

# Medicare Medical Policy

## Orthognathic Surgery

MEDICARE MEDICAL POLICY NUMBER: 400

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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 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.

#### Notes:

- Member benefits may address coverage or non-coverage of specific orthognathic surgery services and these benefits may vary. In the event of a conflict, member benefit language takes precedence over medical policy.
- This policy does **not** address orthognathic surgery **for the treatment of obstructive sleep apnea (OSA)**. Please see Policy Cross References for other possible medical policies.

Service	Medicare Guidelines
	<p><b>Medicare Coverage Criteria:</b> “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 <a href="#">Policy Guidelines</a> below)</p> <ul style="list-style-type: none"><li>• <b>Medicare Coverage Manuals:</b> Medicare does not have criteria for orthognathic surgery in a coverage manual.</li><li>• <b>National Coverage Determination (NCD):</b> Medicare does not have coverage criteria for orthognathic surgery in an NCD.</li><li>• <b>Noridian J-F Local Coverage Determination (LCD)/Local Coverage Article (LCA):</b> While the Noridian LCD for <i>Plastic Surgery</i> (L37020) states, “Corrective facial surgery will be considered cosmetic rather than reconstructive when there is no functional impairment present,” as of the last policy update, no LCD or LCA by any MAC was identified which provides specific coverage criteria for orthognathic surgery, for any indication.</li><li>• Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the service area in which the testing is being performed, Company criteria below are applied for medical necessity decision-making. Medicare statutes and regulation provide general coverage criteria for potentially cosmetic, but additional criteria to interpret or supplement the Medicare criteria are being used in order to determine medical necessity consistently. These additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services <b>because the use of this additional criteria based on peer-reviewed evidence evaluates how orthognathic surgery would be expected to improve patient management and health outcomes</b>. Specifically, the literature review is used to evaluate whether or not</li></ul>

each procedure has established medical necessity, with long-term safety and efficacy. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy. Clinical practice guidelines support orthognathic surgery for individuals who meet the coverage criteria.

- **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)].

Orthognathic Surgery

Company medical policy for [Orthognathic Surgery](#)

**NOTE:** According to Medicare, “unless they pertain to licensure and/or solvency, State laws and regulations that regulate health plans do not apply to MA plans offered by MA organizations.”<sup>1</sup> Therefore, Medicare Advantage members are not subject to individual state mandates. The non-state specific criteria in the Company medical policy are applicable to all Medicare Advantage members.

- I. These services may be considered **medically necessary** for Medicare when the Company medical policy criteria are met.
- II. These services are considered **not medically necessary** for Medicare when the Company medical policy criteria 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

- [Administrative Guideline for Dental Services](#), MP162
- [Sleep Disorder Surgery](#), MP244

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

## POLICY GUIDELINES

### BACKGROUND

According to the American Association of Oral and Maxillofacial Surgeons, “orthognathic surgery is the surgical correction of abnormalities of the mandible, maxilla, or both.”<sup>2</sup> The abnormality may be present at birth (i.e., congenital), may become apparent as the patient develops, or may be the result of a

traumatic injury. The primary goal of treatment is to improve craniofacial function (e.g., speech, swallowing, and/or chewing) by correcting the underlying skeletal deformity.

## **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, current standards of care, 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)*)

In addition:

“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.

The Noridian LCD for *Plastic Surgery* ([L37020](#)) states, “Corrective facial surgery will be considered cosmetic rather than reconstructive when there is no functional impairment present.” However, as of July 2024, no specific Medicare coverage policy or guidance (e.g., manual, NCD, LCD, LCA, etc.) was identified which addresses orthognathic surgery, for any indication.

Since there are not fully established coverage criteria for orthognathic surgery available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. See the [Medicare Coverage Criteria](#) table above for more information regarding the use of internal coverage criteria when Medicare coverage criteria are not fully established.

## **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

CODES*		
CPT	21070	Coronoidectomy (separate procedure)
	21081	Impression and custom preparation; mandibular resection prosthesis
	21082	Impression and custom preparation; palatal augmentation prosthesis
	21083	Impression and custom preparation; palatal lift prosthesis
	21085	Impression and custom preparation; oral surgical splint
	21089	Unlisted maxillofacial prosthetic procedure
	21125	Augmentation, mandibular body or angle; prosthetic material
	21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
	21141	Reconstruction midface, LeFort I; single piece, segment movement in any direction (eg, for Long Face Syndrome), without bone graft
	21142	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, without bone graft
	21143	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, without bone graft
	21145	Reconstruction midface, LeFort I; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)
	21146	Reconstruction midface, LeFort I; 2 pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)
	21147	Reconstruction midface, LeFort I; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)
	21150	Reconstruction midface, LeFort II; anterior intrusion (eg, Treacher-Collins Syndrome)
	21151	Reconstruction midface, LeFort II; any direction, requiring bone grafts (includes obtaining autografts)
	21154	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); without LeFort I
	21155	Reconstruction midface, LeFort III (extracranial), any type, requiring bone grafts (includes obtaining autografts); with LeFort I
	21159	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); without LeFort I
	21160	Reconstruction midface, LeFort III (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); with LeFort I
	21188	Reconstruction midface, osteotomies (other than LeFort type) and bone grafts (includes obtaining autografts)

	21193	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; without bone graft
	21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy; with bone graft (includes obtaining graft)
	21195	Reconstruction of mandibular rami and/or body, sagittal split; without internal rigid fixation
	21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation
	21198	Osteotomy, mandible, segmental
	21199	Osteotomy, mandible, segmental; with genioglossus advancement
	21206	Osteotomy, maxilla, segmental (eg, Wassmund or Schuchard)
	21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
	21209	Osteoplasty, facial bones; reduction
	21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
	21215	Graft, bone; mandible (includes obtaining graft)
	21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)
	21244	Reconstruction of mandible, extraoral, with transosteal bone plate (eg, mandibular staple bone plate)
	21245	Reconstruction of mandible or maxilla, subperiosteal implant; partial
	21246	Reconstruction of mandible or maxilla, subperiosteal implant; complete
	21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial microsomia)
	21248	Reconstruction of mandible or maxilla, endosteal implant (eg, blade, cylinder); partial
	21249	Reconstruction of mandible or maxilla, endosteal implant (eg, blade, cylinder); complete
<b>HCPCS</b>	None	

**\*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 Managed Care Manual, Chapter 10 - MA Organization Compliance with State Law and Preemption by Federal Law, §30.1 – General; <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c10.pdf>. Accessed 7/22/2024.
2. American Association of Oral and Maxillofacial Surgeons. Criteria for Orthognathic Surgery. [https://www.aaoms.org/docs/practice\\_resources/clinical\\_resources/ortho\\_criteria.pdf](https://www.aaoms.org/docs/practice_resources/clinical_resources/ortho_criteria.pdf). Published 2020. Accessed 7/22/2024.

## **POLICY REVISION HISTORY**

<b>DATE</b>	<b>REVISION SUMMARY</b>
10/2023	New Medicare Advantage medical policy
9/2024	Annual review; no changes to criteria