

Medical Coverage Policy

| Effective Date | 12/01/2025 |
|------------------------|------------|
| Next Review Date | 9/15/2026 |
| Coverage Policy Number | 0584 |

Intraoral Prostheses

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Related Coverage Resources

Alveoloplasty
Dental Implants
Orthognathic Surgery

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide quidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

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will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy addresses intraoral prothesis including maxillary prostheses and prostheses used in mandibular resection.

Coverage Policy

Coverage for Intraoral Prostheses varies across plans. Refer to the customer's benefit plan document for coverage details.

If there are benefits available, maxillary prostheses (CPT code 21079, 21080) and prostheses used in mandibular resection (CPT code 21081, 21082) are considered medically necessary when ANY of the following criteria are met:

- in an individual with a congenital defect or developmental malformation which interferes with function
- following an accidental injury to sound natural teeth that occurs after the date of coverage within 12 months of the loss of natural teeth, or as specified in the benefit plan language.
 - > Note: Chewing injuries are not considered accidental injuries.
- loss of natural teeth due to oral cancer which interferes with function
 - > the loss of teeth must have occurred while covered under the plan and replacement must occur within 24 months of the loss of natural teeth, or as specified in the benefit plan language.
- head or neck cancer and EITHER of the following:
 - removal of a tumor
 - a cancer related episode of care that results in reconstruction.

Intraoral prostheses are considered NOT medically necessary for any other indication including but not limited to an individual who lost teeth due to non-cancer related decay or when used in conjunction with non-covered dental implants.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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General Background

A prostheses is often needed to replace missing areas of bone or tissue and restore oral functions such as swallowing, speech, and chewing. Intraoral prostheses may include:

- Interim and Definitive Obturator Covers palate after partial or total loss of maxilla or due to cleft palate. It restores teeth and gums and has an extension which closes the defect or hole for swallowing, eating, chewing, and speaking.
 - CPT codes 21079 21080 maxillary obturator prostheses: The health care provider fabricates an obturator prostheses to provide a separation between the mouth and the surgical site and/or protect the surgical site while assisting the patient's ability to talk and chew. Impressions are made of the mouth. The impressions are used to make models from which a custom obturator prostheses is fabricated. The provider makes an interim or temporary and a definitive obturator prostheses, which separates the nasal and sinus complex from the mouth.
- Palatal Augmentation (Drop) Prostheses Alters palate prosthetically for speech.
 - CPT code 21082: palatal augmentation prostheses used in a maxillary resection procedure: A palatal augmentation prosthesis is used in a maxillary resection procedure. The health care provider fabricates a prostheses used to augment the palate. Impressions are made of the maxilla and palate. The impression is fashioned into a cast model. The prostheses is fabricated from this cast.
- Mandibular Resection Prostheses Replaces the portion of the jaw that has been lost and restores gums and teeth.
 CPT code 21081 mandibular resection prostheses: The health care providers fabricate a prostheses used in a mandibular resection procedure. Impressions are made of the mandible. The impression is fashioned into a cast model, which the provider uses to construct an external prosthetic device.

Congenital Defects

Cleft lip with or without cleft palate is among the most common birth defects. The Centers for Disease Control and Prevention (CDC) estimates that in the United States:

- About 1 in every 1,050 babies is born with cleft lip with or without cleft palate.
- About 1 in every 1,600 babies is born with cleft palate alone.

In the earliest days of development in the womb, there is normally a cleft between the right and left sides of the lip and the roof of the mouth (palate). Sometime during the 6th to 11th week of pregnancy, this split comes together to form the lips and mouth. If the tissue doesn't join, it can cause a cleft lip or a cleft palate. The opening in a cleft lip can be a small slit or a large split that extends from the lip into the nose. The cleft can be on one side or both sides of the lip, or in the middle. The opening in a cleft palate may affect the front, or back, or both parts of the palate. A baby may be born with only a cleft lip or a cleft palate, but some babies are born with both. Children with a cleft lip or a cleft palate, depending on the size of the openings, may have problems eating and breathing. As they grow older, they may also have speech and language delays. Children with cleft lip or palate are also more likely to have ear infections, hearing loss, and problems with their teeth.

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Congenitally missing teeth (CMT) - Tooth agenesis is a condition in which a person is born without some of their teeth. Tooth agenesis can involve both primary (baby) and permanent (adult) teeth. But it most commonly affects permanent teeth. Tooth agenesis affects between 3% and 10% of the U.S. population. It's slightly more common in females. There are three main types of dental agenesis:

- Anodontia: The complete absence of teeth.
- Hypodontia: The absence of one to six teeth.
- Oligodontia: The absence of six or more teeth.

Ectodermal dysplasias (ED) – ED are disorders that affect the skin, sweat glands, hair, teeth, and nails. Some individuals with ED may also have cleft lip and/or palate. ED can additionally cause problems with the immune system as well as hearing and vision. More than 180 specific types of this condition have been identified. Ectodermal dysplasias occur when the outer layer of tissue (ectoderm) of the embryo does not develop normally. If two or more body structures derived from the ectoderm are affected, a person is considered to have ED. ED is a rare disease, defined in the U.S. as a condition that affects fewer than 200,000 people

Dental Trauma

Dental trauma is any injury to the teeth, gums, jawbone or soft tissues of the mouth. Accidents, such as falls, car wrecks and sports-related injuries are the main cause of traumatic dental injuries. Early treatment provides the best chance for full recovery. A significant dental injury can cause an individual to be more vulnerable to oral health issues. Possible consequences of dental trauma may include tooth loss, pain, difficulty chewing or swallowing, and speech issues.

Head and Neck Cancer (HNC)

Head and neck cancer (HNC) survival has improved in recent decades and the population of HNC survivors continues to grow. Generally, the HNC patient oral health needs are complex, requiring multidisciplinary collaboration among oncologists and dental professionals with special knowledge and training in the field of oral oncology. All treatment modalities for HNC produce oral complications, including surgery (e.g. mutilation and physiologic changes), radiation therapy (e.g. mucositis, dysphagia, hyposalivation, osteoradionecrosis), and neoadjuvant, adjuvant and/or concurrent chemotherapy (e.g. mucositis, taste changes, immune suppression). Additionally, newer targeted therapies may also result in oral mucosal complications.

Professional Societies/Organizations

The American College of Prosthodontics published Parameters of Care for the Specialty of Prosthodontics in 2020. Some of the information provided in the Parameters includes:

- Parameter Guidelines: (16) Maxillofacial prosthetics—16A: maxillary defect
 The maxilla functions as a partition between the nasal and oral cavities. Surgical resection of tumors, the tumors themselves, or other treatment may cause communication between these two cavities. Various types of obturator prostheses can function to re-establish this partition. Secondary surgical reconstruction procedures after primary tumor ablation can improve postsurgical anatomy and enhance prostheses stability and success. A prostheses can often restore the patient to normal function.
- Parameter Guidelines: (16) Maxillofacial prosthetics—16B: Mandibular defect
 Resection or loss of a portion of the mandible can result in a variety of functional deficits that are dependent on the extent of the defect (surgery, radiation, and trauma), the concomitant therapy, and the timing of rehabilitative efforts. Prostheses may be fabricated for either a maxillary, mandibular, or combination defect. Secondary surgical

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reconstruction procedures to include osseointegration reconstruction after tumor removal can improve postsurgical anatomy and thus enhance prostheses stability and success. The prostheses can guide mandibular movement and assist in restoring the functions of mastication, deglutition, and speech, as well as restoring more normal facial form.

- Parameter Guidelines: (16) Maxillofacial prosthetics—16D: Soft palate defects
 Treatment of diseases of the soft palate can create defects that are a challenge to restore.
 These tissues are dynamic in function and not easily replaced or duplicated. Pretreatment planning can be invaluable and is strongly encouraged. These prostheses attempt to restore the dynamic function of the palato-pharyngeal complex to control and direct the flow of air, fluid, and food in a normal physiological manner
- Parameter Guidelines: (16) Maxillofacial prosthetics—16E: Composite resection defect
 Composite defects by definition involve multiple facial structures, compromise multiple
 sensory systems, and frequently require multiple integrated prostheses that support,
 contact, and/or function together. Multiple defects have multiple sensory loss and loss of
 control of body fluids.
- <u>Parameter Guidelines: (16) Maxillofacial prosthetics—16F: Traumatic injury</u>
 Traumatic injury often causes unique tissue problems. The prostheses can restore form and function and reestablish partitions between contiguous cavities. The treatment of these problems, especially the more complex ones, often involves multiple surgeries to attempt reconstruction, necessitating multiple prostheses used over time.

The United Kingdom National Multidisciplinary Guidelines note in the background:

• Primary dental implants: The placement of intra-oral implants at the same time as tumour resection may be beneficial for carefully selected patients and where there is continuity of the mandible or in patients who require the prosthetic obturation of significant maxillary defects where retention of the obturator is likely to be compromised or in patients undergoing rhinectomy or orbital exenteration. In patients having segmental resection and reconstruction of the mandible, implant survival and usefulness is improved by delayed placement after suitable prosthodontic planning (Butterworth, et al., 2016).

No guidelines were found / accessible for:

- The Academy of Prosthodontics
- American Academy of Maxillofacial Prosthetics.
- American Association of Oral and Maxillofacial Surgeons. (membership required for access to their Parameters of Care)

Medicare Coverage Determinations

| | Contractor | Determination Name/Number | Revision Effective Date |
|-----|------------|---------------------------|----------------------------|
| NCD | | No determination found | |
| LCD | | No determination found | |

Note: Please review the current Medicare Policy for the most up-to-date information.

(NCD = National Coverage Determination; LCD = Local Coverage Determination)

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Coding Information

Notes:

- 1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
- 2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

| CPT®* Codes | Description |
|----------------|--|
| 21079 | Impression and custom preparation; interim obturator prosthesis |
| 21080 | Impression and custom preparation; definitive obturator prosthesis |
| 21081 | Impression and custom preparation; mandibular resection prosthesis |
| 21082 | Impression and custom preparation; palatal augmentation prosthesis |

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Revision Details

| Type of Revision | Summary of Changes | Date |
|------------------|----------------------|------------|
| Initial Review | New policy statement | 12/01/2025 |

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