SVS | Society for Vascular Surgery

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October 2, 2020

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
US Department of Health and Human Services
Attention: CMS-1695-P
P.O. Box 8013,
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted electronically: http://www.regulations.gov

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,

The Society of 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 5,900 members, offers the following comments on the Centers for Medicare and Medicaid Services (CMS) CY 2021 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs proposed rule.

Inpatient Only List (IPO)

CMS proposed to eliminate the IPO list over the course of three calendar years beginning with the removal of approximately 300 musculoskeletal-related services. CMS is soliciting comments on whether three years is an appropriate time frame for transitioning to eliminate the IPO list; other services that are candidates for removal from the IPO list for CY 2021; and the sequence in which to remove additional clinical families and/or specific services from the IPO list in future rulemaking.

While the added flexibility for physicians to determine the safest place for their patients to receive care is appealing, we do not support CMS proposal to eliminate the IPO list. The options put forth by CMS to eliminate the IPO list do not address subsequent APC placement, beneficiary financial liability or safety measures. In fact, CMS has a concurrent proposal to expand the covered procedures list in the ASC setting, removing several safety measures. Currently the inpatient deducible copayment cap is $1408.00. With the removal of the IPO list and the migration of those services to the outpatient setting, the Medicare beneficiaries may see

substantial increases in their copayment amounts. In addition, there are currently over 370 services on the HOPPS payment schedule that are capped at the $1408 inpatient deducible limit. Will CMS eliminate that cap if they eliminate the IPO list? In conclusion, SVS DOES NOT support elimination of the Inpatient Only list because doing so will increase patient copayments for many procedures while increasing patient risk. In contrast, SVS DOES support 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.

Percutaneous Creation of an Arteriovenous Fistula (AVF) (HCPCS code G2170 and G2171)

Effective July 1, 2020 CMS created two HCPCS G codes for percutaneous creation of an arteriovenous fistula (AVF). Specifically, CMS established HCPCS G code G2170 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed) and HCPCS G code G2171 (Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, CMSn performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed).

G2170 and G2171 replace HCPCS codes C9754 (Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)) and C9755 (Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed) which were established in CY2019, based on two new technology applications.

CMS created G2170 and G2171 to allow for more accurate billing and coding of these services, recognizing that the lack of appropriate coding for these critical services has become an even greater burden given the PHE that was declared effective January 27, 2020 for the COVID-19 epidemic.

However, if CMS' intent was to provide expanded access to this "*crucial physician service*" it is critical that they communicate that with their MACs. National Government Services (NGS) published a proposed local coverage determination (LCD) regarding Percutaneous Arteriovenous Fistula (pAVF) for Hemodialysis (DL38573), which included these two new G Codes on June

24th, 2020 with the comment period ending July 18th, 2020. In the LCD NGS stated "Coverage of the WavelinQ system must await resolution of ongoing safety issues as well as longer-term data" thus eliminating reimbursement for a service that has been covered in the hospital outpatient setting since 2019. First Coast Services Options (FCSO) also issued non-coverage guidance for these services in the office-based setting.

SVS urges the Agency to provide clear messaging to their MACs regarding coverage of G2170 and G2171. CMS' change effectively eliminated coverage for this service to thousands of Medicare beneficiaries during a global health crisis, requiring America's seniors to pay out of pocket for this "critical service".

Changes to the List of ASC Covered Surgical Procedures (ASC-CPL)

CMS proposed two alternatives for changing the way procedures are added to the ASC CPL. Under the first alternative, they proposed to establish a nomination process beginning in CY 2021 for procedures that would be added beginning in CY 2022 under which external stakeholders, such as professional specialty societies, would use suggested parameters to nominate procedures that can be safely performed in the ASC setting and meet all other regulatory standards. CMS would review nominated procedures and propose and finalize procedures to be added to the ASC CPL through annual rulemaking. Under the second alternative proposal, CMS would revise the criteria for covered surgical procedures for the ASC payment system, by keeping the general standards and eliminating five of the general exclusions. The revised criteria would result in the addition of approximately 270 surgery or surgery-like codes to the CPL that are not on the CY 2020 IPO list.

Surgical procedures that (1) are emergent or life-threatening in nature, (2) generally result in extensive blood loss or (3) require major or prolonged invasion of body cavities should NOT be included on the ASC-CPL. CMS' option #2 whereby CMS would keep general standards for inclusion on the ASC-CPL and eliminate several safety guardrails does not serve American's seniors well. The process to approve services in the ASC setting should be guided in an abundance of caution to ensure safety to Medicare beneficiaries.

With regards to financial liability, the Medicare beneficiary responsibility is 20 percent of the Medicare ASC payment after meeting the yearly Part B deductible. However, there is currently no copay cap in place in the ASC setting. As such, a beneficiary can have more financial responsibility in the ASC setting than the OP or IP setting.

SVS urges CMS to (1) reject ASC proposal #2 which would eliminate several safety guardrails and (2) work with the Administration to establish an ASC copay cap for Medicare beneficiaries.

New Services

CMS proposed to approve the new Revascularization, endovascular, open or percutaneous, any vessel(s); with intravascular lithotripsy codes (C9764-7) in the ASC setting. CMS also approved the new percutaneous arteriovenous fistula creation (AVF) codes (G2170-1) in the ASC setting. SVS supports the inclusion of these services on the ASC approved list for CY2021.

Temporarily office-based for CY 2021

CMS proposed to continue to designate CPT Codes 93985 *Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study* and CPT Code 93986 *Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study* as temporarily office-based for CY 2021. SVS supports continuing the temporary status for CY2021 until data are available to demonstrate that the services are performed primarily in the office-based setting.

Office-Based Exemption for Dialysis Vascular Access Procedures

CMS is not proposing to designate CPT codes 36902 and 36905 as office based procedures for CY 2021. CMS reviewed CY 2019 volume and utilization data for CPT code 36902 and determined that this procedure was performed less than 50 percent of the time in physicians' offices. We note that the office-based utilization for CPT code 36902 has fallen from 52 percent in 2018 to 41 percent in 2019. Similarly, CY 2019 volume and utilization data for CPT code 36905 continues to show that this procedure was performed less than 50 percent of the time in physician's offices.

While CMS is not currently proposing an exemption from payment at Physician Fee Schedule non facility PE RVU amounts, characterized by payment indicator "P3" for CY 2021, for dialysis vascular access procedures, they are contemplating implementing such an exemption in the future if necessary and are seeking comment on whether they might be justified in establishing a permanent exemption from Physician Fee Schedule non facility PE RVU amounts for dialysis vascular access procedures in future rulemaking. In past rulemaking, commenters have requested that CMS permanently exempt dialysis vascular access procedures from office-based designations citing scope of practice issues and a fear that if CMS caps the payment at the NF PE RVU rate it may reduce the number of ASCs willing to perform such services.

CMS should maintain payment systems that appropriately reimburse for Medicare beneficiary services. Policies that establish payment rates based on the lowest possible data point contradict the resource-based underpinnings of the Medicare program and often have unintended consequences. Medicare beneficiaries have the right to work with their health care providers to determine the most appropriate setting to receive their care and should not become victims of a failing healthcare system, which is looking to not appropriately reimburse services and to establish the maximum amount of control over where services are performed.

SVS appreciates the opportunity to provide feedback on the proposed rule. If additional information is required, please contact trishacrishock@gmail.com.

Sincerely,

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President, SVS

Matthew Sideman, MD
Chair, SVS Council on Advocacy