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SUBMITTED VIA ELECTRONIC MAILING

Ms. Seema Verma

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1736-FC

P.O. Box 8016

Baltimore, MD 21244-8013

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

Re: CMS 1736-FC, 1736 IFC 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; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHSs) to Report COVID-19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)

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; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals

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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and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHSs) to Report COVID-19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)” published in the Federal Register December 29, 2020. The AAO-HNS appreciates the opportunity to submit comments on the CY 2021 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems final rule with comment period. Our comments will address the payment classifications assigned to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes.

I. APC Assignment and Payment for HCPCS code C9771

In the final rule, CMS is soliciting stakeholder feedback on the 2021 APC placement for new HCPCS code, C9771. CMS created HCPCS code C9771 (*Nasal/sinus endoscopy, cryoablation nasal tissue(s) and/or nerve(s), unilateral or bilateral*), utilizing the ClariFix device, to describe a procedure performed by our specialty. CMS assigned HCPCS code C9771 to clinical APC 5164 (Level 4 ENT Procedures). The AAO-HNS is concerned that CMS’s interim CY 2021 APC assignment for C9771 does not adequately recognize the costs associated with this bilateral ENT procedure. **The AAO-HNS disagrees with this APC assignment and recommends a more appropriate assignment for C9771, based on clinical resource comparability to other otolaryngology-head and neck surgery procedures, is APC 5165 (Level 5 ENT Procedures).**

For CY 2021, CMS has assigned C9771 on an interim basis to C-APC 5164 with a status indicator of J1 and an OPPS payment level of \$2,736.39. The facility resources required for to perform C9771 – including equipment, clinical labor, and supplies, are similar to those used for other types of bilateral, device-intensive nasal and ear procedures that are assigned to C-APC 5165, Level 5 ENT Procedures. The AAO-HNS believes that the ClariFix procedure as described by new HCPCS code C9771 is comparable to CPT code 30468 (*Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)*) and its predecessor code C9749 (*Repair of nasal vestibular lateral wall stenosis with implant(s)*) as well as CPT code 69706 (*Nasopharyngoscopy, surgical, with dilation of the eustachian tube (ie, balloon dilation); bilateral*). Both CPT code 30468 and CPT 69706 are assigned to APC 5165 (Level 5 ENT Procedures).

We agree with CMS that C9771 is a device-intensive procedure, however, the interim device offset amount of \$849.28 does not accurately represent facility costs. We have received pricing input on the device needed to perform the above-named procedure. Due to the confidential and proprietary nature of the information involved, specific invoices supplied to the AAO-HNS can be made available to CMS staff upon request.

Multiple invoices submitted with the New Technology APC application, supported by the AAO-HNS in August 2020, confirmed that the cost of the ClariFix device for a bilateral case is \$1,895. Based on this input, the reimbursement amount does not sufficiently cover the cost associated with this procedure. The invoices indicate that the cost of the C9771 ClariFix system is approximately \$1,895, which alone exceeds the interim ASC payment level of \$1,414.65. Applying the 31% default offset to the APC 5165 payment level would instead result in a device cost of about \$1,577, which more closely approximates invoice costs. The AAO-HNS has concerns that the current payment level, which is significantly below the cost of the device, will result in substantial difficulty scheduling this procedure for the appropriately selected patients and lead to decreased access to care for Medicare patients.

Based on the comparability of C9771 to CPT code 30468 and 69706 based on clinical and resource similarity, which are assigned to APC 5165 (Level 5 ENT Procedures), the AAO-HNS believes that APC 5165 is more appropriate for C9771. **We are requesting that CMS reassign C9771 to APC 5165 for CY 2021 effective January 1.**

A similar APC-assignment first occurred with HCPCS code C9749, which was the predecessor code to 30498. CMS first assigned C9749 to APC 5164 (Level 4 ENT Procedures). However, in the 2019 OPPS/ASC final rule, CMS reassigned C9749 to APC 5165, stating the following:

“[B]ased on further assessment on the nature of the procedure, and input from public commenters and our clinical advisors, we believe that HCPCS code C9749 should be reassigned to APC 5165 (Level 5 ENT Procedures) to more appropriately reflect the resource costs and clinical characteristics associated with the Latera implant procedure. Therefore, after consideration of the public comment we received, we are finalizing our proposal, without modification, to assign the procedure described by HCPCS code C9749 from APC 5164 to APC 5165.”

The AAO-HNS believes that a parallel situation has occurred with C9771 and requests that the HCPCS code be reassigned to APC 5165 (Level 5 ENT Procedures).

II. Proposed Payments for CPT Codes 69705 and 69706

Effective for CY 2021, Medicare will recognize two new CPT codes 69705 and 69706 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, in the CY 2021 OPPS proposed rule, the two newly established CPT codes mapped to different APCs, with CPT 69705 mapping to APC 5164 (unilateral) and CPT 69706 remaining in APC 5165 (bilateral). Both codes were assigned a status indicator of J1 and ASC payment indicator of J8.

In comments filed on the NPRM, the AAO-HNS stated our concerns with CMS' failure to account for the cost of the kit may negatively impact patient access to the unilateral procedure (particularly in ASCs). The proposed 2021 APC assignment for CPT 69705 (unilateral) did 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 failed to account for this fact.

In the final rule, CMS revised the APC placement of CPT code 69705, placing it in APC 5165. The AAO-HNS thanks CMS for heeding concerns stated in our proposed rule comments. **The AAO-HNS appreciates the assignment of CPT code 69705 to APC 5165 for 2021. We believe this new classification more accurately reflects the clinical complexity of the procedure, as well as the associated costs incurred by hospitals and ambulatory surgery centers.**

Thank you in advance for your consideration of this request. If you have any questions or require further information, please contact healthpolicy@entnet.org or 703-535-3725.

Sincerely,



James C. Denny, III, MD, FACS
Executive Vice President and Chief Executive Officer