Medicare Medical Policy

Bariatric Surgery

MEDICARE MEDICAL POLICY NUMBER: 37

Effective Date: 1/1/2024		
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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 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.

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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, **Gastric balloon** for treatment of obesity. Treatment of complications Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage, §180 - Services Related to and Required as a resulting from a prior bariatric surgery (e.g., bleeding, fistula, Result of Services Which Are Not Covered Under Medicare infection, leak, obstruction, etc.) 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**. Other Bariatric Surgical Company medical policy for Bariatric Surgery Procedures Not Otherwise Addressed l. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria Examples (may not be allinclusive): II. These services are considered **not medically necessary** for Medicare Plan members when the Company medical Repeat or Revision Bariatric Surgery policy criteria are not met. See Policy Guidelines below. **Procedures** Vagus nerve blocking therapy Transcatheter bariatric embolotherapy Endoscopic Sleeve Gastroplasty (ESG) Endoscopic or transoral outlet reduction (TORe) following bariatric surgery

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)*.

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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. *(Medicare Managed Care Manual, Ch. 4, §90.5)*

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 Medicare¹, 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.

CODI	CODES*		
CPT	0312T	TERMED 12/31/2022	
		Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of	
		neurostimulator electrode array, anterior and posterior vagal trunks adjacent to	
		esophagogastric junction (EGJ), with implantation of pulse generator, includes	
		programming	
	0313T	TERMED 12/31/2022	
		Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or	
		replacement of vagal trunk neurostimulator electrode array, including connection	
		to existing pulse generator	
	0316T	TERMED 12/31/2022	
		Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator	
	0317T	TERMED 12/31/2022	
		Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator	
		electronic analysis, includes reprogramming when performed	
	0813T	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of	
		intragastric bariatric balloon	
	43290	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric	
	40004	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 <u>Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website</u> 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

 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