Medicare Medical Policy

Bariatric Surgery

MEDICARE MEDICAL POLICY NUMBER: 37

Effective Date: 4/1/2025

Last Review Date: 3/2025

Next Annual Review: 3/2026

MEDICARE COVERAGE CRITERIA 2
POLICY CROSS REFERENCES 4
POLICY GUIDELINES 4
REGULATORY STATUS 5
BILLING GUIDELINES AND CODING 5
REFERENCES 7
POLICY REVISION HISTORY 7

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
Bariatric surgical procedures subject to NCD 100.1 • *Roux-en-Y gastric bypass (RYGBP)* • *Biliopancreatic Diversion with Duodenal Switch (BPD/DS)* • *Gastric Reduction Duodenal Switch (BPD/GRDS)* • *Adjustable gastric banding* • *Sleeve Gastrectomy* • *Vertical banded gastroplasty* • *Intestinal bypass surgery* • *Gastric balloon for treatment of obesity.*	General coverage criteria: • National Coverage Determination (NCD) for Bariatric Surgery for Treatment of Morbid Obesity (100.1) **NOTES:** 1. For information, including examples, of Medicare's requirements for co-morbid conditions and prior medical treatments related to obesity, see the *Local Coverage Article (LCA) for Bariatric Surgery Coverage (A53028).* 2. The following bariatric procedures may be **medically necessary** when NCD criteria are met: A. Roux-en-Y Gastric Bypass (RYGBP) (**open and laparoscopic**) B. Biliopancreatic Diversion with Duodenal Switch (BPD/DS) (**open and laparoscopic**) C. Gastric Reduction Duodenal Switch (BPD/GRDS) (**open and laparoscopic**) D. **Laparoscopic** Adjustable Gastric Banding (AGB) E. **Laparoscopic** Sleeve Gastrectomy 3. According to the above NCD, the following procedures are considered **not medically necessary** for any indication. A. **Open** adjustable gastric banding; B. **Open** sleeve gastrectomy; C. **Open and laparoscopic** vertical banded gastroplasty;

	D. Intestinal bypass surgery; and, E. **Gastric balloon** for treatment of obesity.
Treatment of complications resulting from a prior bariatric surgery (e.g., bleeding, fistula, infection, leak, obstruction, etc.)	*Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage,* §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare **NOTE:** I. Treatment of complications resulting from a prior bariatric surgery may be **medically necessary** when conditions of the above Medicare manual reference are met. This includes possible coverage for treatment of complications related to bariatric surgeries which did **not** meet coverage criteria. II. Removal of vagus nerve blocking neurostimulators ors generators **without** replacement with a new device may be **medically necessary**.
Medicare Coverage Criteria: "MA organizations may create publicly accessible internal coverage criteria… when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs." *(§ 422.101(b)(6) – see Policy Guidelines below*) • **Medicare Coverage Manuals:** Medicare does not have criteria for the bariatric surgical procedures listed below in a coverage manual. • **National Coverage Determination (NCD):** Medicare does not have an NCD for the bariatric surgical procedures below. • **Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, no Medicare Administrative Contractors (MACs) have LCDs for **vagal nerve blocking, bariatric embolotherapy, endoscopic sleeve gastroplasty, or endoscopic or transoral outlet reduction** and only two MACs have an LCD which addresses **repeat bariatric surgery**. However, neither of these are the MAC for the J-F service area. • Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan's service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered "not fully established" as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available. • ***NOTE:*** *The summary of evidence, as well as the list of citations/references used in the development of the Company's internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*	
Other Bariatric Surgical Procedures Not Otherwise Addressed *Examples (may not be all-inclusive):* • *Repeat or Revision Bariatric Surgery Procedures*	Company medical policy for Bariatric Surgery According to NCD 100.1, coverage determinations "for any bariatric surgery procedures that are not specifically identified in an NCD as covered or non-covered" is left to local Medicare contractors; however, Medicare still requires the member "have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity." Thus, in addition to the following

• *Vagus (vagal) nerve blocking therapy (e.g., Maestro)* • *Transcatheter bariatric embolotherapy* • *Endoscopic Sleeve Gastroplasty (ESG)* • *Endoscopic or transoral outlet reduction (TORe) following bariatric surgery*	Company medical policy criteria, these NCD requirements must also be met in order to be eligible for bariatric surgery. I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met for members who meet NCD 100.1 requirements (i.e., BMI, co-morbidity, and unsuccessful prior medical treatments for obesity). II. These services are considered **not medically necessary** for Medicare Plan members when the Company medical policy criteria are not met, or when NCD 100.1 requirements (i.e., BMI, co-morbidity, or unsuccessful prior medical treatments for obesity) are not met. *See Policy Guidelines below.*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. *(§ 422.101(c)(1))*

> "MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or

prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question." *(§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5)*

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

As of the most recent policy review, none of the Medicare Administrative Contractors (MACs) have a local coverage determination (LCD) for **vagal nerve blocking, bariatric embolotherapy, endoscopic sleeve gastroplasty, or endoscopic or transoral outlet reduction.** Only two MACs have an LCD which addresses repeat bariatric procedures (First Coast Service Options LCD L33411 and Novitas Solutions, Inc. LCD L35022), but neither MAC has jurisdiction over the health plan's service area. Note that both of these MACs state that repeat bariatric surgery is generally not medically necessary, but may be reconsidered on appeal.

Since there are not fully established Medicare coverage criteria for certain bariatric procedures (e.g., vagal nerve blocking, bariatric embolotherapy, endoscopic sleeve gastroplasty, or endoscopic or transoral outlet reduction) or for repeat bariatric surgery available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria for these services will be applied.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Only the codes listed on this policy may be used for reporting bariatric procedures. Codes 43631-43634 are specific to gastrectomy and should not be used to report bariatric procedures.

Code 43843 should not be used when there is a procedure-specific bariatric surgery code.

Finally, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[1], indicates CPT code 43842 has been assigned a Status Indicator of "N," which is defined as "Non-covered Services." This is a statutorily excluded service based on the above NCD.

VAGUS NERVE BLOCKING THERAPY

Between January 1, 2013 and December 31, 2022, Category III codes 0312T-0317T were used to report vagus nerve blocking therapy procedures. As of January 1, 2023, these codes were termed. In the absence of a replacement Category I code, an unlisted code would be appropriate to use.

CODES*		
CPT	0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon
	43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
	43291	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
	43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
	43645	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption
	43659	Unlisted laparoscopy procedure, stomach
	43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)
	43771	Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only
	43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only
	43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only
	43774	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components
	43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy)
	43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
	43843	Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty
	43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
	43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
	43847	Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption
	43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
	43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
	43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy

	43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
	43887	Gastric restrictive procedure, open; removal of subcutaneous port component only
	43888	Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only
	43999	Unlisted procedure, stomach
HCPCS	C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
	C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
6/2023	Annual review; combined criteria rows that use the same reference
7/2023	Q3 2023 code updates
1/2024	Q1 2024 code updates
4/2024	Annual review; no criteria changes
4/2025	Annual review; no criteria changes