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September 17, 2021

**SUBMITTED VIA ELECTRONIC MAILING**

Ms. Chiquita Brooks-Lasure

Administrator

Centers for Medicare &amp; Medicaid Services

Department of Health and Human Services

Attention: CMS-1753-P

P.O. Box 8016

Baltimore, MD 21244-8013

[Submitted online at: <https://www.regulations.gov>]**Re: CMS 1753-P Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals**

Dear Administrator Brooks-Lasure:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS),<sup>1</sup> I am pleased to submit the following comments on the “Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals” published in the Federal Register on August 4, 2021. Our comments will address the following issues within the proposed rule: 1) the inpatient only list; 2) the ambulatory surgical center covered procedure list; 3) balloon sinus dilation ASC payments; 4) HCPCS Code 42XXX; 5) comprehensive ambulatory payment classifications; 6) HCPCS Code J7402; and 7) the 2 times rule.

**1. Changes to the Inpatient Only (IPO) List**

In the notice of proposed rulemaking (NPRM), CMS proposes reversing the elimination of the IPO list that was included in the CY 2021 HOPPS final rule and restoring the 298 services that were removed from the list in CY 2021.

<sup>1</sup> The AAO-HNS is the nation’s largest medical organization representing specialists who treat the ear, nose, throat, and related structure of the head and neck. The Academy represents approximately 10,000 otolaryngologist-head and neck surgeons practicing in the United States who diagnose and treat disorders of those areas.

Physicians should generally be permitted to decide the best site of service for Medicare beneficiaries, however there are certain procedures that can only be safely performed within an inpatient setting.

**Therefore, the AAO-HNS supports CMS' proposal to reinstate the IPO list, but strongly urges CMS to consider the removal of procedures from the list on an individual basis.**

Prior to CY 2021, there were over 1,700 procedures on the IPO list, of which 125 are predominantly performed by otolaryngologist-head and neck surgeons. When the IPO list was eliminated, the AAO-HNS stated concerns about patients with head and neck cancer and skull base tumors, who often have significant comorbidities even in earlier stages of disease, being forced to undergo major resections and reconstructions without adequate staff and resource support typically available in the inpatient setting.

For CY 2022, the Agency is proposing to restore the procedures that were removed from the IPO list in CY 2021, which includes procedures commonly performed by otolaryngologist-head and neck surgeons. The AAO-HNS recommends that all procedures that can only be safely performed in an inpatient setting remain on the IPO list. However, **there are certain procedures performed by otolaryngologist-head and neck surgeons that can safely be performed in multiple sites of service, and therefore should not be restored to the IPO list. The AAO-HNS requests that CMS not add the following CPT codes to the reinstated IPO list:** 21141, 21188, 21194, 21196, 21255, 21343, 21344, 21347, 21348, 21366, 21422, 21423, and 21436.

## **2. Ambulatory Surgical Center (ASC) Covered Procedure List**

In the proposed rule, CMS seeks to reverse the changes to the safety criteria for the ASC covered procedure list included in the CY 2021 HOPPS/ASC final rule. As a result of the proposal, 258 of the 267 procedures placed on the list last year would be removed. The Agency is seeking comment on whether any of these 258 procedures should remain on the ASC covered list. **The AAO-HNS believes the following CPT codes describe procedures safely performed in the ASC setting and therefore requests that these codes remain on the ASC covered procedure list:** 21049, 21193, 21195, 21346, 21385, 21386, 21387, 21395, 21408, 31292, 31294, 60260, 60502, 60512, and 69660.

CPT codes 35201, 35231, and 35261, also describe procedures that are performed by otolaryngologist-head and neck surgeons that should remain on the ASC covered procedure list because there are unique circumstances in which they may be performed within an ASC setting. **We therefore request that CPT codes 35201, 35231, and 35261 remain on the ASC covered procedure list.**

Under the NPRM, the Agency proposes to allow external parties, including medical specialty societies, to nominate additional codes to the ASC covered procedure list. **The AAO-HNS supports this proposal and thanks CMS for the opportunity to nominate select codes for the ASC covered procedure list.**

## **3. Balloon Sinus Dilation ASC Payments**

For CY 2022, CMS proposes the following ASC payment rates for a family of balloon sinus dilation codes, which are commonly performed by otolaryngologist-head and neck surgeons: \$1,406.87 for CPT code 31295, \$1,417.28 for CPT code 31296, and \$1,402.50 for CPT code 31297. Medicare considers these services to be office-based procedures, as they are performed in physicians' offices at least 50% of the time. As such, in the ASC setting, each code is paid at the lesser of either the ASC rate or the non-facility practice expense (PE) relative value unit (RVU) amount of the Medicare Physician Fee Schedule (PFS). These proposed ASC payment rates, if finalized, would result in a reduction of greater than 20%

compared to the CY 2021 reimbursement amount. **As a result of the proposed unsustainable ASC reimbursement for CY 2022, physicians performing these procedures may be forced to instead perform them in the hospital outpatient department, where payment for the service captures the full cost of the supplies and equipment, at a higher overall cost to the Medicare program.** This could lead to unnecessary site of service discrepancies, potentially greater cost, and access to care problems for Medicare beneficiaries.

#### 4. HCPCS Code 42XXX

In the NPRM, the Agency proposes that CPT code 42XXX (*Drug-induced sleep endoscopy, with dynamic evaluation of velum, pharynx, tongue base, and larynx for evaluation of sleep-disordered breathing, flexible, diagnostic*) be assigned a payment indicator of R2, signifying that this procedure would be predominantly performed in the physician office. CMS bases this assignment on the premise that this new CPT code is similar to CPT code 31505 (*laryngoscopy, indirect; diagnostic (separate procedure)*). **This recommendation is not appropriate as 42XXX is not an office-based procedure.** In creation of the new code by the CPT Editorial Panel and subsequent valuation by the RUC, 42XXX was only established and valued in the facility setting. Additionally, this procedure is always performed on a patient with known obstructive sleep apnea and requires, by definition, systemic anesthesia which results in potential severe airway obstruction. In contrast, CPT code 31505 is performed safely in an office setting on a patient without known obstructive sleep apnea.

In establishing the correct payment indicator for new CPT code 42XXX, **a more suitable proxy would be CPT code 31546** (*Laryngoscopy, direct, operative, with operating microscope or telescope, with submucosal removal of nonneoplastic lesion(s) of vocal cord; reconstruction with graft(s) (includes obtaining autograft)*). This procedure, commonly performed by our specialty, cannot be performed in the office, as indicated by the fact that Medicare has not valued this site of service.

**Therefore, the AAO-HNS strongly opposes the designation of 42XXX as temporarily office-based and instead recommends that the Agency assign payment indicator G2: “Non-office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight.”**

#### 5. Comprehensive Ambulatory Payment Classification (C-APC)

Under the NPRM, CMS is proposing to recalibrate the APC relative payment weights for services furnished during CY 2022 with existing methodology using CY 2019 claims data. 2019 data is selected in lieu of 2020 data because the CY 2020 claims data includes services furnished during the COVID-19 public health emergency (PHE), which significantly affected outpatient service utilization. **The AAO-HNS appreciates CMS’ dedication to use claims data from 2019 to uphold the integrity of the APC analysis due to the PHE.**

The proposed methodology includes recalibrating the relative payment weights for each APC based on the claims and cost report data for hospital outpatient department services to construct a database for calculating the APC group weights. Under the NPRM, the following changes are proposed to the APC levels.

**a. C-APC 5163 (Level 3 ENT Procedures)**

Under the NPRM, CPT Code 0583T (*Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia*) is assigned to C-APC 5163, with a payment rate of \$1,387.72. **The AAO-HNS supports this proposed addition.**

**b. C-APC 5164 (Level 4 ENT Procedures)**

CMS established HCPCS code C9771 (*Nasal/sinus endoscopy, cryoblation nasal tissue(s) and/or nerve(s), unilateral or bilateral*) effective January 1, 2021. For CY 2022, the Agency proposes to assign C9771 to C-APC 5164 with a status indicator of J1 and an OPPS payment level of \$2,806.94 for CY 2022. As stated in our comments on the CY 2021 HOPPS/ASC proposed rule, the AAO-HNS does not believe the assignment of this service to C-APC 5164 is reflective of the costs outpatient hospital departments incur in performing this bilateral, device-intensive ENT procedure. **We remain concerned that CMS's proposed CY 2022 APC assignment and device offset amount do not accurately reflect the resources associated with performing this procedure.**

HCPCS code C9771 is comparable, with respect to equipment, clinical labor, and supplies, to other bilateral, device-intensive nasal procedures assigned to C-APC 5165, Level 5 ENT Procedures. While Medicare claims data for C9771 are not yet available, independent claims analysis demonstrates that the average charge for the procedure is greater than \$4,500, a level more consistent to the mean reimbursement of C-APC 5165. **The AAO-HNS recommends that CMS reassign C9771 to C-APC 5165 and revise the device offset to \$1,617.63, the default device offset for C-APC 5165.** These revisions would better align Medicare payment with the true procedure resources and help ensure Medicare beneficiaries have access to this innovative treatment for chronic rhinitis.

**c. C-APC 5165 (Level 5 ENT Procedures)**

In the proposed rule, the agency proposes to reassign CPT code 69705 (*Nasopharyngoscopy, surgical, with dilation of eustachian tube (ie, balloon dilation); unilateral*) from C-APC 5164 to C-APC 5165, with a payment rate of \$5,218.17. **The AAO-HNS supports this reassignment and urges the agency to finalize this placement for CY 2022.**

Finally, the following CPT codes are commonly performed by otolaryngologist-head and neck surgeons and are proposed to be removed from C-APC 5165 under the NPRM: 21141, 21188, 21194, 21196, 21255, 21366, 21422, and 21423. **The AAO-HNS opposes this proposal and requests that CMS not remove these CPT codes from C-APC 5165.** These codes represent procedures that should only be performed in an inpatient setting and should therefore maintain a C-APC 5165 assignment.

**6. New HCPCS Code J7402**

In CY 2021, CMS created a new HCPCS code, J7402, to describe the SINUVA® (mometasone furoate) Sinus Implant. In the NPRM, the agency proposes transitional pass-through payment J7402 in the HOPPS and ASC settings effective for three years. **The AAO-HNS supports the proposed pass-through payment for J7402 under the CY 2022 NPRM while claims data is collected, in order to determine appropriate long-term assignment of this code.**

## 7. 2 Times Rule

CMS is proposing to place level 1 ENT procedures (C-APC 5161) on the exceptions list for the 2 times rule. The 2 times rule states that items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or services within the same group.

Level 1 ENT procedures, along with other APCs, were found to be in violation of the rule. However, the Secretary reserves the authority to grant exceptions if specific criteria are met. The agency has determined that C-APC 5161 meets these criteria. However, given the current construct of codes included in C-APC 5161, **the AAO-HNS opposes placing C-APC 5161 on the exceptions list for the 2 times rule.**

## 8. Conclusion

The American Academy of Otolaryngology—Head and Neck Surgery appreciates the opportunity to provide comment and recommendations regarding these important policies on behalf of our members. We look forward to working with CMS as it continues its efforts to promote innovation and improve patient access to quality care. If you have any questions or require further information, please contact [healthpolicy@entnet.org](mailto:healthpolicy@entnet.org).

Respectfully Submitted,



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Executive Vice President and Chief Executive Officer