

September 12, 2022

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
ATTN: CMS-1772-P
P.O. Box 8010
Baltimore, MD 21244-1810

Submitted electronically: <http://www.regulations.gov>

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

Dear Administrator Brooks-LaSure:

The Society for Vascular Surgery (SVS) is a professional medical specialty society, composed primarily of vascular surgeons, that seek to advance excellence and innovation in vascular health through education, advocacy, research, and public awareness. SVS, on behalf of its approximately 6,000 members, offers comments on the Centers for Medicare & Medicaid Services (CMS) calendar year (CY) 2023 Medicare Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule (Proposed Rule).

OPPS Payment Methodology for 340B Purchased Drugs

In the proposed rule, CMS states that it intended to continue the existing policy of paying Average Sales Price (ASP) minus 22.5% for 340B-acquired drugs and biologicals. This was in accordance with the Agency's policy and calculations that were made prior to the Supreme Court decision, *American Hospital Association v. Becerra* (Docket 20-1114). In light of the Supreme Court's decision, CMS acknowledges that it will be required to apply a rate of ASP +6% to drugs and biologicals in the final rule for CY 2023, which will impact the OPPS conversion factor. Additionally, the Agency states that it will have to evaluate the Court's decision on prior calendar years.

SVS appreciates CMS acknowledging the impact of the recent Supreme Court decision and the challenges that it presents. We urge the Agency to provide as much detail as possible in the final rule related to the Conversion Factor modifications that will impact HOPPS payments as a result of the revised policy. Additionally, if the CMS determines that it must revisit prior calendar years, we urge the Agency to provide opportunities for public input regarding how it will carry out retrospective policy changes.

Complexity Adjustment

In CMS' comprehensive APC methodology, if two J1 services are reported together and meet specific frequency and cost criteria, a complexity adjustment can be applied, thus moving the payment rate to the next highest APC. SVS requests that CMS allow a complexity adjustment for CPT Code pair 37187 (venous thrombectomy) and 37248 (venous balloon angioplasty) based on frequency and cost data. CMS currently recognizes CPT Code pair 37187 (venous thrombectomy) with 37238 (venous stent) for complexity adjustment consideration.

Inpatient Only List

For CY 2023, CMS will continue to apply its policy making considerations on a case-by-case basis to determine whether the codified criteria suggest that a procedure should be removed from the Inpatient Only (IPO) list. SVS supports an annual process whereby stakeholders nominate services for removal from the IPO list, and due consideration is given to patient safety and patient financial burden.

Prior Authorization Process

In the CY 2020 OPPS/ASC final rule, CMS established a prior authorization process for certain HOPD services using its authority under 42 U.S.C. § 1395l(t)(2)(F), which allows the Agency to develop a method for controlling unnecessary increases in the volume of covered HOPD services. Prior authorization must be obtained for the following services when provided in the HOPD setting: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, **vein ablation**, cervical fusion with disc removal, and implanted spinal neurostimulators.

SVS is concerned that the Agency continues to misinterpret an increase in the volume of utilization for certain procedures in the HOPD setting as "unnecessary," when such increases may reflect an appropriate site of service shift, a change in practice guidelines, decreases in corresponding/related services or changes in coverage determinations. We urge the Agency to holistically review data (i.e. site of service, guidelines, coverage determinations, etc) prior to expanding prior authorization requirements.

OPPS Payment And Changes For Devices, Drugs, Biologicals, And Radiopharmaceuticals

CMS proposes a change to the nomenclature of skin substitute products, effective January 1, 2024. Specifically, CMS proposes to change the terminology applicable to these products from "skin substitutes" to "wound care management products." SVS does not support the CMS proposed terminology change and encourages the Agency to work with specialty societies and the AMA CPT Editorial Panel to address terminology confusion.

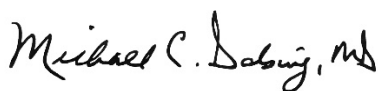
Temporarily Office Based

CMS reviewed CY 2021 volume and utilization data for several procedures, including two vascular duplex scan procedures (CPT Codes 93985 and 93986). Based on low volume, CMS is proposing to continue to designate these two vascular duplex scan procedures as temporarily office-based for CY 2023. SVS appreciates CMS' proposal to extend the temporary designation

for CY2023 to allow for further analysis before determining if it is appropriate to permanently designate them as office based.

If you have questions regarding the SVS' comments, please contact the SVS' Director of Advocacy, Megan Marcinko, at mmarcinko@vascularsociety.org.

Sincerely,



Michael C. Dalsing, MD MBA
President, SVS



Matthew J. Sideman, MD
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