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February 3, 2025

**Via: Electronic**

The Honorable CMS Administrator  
Chiquita Brooks-LaSure  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1807-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-8150

**RE: Medicare and Medicaid Programs;  
CY2025 Payment Policies Under the  
Physician Fee Schedule (MPFS) and Other  
Changes to Part B Payment and Coverage  
Policies; Medicare Shared Savings  
Program Requirements; Medicare  
Prescription Drug Inflation Rebate  
Program; and Medicare Overpayments  
(CMS 1807-P)**



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Dear Administrator Brooks-LaSure

The Maxillofacial Foundation and the American Academy of Maxillofacial Prosthetics (AAMP) appreciate this opportunity to nominate the following codes as being misvalued:

<b>CPT Code</b>	<b>Prosthesis Description</b>
21076	Impression and custom preparation; surgical obturator prosthesis
21077	Impression and custom preparation; orbital prosthesis
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
21083	Impression and custom preparation; palatal lift prosthesis
21084	Impression and custom preparation; speech aid prosthesis
21085	Impression and custom preparation; oral surgical splint
21086	Impression and custom preparation; auricular prosthesis
21087	Impression and custom preparation; nasal prosthesis

The Maxillofacial Foundation and AAMP are joined by the American College of Prosthodontists (ACP), the Head & Neck (H&N) Cancer Alliance along with Chairs of the Departments of Otolaryngology/H&N Surgery at M.D. Anderson Cancer Center (Dr. Jeff Myers), Memorial Sloan-Kettering Cancer Center (Dr. Richard J. Wong), Mayo Clinic (Dr. Eric J. Moore), University of California at San Francisco (Dr. Patrick Ha), Northwell Health (Dr. Brett A. Miles), Methodist Hospital (Dr. William Lydiatt), and Dr. Terry Day, National Medical Director of H&N Surgery, Sarah Cannon Cancer Institute who support these nominations.

The American Academy of Maxillofacial Prosthetics (AAMP) is a national organization that was chartered in 1953. Maxillofacial Prosthodontics is a subspecialty of Prosthodontics with a dedicated focus to provide rehabilitation services to patients who have suffered compromise of oral and/or facial anatomy from acquired and/or congenital defects. The Maxillofacial Foundation and the AAMP have undertaken an initiative to review the valuation of CPT codes specific to maxillofacial prosthetics to assure they are reimbursed appropriately. We have also included definitions and complete descriptions of the prostheses described in each code in Appendix A.

The recent CMS initiative to provide coverage for dental procedures that are inextricably linked to other covered medical services makes it even more important that reimbursement for medically necessary maxillofacial prosthetic services is appropriate and includes reimbursement for all the required clinical staff time, supplies, and equipment needed. Therefore, we are taking this opportunity to nominate the above listed CPT codes: 21076 through 21087, as being misvalued for direct practice expenses. For the sake of clarity, our nomination of these codes as being misvalued is limited to misevaluation of the direct practice expenses required. The current clinical staff time, supplies, and equipment included as direct practice expense inputs has many omissions and needs to be updated. For example, many supply inputs do not include pricing and many supplies and equipment are missing. The appendices to this letter include recommendations for deletion of certain supplies and equipment, addition of supplies and equipment (with pricing) and recommendations for clinical staff time. We also have included invoices for the supplies and equipment. Where supplies are purchased in bulk (e.g., a package of 10 where only one or two are used for a specific patient) we have included the price of the bulk purchase and the price for each patient use. For some equipment and supplies, we were unable to obtain paid invoices. In those situations, we have included price quotes from reputable suppliers such as Henry Schein.

We are not nominating these codes as being misvalued for physician work. We urge CMS to take this opportunity to act on our recommendations by finalizing them in the CY 2026 MPFS final rule.

## **Introduction / Background**

Maxillofacial prostheses are medically necessary and are the accepted treatment for patients with head and neck cancer who have their palate, alveolar ridge, maxilla, mandible, and/or facial bones resected. Patients with congenital conditions such as cleft palate, cleft lip, and craniofacial syndromes may also require maxillofacial prosthetic rehabilitation.

Maxillofacial Prosthodontists (MFP) have completed extensive and highly specialized training with a dedicated focus to offer rehabilitation services to patients who have incurred compromise of the oral and/or facial anatomy that results from treatment such as tumor ablation surgery for head and neck cancer, trauma, craniofacial anomalies and congenital defects as well as other medical conditions. These conditions grossly affect facial appearance, and the bodily functions of speaking, swallowing, and chewing. They also adversely affect a patient's self-image and psychological health. Several studies evaluating the quality of life of head and neck cancer patients found that patients experience high levels of emotional distress, disturbed body image, physical limitations, and impaired social relationships. For example, swallowing and speech are severely affected by radiation-induced xerostomia.<sup>1,2</sup> The use of custom prosthetics to allow these cancer patients to speak, swallow, and chew is medically necessary care. For patients that lose part of the palate, an obturator prosthesis is life changing. It allows a patient to be able to eat, speak, and swallow by mouth without the use of a feeding tube. Maxillary obturators are used for defects of the hard palate, pharyngeal obturators are used for defects of the soft palate, and a combination of maxillary and pharyngeal obturators are used when both the maxilla and pharynx are involved.<sup>1,3</sup> All of the intraoral prostheses involving the maxillary

pharyngeal complex restore speech and swallowing first, followed by masticatory function.

The use of dental implants to retain obturators (e.g., so they don't move and lose function) for large defects is the accepted treatment at most medical/cancer centers. The use of dental implants to retain an obturator is not an "aesthetic or dental" issue; rather, they are used to restore oral and masticatory function.<sup>1,3,4</sup>

Oral rehabilitation is the accepted treatment for head and neck cancer patients and is a major contributor to improvement of the quality of life of head and neck cancer patients. CPT Codes 21076-21088 are covered services, and they are inextricably linked to other covered services (i.e., resection of tumors of the head and neck).

Here are some examples:

For obturator patients (CPT Code 21080), the use of dental implants to retain obturators for large defects is the accepted treatment at most cancer centers.

For patients that lose a portion of the maxilla or mandible due to surgical reconstruction, a resection prosthesis (CPT Code 21081) improves speech outcomes better than just standard surgical reconstruction or maxillary obturators.<sup>3,5</sup> For both maxillary and mandibular surgical reconstruction with implant supported prostheses, better functional outcomes are obtained with respect to mastication, speech, and swallowing.<sup>3,4,5</sup>

A palatal augmentation prosthesis (CPT Code 21082) which lowers the palatal vault to make contact with the resected/reconstructed tongue improves the palatolingual contact during articulation and swallowing. This improves swallowing by enhancing the oral to pharynx bolus transportation and basal tongue pressure.<sup>3,6,7</sup>

A palatal lift prosthesis (CPT Code 21083) used for palatopharyngeal incompetency improves patient's speech by reducing hypernasal speech and the reflux caused by velopharyngeal incompetency. It enhances swallowing function by eliminating functional blockage at the oropharyngeal isthmus, facilitating food bolus transport from the oral cavity to the pharynx.<sup>1,8</sup>

A speech aid prosthesis (CPT Code 21084) contributes to intelligible speech.<sup>1,8</sup> For all of the facial prostheses (CPT Codes 21077, 21086, 21087), the prostheses decrease mental pain and help patients in the adjustment to the loss of their face and allows them to return to society with their dignity intact.<sup>1,3,9</sup> Facial prostheses (nasal and some orbital) protect exposed sinus cavities and contribute to normalizing the voice by replacing absent anatomy with a prosthetic substitute after traumatic injury or cancer resection surgery. Nasal prostheses support eyeglasses. In addition to restoring facial symmetry auricular prostheses support eyeglasses, hearing devices, and when the meatus is intact, provides some acoustic gain.

### **Maxillofacial Prosthetic Services are Undervalued**

Maxillofacial Prosthodontists are very concerned with the continuing inadequate reimbursement for maxillofacial prosthetic services. In 1995, the AAMP and the American Association of Oral and Maxillofacial Surgeons (AAOMS) made recommendations to CMS who developed national pricing for these codes effective in CY 1996. This pricing included physician work Relative Value Units (RVUs), practice expense (PE) RVUs, and malpractice RVUs that were implemented in CY 1996 and published

in the Federal Register (60 FR 63124 December 8, 1995). The methodology CMS used to establish PE RVUs was deeply flawed. CMS stated the following in the Federal Register (Vol.60, No. 236, December 8, 1995, P 63151): “Therefore, we imputed the practice expense and malpractice expense RVUs from the work RVUs based on the practice cost shares provided by the AAOMS. Those shares are 54.7% for practice expense and 4.4% for malpractice expense. Comments in response to this proposal for practice expense RVUs were unanimous in objecting to the proposed methodology. The comments stated that the practice expense and malpractice shares for the subspecialty of maxillofacial prosthetics differed substantially from those of maxillofacial surgery. This was primarily due to the amount of clinical staff time, and expensive materials and supplies used in fabricating the prostheses. Those commenting unanimously agreed that the practice expense RVUs were too low.”

However, CMS finalized its proposal without change, in spite of the comments, because it believed that in the absence of charge data, the maxillofacial surgery shares were the best available information upon which to base payment. CMS also said it was “working on a resource-based practice expense study and, as part of this effort, hope to have more definitive data in the future. At that time, we will reevaluate all maxillofacial practice expense RVUs.” Such a reevaluation was never done.

These maxillofacial prosthesis codes were created 30 years ago and the practice expenses have not been reviewed since that time. The majority of the head and neck cancer patients treated are over 65 years of age and covered by Medicare. Therefore, it is necessary that Medicare establish appropriate reimbursement for these services. Due to increasing financial pressures, many clinics are not taking on new maxillofacial prosthetic patients, and are phasing out those services, thereby impairing access for patients requiring this medically necessary care.

We also note that, for physician work, CMS adopted the recommendations of the AAMP and we are not nominating these codes as misvalued for physician work at this time – we are only nominating them for misvaluation of the practice expenses.

The PE RVUs are grossly undervalued because they do not include the current state-of-art technology and materials routinely used to fabricate standard-of-care prostheses, as described below and in much greater detail in Appendices B-L. Lastly, we note that the volume of these procedures is so low that increasing the PE RVUs for these codes will almost certainly not have any appreciable effect on the PE RVUs for other MPFS services (i.e., any budget neutrality adjustment will not result in change to PE RVUS for other services). We are submitting representative invoices for supplies and equipment for the nominated codes.

### **Practice Expense Discussion**

Perhaps the codes that have undergone the greatest transformation are CPT Codes 21080 (fabrication of an obturator prosthesis) and 21081 (fabrication of a mandibular resection prosthesis). When the PE values were developed for these codes, surgical reconstruction of the mandible was in its infancy. Most mandibular cancers were not surgically reconstructed; specifically, the cancer was resected and the mandible allowed to swing. In other words, the mandibular continuity was disrupted. At that time, a removable prosthesis was used to guide the mandible into proper alignment with the maxilla. With the advent of microvascular reconstruction with free flaps in the late 1980's, surgical reconstruction became the norm. Initially, prosthodontic rehabilitation in the oncological treatment pathway was the final procedure after oncologic therapy.<sup>1,3</sup> However, with the development of virtual surgical planning, surgical resection, reconstruction, maxillofacial prosthetic rehabilitation can be executed precisely in one surgery.<sup>1,3</sup> Virtual surgical planning maximizes intraoral rehabilitation and significantly improves oral function, oral diet, and oral health quality of life.<sup>1,3</sup>

Virtual surgical planning also is used for maxillary reconstruction. Today, a resection prosthesis can be fabricated for either the maxilla or mandible. Just as virtual surgical planning improves oral rehabilitation for mandibular defects, virtual surgical planning improves oral rehabilitation for maxillary defects, since speech outcomes are better than just standard surgical reconstruction or maxillary obturators.<sup>1,3</sup> For combined maxillary and mandibular defects, surgical reconstruction with implant supported prostheses yield better functional outcomes with respect to mastication, speech, and swallowing.<sup>1,3</sup> Yet, the PE inputs associated with the accepted treatment protocols of today, for CPT Codes 21080 and 21081 were not factored into the PE RVU – in large part because they did not exist in 1995.

The most time consuming extraoral prosthesis to fabricate is an orbital prosthesis (CPT Code 21077) with respect to staff work because setting the gaze of the eye has to be done by the doctor with the patient present and most of the sculpting has to be done by hand with the patient present. There is limited, to no, use of 3D technology in the waxing process. Today, most orbital prosthetic globes are hand painted which requires additional time. On the other hand, an auricular prosthesis (CPT Code 21086) can use 3D technology to aid with waxing. For a nasal prosthesis (CPT Code 21087), preoperative scanning aids in creating a prosthesis that is shaped similarly to the patient's resected nose. This is extremely important to patients, as the nose is a very important part of their facial appearance.

For all extraoral prostheses (CPT Code 21077, Orbital Prosthesis, CPT Code 21086, Auricular Prosthesis, CPT Code 21087 Nasal Prosthesis), the use of craniofacial implants to retain the prostheses was not the standard of care in the early 1990s. Today, they are routinely used for maxillofacial rehabilitation. In addition, the use of color measurement devices to aid in achieving the correct skin color was not yet developed. Today, they are widely accepted and used. All of this new technology requires additional equipment and supplies which were not factored into the original PE values.

## **Summary**

In summary, utilization of maxillofacial prosthodontics is an essential service for patients who are unable to speak or swallow due to their medical condition or post-surgical resection of head and neck tumors. Use of these prostheses is both the standard of care that enables patients to speak and swallow normally and medically necessary procedures. These maxillofacial services enable head and neck cancer patients to lead normal lives and be able to perform activities of daily living. Without making our recommended revisions, head and neck cancer patients may not have access to these essential medical care procedures because it is not financially feasible for maxillofacial prosthodontists to perform these procedures.

## **Recommendations**

The AAMP and The Maxillofacial Foundation along with our supporting associations nominate CPT codes 21076-21087 as being misvalued due to missing and incorrect equipment and supply practice expense inputs. These missing and incorrect supplies and equipment are detailed in Appendices B-L to this letter. We request that CMS agree that these codes are misvalued and make our recommended changes to the PE inputs in the MPFS proposed rule for CY 2026.

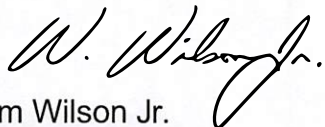
Thank you for the opportunity to submit these nominations. We stand ready to work with CMS and will respond to any questions or requests for further information.

Sincerely,



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President of the Maxillofacial Foundation

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