



October 1, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1736-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1736-P; CY 2021 Proposed Rule 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 International Society for Advancement of Spine Surgery (ISASS) appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (*Proposed Rule*) on the revisions to Medicare policies under the Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Payment Systems for calendar year (CY) 2021.

ISASS is a multi-specialty association dedicated to the development and promotion of the most current surgical standards, as well as the highest quality, most cost-efficient, patient-centric, and proven cutting-edge technology for the diagnosis and treatment of spine and low back pain.

This letter includes ISASS recommendations and comments regarding the following:

- Pre-Approval for Neurostimulator Implantation and Cervical Fusion
- Elimination of the Inpatient Only Procedure (IPO) List
- Transitional Pass Through Payments
- APC Placement for New CPT Codes 0627T-0630T

Pre-Approval for Neurostimulator Implantation and Cervical Fusion

Last year, CMS finalized a proposal to establish a process through which hospitals must submit a prior authorization request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for



processing. The change applied to five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.

This year, the agency proposes to expand prior authorization requirements for two additional services: cervical fusion with disc removal and implanted spinal neurostimulators to curb what they believe may be unnecessary utilization.

ISASS strongly disagrees with this proposal and the rationale provided by the agency. We strongly urge CMS to not apply the prior authorization requirement to both of these procedures as this requirement creates an improper and unnecessary burden on physicians and physician practices. We also dispute the CMS claim that prior authorization will reduce unnecessary utilization. There is evidence that prior authorization impacts unnecessary authorization but merely causes delay in appropriate care. There is not evidence that utilization is increasing at significant rates for these procedures, but there is considerable evidence to illustrate the costs for patients and practices from prior authorization policies used by private payers.

For example, Karrison et al in a 2009 study found that when time spent in acquiring prior authorization is converted to dollars, they estimated that the national time cost to practices of interactions with plans is at least \$23 billion to \$31 billion each year.¹ This financial burden and cost has only increased in the ensuing twelve years and we believe this cost to be an unnecessary and unjustified burden for physicians performing neurostimulator implantation.

Other studies have confirmed and added to the body of evidence showing the detrimental impact of prior authorization burdens to patient access. A 2019 AMA survey found that 64% of patients surveyed experienced at least a one-day delay in scheduling, and another 26% experienced delays of 3 or more days so that 91% of respondents experienced delays in necessary care. 24% of physicians surveyed reported a delay related to prior authorization led to adverse patient events, and 16% reported hospitalizations directly attributable to prior authorization. Furthermore, the same study found that prior authorization efforts add 14.4 hours of staff time per week to their workload with 30% of respondents reporting to have a Full Time Employee (FTE) dedicated to prior authorization. The same survey found the prior authorization burden to have increased significantly over the past 7 years, with 86% of respondents reporting increased prior authorization costs to their practice in the previous five years.² A study from the Cleveland Clinic estimated their annual costs for prior authorization activities to exceed \$10 million a year.³

These studies apply equally to the Neurostimulator procedures and Cervical Fusion procedures identified by CMS in the proposed rule and demonstrate that imposing these burdens will result in unnecessary delays for patients in access to these critical procedures.

¹ Health Affairs, 28, no.4 (2009):w533-w543 What Does It Cost Physician Practices To Interact With Health Insurance Plans? Theodore Karrison and Wendy Levinson Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra,

² <https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf>

³ <https://www.ama-assn.org/practice-management/sustainability/inside-cleveland-clinic-s-10-million-prior-authorization-price>



We believe it is essential to continue to increase access to non-opioid pain treatment and cervical spine fusion and spinal cord stimulation is a very important alternative to opioid prescriptions. We urge CMS to revise their proposal to decrease access to this and to cervical fusion through the imposition of a costly and burdensome prior authorization process.

Elimination of Inpatient Only Procedure (IPO) List

The Inpatient Only (IPO) List was created to identify services that require inpatient care because of the invasive nature of the procedure, the need for postoperative recovery time or the underlying physical condition of the patient. CMS stated in the proposed rule that they concluded that the list is not necessary to identify services that require inpatient care because of changes in medical practice, including new technologies and innovations. As a result, beginning in 2021, CMS proposes to eliminate the IPO list over three calendar years, starting with the removal of 300 musculoskeletal-related services in 2021. CMS also proposed a three-year period of implementation with different procedures phased out across the three years.

ISASS is opposed to the proposed elimination of the Inpatient Only List and asks CMS to revise their proposal to maintain the IPO list as is for CY 2021 and beyond. We believe the IPO list helps maintain a standard of safety and quality for Medicare patients by keeping more complicated procedures limited to the inpatient setting where patients recovering can be ensured more intensive post-operative care and monitoring for potential complications from intensive procedures and care. If there are specific procedures that are felt to be safely performed in Outpatient settings, CMS already has a process by which stakeholders can apply to remove services from the IPO list. CMS has annually moved procedures off of, or onto, the IPO list, and we believe this process has served providers, facilities, and most importantly, patients well by ensuring safe and appropriate follow-up care for intensive procedures on at-risk patients. We do not believe it is necessary to move away from this process at this time and urge CMS to delay any elimination of the IPO list for CY 2021 and beyond.

If CMS proceeds with the proposal, we would urge delay of removal of all spine related procedures to the final year of the transition. We believe spine procedures to be very high risk and require patients to be treated and recover in in-patient settings whenever possible and we do not think it advisable to allow all spine surgery to be performed in outpatient or ASC settings.

The specific CPT codes listed in Table 31 from the proposed rule include all of the following: 0095T, 0098T, 0163T-0165T, 0202T, 0219T-0220T, 22210-22865, and 27280. We recommend all of these procedures remain on the IPO list for as long as possible.

In regards to Lumbar Total Disc Replacement, Revision, and Replacement in particular (CPT codes 0163T, 0164T, 0165T, 22857, 22862, and 22865 respectively) we would strongly



recommend that CMS consider these codes as a distinct category as there is Medicare National Coverage Decision that does not allow the procedure on Medicare patients. Therefore, the volume of Medicare patients is at or near zero already, and any changes in site-of-service could lead to drastic changes in APC and DRG classifications that are the result of miscoding by definition. Yet, the payment impacts would be profound, detrimental, and subject to tremendous annual fluctuation. Should CMS choose to not treat procedures with low Medicare volumes like CPT 22857, 22862, and 22865 separately and in a way that maintains stability and consistently we would recommend CMS reconsider the NCD itself. The NCD is over 15 years old, and significant literature and data have been developed since the initial establishment and a review is overdue and warranted. In the interim CMS should address low volume and NCD covered procedures in a separate fashion moving forward.

Transitional Pass Through Payment Policy for Spine Jack System

ISASS supports the approval of a Transitional Pass-Through (TPT) payment for the Spine Jack system/device (procedurally) to treat vertebral compression fractures (VCFs). There exists a wide variety of FDA approved systems/devices for treating vertebral compression fractures as well as techniques in treating VCFs like: vertebroplasty, high pressure balloons, curved balloons, stents, bipedicular, unipedicular, and so on. The major concern with these approaches has been the inability to maintain the reduction of the VCF until the cement can be properly extruded and cured for stabilization.

The SAKOS⁴ trial demonstrated superiority for the SpineJack system over Balloon Kyphoplasty (BKP) with regards to absence of adjacent level fractures (ALF) and midline vertebral body (VB) height sustained restoration at 12 months post-procedure. Additionally, SpineJack may obviate the need for larger interventions to obtain the same results which will provide cost savings for the health system while providing a better quality of life for patients.

A TPT payment code will help to remove the financial burden from hospitals while allowing physicians to bring substantial clinical improvements to patients such as maintained maintained vertebral height with sagittal restoration.

APC Placement for New CPT Category III codes 0627T-0630T

ISASS disagrees with the proposed APC designation for CPT codes 0627T and 0630T as discussed below.

⁴ Noriega D, Marcia S, Theumann N, Blondel B, Simon A, Hassel F, Maestretti G, Petit A, Weidle PA, Mandly AG, Kaya JM, Touta A, Fuentes S, Pflugmacher R. A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study). Spine J. 2019 Nov;19(11):1782-1795. doi: 10.1016/j.spinee.2019.07.009. Epub 2019 Jul 17. PMID: 31325625.



CMS assigned the procedures to APC 5443-Level 3 Nerve Injection. APC 5443 includes injection of anesthetic and neurolytic agents into nerves or other anatomical structures.

Examples of these codes are as follows:

CPT 62280 (Injection/infusion of neurolytic substance (e.g. alcohol, phenol, iced saline solutions), with or without other therapeutic substances; subarachnoid).

CPT 64446 (Injection, anesthetic agent; sciatic nerve, continuous infusion by catheter including catheter placement).

CPT 64520 (Injection, anesthetic agent; lumbar or thoracic; paravertebral sympathetic).

Nerve injections address a different pain source altogether by destroying the nerve or temporarily block the pain signals. They are not injected into degenerated intervertebral discs which are a different pain source. Primary Codes 0627T and 0629T do not involve injection of an anesthetic agent or neurolytic substance into nerves or other anatomical structures. Instead these codes describe the percutaneous placement of an allogeneic cellular and/or tissue-based biologics to supplement and support degenerated intervertebral discs in patients.

Disc Matrix material is a viable allograft indicated for use as an intervertebral disc filler and supplemental tissue therapeutic for intervertebral disc degeneration. The final product is composed of two components including disc tissue scaffolding and a cellular component. The scaffolding component is derived from cadaveric intervertebral disc material that has been dried and milled to a final size of less than 300 um. The cellular component consists of a minimum of 6,000,000 spine-derived cells that have been preserved in cryoprotectant. Both components are obtained from donors.

The average cost of the VIA Disc Matrix Kit for example includes all the above tissue and processes and is priced at \$8,000 per kit.

We believe the non-device related cost associated with CPT codes 0627T and 0629T are more appropriately cross-walked to the Musculoskeletal Procedures Category, and more specifically CPT code 22514 (Percutaneous Vertebroplasty and Vertebral Augmentation) which describes percutaneous injection of material into a damaged vertebral body utilizing a viscous polymer cement; the procedure does not restore the original shape to the vertebra, but it does stabilize the bone. Both augment existing structures, bone cement supports the osseous structures and Disc Matrix supplementation has been shown in biomechanical studies to support the disc. The Allogenic Disc Supplementation procedure utilizes a viscous disc tissue allograft injected into the center of the nucleus pulposus. Both involve mixing a liquid and a powder in a closed contained system. The control of the delivery is the same, by injection pressure. Both are viscous materials and both are liquid/powder mixtures that are subject to filter packing. Both target the spinal column. Vertebral augmentation targets the vertebral body while Allogenic Disc Matrix injection targets the intervertebral disc and both require imaging guidance for safe and proper targeting of anatomy.

CPT code 22514 has been assigned to APC 5114. In CY 2020, the device off-set for APC 5114



was 22.7%; therefore, the non-device costs are 77.3% (100% minus 22.7%). The CY 2020 Final Geometric Mean Cost for APC 5114 was \$5,853; therefore, the non-device cost is \$4,524 (\$5,853 x 77.3%). As with the vertebroplasty codes, these codes do not capture the resource costs associated with the allogenic tissue-based product or the targeting of the injection into the center of the nucleus pulposus of the disc.

The Total Estimated Cost of 0627T and 0629T is the addition of the non-device related costs of APC 5114 (\$4,524) plus the device related costs (\$8,000) or \$12,524 and is closest to New Technology APC Level 38 (APC 1575) with a CY 2021 Projected Payment Rate of \$12,500.50.

Since CPT codes 0628T and 0630T are add-on codes and should be used in conjunction with their primary procedural codes, we recommend CMS use the device related cost for each additional VIA Disc mixing system kit of \$8,000 plus an incremental thirty minute non-device cost to capture the additional operative time and costs in performing a separate intervertebral disc injection.

The Total Estimate Cost of 0628T and 0630T is closest to APC Code 1571 New Technology - Level 34 (\$8001-\$8500) with a CY 2021 Projected Payment Rate of \$8,250.50.

We recommend assignment of these New Technology Levels for CPT codes 0627T-0630T

Thank you for your time and consideration of the International Society for Advancement of Spine Surgery's comments. We greatly appreciate the opportunity to participate in efforts to more efficiently and accurately capture current care delivery. We commend CMS on its comments, please do not hesitate to contact Morgan Lorio, MD at mloriomd@gmail.com.

Sincerely,

Morgan Lorio, MD
Chair, ISASS Coding and Reimbursement Task Force