



September 13, 2022

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
Mail Stop C4-26-05, 7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted via: www.regulations.gov

Re: File Code CMS-1772-P; Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; (July 15, 2022)

Dear Administrator Brooks-LaSure:

The Society of Interventional Radiology (SIR) is a professional medical association representing approximately 8,000 members, including most US physicians practicing in the specialty of vascular and interventional radiology. The Society is dedicated to improving public health through pioneering advances in minimally invasive, image-guided therapies. Therefore, SIR appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) CY 2023 Revisions to Payment Policies under the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs proposed rule.

Payment Rates

Proposed: In the CY 2023 proposal, CMS would use CY 2021 claims data for rate-setting and the CY 2019 hospital cost report data instead of CY 2020. With this data, CMS proposed a 2.7 percent increase to the Outpatient Department (OPD) fee schedule resulting in a conversion factor (CF) of \$86.785 for hospitals meeting the reporting criteria and applying the 2 percent reduction to those that do not work with a CF equal to \$85.093.

However, due to a Supreme Court ruling filed on June 15, 2022, related to the 340B Drug Discount Program, Health and Human Services (HHS) Secretary cannot vary payment rates for drugs and biologicals among groups of hospitals in the absence of having surveyed hospitals' acquisition costs. This decision would reverse the average sales price (ASP) -22.5 percent payment for 340B acquired drugs and replace it with the ASP +6 percent, which was in place prior to CY 2018. The decision by the Supreme Court concerned the payments for CYs 2018 and 2019 but has implications for CY 2023. CMS provided an alternate payment file for CY 2023 HOPPS rates which consider the shift from average sales price (ASP) -22.5 percent to ASP +6 percent; this will result in CMS returning money to hospitals. However, the changes would have to be budget-neutral, meaning CMS would have to make decreases elsewhere under HOPPS to pay the adjustments.

CMS indicated they were still formally proposing the rates as they were published but also alerted stakeholders to the pending changes. CMS will also need to determine how to address the 2018-2022 payment rates relative to the 340B Drug Discount Program at the time and how the additional monies paid out are transferred in a budget-neutral manner moving forward. More details are provided later in this summary about the 340B Drug Discount Program updates and alternate impacts to reimbursement as released by CMS.

Comments: SIR is concerned about how the budget-neutral redistribution of monies related to the 340B Drug Discount Program will be conducted. Hospitals continue to work through the impact related to the public health emergency of

COVID-19; the potential for significant reimbursement cuts will impact continued advancement and technology updates for many specialized services, like interventional radiology. SIR urges CMS to work with various stakeholders as they develop a plan and proposal for addressing the payback related to 2018-2022 so it is equitable. Additionally, this plan should include how to address and provide transparency to future drug payment policies appropriately.

As payment policies continue to shift, it is pertinent for CMS to address how the payment policy was derived and provide that detail to stakeholders. As addressed in previous court rulings related to the 340B Drug Discount Program, this includes survey data of drug pricing paid by hospitals. Developing a process as used by the AMA Specialty Society Relative Value Scale Update Committee (RUC), which performs surveys of providers and details the data to appropriately value codes under the Medicare Physician Fee Schedule (MPFS), would be an option. Providing this level of transparency and valuation of drug payments to hospitals would address many comments related to the arbitrary pricing previously employed.

Lastly, SIR recommends CMS outline stakeholder accountability for payment incentive programs, especially those where participants are to use the additional monies for increased access to care and other health improvement programs. Providing clear and proper participation instructions will ensure that any future rulemaking pricing models do not result in similar outcomes as the 340B Drug Discount Program.

Complexity Adjustment Payments in Ambulatory Surgical Centers

Proposed: Over the years, CMS has received comments from stakeholders concerned about the payments for services in the ASC, already paid at a much lower rate than hospitals, and the lack of complexity adjustments incentivizes procedures in the hospital setting. Therefore, in response to CY 2023, CMS evaluated differences in payments for HOPPS and ASC code pairs that included a primary procedure and add-on codes eligible for complexity adjustments under HOPPS and performed in the ASC setting.

CMS proposed to assign each eligible code combination a new C code that describes the primary and the add-on procedure(s) performed. C codes are only valid for hospitals and ASCs; they cannot be billed in office-based settings or by physicians paid under the Medicare Physician Fee Schedule (MPFS). The new C codes would be added to the ASC CPL, and when an ASC bills the C code, they will be paid the higher payment rate, which includes the code combination for the more complex and costlier procedure performed. CMS expects the list of codes would be adjusted annually to account for changes in procedures and payments.

Comments: SIR applauds the creation of the complexity adjustment payments for several services specific to the ASC setting. The current reimbursement for many of these procedures creates an incentive to be performed in the hospital rather than ASC. By creating the complexity adjustment payments to correlate to the C-APCs in the outpatient hospital, CMS is creating a more equitable approach to services. This policy also aligns with other similar payment policies, such as site-neutral payments for nonexcepted off-campus provider-based departments, intended to address the incentive for hospitals to purchase physician practices and repackage them as outpatient hospital departments.

Supervision by NPPs of Hospital and CAH Diagnostic Services Furnished to Outpatients

Supervision requirements for diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests paid under the MPFS are outlined at the code level in the files provided by CMS. Prior to 2020 and the waivers and provisions related to the COVID-19 pandemic, only physicians could supervise the performance of diagnostic tests as defined by Medicare law. The revisions were made to ensure adequate health care professionals were available to support critical COVID-19-related and other diagnostic testing needs. In addition, professionals were needed to provide necessary medical care during the PHE as outlined in the President's Executive Order 13890 on "Protecting and Improving Medicare for Our Nation's Seniors." It directed the Secretary of HHS to identify and modify Medicare regulations that contained more restrictive supervision requirements than the existing scope of practice laws or limited healthcare professionals from practicing at the top of their license.

CMS proposed changes for CY 2023 required clarification and consistency in defining physician supervision in relation to certain non-physician practitioners (nurse practitioners, physician assistants, clinical nurse specialists, and certified nurse midwives). In addition, it emphasized that non-physicians may perform diagnostic tests, without physician supervision, to the extent of the authorization of their scope of practice and applicable State law.

CMS also proposed to update the definitions for general and personal supervision. Currently, direct supervision is the only one that indicates "supervising practitioner" as the person who can supervise the procedure. The definitions for general and personal both refer to only a physician providing the level of supervision.

Comments: SIR agrees consistency in the terminology used for supervision definitions is appropriate but cautions CMS' proposals to roll back supervision guidelines. The continued proposals and regulatory changes to allow non-physician practitioners (NPPs) to supervise services of various complexities begin to undermine the expertise of the physician and the value of their work.

State laws vary widely in defining the scope of work for many NPPs. In addition, many healthcare providers confuse physician supervision with physician work, thinking they are the same thing, creating scenarios for abuse and inadequate support for clinical staff. CMS has already rolled back therapeutic services supervision in the hospital setting, creating difficult situations for staff and hospitals of highly specialized care directly impacting patients. SIR requests CMS include stakeholders and clinical staff from various specialties to be able to speak to the impact appropriately these continued changes have on services provided to beneficiaries.

Transitional Pass-through Status for Devices

TriSalus Life Sciences® TriNav Infusion System Extend Pass-through Status

Proposed: CMS proposed to use CY 2021 claims data for rate setting for CY 2023, which follows the usual 2-year difference in data for rate setting due to allowance for 1-year of timely filing for billing. However, CMS proposed to use the CY 2019 hospital cost report data instead of CY 2020. As a result, the cost reports submitted to CMS by hospitals lagged one year behind the claims data, and CMS continues to believe the data from 2020 may create issues for rate setting.

CMS makes transitional pass-through payments for certain eligible devices for at least two years but not more than three years. As outlined in the CY 2023 proposed rule, there are 11 device categories eligible for pass-through payment. Table 30 within the proposed rule includes HCPCS C1982, *Catheter, pressure-generating, one-way valve, intermittently occlusive*, with an effective date of 1/1/2020 and pass-through expiration of 12/31/2022.

Comments: The TriSalus Life Sciences® TriNav Infusion System is used by interventional radiologists to target and deliver treatment to liver tumors where other traditional catheters are less effective. The incidence of liver cancer continues to increase, and the health disparities across racial, ethnic, gender, and education groups¹ creates a scenario where access to innovative and equitable care for many beneficiaries becomes difficult. SIR is dedicated to ensuring access to care is not a reason why a beneficiary, in this case, someone with liver cancer, is not provided the same level and innovative technology as available anywhere else to any other beneficiary with the same diagnosis. Added to this is the ongoing public health emergency (PHE) in response to the COVID-19 pandemic, the potential issues that come with costs and reimbursement for new technology, and how can and has limited access to appropriate healthcare².

The pass-through payments for new and emerging device technology by CMS allow hospitals to purchase this

¹ Licciulli, S, Reflecting on the Racial Disparities in Liver Cancer, American Association for Cancer Research, October 18, 2021. <https://www.aacr.org/blog/2021/10/18/reflecting-on-the-racial-disparities-in-liver-cancer/>

² Global Liver Institute, RE: Liver Health is Public Health: 2021 Liver Health Policy Priorities. December 18, 2020. <https://static1.squarespace.com/static/53bafd3ce4b0ae714af7153f/t/5ff879f02dbf216159fdffde/1610119665076/GLI+President-Elect+Biden+Liver+Health+Letter.pdf>

technology, offset costs, and provide access to cutting-edge technology to all beneficiaries. The impacts on hospitals due to COVID-19 and the PHE continue to present issues. SIR has concerns with the CMS proposal to allow the expiration of pass-through payment for HCPCS C1982 for the TriNav Infusion System.

Within CYs 2021 and 2022, CMS outlined claims data was significantly impacted due to the PHE for COVID-19. It is the same time period during which HCPCS C1982 was the billable code for the TriNav Infusion System and assigned pass-through status. As a result of the limitations and changes in priority care during and as a direct result of the PHE for COVID-19, it is likely claims data does not reflect the device usage and cost for ratesetting purposes had there not been an ongoing pandemic.

Hospitals are less likely to make the investment and offer without accurate utilization and cost data to establish accurate rate setting for new and innovative technologies like the TriNav Infusion System (HCPCS C1982) for liver cancer treatment this cutting-edge technology. Consequently, it will further impact many marginalized beneficiaries and limit the demonstration of the clinical benefits of using the TriNav Infusion System.

SIR urges CMS not to finalize the removal of C9182 from pass-through status effective 12/31/2022 as outlined in the CY 2023 OPPTS proposed rule, instead use their equitable adjustment authority to extend pass-through status for an additional four quarters, expiring at the end of the fourth quarter of 2023 (December 31, 2023). This extension of pass-through status is like the equitable adjustment authority exhibited for other pass-through devices, such as C1823, finalized in the CY 2022 OPPTS final rule. In this similar situation, the pass-through status was extended for four quarters. SIR believes the continuation of pass-through status for C1982 will promote access to this innovative technology and ensure all Medicare beneficiaries with liver cancer have access to the necessary and equitable care.

If CMS does not extend pass-through status for an additional four quarters, through December 31, 2023, for C1982, SIR requests CMS consider a second option for hospitals to recoup the device expense. It will provide a complexity adjustment to CPT codes 37242 (*Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (e.g., congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms)*) and 37243 (*Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction*) when billed with C1982. Both CPT codes 37242 and 37243 are proposed to be assigned to C-APC 5193 (*Level 3 Endovascular Procedures*) with a payment rate of \$10,760.97 for CY 2023. By providing a complexity adjustment to code 37242 or 37243 and moving them into C-APC 5194 (*Level 4 Endovascular Procedures*) with a proposed CY 2023 payment rate of \$17,495.14 when billed together with C1982, this would appropriately capture and reimburse hospitals for the TriNav Infusion System.

Without the data not directly impacted by the PHE for COVID-19, the value for C1982 is inaccurate and likely presents an undervalue of this technology. Numerous studies have shown the TriNav Infusion System technology billed with C1982 increases the delivery of therapeutics into liver tumors across therapeutic classes while also decreasing toxicity by lowering off-target deposition. Without the appropriate valuation, reimbursement to hospitals will be insufficient to cover treatment costs and create barriers to adopting treatment facilitated by devices billed using HCPCS C1982. This treatment method will not be available for many patients.

EVOKE® Spinal Cord Stimulation System Pass-through Status

Proposed: CMS outlined the application by Saluda Medical Inc. for pass-through payment status for Evoke® Spinal Cord Stimulation (SCS) System for CY 2023. Per Saluda Medical Inc., the Evoke® SCS System is a rechargeable, upgradeable spinal cord stimulation system that provides closed-loop stimulation control by measured evoked compound action potentials (ECAPs). The device treats chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain, and leg pain, and the

battery has a useful life of up to 10 years.

CMS raised concerns about the technology and whether it met the criteria required for pass-through status. Specifically, CMS is seeking comments on the following:

- Concerns were raised about the sample size used in the EVOKE and AVALON studies
- The ability to generalize these studies to the US population
- The comparator arm in the EVOKE study suggests we should have compared the closed-loop technology to the standard of care instead of the EVOKE open-loop

Comments: SIR requests CMS approve the Evoke® SCS System transitional pass-through application. We believe this closed-loop technology has benefits beyond the existing neuromodulation devices, which are currently all open-loop technology and something that is currently considered standard of care.

CMS requested comments related to the substantial clinical improvement of this device category. SIR believes the Evoke® SCS System double-blinded Randomized Control Trial (RCT) clearly demonstrates this substantial clinical improvement of closed-loop SCS over open-loop SCS. It is a high-quality multicenter, parallel arm, double-blinded RCT with 36 months of follow-up. It was published in two high-impact factor peer-reviewed journals: Lancet and JAMA Neurology. The Avalon trial also corroborated this study, a prospective single-arm open-label trial with a subject that lasted two years.

To increase patient access to this new and effective technology, SIR believes the application by Saluda Medical Inc. is supported and urges CMS to approve the pass-through payment.

The technology in the Evoke® SCS System is new, having introduced closed loop neurostimulation based on evoked compound action potentials that can serve to inhibit pain signals in the spinal cord when activated. The experience of certain interventional radiologists (IRs) can provide superior pain control by adjusting the degree of stimulation in an automatic feedback loop to produce better pain control. This closed-loop stimulation is well-tolerated by patients and has much less over and under-stimulation as compared with traditional open-loop systems as it provides much less positional change of stimulation. Traditionally the open-loop systems provide what stimulation is programmed into the system and needed increases or decreases in the amount of stimulation must be done manually. This system makes attaining an appropriate amount of stimulation much more consistent and the stimulator adjustments easier.

Regarding whether this meets the device category criteria, the closed-loop system is unique because all other systems on the market are open-loop systems. However, according to IRs with experience with neuromodulation devices and an evaluation of the recent literature, the Evoke® SCS System appears to be the only closed loop.

Regarding the substantial clinical improvement, the Evoke® SCS System's open loop function is like the other existing products on the market. Still, it can also measure the evoked compound action potentials in the open-loop system. Comparing these two groups can likely separate the difference between the open and closed loop symptoms as there are identical similarities between these two modes except for when the closed loop capability is applied. The presence of the same device in both treatment arms, as seen in the Evoke® SCS System study, illustrated the efficacy of the ECAP amplitude regulation versus the same system without it. This study was a high-quality investigation with a double-blinded randomized control trial protocol. Given the ability to measure the neural response in the open loop mode, the closed-loop system may be even more effective when compared to other open-loop systems without the neural response control capability. Although another system would have been helpful to determine how the closed loop Evoke® SCS System compares to traditional systems, the double blinding component of the DBRCT would not have been possible with two different systems; they look different and are labeled differently on the outside.

Regarding whether a comparison to some of the existing SCS systems would be helpful to determine the efficacy of the

Evoke® SCS System compared to existing systems, the comparison of closed-loop versus open-loop systems to determine the efficacy of the closed-loop system would have been necessary to use the Evoke® SCS System as no other system has the capability of using both open and closed loop settings. In addition, the open loop system has the advantage of monitoring the neural response, which, in theory, should be an advantage over other open loop systems, thereby rendering it a different comparator.

Regarding the adequacy of subject sample size in the EVOKE and AVALON trials, the power calculations to determine the appropriate sample sizes using a standard confidence interval determined the number of subjects needed to detect the difference in the primary endpoint between the groups. It is based on the projected response rate of the closed loop system versus the open loop system, a clinically acceptable margin, the Polled standard deviation, and several other typical elements. The Evoke® SCS System trial involved 134 patients at 13 centers with 1-to-1 randomization and had a composite primary endpoint, including a $\geq 50\%$ improvement in overall back and leg pain and no increase in pain medications. This trial showed statistical superiority of closed loop-controlled compared with open-loop stimulation. The fact that the study demonstrated statistical superiority with a smaller study size indicates a substantial difference in back pain and medication use to attain this statistical significance with only 134 subjects. It also confirms the suspected difference in clinical performance between the closed and open loop systems. The trial also showed statistically significant superiority out to 24 months. The Evoke® SCS System was also investigated in the AVALON trial, a prospective single-arm open-label trial with 50 patients for two years. These patients had significant improvements in quality of life, function, and sleep over the 24 months. This degree of improvement speaks to the magnitude of improvement necessary to establish statistical significance in a trial with 50 patients. It is likely to continue with a larger trial as it is highly predictive of clinical success in a study with additional power.

The Evoke® SCS System trial was a double-blinded randomized control trial conducted at 13 US sites and included spinal cord stimulation with chronic back and leg pain refractory to conservative management. The Avalon trial was conducted in Australia in patients with chronic back and leg pain refractory to conservative management and candidates for spinal cord stimulation. The difference between the trials was that the Evoke® SCS System trial was a prospective multicenter, double-blind, randomized control trial, and the Avalon trial was a multicenter, single-arm trial but was not randomized to who received treatment. In addition, the Evoke® SCS System compared closed-loop stimulation to open-loop stimulation, and the Avalon trial did not. However, the patient population in Australia is otherwise entirely comparable to the US population, and the trial results were very similar. For example, the responder rates at 24 months for patients receiving $\geq 50\%$ pain reduction and those patients receiving $\geq 80\%$ pain reduction were 89.5% and 68.4% for the Avalon trial compared to 84% and 50%, respectively.

Evidence includes a rigorous double-blind, parallel-arm randomized control clinical trial that provides Oxford Level I evidence and collected real-time neurophysiologic data directly from the spinal cord. Comparing spinal cord activation data that is controlled versus uncontrolled activation data has not been done previously. The controlled or closed loop data was shown to be significantly better for pain reduction of $\geq 50\%$ than the open loop data. All the neuromodulation systems currently on the market are open-loop systems. It was accomplished all with no difference in safety profiles or adverse events. The Evoke® SCS System trial also observed improvements in health-related quality of life, physical and emotional functioning, and sleep and saw an opioid reduction or elimination. The responder rates of 89.5% and 68.4%, and 84% and 50% for $\geq 50\%$ and $\geq 80\%$ pain reduction in the Avalon and Evoke® SCS System trials, respectively, are among the highest shown for any randomized controlled trial of spinal cord stimulation to date. The individual optimization of the closed loop therapy and the ability to control may have contributed to these high responder rates. The available data has demonstrated that closed-loop therapy provides a significant clinical benefit and advantage compared to open-loop therapy. Given currently available systems offer only open-loop therapy, the availability of the closed-loop ECAPS system provides a unique and clinically important benefit.

SIR appreciates the opportunity to provide meaningful feedback on the CY 2023 MPFS proposed rules. If you have any questions, don't hesitate to contact SIR's Manager of Coding and Reimbursement, Ashley Maleki, at amaleki@sirweb.org or (703) 844-0378.

Sincerely,



Parag J. Patel, MD, FSIR
President, Society of Interventional Radiology

Cc: Keith M Hume
Executive Director, Society of Interventional Radiology