AMERICAN ACADEMY OF
OTOLARYNGOLOGY-
HEAD AND NECK SURGERY®

October 5, 2020

SUBMITTED VIA ELECTRONIC MAILING

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1717-P
P.O. Box 8016
Baltimore, MD 21244-8013

[Submitted online at: https://www.regulations.gov]

Re: CMS 1736-P Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals

Dear Administrator Verma:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS),[1] 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; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-Owned Hospitals" published in the Federal Register on August 12, 2020. Our comments will address the following issues within the proposed rule: 1) Proposed Payment for New CPT Codes 697XX and 697X1 2) July 2020 HCPCS Codes 3) Inpatient Only List 3) Ambulatory Surgical Center Covered Procedure List 4) Prior Authorization 5) Proposed OPPS APC-Specific Policies.

A. Proposed Payment for New CPT Codes 697XX and 697X1

[1] 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.

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Effective for CY 2021, Medicare will recognize two new CPT codes 697XX and 697X1 for eustachian tube balloon dilation (ETBD) for unilateral and bilateral procedures, respectively. Historically, ETBD procedures performed in a facility setting used one HCPCS code, C9745, which did not differentiate between unilateral or bilateral procedures, and mapped to one APC 5165. However, with the two newly established CPT codes, CPT 697XX now maps to APC 5164 (unilateral) and CPT 697X1 remains in APC 5165 (bilateral). Both codes have been assigned a status indicator of J1 and ASC payment indicator of J8.

The new APC assignment for CPT 697XX (unilateral) does not account for the fact that each procedure (regardless of unilateral or bilateral) requires the use of one full balloon kit with a total supply value of $2,180.00. The kit is the most expensive component of the procedure and CMS' proposed reduced payment for the unilateral procedure fails to account for this fact. The AAO-HNS has concerns that CMS' failure to account for the cost of the kit may negatively impact patient access to the unilateral procedure (particularly in ASCs). In fact, in the CY 2021 Physician Fee Schedule proposed rule, CMS assigns a very similar non-facility payment rate for CPT 697XX and CPT 697X1; $3,092.81 and $3,183.14, respectively. This similar valuation is based on the practice expense RVUs for both procedures which assume the full cost of the kit. This practice expense reflects the RUC recommendation for both codes which CMS proposes to accept and the AAO-HNS supports. **As such, we recommend that both procedure codes (CPT codes 697XX and 697X1) remain in the original APC 5165, as the clinical similarities and cost to the facility for unilateral and bilateral procedures are comparable.**

In the event CMS does not accept this recommendation, the AAO-HNS urges the agency to reconsider the calculation of the device-intensive pass-through for ASC payments for APC 5164. In order to fully reflect the costs of the kit for unilateral procedures in an ASC, CMS should pass-through the same dollar amount as calculated for APC 5165. Otherwise, the ASC payment will be further deflated below the actual cost of the kit.

B. New HCPCS Codes Effective July 1, 2020

For CY 2021, CMS is soliciting comments on the proposed APC and status indicator assignments for the HCPCS codes implemented on July 1, 2020, all of which are listed in Table 7 of the proposed rule. The AAO-HNS thanks CMS for assigning a C-code to describe the SINUVA® (mometasone furoate) Sinus Implant, thereby allowing transitional pass-through payment status for reimbursement under the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgery Center (ASC) payment systems for three years. **We support the assignment of the new code, C9122, Mometasone furoate sinus implant, 10 micrograms (Sinuva), to APC 9346 as well as its proposed reimbursement for 2021.**

C. Changes to the Inpatient Only (IPO) List

CMS proposes to commence a transition of all services off of the IPO, beginning in CY 2021 with all musculoskeletal procedures. The current IPO list has been in existence since 2000 and has served both patients and providers well. The AAO-HNS is concerned that the complete elimination of the IPO could result in unintended consequences that jeopardize patient safety. As this country moves toward value-based care, there will be intense pressure to lower costs above all other considerations. Even though the CMS proposal would not prohibit physicians from

selecting the inpatient setting to perform the procedure, there is a distinct possibility that the private payers in the United States will try to force physicians to move patients out of the inpatient setting, even when it places patient safety at risk.

There are currently over 1,700 procedures on the IPO list, of which, 125 are predominantly performed by otolaryngologists. The AAO-HNS is pleased that CMS is proposing to allow physicians to perform these procedures in the setting that they determine most appropriate for the patient. **We agree that physicians should be permitted to decide the best site of service for each individual patient. The current process for removal of procedures from the IPO has worked well and we would encourage CMS to continue with the process in place.** The AAO-HNS is particularly concerned 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.

At a minimum, it would likely lead to a significant increase in administrative burden for physicians and their staffs if the patient's best interest requires inpatient care. These cases would likely be subject to inconsistent review across the private payer spectrum, leading to inconsistent care for the patient population. If CMS moves forward with this proposal, we request a five-year transition period that would allow adequate data collection on clinical results, patient safety and pricing.

D. Ambulatory Surgical Center Covered Procedure List

For CY 2021, CMS is proposing to add eleven procedures to the ASC covered procedure list (ASC-CPL.) **The AAO-HNS is pleased that CPT code 21365 is among the codes being added to this list, as we believe this procedure commonly performed by our members can be done safely in the ASC setting. The AAO-HNS supports the addition of the proposed eleven new procedures to the ASC-CPL for 2021.** We appreciate that CMS is working to build on its efforts to maximize patient and physician choice and access to care by exploring broader approaches to adding procedures to the ASC–CPL. If correctly implemented, these changes will further increase the availability of ASCs as an alternative site of care for Medicare beneficiaries, often at a lower cost than other options.

CMS is also soliciting comments on two alternate proposals which address new ways to add procedures to the ASC covered procedure list**.** One proposal would allow medical specialty societies, and other stakeholders, to nominate procedures to be added to the ASC-CPL. We appreciate that CMS is seeking various options that would allow physicians more autonomy in shared decision-making. The AAO-HNS supports the section in the first alternate proposal that calls for nominations of procedures from specialty societies and other stakeholders. However, we have concerns that eliminating the five criteria in 42 CFR 416(c)(1) through in 42 CFR 416(c)(5) would allow procedures that can only be safely be performed in a hospital to be performed in an ASC. The requirements listed in the CFR are primarily for the safety of the patient. Both alternative proposals would remove the five criteria in the CFR. **Therefore, while the AAO-HNS supports the nomination process for new codes, the AAO-HNS opposes the two**

alternate proposals as the elimination of the five criteria could create unintended patient safety consequences.

E. Prior Authorization

Through comments filed in recent rulemaking as well as in multiple meetings with the agency, the AAO-HNS has opposed any application of prior authorization processes in the Medicare program, including the hospital outpatient department. The prior authorization process for certain HOPD services implemented on July 1, 2020 is burdensome and costly to physician practices. This new program requires physicians and their staff to spend a significant amount of time each week negotiating with Medicare Administrative Contractors. As a result, patients are now experiencing barriers to medically necessary otolaryngology procedures such as rhinoplasty (for nasal airway obstruction), blepharoplasty (for obstructive vision loss), and botulinum toxin injections (for facial spasms), even for treatments and tests that are eventually routinely approved.

For CY 2021, CMS is proposing to add two new categories to the list of services that require prior authorization in the hospital outpatient department - cervical fusion with disc removal and implanted spinal neurostimulators. **Although the AAO-HNS is pleased that CMS is not proposing to include any additional procedures performed by otolaryngologist-head and neck surgeons to the list of services requiring prior authorization, we reiterate our strong opposition to all efforts by CMS to either continue existing prior authorization requirements or add new procedures to the prior authorization list. CMS's timeframe to complete prior authorization reviews is also of concern. CMS issues decisions within 10 business days and this timeframe, unless an urgent request is made, potentially endangers patient safety and should be reduced.**

F. Proposed OPPS APC-Specific Policies

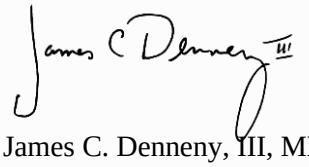
In reviewing the claims data available for CY 2021, CMS proposes to create an additional Neurostimulator and Related Procedures APC level to allow for a more even distribution of the costs between the different levels, based on their resource usage and clinical characteristics. CMS is proposing to establish a five-level APC structure for the Neurostimulator and Related Procedures series. Historically, the hypoglossal nerve stimulation procedure (utilizing the Inspire Upper Airway Stimulation system), reported using CPT codes 64568 and 0466T, had been placed in the Level 4 Neurostimulator and Related Procedures APC 5464. CMS is proposing to move this procedure to the new Level 5 APC. **The AAO-HNS supports the APC assignment of 5465 for CPT codes 64568 and 0466T. This assignment provides appropriate reimbursement which will allow otolaryngologist sleep surgeons to continue to provide this procedure in the hospital outpatient setting.**

As noted in our comments filed on the CY 2021 Medicare Physician Fee Schedule proposed rule and in multiple meetings with the agency, the AAO-HNS is proposing new category I CPT codes to replace CPT code 0466T. These new codes will more accurately describe the procedure and work performed by our members in implanting hypoglossal nerve stimulators. Should AMA grant these new category 1 codes, the AAO-HNS recommends that these new CPT codes likewise be assigned to APC 5465.

G. 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.

Respectfully Submitted,



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