into four strata based on the restrictiveness of the Medicare contractors' eligibility specifications for bariatric surgery (Table 3). We selected for review a total of 120 claims, consisting of 30 claims from each stratum.

Table 3: Strata in Sampling Frame

Stratum	Medicare Contractor and Jurisdiction	No. of Claims	Total Payments	No. of Sampled Claims
1 (LCAs)	Noridian (JE and JF)	3,133	$40,368,957	30
2 (LCD for LSG only)	Palmetto (JJ and JM)	3,259	32,426,198	30
3 (LCDs)	Novitas (JH and JL) First Coast (JN)	8,562	91,867,593	30
4 (NCD only)	NGS (J6 and JK) WPS (J5 and J8) CGS (J15)	9,867	110,552,822	30
Total		**24,821**	**$275,215,570**	**120**

SOURCE OF RANDOM NUMBERS

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the claims in each stratum. After generating 30 random numbers for each stratum, we selected the corresponding frame items.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the amount in the sampling frame paid to hospitals that did not meet Medicare national requirements or Medicare contractors' eligibility specifications for bariatric surgery.

APPENDIX E: SAMPLE RESULTS AND ESTIMATES

Table 4: Sample Results

Stratum	No. of Claims in Sampling Frame	Value of Frame	Sample Size	Value of Sample	No. of Claims That Did Not Meet NCD Requirements or Eligibility Specifications	Value of Claims That Did Not Meet NCD Requirements or Eligibility Specifications
1 (LCAs)	3,133	$40,368,957	30	$353,265	20	$226,186
2 (LCD for LSG only)	3,259	32,426,198	30	284,233	7	67,285
3 (LCDs)	8,562	91,867,593	30	319,781	5	47,747
4 (NCD only)	9,867	110,552,822	30	352,149	1	9,820
Total	**24,821**	**$275,215,570**	**120**	**$1,309,428**	**33**	**$351,038**

Table 5: Estimated Value of Payments for Claims in the Sampling Frame That Did Not Meet Medicare National Requirements or Medicare Contractor Eligibility Specifications *(Limits Calculated for a 90-Percent Confidence Interval)*

Point estimate	$47,787,468
Lower limit	34,844,074
Upper limit	60,730,862

APPENDIX F: CMS COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: November 9, 2021

TO: Amy J. Frontz
Deputy Inspector General for Audit Services
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Hospitals Did Not Always Meet Differing Medicare Contractor Specifications for Bariatric Surgery (A-09-20-03007)

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 serves the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes. CMS takes the health and safety of its beneficiaries seriously, and is committed to providing them with access to medically necessary services and, at the same time, working to protect the Medicare Trust Funds from improper payments.

Regarding the variation between the various coverage requirements OIG notes in its report, it is important to keep in mind that the Social Security Act is the primary authority for all coverage provisions and subsequent policies. Generally, Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury, or to improve the functioning of a malformed body member, and within the scope of a Medicare benefit category. In certain cases, CMS deems it appropriate to develop a National Coverage Determination (NCD) for an item or service to be applied on a national basis for all Medicare beneficiaries meeting the criteria for coverage. Medicare Administrative Contractors (MACs) may also develop Local Coverage Determinations (LCDs) when there is no NCD or when there is a need for additional guidance that is consistent with an NCD in a geographical area.

NCDs describe the circumstances for Medicare coverage nationwide for a specific medical service, procedure, or device. NCDs generally outline the conditions for which a service is considered to be covered, or not covered, under §1862(a)(1) or other applicable provisions of the Social Security Act (that is, a determination as to whether the service is reasonable and necessary).

NCDs are developed through an evidence-based process, with opportunities for public participation. In some cases, CMS' own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC). This process may involve the review of medical, technical,

and scientific evidence. This process is the same for all NCDs, including those related to bariatric surgery, and CMS will continue to monitor the scientific evidence and evaluate whether an update to this NCD is necessary.

LCDs are decisions by MACs regarding whether to cover a particular service in their jurisdictional area in accordance with §1862(a)(1)(A) of the Social Security Act. LCDs may be developed in the absence of a specific statute, regulation, national coverage policy, national coding policy, or as an adjunct to a national coverage policy.

Congress expressly delegated to MACs the function of developing LCDs, as defined in section 1869(f)(2)(B) of the Social Security Act. The statute does not mandate that LCDs be uniform across all MAC jurisdictions. As such, CMS does not have the authority to dictate that all MAC LCDs be uniform. However, CMS will intervene if a given LCD conflicts with national coverage or the MAC did not follow the LCD development process outlined in chapter 13 of the Medicare Program Integrity Manual.

The MACs were set up to serve a variety of jurisdictions and to provide flexibility in serving those sometimes-diverse jurisdictions, so there are a number of valid reasons why variation at the MAC level is appropriate. The MACs' jurisdictions may differ by medical needs, geography, and basic rural/urban infrastructure (including digital, roadways and distance). For example, the Centers for Disease Control and Prevention (CDC) has found notable racial and ethnic and geographic disparities among adults with obesity.[1] Such disparities may necessitate variation among the MACs. Furthermore, medical policies for the various jurisdictions might vary on the basis of the available medical workforce and medical infrastructure. This would be particularly true for cutting edge/less well-established interventions, as these should be appropriately performed by highly select providers in highly qualified settings. For example, in the absence of tandem mass spectrometry, certain complex metabolic/genetic diagnoses should not be undertaken. Similarly, complex bariatric procedures on high risk patients should not be undertaken at institutions without intensive care units and rapid transfer capabilities. The MACs interact with groups representing beneficiaries and the local medical community.

The 21st Century Cures Act amended section 1862(l)(5)(D) of the Social Security Act to specify requirements for the LCD process including that MACs publish a summary of evidence that was considered by the contractor during the development of an LCD. Generally, LCDs are developed using an established process which includes consultation, publication of proposed LCD, or more open meetings concerning the proposed policy, opportunity for public comment in writing, publication of a final LCD that includes a response to public comments received and notice to public of new policy 45 days in advance of the effective date. When developing an LCD, MACs must use the available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines.

In addition to an LCD, a MAC may publish a Local Coverage Article (LCA). LCAs address coding or medical review related billing and claims considerations, and may include any newly developed educational materials, coding instructions or clarification of existing medical review related billing or claims policy. It is important to note that LCAs contain coding or other supplemental guidelines that complement an LCD but do not establish new coverage criteria or requirements.

[1] https://www.cdc.gov/obesity/data/prevalence-maps.html#race

CMS takes the health and safety of Medicare beneficiaries very seriously. Variations between eligibility specifications contained in LCDs, so long as the variations are not in conflict with the NCDs or other national policy, in and of themselves are not an indication of increased risk to beneficiary health or safety, nor can eliminating variations in eligibility requirements ensure the health and safety of beneficiaries. In addition, OIG's audit did not use a medical review contractor to determine whether these services were medically necessary, nor did the OIG have a clinician evaluate either the health benefits or adverse events associated with these procedures. Moreover, the OIG did not find that any MAC was implementing a lesser standard than the NCD applicable to bariatric surgery, and the OIG found only a single claim that failed to comply with the NCD. Therefore, we do not believe that this report supports any claim or assertion that beneficiaries' health and safety may have been affected due to lack of specificity within the NCD or variation among LCDs; however, CMS will continue to monitor the scientific evidence related to bariatric surgery procedures. Based on the scientific evidence, CMS will evaluate whether an update to the NCD is necessary. If it is determined that an update is necessary, CMS will follow the established process for NCDs, which includes opportunity for public comment.

CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including automated system edits within the claims processing system, and conducting prepayment and post-payment reviews. For example, CMS's Recovery Audit Contractors were approved to begin reviewing medical necessity and documentation requirements for bariatric surgery in February 2017.[2] As part of this strategy, CMS recovers identified overpayments in accordance with agency policies and procedures.

Additionally, CMS has taken action to prevent improper Medicare payments by educating physicians and hospitals on proper billing. CMS educates health care providers on Medicare billing through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services determine whether any eligibility specifications in the Medicare contractors' LCDs and LCAs should be added to the NCD for bariatric surgery and, if so, take the necessary steps to update the NCD by, for example:

- specifying when BMI should be measured
- specifying what constitutes medical treatment for obesity (e.g., by including specific requirements for a beneficiary's participation in a weight management program), and
- including additional requirements needed to ensure that beneficiaries are appropriate candidates for bariatric surgery (e.g., the requirements that a physician other than a surgeon evaluate the beneficiary before surgery and that the beneficiary have a mental health evaluation, which includes a statement regarding the beneficiary's motivation and ability to follow postsurgical requirements).

[2] https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Approved-RAC-Topics-Items/0008-Bariatric-Surgery-Medical-Necessity-and-Documentation-Requirements

CMS Response

CMS does not concur with this recommendation. CMS will continue to monitor the scientific evidence related to bariatric surgery procedures. Based on the scientific evidence, CMS will evaluate whether an update to the NCD is necessary. If it is determined that an update is necessary, CMS will follow the established process for NCDs, which includes opportunity for public comment.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services work with the Medicare contractors to review eligibility specifications in the applicable Medicare contractors' bariatric surgery LCDs and LCAs (i.e., those specifications that were not added to the NCD in response to our first recommendation), and determine which, if any, of those additional specifications should be requirements rather than guidance (i.e., included in LCDs, not LCAs).

CMS Response

CMS does not concur with this recommendation. As stated above, Congress expressly delegated to MACs the function of developing LCDs, as defined in section 1869(f)(2)(B) of the Social Security Act. The statute does not mandate that LCDs be uniform across all jurisdictions. As noted above, there are a number of valid reasons why variation at the local MAC level is appropriate. The MACs were set up to serve a variety of jurisdictions and to provide flexibility in serving those sometimes-diverse jurisdictions. The jurisdictions may differ by medical needs, geography, and basic rural/urban infrastructure (including digital, roadways and distance). The MACs interact with groups representing beneficiaries and the local medical community.

Based on the information within this report, we believe that there is no conflict with the national policy, that the MACs' LCDs are consistent with their statutory authority, and the MACs have complied with the scope of their contracts. CMS will require the MACs to continue to follow the established LCD process, including the reliance upon evidence of general acceptance by the medical community, for establishing any such determinations.

OIG Recommendation

The OIG recommends that the Centers for Medicare & Medicaid Services educate hospitals on the NCD requirements for bariatric surgeries if the NCD has been updated in response to our first recommendation.

CMS Response

Given CMS does not concur with the first recommendation, CMS does not concur with this recommendation. However, CMS will continue to educate hospitals regarding proper billing and Medicare requirements for Medicare covered items and services.