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September 24, 2018

SUBMITTED VIA ELECTRONIC MAILING

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8016
Baltimore, MD 21244-8013

[Submitted online at: <https://www.regulations.gov/document?D=CMS-2018-0076-0621>]

Re: CMS-1695-P Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model

Dear Administrator Verma:

On behalf of the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS), I am pleased to submit the following comments on the “Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for a Potential CMS Innovation Center Model” published in the Federal Register on July 31, 2018. Our comments will address the following issues within the proposed rule: 1) removal of CPT Code 31241 from the Inpatient Only (IPO) list, 2) site of service parity adjustments, and 3) creation of a new level III comprehensive APC (C-APC) for ENT.

I. Removal of CPT Code 31241 from IPO List

For CY 2019, CMS is proposing to remove the procedure described by CPT Code 31241 *Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery* from the IPO list. **The AAO-HNS fully supports the removal of this code from the IPO list, as well as the assignment of the procedure described by CPT Code 31241 to C-APC 5153 (Level III Airway Endoscopy) with a status indicator of “J1.” The AAO-HNS appreciates the agency’s willingness to listen to input from the Academy and other stakeholders regarding the**

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safety and efficacy of this procedure when performed in the outpatient setting. In removing this code from the IPO list, CMS rightly defers the decision of what constitutes the most appropriate site of service for each individual patient to the physician and the patient through a shared decision-making process. The otolaryngology community already utilizes well-defined criteria to guide the selection of the appropriate site of service based on the procedure and individual considerations unique to each patient. We strongly support that the determination of how to best provide adequate and timely care to a Medicare beneficiary should fall under the purview of the patient-surgeon relationship.

CPT Code 31241 is a newer Category I CPT Code, effective January 1, 2018, describing a now-commonly performed procedure for transnasal endoscopic ligation of the sphenopalatine artery. In the Hospital Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) 2018 Final Rule, CMS assigned status indicator “C” to CPT Code 31241 and listed it among the “Codes That Would Be Paid Only as Inpatient Procedures” for CY 2018. While some patients undergoing this procedure may require inpatient admission due to their overall clinical condition, the procedure is often performed in an outpatient setting, with most patients staying one night for observation following the procedure.

As noted in the CY 2012 OPPS/ASC final rule with comment period, CMS utilizes a set of criteria when reviewing procedures to determine whether or not they should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. A procedure is not required to meet all of the established criteria to be removed from the IPO list. The criteria include the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that CMS has already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by CMS for addition to the ASC list.

In the CY 2019 proposed rule, CMS solicited comments on whether removal of 31241 from the IPO list is appropriate because it meets criterion 3, and also requests input on whether the procedure meets any of the other five criteria for removal from the IPO list. **The AAO-HNS agrees that 31241 meets criterion 3 for removal, and also meets the other four stated criteria as well. We strongly believe the physician performing CPT Code 31241 should be given the option to exercise their clinical judgment as to whether a patient should be admitted to the hospital with an inpatient status. As such, we request this proposal be finalized for the CY 2019 fee schedule.**

II. Site of Service Differentials

For 2019, CMS is proposing to apply a Physician Fee Schedule (PFS)-equivalent payment rate for an Evaluation and Management (E/M) clinic visit service when provided at an off-campus provider-based department (PBD) that is paid under the OPPS. While non-excepted off-campus PBDs already receive a reduced site-specific PFS rate for clinic visits (identified by HCPCS code G0463), CMS proposes to extend that reduced rate for clinic visits to *all* off-campus PBDs in CY 2019, even those excepted under Section 603 of the Bipartisan Budget Act of 2015. In proposing the policy change, CMS cites concerns

that the higher payment made under the OPFS, as compared to the payment under the PFS, is likely to be incentivizing providers to furnish care in the hospital outpatient setting rather than the physician office setting.

The Medicare Payment Advisory Commission (MedPAC) has regularly noted that Medicare should not provide higher reimbursements for a given service when it is provided in a costlier site of service, but instead should make resource-based payments needed to provide high quality care in the most efficient setting. In the proposed rule, CMS cites findings from MedPAC's March 2018 Report to Congress, noting that the "large source of growth in spending on services furnished in HOPDs appears to be the result of the unnecessary shift of services from (lower cost) physician offices to (higher cost) HOPDs." Clinic visits are the most common service billed under the OPFS and are often furnished in the physician office setting. **The AAO-HNS agrees with CMS' proposal to allow clinic visits at non-excepted off-campus hospital outpatient departments (HOPD) to be paid under the PFS at the non-facility rate instead of the facility rate, and believes this proposal to align payment policies may assist in removing the incentive for hospitals to purchase independent physician practices.** The AAO-HNS continues to encourage CMS to create incentives for services to be performed in the most cost-effective location.

While CMS is proposing to pay the PFS-equivalent rate for HOPD clinic visits for CY 2019, the Agency notes it is exploring other methods to control for unnecessary increases in the volume of outpatient services. Specifically, CMS seeks comment on the use of prior authorization (PA), which would require a physician to obtain approval of coverage for a certain service from CMS before furnishing that service, as an alternative way to manage overutilization. **The AAO-HNS joins the American College of Surgeons in strongly opposing the use of PA under the Medicare program, as the extensive PA requirements currently imposed by private payors—including Medicare Advantage organizations—already place an extraordinary administrative burden on physicians and their practices.** The physician community must deal with a large number of non-aligned PA policies instituted by private payers. We would also like to note that the data supporting this strategy as an instrument of cost containment is mixed at best. We believe increasing the routine use of PA as a means to deter physicians from ordering or providing medically necessary treatment for beneficiaries, rather than as a legitimate mechanism for identifying overutilization, is not in the patient's best interest, and therefore, we do not support PA as a means for CMS to shift care between sites of service or reduce volume.

III. New C-APC Level III ENT Procedures

Since the introduction of comprehensive APCs (C-APCs) for HOPPS payment in CY 2015, CMS has continued to create additional C-APCs and modify the policies governing development and use of these payment groupings. Under the existing criteria, CMS defines C-APCs to include the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. CMS packages payment for the adjunctive and secondary items, services, and procedures into the most costly primary procedure at the claim level. For CY 2019, CMS is proposing to create a new C-APC 5163 for Level III ENT Procedures. This proposal would increase the total number of C-APCs to 65 across all specialties. **As stated in our previous comment letters regarding implementation and expansion of C-APCs, the AAO-HNS continues to have concerns about whether the rates associated with the C-APCs adequately or accurately reflect all of the procedures and costs associated with these bundled payments.**

While the Academy understands CMS' desire to pay for services in a more prospective manner under the OPFS, doing so without accurate data may have unintended consequences. For procedures that are

typically billed alone, the proposal to create a new C-APC for Level III ENT Procedures would increase individual payment rates. However, within our specialty, in order to perform the highest quality, efficient care, otolaryngologist-head and neck surgeons often perform multiple procedures on the same patient on the same day. **The AAO-HNS is therefore concerned that for those procedures that are frequently billed in combination during the same outpatient session (i.e., those contained in Level III ENT Procedures), the proposed C-APC payment rates may not adequately reflect the true costs of all services provided.**

The AAO-HNS encourages CMS to analyze the claims data and report on the impact of C-APC changes on all affected codes before applying further expansion of C-APC policymaking. We are concerned that CMS does not have the appropriate inputs needed to further develop additional C-APCs, such as 5163 for Level III ENT Procedures. Sufficient time should be allowed for the Agency and stakeholders to study the impact of the recent APC restructuring before another major change is implemented. **The AAO-HNS urges CMS to delay implementation of C-APC 5163 and development of additional C-APCs until more long-term cost data can be collected and analyzed.**

IV. ASC Payment for HCPCS C9749

In the proposed rule, CMS is soliciting stakeholder input on the 2019 ASC payment level for a new HCPCS code, C9749 (*Repair of nasal vestibular lateral wall stenosis with implant(s)*). CMS created this new code on April 1, 2018, to describe a repair procedure commonly performed by our specialty. The AAO-HNS thanks CMS for the opportunity to comment on the appropriate reimbursement level for this procedure when performed in the ASC setting.

Although we agree with CMS' designation of C9749 as device-intensive, the Academy has concerns regarding the proposed payment level of \$1,270.70. We have received pricing input on the device needed to perform the above-named procedure. Based on this input, the proposed ASC reimbursement amount does not sufficiently cover the full cost of the procedure; in fact, it fails to cover the cost of the device implant alone. 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. The AAO-HNS urges CMS to reconsider the proposed payment rate for C9749 in the ASC setting.

Conclusion

The AAO-HNS appreciates the opportunity to provide comments and recommendations regarding these important policies on behalf of our members. We look forward to working with CMS as it continues its efforts to reduce regulatory burdens for providers and improve patient access to quality care. If you have any questions or require further information, please contact healthpolicy@entnet.org.

Respectfully Submitted,



James C. Denny, III, MD
Executive Vice President and CEO