Via Electronic Submission

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS–1772–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: 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 [CMS-1772-P]

Dear Administrator Brooks-LaSure,

The Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, is submitting this letter in response to the proposed changes to the Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system for calendar year (CY) 2023 (the “Proposed Rule”).

For nearly 30 years, MDMA has represented the medical device industry in Washington, DC, supporting policies that promote medical innovation and patient access to lifesaving and life-changing medical technologies. MDMA's membership is broad and diverse, ranging from small start-ups to multi-national medical device companies. It is a long and risky venture to develop novel medical innovations, and those that succeed have changed the face of medicine and redefined what is possible in the diagnosis and treatment of deadly diseases and prevalent conditions like cancer, heart disease, diabetes, and stroke.

We support efforts by the Centers for Medicare and Medicaid Services (CMS) to improve the accuracy of payment rates and ensure that providers are incentivized to provide high quality care.

in an efficient manner. Medicare’s payment rates must accurately reflect the costs of providing appropriate care in order to ensure that beneficiaries have access to the best care available today and that providers can invest in the technologies that will allow care to continue to improve.

In order to ensure that the hospital outpatient and ASC payment systems continue to provide Medicare beneficiaries access to appropriate, innovative care, MDMA asks CMS to take the actions set forth below.

I. **Comments on New Assignments and Reassignments for New Technology Ambulatory Payment Classifications (APCs) and Other APCs**

   A. **CMS should reallocate Current Procedural Terminology (CPT®) code 0671T to APC 5492.**

CMS proposes to assign CPT code 0671T (Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more) to APC 5491 (Level 1 Intraocular Procedures). This code is for a micro-invasive glaucoma surgery (MIGS) procedure that is not done on the same day as a cataract procedure. This procedure offers an important treatment option for beneficiaries with glaucoma who do not also need a cataract removal, through the insertion of a MIGS device to increase the outflow of ocular fluid and lower intraocular pressure by creating a bypass through the trabecular meshwork. CMS’s proposed APC assignment for this code undervalues the service and, based on claims data and clinical similarity of procedures, the agency instead should assign CPT code 0671T to APC 5492 (Level 2 Intraocular Procedures).

Since CPT code 0671T was first effective January 1, 2022, there are no claims in the CY 2021 hospital data set for the code. However, prior to January 1, 2022, this procedure was reported using CPT code 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion). As such, we understand that CY 2021 claims for the service now described by CPT code 0671T can be located by identifying claims with CPT code 0191T that do not include the code for a cataract procedure (e.g., CPT codes 66982 and 66984). Further, as we understand it, such CY 2021 claims have a geometric mean that far exceeds the geometric mean of APC 5491. The geometric mean for such claims also exceeds the geometric mean of APC 5492; however, we believe that assignment of the service to APC 5492 would be appropriate in light of such claims data.

Considering clinical coherence, assignment of CPT code 0671T to APC 5492 is more appropriate than assignment to APC 5491. That is because the service described by CPT code 0671T is closer clinically to procedures assigned to that APC 5492. In particular, the service seems most similar to the services described by CPT codes 0449T (Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device) and 0253T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal

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2 Copyright 2021 American Medical Association (AMA). All rights reserved. CPT® is a registered trademark of the AMA.
approach, into the suprachoroidal space), both of which are assigned to APC 5492. Both of these procedures are for the insertion of an aqueous drainage device in the eye. As such, consideration of clinical coherence in deciding on the APC assignment for CPT code 0671T leads to the conclusion that the procedure should be assigned to APC 5492.

For these reasons, we recommend that CMS assign CPT code 0671T to APC 5492 for CY 2023.

B. CMS should reassign Healthcare Common Procedure Coding System (HCPCS) code C9780 to APC 1575.

HCPCS code C9780 (Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance) was created on October 1, 2021, to describe the procedure associated with the use of the Surfacer® Inside-Out® Access Catheter System. The Surfacer System is designed to address central venous occlusion, which affect more than 40% of patients with central venous catheters and can compromise a hemodialysis patient’s ability to receive therapy. Starting on October 1, 2021, and continuing for CY 2022, the code was assigned to APC 1534 (New Technology – Level 34 ($8001-$8500)) with a payment rate of $8250.50. In the Proposed Rule, CMS proposes to continue assigning C9780 to APC 1534 with the same payment rate.

Given the timing of when this code was created, no CY 2021 claims data is available upon which to base APC assignment; however, hospital providers have noted that the cost of performing the procedure greatly exceeds the current and proposed CY 2023 payment. One such hospital presented during the August 22, 2022, meeting of the CMS Advisory Panel on Hospital Outpatient Payment, noting that its calculated cost for performing the procedure was approximately $12,500. We believe maintaining the current assignment of C9780 to APC 1534 creates a significant and inappropriate financial disincentive to its adoption by providers and will negatively impact Medicare beneficiary access to this important technology. We believe CMS should reassign C9780 to APC 1575 (New Technology – Level 38 ($10,001-$15,000)), which has a payment rate more reflective of the cost to hospitals for performing the procedure.

C. CMS should consider the temporary reassignment of CPT code 0424T to APC 1581 in conjunction with the expiration of the Transitional Pass-Through (TPT) payment for HCPCS code C1823.

Phrenic nerve stimulation therapy, which was approved by the U.S. Food and Drug Administration (FDA) in 2017, is an innovative treatment for an underserved population of patients suffering from central sleep apnea (CSA). Phrenic nerve stimulation is reimbursed using CPT code 0424T

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(Insertion or replacement of neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)) and HCPCS code C1823 (Generator, neurostimulator (implantable), nonrechargeable, with transvenous sensing and stimulation leads). CPT code 0424T is assigned to APC 5465 (Level 5 Stimulator and Related Procedures) with a proposed CY 2023 payment rate of $29,932.25, and an additional TPT payment is provided for the device described by HCPCS code C1823 (the remedē® System).\footnote{See Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818 (Nov. 21, 2018), at 58,936-58,939.} MDMA is concerned about continued Medicare beneficiary access to phrenic nerve stimulation therapy following expiration of the separate TPT payment for C1823, which is currently scheduled for December 31, 2022.

We understand that the manufacturer of the remedē® System is submitting data to CMS demonstrating a significant disparity between the geometric mean cost of the implant procedure and Medicare payment. MDMA believes that the expiration of TPT payment for any device should be accompanied by an evaluation of whether reassignment to a different APC is warranted to preserve patient access. This includes the consideration of temporary reassignment to a New Technology APC to allow for the collection of additional claims data, as requested by the manufacturer of the remedē System.

\textbf{D. CMS should reconsider the proposed assignment of new CPT code 37X01 to APC 5164 based upon cost information submitted by the manufacturer.}

CMS has proposed to assign new Category I CPT code 37X01 (Repair of nasal valve collapse with low-energy, temperature-controlled based (\textit{i.e.}, radiofrequency) subcutaneous/submucosal remodeling) to APC 5164 (Level 4 ENT Procedures). The procedure described by CPT code 37X01 utilizes a single use medical device called the VivAer™ Stylus to treat nasal airway obstruction by shrinking and shaping submucosal tissue, including cartilage in the internal nasal valve area. The VivAer Stylus remodels the obstructed nasal passages by creating coagulation lesions in the submucosal tissue while sparing the mucosal surface. As the lesions heal, the tissue retracts thereby opening the air passages and improving the flow of air through the nose.

MDMA is concerned that the proposed payment rate could lead to decreased access to the therapy for Medicare patients. Specifically, we are concerned that the proposed payment rate for APC 5164 ($2,896.26) could be too low to adequately account for the costs of the resources (including the device cost) required to perform this procedure in the hospital outpatient department setting, and that the proposed ASC payment rate of $1,474.97 is substantially below the cost for providers to acquire the device alone.

MDMA understands that the manufacturer of the VivAer Stylus is submitting cost information for the device, along with information supporting clinical and resource comparability between CPT code 37X01 and the device-intensive nasal and ear procedures assigned to APC 5165 (Level 5 ENT Procedures). As a matter of general policy, we support CMS’s use of the best available data to determine APC assignment and calculate device offset amounts for new CPT codes, which includes invoices and other pricing information provided by the device manufacturer. We ask that
CMS consider the information submitted by the manufacturer of the VivAer stylus to determine whether assignment to an APC other than APC 5164 is warranted.

**E. CMS should assign new hernia procedure codes predominantly associated with laparoscopic procedures to APCs 5361 and 5362.**

Beginning January 1, 2023, abdominal hernia repair procedures will be reported with a new range of CPT codes, 49X01 through 49X12, which combine various surgical approaches (i.e., open, laparoscopic and robotic) in the same code description. In the Proposed Rule, CMS is proposing to assign all the new CPT codes for hernia repairs to APC 5341 (Abdominal/Peritoneal/Biliary and Related Procedures) despite substantial differences in resource utilization. The proposed APC placement of these new codes will result in inadequate payments to hospitals relative to the costs of performing these procedures with a minimally invasive approach. We are concerned this will significantly impact Medicare beneficiary access to a minimally invasive hernia repair.

MDMA understands that approximately 60% of hernia procedures are currently performed with a minimally invasive approach. The geometric mean cost of these procedures as set out in the addenda to the Proposed Rule significantly exceed the proposed APC 5341 payment rate of $3,235. In contrast, CPT coding and payment for inguinal hernia repairs have remained intact for FY 2023, and the geometric mean costs for open procedures and laparoscopic procedures aligns to the payment. As a result, we are concerned that finalizing the assignments as proposed will significantly impact providers’ financial ability to offer minimally invasive procedures as a treatment option for Medicare beneficiaries.

To maintain consistency in the methodology of payment assignment and clinical homogeneity, and to ensure continued beneficiary access to minimally invasive surgery procedures, we propose that CMS assign the new hernia procedure codes predominantly associated with laparoscopic procedures to APCs 5361 and 5362, which are specific to laparoscopic procedures and include other abdominal laparoscopic procedures.

**F. CMS should finalize the proposal to assign CPT code 19281 to APC 5072.**

According to Addendum B released with the Proposed Rule, CMS proposes to assign CPT code 19281 (Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous; first lesion, including mammographic guidance) to APC 5072. MDMA agrees with the proposed assignment, as we understand that the geometric mean for CPT code 19281 is well above the geometric mean for APC 5071. Clinically, APC 5072 also includes a series of percutaneous image-guided breast biopsy procedures (CPT codes 19081-19086), which further supports the assignment of CPT code 19281 into the same APC. We request that CMS finalize this proposal.

**G. CMS should assign CPT codes 19283, 19285, and 19287 to APC 5072.**

CPT codes 19281 through 19288 describe a set of breast localization placement procedures that differ only by the type of imaging guidance used (e.g., mammographic, stereotactic, ultrasound, MRI). For clinical coherence, CPT Codes 19283, 19285, and 19287 should be assigned to APC
5072 alongside 19281. Further, the geometric means of CPT codes 19283 ($1,035.46) and 19285 ($1,032.06) are close to the geometric mean of CPT code 19281 and much above the geometric mean for APC 5071. Therefore, for clinical and resource consistency we request that CMS assign 19283, 19285, and 19287 to APC 5072.

H. CMS should assign CPT code 0697T to New Tech APC 1523.

CMS is currently reviewing a New Technology APC application for CPT code 0697T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; multiple organs). The technology used in CPT code 0697T is known as CoverScan. The New Technology APC application for CoverScan was submitted by the manufacturer to CMS on August 3, 2021, while the technology was under FDA review. FDA clearance was received on May 19, 2022, and the manufacturer notified CMS of that clearance on the same date.

MDMA understands that, as described in the New Technology APC application, the CoverScan multi-organ technology requires more resources than single-organ MR protocols. The current level of reimbursement for single organ MR protocols (billed under CPT codes 0648T and 0723T) is well below the cost of furnishing the multi-organ CoverScan MR service, and we are concerned that assignment to the same APC as codes 0648T and 0723T will limit access for Medicare beneficiaries to this medically necessary, multi-organ MR service. For these reasons, we urge CMS to assign CPT code 0697T to APC 1523 for CY 2023 as requested by the manufacturer.

II. Comments on Applications for TPT Payment and Policies Related to the TPT Payment Program

A. CMS should extend TPT device categories expiring on December 31, 2022, or in CY 2023 for four additional quarters due to ongoing pandemic-related disruption in hospital operations.

MDMA strongly supported and appreciates CMS’s use of its equitable adjustment authority to extend TPT payments for device categories whose eligibility would have been discontinued in CY 2022 for an additional four quarters.8 We urge the agency to provide similar treatment for TPT categories scheduled for expiration on December 31, 2022, or in CY 2023.

We believe that the COVID-19 pandemic continues to drive utilization patterns that differ significantly from normal, non-pandemic years. Moreover, the COVID-19 public health emergency (PHE) has diverted provider resources away from technology reviews, physician and staff training, patient education, and other operational activities necessary to facilitate the evaluation and adoption of new technologies into care delivery. Those effects have continued even as elective procedure volumes have begun to recover. In short, we believe that the PHE continues to negatively affect use of TPT technologies.

8 See 87 Fed. Reg. at 44,578.
Although CMS is proposing to use 2021 claims data for 2023 OPPS rate setting, CMS is proposing to use cost report data from periods prior to the PHE, acknowledging the impact of the PHE on hospital costs and utilization.\(^9\) Notably, the devices for which CMS is proposing to discontinue TPT payment, identified in Table 30 of the Proposed Rule,\(^10\) have virtually no utilization and claims history that is unaffected by the pandemic.

For these reasons, we recommend that CMS again use its equitable adjustment authority under Section 1833(t)(2)(E) of the Social Security Act (SSA) to extend TPT eligibility for device categories set to expire on December 31, 2022, or in CY 2023 for an additional four quarters.

**B. CMS should approve the MicroTransponder® Vivistim® Paired Vagus Nerve Stimulation (VNS) System for TPT payment.**

In the Proposed Rule, CMS reviews the TPT payment application for the Vivistim System, which is “intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.”\(^11\) The application was submitted under the TPT Alternative Pathway for devices that have received a Breakthrough Device Designation from the FDA. In its discussion regarding the application in the Proposed Rule, CMS questions whether the Vivistim System is described by previous neurostimulator categories and, therefore, fails to satisfy the newness criteria for TPT payment eligibility.

We have become increasingly concerned about the criterion for newness in the TPT payment program, particularly with regard to the alternative pathway for FDA Breakthrough Devices and the misalignment between New Technology Add-on Payment (NTAP) program under the Hospital Inpatient Prospective Payment System (IPPS) and the TPT program under the OPPS. CMS has established an alternative pathway for FDA Breakthrough Device applicants in both the NTAP and TPT programs; however, while devices with an FDA Breakthrough Device Designation are deemed to satisfy CMS’s newness criterion under the NTAP program, they may not meet the newness criterion under TPT based upon device category assignment. We find it difficult to understand how a device can be “new” when provided in the hospital inpatient setting and “not new” when provided to hospital outpatients.

MDMA urges CMS to consider any FDA Breakthrough Designated Device as “new” under both the NTAP and TPT programs and to approve the Vivistim System for TPT payment. We also caution the agency against continuing down the path of turning the process of defining new TPT categories for non-breakthrough devices into an impossible exercise focused on excluding all potential future innovations, both knowable and unknowable, to preserve their potential TPT eligibility. Instead, CMS should consider the totality of evidence when assessing whether a device falls into an existing TPT device category or qualifies for a new device category, considering factors such as differentiated clinical benefits (as reflected in substantial clinical improvement), different mechanisms of action, or other evidence-based improvements.

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\(^9\) Id. at 44,680-44,682.

\(^10\) Id. at 44,583.

\(^11\) Id. at 44,583-44,585.
C. CMS should approve the Evoke® Spinal Cord Stimulation (SCS) System for TPT payment.

The Evoke SCS System is the first implantable spinal cord stimulation system that provides closed-loop stimulation (i.e., therapy that adjusts automatically based upon detected changes in certain biological indicators), and which is used in the treatment of chronic intractable pain of the trunk and/or limbs. In its discussion of the application, CMS raised questions about whether information submitted by the applicant is sufficient to establish that the Evoke System represents a substantial clinical improvement (SCI) over previously available technology. Specifically, the agency notes that the applicant has not provided a comparison to existing closed-loop systems, and questions the study size and generalizability of results from studies conducted in Australia to the US Medicare population.12

We agree with CMS’s assessment that there are no existing pass-through payment categories that describe the Evoke SCS System. Additionally, the Evoke SCS System meets the other eligibility requirements set forth in 42 C.F.R § 419.66(b). Addressing CMS’s concerns over SCI referenced above, we note that the applicant collected in-vivo, real-time, continuous neurophysiological data directly from the spinal cord in response to treatment during daily use. The randomized controlled trial compared the controlled level of spinal cord activation (and the associated pain relief afforded with a novel closed-loop technology) with uncontrolled stimulation provided by open-loop technology. We do not believe the fact that the uncontrolled stimulation was provided by an Evoke system with the closed-loop functionality disabled undermines the study results. In fact, the use of an Evoke generator in both study arms actually supports the double-blinded design. Moreover, the Evoke study was powered adequately to detect differences in the primary outcome between groups. The 24-month data was published in JAMA Neurology, with the authors stating, “The double blind, parallel-arm randomized clinical trial design of the study provides the highest rigor of any study in neuromodulation to date and to our knowledge.”13

MDMA urges CMS to approve the Evoke SCS System for TPT payment, which will support increased patient access to this innovative technology.

D. Comment in Response to the Proposal to Publicly Post All TPT Applications

Similar to plans the agency recently finalized with regard to the NTAP program, CMS is proposing to begin publicly posting all TPT applications starting with applications received on or after January 1, 2023.14 The justifications provided for this change in the TPT application process are substantially similar to those provided in relation to the NTAP program, for which a similar policy was adopted in the FY 2023 IPPS final rule, including freeing up agency resources that are currently used to prepare a summary of the complex materials contained in each application for publication in the annual proposed rule, allowing those resources to be dedicated to processing and analyzing a growing number of applications; preventing inadvertent misrepresentations and

12 Id. at 44,607.
omissions in the CMS-prepared summaries; and fostering more informed public comment and greater stakeholder engagement, especially by external experts.\footnote{Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates, 87 Fed. Reg. 48,780 (Aug. 10, 2022), at 48,986-48,990.}

In our comments on the IPPS proposed rule, MDMA expressed concerns about the lack of clarity regarding the timing of posting individual applications and the fact that CMS did not provide a mechanism for the submission of confidential or proprietary information.\footnote{Letter from Mark Leahey, President and CEO, Medical Device Manufacturers Association, to Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services (June 17, 2022), 5-6, https://www.regulations.gov/comment/CMS-2022-0074-1209.} We appreciate that CMS took steps to address those concerns with improvements to the NTAP application posting process in the IPPS final rule, and that those improvements are reflected in the proposed TPT posting process. As a result, we do not object to the agency’s proposal.

As we similarly noted with regard to the NTAP program, MDMA believes that the TPT program represents a significant policy success for the Medicare program. It has helped reduce disincentives to the adoption of new technologies that are inherent in the OPPS, which has accelerated access to those technologies for Medicare beneficiaries and encouraged investment in the development of innovative new products and therapies. We appreciate the significant effort and resources that CMS has dedicated to the management of the TPT program, and we hope the agency will proceed on any reasonable steps to improve the efficiency and capacity of the application and review process.

\textbf{E. CMS should provide additional guidance regarding the source of the device offset for TPT payments in ASCs.}

In our comments on the CY 2022 OPPS/ASC proposed rule, MDMA expressed concern the lack of a clear methodology for valuation of pass-through devices used in the ASC setting. We appreciate CMS’s effort to provide additional guidance through the publication MLN 12679, Update of the ASC Payment System, in April 2022, as well as the assistance that has been provided to individual companies and ASCs in resolving related claims processing issues. We do ask, however, that CMS provide further clarification on the source of the offset for the portion of total ASC payment related to device value for the corresponding CPT code.

MLN 12679 cites Addendum FF as the correct source for this offset value; but, according to the experience of our members, providers should refer to the ASC Code Pairs file in order to obtain the correct offset. In the case of code pair 0408T and C1824, for example, Addendum FF cites an offset of 50.73\%, while the Code Pairs file cites an offset of 67.02\%, representing a significant difference in the payment value for the portion of the payment assigned to the procedure. We understand that one of our members has provided multiple instances in which confusion resulted for providers who referenced Addendum FF instead of the Code Pairs file, several of which took multiple months to rectify with relevant Medicare Administrative Contractors (MACs). Clarifying the source of the offset is in the best interest of providers who wish to offer devices with pass-through status in ASCs.
III. CMS should ensure that device intensive designations and device offset calculations are based upon accurate data. Specifically, in the CY 2023 final rule, CMS should address circumstances where there is clear evidence that costs for an “insertable” device are not accurately reflected in claims and cost report data by utilizing a subset of correctly coded claims, more recent Medicare claims and cost report data that reflect improved coding, invoice data submitted by the device manufacturer, or a combination of such sources. In addition, CMS should use pricing data provided by the manufacturer to establish the device offset amount for new HCPCS code C9781.

The device-intensive procedure designation has been a pivotal policy in facilitating the movement of procedures out of the hospital outpatient setting and into the ASC setting. The device-intensive procedure policy recognizes that the cost of a device is set regardless of the setting in which it is used, and that ASCs need to be reimbursed adequately for the costs of such devices. Without this policy, the broad group of device-intensive procedures would be financially impractical in the ASC setting.

Unfortunately, we are concerned that issues related to the accuracy of claims data are resulting in the inappropriate denial of device-intensive status for some procedures using insertable devices (i.e., devices not retained in the body post-procedure), as opposed to implantable devices. Effective January 1, 2019, CMS modified the device-intensive criteria to “allow procedures that involve single-use devices, regardless of whether or not they remain in the body after the conclusion of the procedure, to qualify as device-intensive procedures.”17 Device-intensive status was previously reserved for procedures with implanted devices. However, we believe that the underreporting of high cost insertable devices has been pervasive and persistent. As discussed in previous public comments from MDMA and other stakeholders, the inaccuracies in the data are the result of hospital confusion about coding for procedures utilizing insertable devices.18

We appreciate that CMS has recognized and taken a step toward addressing this confusion. In March 2022, the agency issued an update to the Medicare claims processing manual that reinforced the requirement that claims that “report procedure codes that require the use of devices must also report the applicable HCPCS codes and charges for all devices,” and that added clarifying language that “[f]or procedure codes that require the use of devices that are not described by a specific HCPCS code, hospitals should report HCPCS code C1889 (Implantable/insertable device, not otherwise classified) and charges for all devices that are used to perform the procedures.”19 Still, other causes of confusion remain—such as the fact that Revenue Code 278 (Other Implants) does not include a reference to “insertable” devices. Moreover, efforts by manufacturers to educate hospitals about the updated coding guidance have been hampered by the COVID-19 PHE. Finally, any improved coding resulting from the updated guidance and manufacturers’ outreach to hospitals is not reflected in the claims and cost report data that CMS used to develop the Proposed Rule, which predates the update.

17 83 Fed. Reg. at 58,944-58,948.
18 Letter from Mark Leahey, President and CEO, Medical Device Manufacturers Association, to Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services (Sep. 17, 2021), 9-11,  https://www.regulations.gov/comment/CMS-2021-0124-18141 (identifying CPT codes 66174 and 58674 as examples).
CMS has an obligation to use accurate data to inform policy decisions. When faced with clearly inconsistent or inaccurate cost data reporting, CMS has taken action to adjust the calculation methodology or data used to avoid inequitable payment policy. CMS should exercise similar discretion here for device intensive designation and device offset calculations for procedures involving insertable devices, in particular those with a low volume of claims. For procedures that require the use of an insertable device, and for which there is evidence that cost reporting provides an inaccurate representation of device cost, CMS should use an alternative data set, such as a subset of accurate hospital claims data, more recent Medicare data that reflects improved coding, or manufacturer invoices, to determine device intensive status and calculate the device offset percentage. Adopting this approach would ensure accurate information is used to inform device-intensive designations, which will safeguard patient access to procedures that would otherwise be cost-prohibitive in the ASC setting.

Lastly, we urge CMS to use invoices submitted by the manufacturer and providers to establish the device offset for new HCPCS code C9781 (Arthroscopy, shoulder, surgical; with implantation of subacromial spacer, includes debridement, subacromial decompression, acromioplasty, and biceps tenodesis when performed). The procedure described by HCPCS code C9781 is furnished in the hospital outpatient setting and may be furnished in the ASC setting. HCPCS code C9781 is a new procedure that involves a new technology and, as such, CMS does not have any claims data on this new procedure. It is our understanding that CMS has not used pricing data that was submitted to support APC assignment to determine the device offset amount. As a result, payment for HCPCS code C9781 in the ASC setting is $4,017 under the Proposed Rule. This significant underpayment will eliminate ASCs as a viable site of service and thereby eliminate a potentially more convenient point of patient access.

In the CY 2017 OPPS/ASC final rule, CMS finalized a policy to apply device-intensive status at the HCPCS code level, with a default device offset for new HCPCS codes “to ensure ASC access for new procedures codes until claims data become available.” In adopting this policy, CMS also noted that “in certain rare instances, for example, in the case of a very expensive implantable device, we may temporarily assign a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer.” MDMA recommends that CMS use invoices, if available, to designate the appropriate device offset for HCPCS code C9781, consistent with its well-established policy.

IV. CMS should remove CPT code 47550 from the Inpatient Procedure Only (IPO) list.

Intraoperative biliary endoscopy, as reported by CPT code 47550 (Biliary endoscopy, intraoperative (choledochoscopy)), has been on the IPO list for more than 20 years. The procedure allows for direct visualization and identification of abnormalities of tortuous anatomy and aids in the facilitation of the primary procedure, including diagnostic brushing/washing, biopsy(ies), stone removal, strictures, and stenting within the biliary tract. The code is designated by the AMA CPT Editorial Committee as an “add-on” code and is never reported by itself; it is only reported

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20 Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 81 Fed. Reg. 79,562 (Nov. 14, 2016), at 79,658.
21 Id.
secondary to a primary procedure. The primary procedures with which CPT code 47550 is used are not on the IPO list.

MDMA strongly recommends CMS remove CPT code 47550 from the IPO list for CY 2023, as we believe the procedure meets CMS’s criteria for removal. Several clinical articles published over the last several decades support the safety and effectiveness of biliary endoscopy when performed in an outpatient setting.22

We note that the CMS Advisory Panel on Hospital Outpatient Payment voted unanimously to recommend the removal of CPT code 47550 from the IPO list at its meeting on August 23, 2022.23 Removing this procedure from the IPO list will increase access for Medicare beneficiaries and allow physicians to determine the most appropriate setting for their Medicare patients.

V. CMS should provide reimbursement under the OPPS for medical technologies that are used during dialysis but that do not qualify as renal dialysis services.

We understand that CMS continues to evaluate how to facilitate Medicare reimbursement for treatments using medical devices that are administered during dialysis procedures but that are not “renal dialysis services” under the Medicare statute. These treatments can and should be reimbursed by Medicare in other settings of care, including in the hospital outpatient setting through the OPPS. MDMA supports a CMS policy clarifying that such treatments—and the dialysis procedures that accompany them—are appropriately reimbursed through the OPPS benefit.

VI. CMS should finalize its proposed policy providing a blended payment for procedures involving a device provided under a Category B investigational device exemption (IDE) when necessary to preserve the integrity of the IDE study, and provide guidance regarding how it will exercise its discretion to identify when such a blended payment is warranted.

MDMA supports the adoption of a general policy under which CMS will establish special coding and payment for procedures involving the use of Category B devices when differences in coding and payment on claims for patients in the treatment arm compared to those receiving a placebo would undermine the validity of the IDE study.24 As discussed in the preamble, the proposal is based on previous actions taken by CMS related to specific Category B devices. We note that the Proposed Rule does not provide details regarding the process for manufacturers to engage CMS in discussions regarding the appropriateness and need in relation to specific IDE studies and other operational issues. MDMA asks that CMS promptly update its guidance related to coverage of

IDE clinical studies to provide additional information for manufacturers regarding implementation and operation of the new policy.

VII. CMS should finalize the proposal to create new HCPCS codes to replace CPT add-on codes for certain “Software as a Service” diagnostic technologies billed with an associated imaging service, and to provide separate payment for those codes that is equivalent to the payment provided when the services are furnished without an associated imaging service.

In the Proposed Rule, CMS reviews the recent introduction of several important advancements in diagnostic technology that utilize software and artificial intelligence (AI) to assist practitioners in making clinical assessments needed for diagnosis and treatment of patients, as well as efforts undertaken to establish coding and payment for those technologies.\(^2^5\) CMS notes that the coding established for these technologies by the AMA CPT Editorial Panel describes their use in conjunction with a corresponding imaging service using an add-on code that is not eligible for separate payment under the OPPS. Recognizing feedback from stakeholders that these technologies are not consistent with the established definition for an add-on service—i.e., they are “separate and distinct services that should be paid separately, rather than as services that are ancillary, supportive, dependent, or adjunctive to a primary service into which their payment is packaged”\(^2^6\)—CMS is proposing to establish new HCPCS codes to replace the CPT add-on codes for Medicare claims processing, and to assign those new HCPCS codes to the identical APCs with the same status indicator as the corresponding standalone codes.

Specifically, CMS is proposing to establish two new HCPCS C-codes—C97X1 (Quantitative magnetic resonance analysis of tissue composition (e.g., fat, iron, water content), includes multiparametric data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure)) to replace CPT add-on code 0649T for the LiverMultiScan procedure, and C97X3 (Quantitative magnetic resonance cholangiopancreatography (QMRCP) includes data acquisition, preparation, transmission, interpretation and report, performed in the same session and/or same date with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure)) to replace CPT add-on code 0724T for the QMRCP procedure. MDMA agrees that these are not add-on services. We strongly support finalizing the proposal to establish HCPCS codes C97X1 and C97X3 and to provide payment for LiverMultiScan and QMRCP as separate and distinct services under the OPPS.

In addition, consistent with the above policy, CMS should issue a HCPCS C-code to replace CPT add-on code 0698T (Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure); multiple organs (List separately in addition to code for primary procedure)). This code will provide separate payment for the new CoverScan technology discussed previously in Section I.H. of this comment letter, following the same rationale CMS has proposed for LiverMultiScan and QMRCP.

\(^2^5\) Id. at 44,684-44,688.
\(^2^6\) Id. at 44,687.
With regard to CMS’s comment solicitation seeking stakeholder recommendations for the development of a “payment approach that would broadly apply to SaaS procedures,”27 we appreciate CMS’s careful and deliberative approach in seeking to better understand the growing use of AI and software algorithms in health care delivery, including direct application in the provision of care to beneficiaries, and in evaluating how these innovative technologies should be incorporated into Medicare payment systems. As we noted in comments submitted in response to a previous request for information (RFI) contained in the CY 2022 Medicare PFS proposed rule, AI services—including SaaS technologies—are varied and diverse, and a one-size-fits-all answer to addressing payment could be challenging or even impossible to develop depending on the payment system and policy question presented.28

With regard to the specific proposal discussed above, we believe CMS should exercise caution with regard to expanding this approach to clinical areas beyond diagnostic imaging where AI and SaaS are used in very different ways with vastly varied costs. CMS instead should consider technology-specific payment strategies for future innovations in the AI and SaaS space. We also recommend that CMS work with experts in the field to establish clear and consistent definitions for AI, SaaS and related terminology as a foundation for smart policy moving forward. MDMA recommends using the AI Taxonomy adopted by the AMA CPT Editorial Panel in September 2021 as a starting point. Standard definitions are essential to move forward with appropriate valuation of AI algorithms and SaaS.

As CMS has noted in various RFIs, new applications of AI, software and algorithms in health care delivery are developing rapidly. CMS must balance the need for appropriate and timely reimbursement mechanisms with careful consideration of the various factors involved and the potential impact on the development and adoption of future innovations. To date, CMS has approached information gathering largely through RFIs and other efforts tied to specific payment systems and isolated policy issues. We encourage CMS to establish a separate, comprehensive RFI on this subject which will allow the Agency to share its assumptions, concerns and questions more thoroughly with all interested parties, and provide an opportunity for the public to respond in a more focused and thoughtful manner.

VIII. CMS should finalize the proposal to create a special payment policy designed to provide appropriate ASC payment for code combinations that are eligible for complexity adjustments under the OPPS.

We applaud CMS for proposing this payment policy for qualifying procedure combinations as the adjusted payment rates will more appropriately reflect the resources required to deliver these services, and encourage CMS to implement this policy for CY 2023. However, we do have two additional comments for CMS’ consideration as it implements this policy.

27 Id. at 44,688-44,689.
28 Letter from Mark Leahey, President and CEO, Medical Device Manufacturers Association, to Chiquita Brooks-LaSure, Administrator, Centers for Medicare and Medicaid Services (Sep. 13, 2021), 5-6, https://www.regulations.gov/comment/CMS-2021-0119-33020.
First, it is not clear why CMS needs to create new C-codes for ASCs to report the combination of a primary and add-on procedure as they are clearly both reported with existing HCPCS codes. Complexity adjustments in the hospital outpatient setting do not require the creation or billing of C-codes to describe the combined primary and add-on procedure, and the payment adjustment is addressed automatically by the claims processing system. It is unclear to us why CMS is proposing to create specific C-codes for these procedure combinations, unless there is a limitation within the claims processing system to implement this policy. Therefore, we recommend that CMS utilize the combination of the qualifying HCPCS codes to automatically trigger the adjusted payment level, and not create specific C-codes for ASC billing. We believe that annual changes to the C-code list will add confusion for ASC billing and create unnecessary administrative burden on providers, MACs and CMS itself. Should the C-codes be required to appropriately administer this policy change, we request that CMS include additional details in the CY 2023 Final OPPS rule to better understand the rationale for these new codes.

Second, we recommend that CMS analyze the impact of this new policy on the affected codes annually and seek public comment on whether further adjustments to the methodology are needed.

Finally, regardless of whether CMS does or does not create specific C-codes, we recommend that CMS list the primary and add-on code combinations that qualify under this policy (including the payment rates) in an additional Addendum in the ASC payment files. We believe this will be the most straight-forward way for providers to find the code combinations that qualify for this adjustment, and will also allow for easier comparison for year-to-year changes in coding combinations that qualify for this special payment policy.

IX. MDMA opposes the addition of a new category of procedures to the list of hospital outpatient department (HOPD) procedures requiring prior authorization. In addition, we strongly reiterate our previous comments raising concerns about the expansion of prior authorization requirements in the Medicare fee-for-service (FFS) program—concerns that are shared by Congress and other stakeholders, and for which CMS has yet to provide any significant response.

CMS is proposing to add a new service category—“facet joint interventions,” which includes facet joint injections, medial blocks and radiofrequency ablation—to the list of procedures for which a provider must obtain prior authorization from its Medicare Administrative Contractor (MAC) before providing the therapy to a Medicare beneficiary.29 We strongly oppose this proposal.

First, we believe there are questions whether Medicare claims data supports the expansion. The HOPD prior authorization program specifies that prior authorization is to be used for controlling service volume increases that are unnecessary.30 An MDMA member analyzed publicly available claims data and was unable to replicate the agency’s analysis or confirm the cited seven percent annual volume increase for facet radiofrequency ablation procedures under CPT codes 64633-64636. We have previously stated our “concerns regarding the lack of transparency in the analytical approach and the difficulty in accessing the data set used by CMS to determine that [a

30 See Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 84 Fed. Reg. 61142 (Nov. 12, 2019), at 61,446-61,456.
procedure proposed for prior authorization] had rates of growth that suggested inappropriate use;” and that “[p]rior authorization, which inherently increases burden and cost for providers and beneficiaries, should not be based on unsupported assumptions or arbitrary and non-transparent decision-making.” CMS should share the volume increase analyses conducted for all procedures that have been added to the HOPD prior authorization list since its inception. These analyses will help interested stakeholders understand the rationale behind these policy decisions and provide necessary insights for CMS’s future policy making.

Our concerns regarding the implementation and expansion of HOPD prior authorization in the Medicare FFS program go beyond the lack of transparency and are founded upon the belief that unnecessary and excessive use of prior authorization delays and in some cases may prevent access for beneficiaries to medically necessary care and imposes administrative burden and cost on providers. Those concerns were detailed in an April 2021 letter to CMS signed by 40 stakeholder groups. We reiterate and update the request set forth in that letter—that the agency withhold action on any further expansion of prior authorization requirements until:

- CMS has conducted a thorough analysis of the impact of prior authorization on the procedures for which it has been implemented, including the extent to which the MACs have been able to meet the timeframes for processing prior authorization requests, and the cost and other burdens imposed upon providers and beneficiaries relative to the benefit to the Medicare program from reductions in inappropriate utilization; and

- the agency has established specific criteria, through a transparent process incorporating feedback from beneficiaries and other stakeholders, to guide its decision-making related to the use of prior authorization.

Similar concerns and a similar request were expressed in a letter sent to CMS from a bipartisan group of 50 Members of Congress, which noted “that CMS is proposing to move forward with this expansion of prior authorization without the necessary guardrails to ensure beneficiary access to care is protected.” To date, CMS has taken no action to respond to the specific concerns raised by stakeholders and Congress, or to implement or even request additional comment on the recommendations for improving the program. We find this refusal to act alarming given the severity of the potential impact on beneficiaries and providers from unnecessary prior authorization—in particular questions about the role that prior authorization could play in exacerbating disparities in access to care for underserved communities and other health inequities, about which CMS and the Administration otherwise expresses profound concern.

In summary, MDMA strongly disagrees with the agency’s proposal to impose burdensome prior authorization requirements on facet joint interventions. Instead, CMS should leverage tools at its disposal, including audit and enforcement resources, to monitor utilization and identify practitioners who may be performing procedures that are not reasonable and medically necessary. CMS should immediately publish complete details regarding the volume analysis used to justify the proposed expansions and the HOPD prior authorization requirements that are currently in place, proceed with a full evaluation of the impact of the HOPD prior authorization program on beneficiaries and providers, and engage stakeholders in the development of criteria to guide future decisions regarding prior authorization requirements.

**Conclusion**

Thank you for the opportunity to provide comments on the CY 2023 OPPS and ASC proposed rule. MDMA looks forward to working with CMS as it develops the final rule. If we can be of any further assistance, please contact me at mleahey@medicaldevices.org or (202) 354-7171.

Sincerely,

Mark Leahey
President and CEO
Medical Device Manufacturers Association