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September 6, 2022

**Via Electronic Mail**

Chiquita Brooks-LaSure, Administrator  
Centers for Medicare and Medicaid Services  
Attn: CMS-1770-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**Re: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies—CMS-1770-P**

Dear Administrator Brooks-LaSure,

The Advanced Medical Technology Association (AdvaMed) appreciates the opportunity to comment on the CY 2023 Physician Fee Schedule Proposed Rule, CMS-1770-P. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

Our comments cover issues raised in the rule where we support specific CMS proposals and others where we recommend modifications to ensure Medicare beneficiary access to high quality medical technologies and procedures. Our letter includes comments under the following categories:

- Determination of Practice Expense Relative Value Units
  - CMS request for public comment on strategies for updates to practice expense data collection and methodology



- Public comments on strategies for improving global surgical package valuation
- Separate Payment for the Service Described by CPT 92229 in the Federally Qualified Health Centers (FQHCs)
- Payment for Medicare Telehealth Services Under Section 1834(m) of the Act
- Expansion of Category 3 covered services
- Proposed Valuation of Specific Codes
- Non-Face-to-Face/Remote Therapeutic Monitoring Services
  - Review of new RTM device code: cognitive behavioral therapy monitoring
  - Moving forward on RTM and other digital devices
- Payment for Skin Substitutes
- Rebasing and Revising the Medicare Economic Index (MEI)
- Clinical Laboratory Fee Schedule (CLFS)
- Removal of Selected National Coverage Determinations
- Establishing a National Payment Rate for 0583T, an In-Office Tympanostomy Procedure Using the Tula System

### **Determination of Practice Expense (PE) Relative Value Units (RVUs)**

#### Soliciting Public Comment on Strategies for Updates to Practice Expense Data Collection and Methodology

We thank CMS for an opportunity to comment on updates to the practice expense methodology used for the PFS. We believe that the methodology used for the calculation of practice expense needs to be reviewed and revised to account for the ongoing changes in the delivery of medical care, especially the advances in medical technology. We appreciate that CMS has recently updated the data for supplies, equipment and clinical labor and contracted with RAND to develop and assess potential improvements in the current PE methodology. Instead of iterative steps CMS should develop a comprehensive plan that allows for public comment.

As a first step, we note that CMS needs a methodology that will allow the Agency to provide frequent updates of practice expense data similar to other updates to the PFS (e.g., the 5-year updates to malpractice). ***We urge CMS use a methodology that will allow more frequent updates of practice expenses, or alternatively invite stakeholders to submit updated practice expense information on an as needed basis,*** to avoid last year's significant shifts for certain physician specialties because clinical labor costs had not been updated for 20 years.

We further urge CMS to consider the unique practice expense requirements associated with the delivery of services reliant on expensive equipment. Many specialty practices, such as radiation oncology, are dependent on expensive equipment to provide beneficiaries' care. The costs associated with acquiring, maintaining, and updating this equipment are also highly specialized, and we therefore recommend CMS work with



specialists in these fields to better understand their true cost and ensure physicians and their practices are appropriately reimbursed for expenses incurred.

To promote predictability and stability in physician payments and to mitigate the financial impacts of significant fluctuations in relative weights that might accompany updates, we also recommend that CMS also consider a threshold for limiting the level of reductions in payments that would occur in a single year because of the updates and transition over a timeline consistent with the threshold. CMS has implemented similar measures in the past, both through statutory requirement and under its own authority, in an effort to avoid significant disruptions to the Medicare payment system. In the CY 2016 PFS Final Rule, CMS finalized the phase-in policy of significant RVU reductions for services that are not new or revised codes. In this policy, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period.<sup>1</sup>

We further note that in the FY 2023 IPPS Final Rule, CMS will implement a permanent 10 percent cap on the reduction in an MS-DRG's relative weight in a given fiscal year, with CMS applying a budget neutrality adjustment to the standardized amount for all hospitals to ensure application of the cap does not increase estimated aggregate payments for MS-DRGs. At the present time, AdvaMed is not advocating for a specific threshold of reduction protection because of updates, only for consideration of the concept as a way to protect physician practices against some of the negative financial consequences accompanying the update.

In the short term, CMS needs to develop a payment policy that recognizes AI, software as a service (SaaS), and software as a device (SaaD) as a direct practice expense. While we appreciate CMS' efforts to date to provide national pricing for certain of these digital technologies, we urge the Agency to ensure that its current assumptions in the PE methodology do not undervalue AI, SaaS, and SaaD used in providing specific services to specific Medicare beneficiaries. We point out that the RAND corporation in its report for CMS on Practice Expense Data Collection and Methodology noted that some services, for example, those using AI, may not be appropriately accounted for under the current methodology used by CMS. For the rapidly evolving technologies used in health care today, many software-powered services are not simply part of equipment hardware and should be attributed to a specific service. CMS' assumption that software and licensing fees are always an indirect cost is not correct. In fact, software that is not part of hardware or equipment and can be attributed to a specific service has been and should be considered a direct cost. ***As such, AI, SaaS, and SaaD when used for a service attributed to a specific patient should be considered direct PE. It is critical that CMS correct its assumptions about AI, SaaS, and SaaD so that beneficiaries have access to the benefits that accompany physicians' use of these services and recognize in its assumptions***

<sup>1</sup> 80 Fed. Reg. 70927 through 70931



***the need to reflect the costs of innovation and updating of AI and other software.***

As part of its comprehensive review of PE, AdvaMed recommends that CMS develop criteria to evaluate AI, SaaS, and SaaD that will differentiate the types of technologies (e.g., algorithmic, self-learning, augmented intelligence). We recommend that CMS consider the AMA's CPT new Appendix S for AI as an approach to consider for structuring this differentiation.<sup>2</sup> A taxonomy like the Appendix S will also create more uniformity in coding and, in the end, coverage and payment, which will accelerate future access to AI, SaaS, and SaaD technologies. We also recommend that the Agency seek stakeholder input through NPRMs for each step of the development of a framework for making decisions on a framework for differentiating these technologies by type and complexity that will lead to consistent decisions about value and payment across Medicare's benefit categories. Medicare may also need to hire a contractor with expertise in these issues to review how each type of AI, SaaS, and SaaD functions, a technology's specific clinical utility, and how it interacts with the clinician and extracts more information from data. We urge CMS once again to use stakeholder input for providing real world perspectives on a contractor's findings.

AI, SaaS, and SaaD should *not* be viewed as "operating in the background" simultaneously for patients. Some types of AI, SaaS, and SaaD should be paid separately because of the added value they provide for a specific patient's condition, while other types may not need to be paid separately. Furthermore, AI, SaaS, and SaaD may be unique to a specific service and patient diagnosis, warranting an approach to value PE on a case-by-case basis. CMS should also consider the different business models through which AI, SaaS, and SaaD are made available to hospitals, physicians, and other providers, including: (1) a subscription model where the customer pays a monthly fee independent of the number of uses; (2) a per click model where the customer pays each time the AI is used; (3) a yearly fee; (4) a licensing model; and (5) an add-on payment to a piece of capital equipment. The contractor should analyze how and when these models are used and how they can be incorporated Medicare's payment systems.

In summary, while we are pleased that CMS has provided national pricing for certain AI systems, we believe that access to a higher standard of care for Medicare beneficiaries will be jeopardized unless CMS takes a much broader approach to developing a framework across the program's benefit categories for differentiating AI, SaaS, and SaaD, understanding their value in the context of specific health care services, and how value should be translated into specific payments. These consequences may be especially serious for medically underserved communities in both rural and urban areas, and as such, will contribute to exacerbating existing disparities in health care outcomes for certain racial and ethnic groups.

<sup>2</sup> <https://www.ama-assn.org/system/files/cpt-appendix-s.pdf>



Beyond these comments, we note that the sheer variety of AI, SaaS, and SaaD technologies used in health care delivery today and expanding significantly in the future, with their different designs and intended uses, makes it very difficult to generalize about the impact these technologies will have on values of individual components of the RVU for a service. This may require that CMS evaluate each individual physician service with AI, SaaS, and SaaD on a case-by-case basis to determine how they should be appropriately valued.

As previously indicated, we recommend CMS develop comprehensive criteria for evaluating AI, SaaS, and SaaD but as part of an immediate solution we urge CMS to carefully evaluate and define differences between types of AI, SaaS, and SaaD technologies. This evaluation should include consideration of how costs will vary based on the individual service, the information provided, physician specialty, patient cohort, the operational model for incorporating the technology into clinical practice and how the clinical information is used for the diagnosis and treatment of a specific disease. Until a revised payment methodology is established, we recommend CMS follow the methodology it used for determining the RVUs for Fractional Flow Reserve Computed Tomography for cardiac disease (e.g., HeartFlow). In this case, CMS cross-walked the cost for this service to services with similar established RVUs.

CMS has signaled in the CY 2023 OPPS Proposed Rule that the Agency is considering recognizing software itself as a service. We believe a comprehensive understanding and approach dedicated to evaluating a cost methodology for AI, SaaS, and SaaD is also critically needed for physician services.

For these reasons, ***AdvaMed urges CMS to publish a separate Request for Information (RFI) for all stakeholders to provide their recommendations for a comprehensive rethinking of the overall assumptions and payment methodology for AI, SaaS, and SaaD in all Medicare payment systems with a separate focus on the methodology CMS uses for measuring practice expenses in the PFS to reflect current and future trends in health care delivery. It is urgent that CMS start this process immediately if beneficiaries are to benefit from wide variety of digital advances in health care delivery and providers are to be encouraged to incorporate these advances into their practices.***

#### Soliciting Public Comment on Strategies for Improving Global Surgical Package Valuation

CMS is seeking public comment on strategies to improve the accuracy of payment for global surgical packages under the PFS. Our comments for this proposal are very general. Whatever changes CMS makes in valuation of global surgical valuations and their impact on current valuations should move forward only through a future proposed rule. As discussed above, any major changes to valuations should be phased in to protect beneficiaries from compromised access to care and to mitigate financial swings to physicians. Changes should also consider health equity concerns and address current disparities in access that exist for racial and ethnic minorities.



## **Separate Payment for the Service Described by CPT 92229 in the Federally Qualified Health Centers (FQHCs)**

CMS proposes separate payment for chronic condition management (CCM). As with CCM, the lack of separate payment for CPT 92229 outside of the FQHC PPS has emerged as a barrier for adoption by FQHCs, and as a result, a hurdle for access in the most vulnerable communities. We note that the Medicare Outpatient Prospective Payment System (OPPS) has assigned CPT 92229 to Ambulatory Payment Classification (APC) 5733 (Level 2 Minor Procedures) with a status indicator of "separate payment". In addition, CMS permits separate payment for glaucoma screening as a stand-alone billable visit if no other services are furnished on the same day. Separate payment for CPT 92229 in the PPS for FQHCs and RHCs will similarly encourage access to the service for Medicare beneficiaries.

## **Payment for Medicare Telehealth Services under Section 1834(m) of the Act**

### Requests to Add Services to the Medicare Telehealth Services List

AdvaMed continues to commend CMS for its strong leadership on ensuring beneficiary access to telehealth and other communication technology-based services during the public health emergency (PHE). In this year's Proposed Rule, CMS would expand the current Category 3 List to cover additional services--both those now on the List on a temporary basis and those not on the current List--through the end of 2023 while stakeholders gather data to support their possible permanent inclusion on the List.

***AdvaMed supports these proposals, and we especially appreciate CMS' proactive efforts to use the Category 3 concept the Agency introduced in 2021 to expand the breadth of what could be covered telehealth services beyond the PHE.***

AdvaMed also supports CMS' decision to simplify the process when all telehealth flexibilities introduced during the PHE will end to correspond to the 151-day extension for specific waivers provided in the Consolidated Appropriations Act, 2022 (CAA, 2022).

Regarding new Category 3 services, AdvaMed requests that CMS adopt its proposal to add to the Category 3 List CPT codes 95970, 95983, and 95984 for deep brain stimulation analysis and programming.

***As we did last year in our comment letter on the CY 2022 PFS Proposed Rule, AdvaMed again argues that CMS should continue the concept of interim coverage under Category 3 after the PHE ends and establish a permanent Category 3 program for making decisions about potential telehealth services for which CMS requires additional evidence before being placed on the List.***

Under this option, CMS would allow the addition of services to the Telehealth List as Category 3 services to provide clinicians the necessary time to develop the evidence required for adding services to the Telehealth List on a permanent basis. It would avoid situations where CMS decides to disapprove adding a service to the List on an



annual basis through the PFS rule when a requestor has had insufficient time to develop evidence to make the case for a service being added to the List. This pathway could be limited, for example, specifically to services that would fall into Category 2 services, where evidence on outcomes is generally required for approval. In this way, services could be added on an interim basis as requests are made and this would signal the beginning of evidence generation for ultimate approval/disapproval. A timeframe for generating the evidence would be specified for generating necessary evidence. This pathway might be especially useful if Congress amends the telehealth benefit to eliminate the rural restriction, allows the home to be a site of service, or expands the categories of practitioners who are permitted to provide telehealth services.

***In the interim, we ask that CMS extend the Category 3 List through the end of 2024 to ensure that sufficient data can be collected to make the case for including these services on the Telehealth Services List on a permanent basis.***

We note that our proposal for a longer timeframe for assessing Category 3 services corresponds to legislation already passed by the House July 27, 2022, to extend telehealth waivers through the end of 2024. Extending the Category 3 List through the end of 2024 would also allow CMS to assess the benefits of making Category 3 a permanent part of the telehealth program beyond the PHE.

**Beyond the PHE**

We recognize that CMS rulemaking cannot address provisions of Medicare statute that limit the availability of telehealth services to beneficiaries living in rural areas and do not allow the home as a site of care. We believe that waiving of these two requirements during the PHE has demonstrated the effectiveness of telehealth as an important source of care for beneficiaries, and especially for the growing number of patients aged 85+ and those with multiple chronic conditions, regardless of whether a pandemic limits access to office-based or facility-based care. We strongly urge that CMS support efforts in the Congress to address the statute's limitations that impede beneficiary access to telehealth. AdvaMed continues to be on record as supporting permanent changes to the statutory authority for telehealth services and we urge CMS to work with Congress to make the PHE waiver expansions permanent.

**Support for Proposal that Ambulatory Continuous Glucose Monitoring is a Non-Face-to-Face Service**

AdvaMed agrees with CMS' assessment that Ambulatory Continuous Glucose Monitoring, CPT code 95251, is an inherently non-face-to-face service, and therefore, does not describe a service that is a substitute for an in-person visit. Real-time CGM is a glucose monitoring technology that continuously measures interstitial glucose levels and displays the current blood glucose level, its direction and rate of change. The data is available on patients' personal CGM receiver and smart device, as well as being accessible online by their providers when given patient permission.



The ability to monitor a patient's CGM data is a powerful tool for physicians to help patients manage their diabetes. Physicians can view, analyze, and interpret CGM data without a patient's physical or virtual presence. CPT code 95251 also does not require any E/M visit (in-person or telehealth). **CMS should finalize its proposal that CPT code 95251 is inherently a non-face-to-face service and should not add this service to the Medicare Telehealth Services List.**

Furthermore, CMS should ensure that its policies relative to CPT code 95251 under the Physician Fee Schedule are aligned with the CGM coverage criteria under Local Coverage Determination (LCD) L33822.<sup>3</sup> L33822 requires Medicare beneficiaries to meet "in-person" with their treating practitioner within six months prior to the original CGM prescription and every six months thereafter to continue CGM therapy. The term, "in-person" is not defined in L33822, nor in CMS' regulations, nor the Social Security Act. The regulation at 42 CFR 410.38(c)(5) implies that "in-person" means being physically present, but because "in-person" is not an explicitly defined term, this is unclear and cautious suppliers may require the beneficiary to be physically present during the six-month visits and not recognize a telehealth-provided E/M visit to meet this requirement.

Under NCD 280.14, an insulin pump, often used by the same patients that use CGM, requires that the visits with the treating physician be "face-to-face," a term that is defined at 42 CFR 410.38(c)(5) to be "in-person or telehealth."<sup>4</sup>

Interpretation of CGM data under 95251, an inherently non-face-to-face service, is very frequently done by provider in connection with the six-month visits required for continued CGM coverage. However, the language of L33822 seems to require the patient to be physically present for the office visit portions of that service, even though office visits generally have been deemed eligible telehealth services by CMS and the policy for insulin pumps allows such periodic visits to be done via telehealth. Physicians do not need to physically see the beneficiary to view, analyze, and report their CGM data (CPT code 95251) and could easily perform the office visit portions of the required six-month visit for CGM coverage, absent the requirement of L33822 that such visits be "in-person." Physicians should be allowed the flexibility to furnish the six-month visits for these beneficiaries via telehealth.

**AdvaMed therefore recommends CMS ask the DME Medicare Administrator Contractors (DME MACs) to clarify the existing requirement of L33822 that Medicare beneficiaries meet "in-person" with their prescribing practitioner every six-months, to permit these visits to occur via "in-person" or telehealth.**

<sup>3</sup> Local Coverage Determination: Glucose Monitors L33822 <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDID=33822&ContrID=140>

<sup>4</sup> National Coverage Determination: Infusion Pumps 280.14 <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDID=223&ncdver=2>



### Expiration of PHE Flexibilities for Direct Supervision Requirements

Prior to the PHE, direct supervision of diagnostic tests, services incident to physician services, and other specified services required the immediate availability of the supervising physician or other practitioner. CMS interpreted this "immediate availability" to mean in-person, physical availability, and not virtual availability. During the PHE, CMS changed the definition of "direct supervision" to allow the supervising professional to be immediately available through a virtual presence using real-time audio technology for the direct supervision of diagnostic tests, physician services, and some hospital outpatient services. This flexibility has also facilitated the provision of telehealth services by clinical staff of physicians and practitioners' services incident to their own professional services. CMS finalized continuation of this policy through the end of the year in which the PHE ends.

***AdvaMed urges CMS to make these changes permanent. By doing so, CMS will expand access to care for a growing 85+ population and for persons with multiple chronic conditions, for whom office-based care has become difficult or impossible. The result will be better care management and care outcomes for patients.*** Virtual/digital technologies, liberated from restrictions in regulations and other coverage policies during the PHE, and in this case, virtual direct supervision, have demonstrated how they make possible safe and quality care in beneficiaries' homes. This new knowledge should transform our understanding of how care can be delivered in the future. We urge CMS to undertake a comprehensive review and revision of its regulations and other coverage policies to reflect our expanded understanding of what is possible for the delivery of care in the community and lead the nation in defining new pathways to coverage and payment for digitally based services.

### **Valuation for Specific Codes**

#### Anterior Abdominal Hernia Repair (CPT codes 49X01-49X15)

At its February 2021 meeting, the CPT Editorial Panel established new codes to report abdominal hernia repair procedures effective January 1, 2023. The existing codes were identified by the RUC due to a site of service anomaly and a separate request was received from the specialty society to update code descriptors to better describe these procedures as performed in current practice. New CPT codes were established, and the codes are now characterized by three factors: (1) whether the hernia is initial or recurrent; (2) whether the hernia is reducible or incarcerated/strangulated; and (3) the total length of the hernia defect (< 3cm, 3-10cm, or > 10cm in length). The CPT codes no longer indicate the type of abdominal hernia (ventral, incisional, umbilical, epigastric, or spigelian), or the surgical approach (open, laparoscopic, or robotic assisted).

The specialty societies collected data on typical site-of-service, hospital stays and associated Evaluation and Management (E/M) visits for the new codes through the RUC



survey process. The RUC recommendations for this family of codes differentiate the post-operative periods based on discharge status, same-day, overnight with an E/M visit on the same date, or if the patient is admitted to the hospital. CMS did not accept the recommendations of the RUC on the post-operative period and subsequent patient follow-up, noting that many of the new CPT codes for abdominal hernia repair already include a post-operative time in their valuation and the work associated with a follow-up visit should not be included for the service where the 23-hour policy is applied.

Consequently, CMS is proposing to reduce the RUC recommendations for the services identified that are subject to the 23-hour stay policy (49X02, 49X03, 49X04, 49X05, 49X08, 49X09), and also proposed to apply the 23-hour rule to the new CPT codes that are proposed as payable in the inpatient setting only under the OPPS for CY 2023 (49X06, 49X10, 49X11, 49X12, 49X13, 49X14). This proposal results in arbitrary reductions in RVUs, although the RVUs recommended by the RUC were determined through a validated RUC survey. **AdvaMed therefore requests that CMS consider the RVUs for the new abdominal hernia repair codes as recommended by the RUC, and work with the relevant specialty societies to address any discrepancies related to the application of the 23-hour policy.**

#### Percutaneous Nephrolithotomy (CPT codes 50080, 50081)

The CPT® Editorial Panel revised the descriptors for the Percutaneous Nephrolithotomy codes (CPT-4 codes 50080 and 50081) at the September 2021 meeting. As CMS notes, these codes were identified via the site of service anomaly screen, to be performed less than 50 percent of the time in the inpatient setting, but both codes have 90-day global periods. During the review, the descriptors were revised and image guidance and nephrostomy tube placement were added. These services were not included in the previous descriptors and had been reported separately.

For CPT 50080, CMS agreed with the RUC recommended intra-service time of 90 minutes and 244 minutes of total time. However, CMS disagreed with the RUC recommended work RVU of 13.50 and is proposing a work RVU of 12.11 for CPT code 50080 based entirely on the percentage of change from current intra-service time of 117 minutes, with no consideration for intensity of service.

Work RVUs take into consideration intensity of service in addition to time, and we submit that revisions to the code descriptor to add services which were previously separately reportable (image guidance and nephrostomy tube placement) increase the intensity of the service, which is appropriately reflected in the RUC recommendation.

CMS' proposed work RVU for CPT code 50080 is based on a comparison to the work RVUs of only two CPT codes with 90 minutes of intra-service time, 36830 (*Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (e.g., biological collagen, thermoplastic graft)*), and CPT code 36818 (*Arteriovenous anastomosis, open; by upper arm cephalic vein*)



*transposition).* Neither of these codes is clinically similar to nephrolithotomy and neither reflects the work intensity required for the nephrolithotomy procedures.

***AdvaMed respectfully requests that CMS instead consider that the recommended RUC RVUs be consistent with the work for numerous other procedures of comparable length, including surgical procedures that are more clinically similar to nephrolithotomy than CPT codes 36830 and 36818.*** There are more than 250 codes with the same intraservice time as proposed for 50080 (90 minutes), and one third of these codes have work RVUs greater than 13.5. In addition, there are 5 codes with intraservice times of 90 minutes and work RVUs between 13.46 and 13.50. These include 55875 (transperineal placement of biodegradable material, periprostatic, single or multiple injection(s), including image guidance, when performed) which has comparable total time (249 minutes) to 50080 and is a better clinical comparator to 50080 than the two arteriovenous codes that CMS has proposed to use as a reference. ***We further request that CMS maintain the proposed differential of 8.50 in work RVUs between 50080 and 50081, which would align to the RUC-recommended work RVUs of 20.61 for 50081.***

#### Long-Term Electrocardiography Monitoring (LT-ECG) Services (CPT Codes 93241-93248)

AdvaMed's comments address two different issues raised in the proposed rule on External Extended Electrocardiography Monitoring Services (LT-ECG services): (1) a proposed national payment rate under the PFS for LT-ECG services; and (2) appropriately valuing artificial intelligence and software algorithms used for these services.

#### *Proposed Supply Cost for Supply Item SD339*

AdvaMed appreciates CMS's proposal to update payment for SD339 (extended external ECG patch). CMS proposes to increase the supply cost for SD339 to \$245.69 from previous \$200.15, and in doing so indicates that it received two additional invoices that priced the supply item at either \$265.00 or \$226.38. CMS proposes averaging these two prices together to establish the proposed price of \$245.69 for the SD339 supply.

***AdvaMed agrees with CMS's approach to pricing this supply item and believes that using updated invoices and other cost data submitted by device manufacturers to calculate the supply costs most accurately reflects current costs and accounts for inflation and supply chain constraints not represented on invoices previously submitted.***

#### *Proposed National Payment Rate for LT-ECG Services*

AdvaMed appreciates CMS's proposal for a National rate for CPT codes 93241-93248. However, we request that CMS reconsider the National payment rate set forth in the proposed rule.



In the fall of 2021, AdvaMed entered into a contract with KPMG LLP (KPMG) to respond to CMS's request for additional information about the costs incurred to provide LT-ECG services. The analysis included cost information from four companies representing nearly 87% of the independent diagnostic testing facility space, which are members of AdvaMed (referred to in this section of our comment letter as the Participating Companies).

Each of the Participating Companies are enrolled Medicare providers and offer LT-ECG services through a vertically integrated model, commonly referred to as an independent diagnostic testing facility (IDTF). **It is our understanding that IDTF providers account for 99 percent of the LT-ECG services billed to Medicare for all provider types.**

Under vertical integration, the same company which develops and manufactures LT-ECG services and artificial intelligence (AI) software systems also delivers the services associated with collecting, scanning, and analyzing the ECG data, and preparing custom reports for physician interpretation, as reported with CPT codes 93243 and 93247.

KPMG obtained actual and projected cost data specific to the provision of LT-ECG services from each of the Participating Companies projected for the period 2020 into 2024. KPMG performed the analysis in the fall of 2021. Therefore, KPMG was provided historical cost data for 2020 and three-quarters of 2021. The Participating Companies provided KPMG with projected service levels and costs for the fourth quarter of 2021 and 2022 through 2024. We note that projected cost data may change due to a number of factors including inflation, changes in supply chain costs, etc.

KPMG analyzed each Participating Company's data to determine the assumptions and allocation methods used in each cost model. To develop a consistent basis for analysis, KPMG disaggregated the major cost categories and reclassified costs as necessary to make the classification of costs consistent across the Participating Companies. This methodology ensured that no double counting of costs would be included in the totals.

The Participating Companies' costs were segregated into these categories—cost of goods sold<sup>5</sup>, direct labor<sup>6</sup>, and other indirect costs (e.g., IT support, finance, rent)<sup>7</sup>. All three categories are necessary to fully account for and understand the resources expended by an IDTF to provide LT-ECG services. The table below reflects how these cost categories map to the PE RVU input.

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<sup>5</sup> Cost of goods sold is the total cost directly related to the production of a product or the provision of one service per patient (including the product's form factor components and clinical software that is embedded into the device to allow retrieval and analysis of the ECG recordings).

<sup>6</sup> Direct labor is the cost of payroll that can be specifically and consistently assigned to, or associated with, manufacturing a product or provision of a service.

<sup>7</sup> Indirect costs represent the costs of doing business not readily identified with a specific product or service but are necessary to operate a company and conduct the services it provides.



<b>AdvaMed Analysis Cost Categories</b>	<b>Medicare PFS Payment Rates Formula - PE RVU</b>
Cost of Goods Sold	Direct PE RVU
Direct Labor	Direct PE RVU and Indirect PE RVU
Other Indirect	Indirect PE RVU

Importantly, the three categories above **do not** consider the consumption of non-device assets used in the delivery of LT-ECG services (e.g., software and processing). These additional costs are necessary for efficient and effective delivery of the services.

In addition to the three cost categories above, the analysis also considered the costs associated with the purchase of capital equipment<sup>8</sup>, regulatory, and research and development ("R&D")<sup>9</sup>. These are **ongoing** costs that the Participating Companies incur to provide high-quality services to Medicare beneficiaries that should be recognized for reimbursement. Further, we note that KPMG's cost analysis reported direct and indirect costs without consideration of a profit margin. This final cost calculation therefore reflects only the inputs to the costs and not the final recommended payment amount.

For anti-trust reasons, we are unable to discuss the specific findings of this cost analysis in public comments and have submitted another letter whose contents we ask be considered confidential. When compared to the KPMG final cost calculation per service, CMS's proposed rates do not adequately cover the costs for vertically integrated IDTFs to provide LT-ECG services. The KPMG analysis demonstrates that CMS' proposed payments do not adequately account for all costs associated with manufacturing and delivery of LT-ECG services (e.g., the patch device, software, and processing per patient) that are necessary for the efficient and effective delivery of services. We strongly support the detailed KPMG aggregated model and request that CMS set a fair and representative National payment rate that incorporates the costs calculated within this analysis.

**AdvaMed therefore requests CMS price LT-ECG monitoring in a manner that recognizes the total cost to produce LT-ECG technologies, including capital expenditures and research and development.**

#### *IDTF Costs Not Well Reflected in the PFS*

AdvaMed believes that an underlying problem for establishing payment rates for LT-ECG is the IDTF model itself, which does not easily fit into CMS's methodology for

<sup>8</sup> Capital equipment consists of items used to manufacture a product or provide a service. Examples of capital equipment include machinery used on the production line and servers used to store and process the clinical analysis software.

<sup>9</sup> R&D is the process by which a company works to obtain new knowledge it might use to create or improve technology, products, services, or systems it utilizes to manufacture a product or deliver a service.



paying for physician services. We urge CMS to consider refinements to its practice expense (PE) data collection and methodology to appropriately reimburse the full range of Medicare providers, including various IDTF models. The PE allocation system has various shortcomings due to reliance on out-of-date data sources, such as the Physician Practice Information (PPI) Survey. The PE cost measures based on the 2006 PPI Survey of expenses have not been regularly updated and thus do not reflect current costs in the U.S. economy and health care system. Specifically, the IDTF model was not represented in the survey, which primarily includes physicians and selected non-physician practitioners (NPPs). Currently IDTF costs are represented via blended, supplemental survey from the National Coalition of Quality Diagnostic Imaging Services and the American College of Radiology. There are three IDTF segmented markets with different cost structures which include: (1) Radiology Imaging Services; (2) Mobile Units; and (3) Remote Cardiac Monitoring Services. We do not believe the data currently used to value IDTF monitoring services is comprehensive or accurate. IDTF providers are diverse and varied, spanning multiple medical specialties and incorporating modalities that vary in their cost structures. Alternative data sources are necessary to update the current PE allocation process to include different IDTF cost structures and improve compatibility of the IDTF practice expense, including unique AI and software algorithms.

**AdvaMed therefore recommends CMS:**

- **Reevaluate the PPI Survey methodology and incorporate IDTF-specific questions into the next iteration of the PPI Survey or develop a separate survey to collect IDTF data that represent IDTFs accurately; and**
- **Work with a contractor with expertise in survey methodology and the IDTF provider type to develop a survey to appropriately capture the unique cost structure of IDTFs, including expenses related to research and development and unique AI and SaaS.**

Cardiac Ablation Services Bundling (CPT codes 93653-93657)

Prior to the CY 2022 PFS Proposed Rule, the CPT Editorial Panel revised electrophysiology (EP) ablation code descriptors for 93653 and 93656 to bundle additional services. Because of these changes, EP ablation codes were surveyed in the fall of 2020 by the American College of Cardiology (ACC) and the Heart Rhythm Society (HRS) for the RUC. The results from the physician work surveys demonstrated notable reductions in ablation procedure times for all arrhythmias, and in particular, significant time reductions for the bundled codes. In late 2020, ACC and HRS were concerned that the survey respondents did not fully understand the bundling of EP services in the newly created code descriptors and requested the CPT Editorial Panel rescind the coding changes for CY 2022. However, the CPT Editorial Panel Executive Committee did not rescind these changes. The surveying specialties then resurveyed these codes, and the second survey results were presented at the April 2021 RUC meeting. The RUC submitted final recommendations for revised codes 93653-93657 for



CY 2022 in May 2021, though CMS decided to delay consideration of this recommendation until the CY 2023 cycle.

For CY 2022, CMS opted to maintain the physician times and work RVUs for codes 93654 and reduce both 93655 and 93657 by 26.7%. For codes 93653 and 93656, CMS maintained the previously established times and values without accounting for the newly bundled work that was previously separately reported. The combination of these bundled codes experienced a 30-36% decrease in reimbursement from the prior year.

In the CY 2023 PFS Proposed Rule, CMS reviewed the April 2021 RUC recommendations based on the resurvey but did not accept the recommendations. The Agency noted that in its view, the reductions in service time found in the surveys were not commensurate with the reductions in RVUs recommended by the RUC. Instead, CMS recommends significantly lower work RVU for the codes beyond the RUC recommendations. For 93653, CMS proposes a work RVU of 13.80, based on a comparator code – 37299 (Revascularization, endovascular, open or percutaneous, tibial/peroneal artery, with atherectomy includes angioplasty within the same vessel when performed) – with 5% less total time than the amount reported through the RUC surveys, leading to a proposed work RVU that is 8% less than the RUC recommended RVUs. CMS notes that the comparator code has the same intra-service time (120 minutes) as the RUC survey for code 93653.

However, CMS' focus on physician times does not account for important differences in the services such as procedure intensity (for example, CPT Code 93653 is performed on a beating heart with risk of multiple complications such as cardiac perforation/tamponade) and technical skill of the physician that is managing multiple imaging modalities, electrogram signals, and ablation energy parameters simultaneously while holding a catheter tip within a 2-3 mm space. Additionally, the comparator code 37229 is performed the majority of time in a different site of service. While 93653 is conducted entirely in inpatient and hospital outpatient settings, 37229 is performed in the physician's office approximately 75% of the time. This further highlights the increased complexity and risk of ablation services compared to the comparator code.

AdvaMed believes that CMS' proposed reductions do not appropriately reflect the skills, technical intensity, and risks of ablation procedures. Additionally, the proposed reductions come on top of reductions in last year's PFS final rule and may jeopardize the availability of these services to Medicare beneficiaries. Ablation has been shown to improve patient quality of life and decrease hospitalizations and mortality, with particular benefits seen in patients with heart failure.<sup>10,11,12</sup> Evidence also continues to

<sup>10</sup> Mark, Daniel B., et al. "Effect of catheter ablation vs medical therapy on quality of life among patients with atrial fibrillation: the CABANA randomized clinical trial." *Jama* 321.13 (2019): 1275-1285.

<sup>11</sup> Noseworthy, Peter A., et al. "Atrial fibrillation ablation in practice: assessing CABANA generalizability." *European heart journal* 40.16 (2019): 1257-1264.

<sup>12</sup> Marrouche, Nassir F., et al. "Catheter ablation for atrial fibrillation with heart failure." *New England Journal of Medicine* 378.5 (2018): 417-427.



support the value of earlier ablation, which is associated with improved patient outcomes and a significant reduction in healthcare resource use through the avoidance of complications such as stroke, myocardial infarction, tachycardia, and heart failure.<sup>13,14,15,16</sup> The significant reductions in payment could reduce the number of physicians offering ablation services.

***AdvaMed urges CMS to re-examine its proposed valuations for cardiac ablation codes and consider, at a minimum, the April 2021 AMA RUC recommendations.***

New G-codes for Reporting and Payment of Chronic Pain Management Codes (CPM)

CMS has proposed the creation of two new G-codes (GYYY1 and GYYY2) to recognize the resources involved with chronic pain management. This will better differentiate the comprehensive work performed by clinicians that manage acute and chronic pain episodes outside of the traditional E/M codes. We believe these new codes function as useful tools for primary care doctors to provide care for patients experiencing chronic pain. Given the specialized nature and usually complex causes associated with pain symptoms, we would also like to encourage CMS to ensure that Medicare beneficiaries have timely and unhindered access to pain specialists.

***AdvaMed supports CMS' proposal to create two new codes to establish a bundled payment for integrated multimodal pain care.*** We agree that the creation of distinct codes for the management of patients with chronic pain provides a better payment mechanism versus add-ons to E/M codes, particularly related to the correct comment on the time spent on correct dosing of medications. As stated by CMS, these bundles would directly align financial incentives with Federal efforts to address pain management.

With regard to the request to comment on permitting billing of CPM services for beneficiaries who have already been diagnosed with chronic pain (in addition to those being diagnosed with chronic pain during the visit); we would respectfully suggest inclusion of all patients with adequate medical documentation that they have met the definition of chronic pain. Patients already diagnosed and meeting the definition of chronic pain may still benefit from improved care coordination, medication

<sup>13</sup> Kuck, Karl-Heinz, et al. "Catheter ablation or medical therapy to delay progression of atrial fibrillation: the randomized controlled atrial fibrillation progression trial (ATTEST)." *EP Europace* 23.3 (2021): 362-369a.

<sup>14</sup> D'Angelo, Robert N., et al. "Very early versus early referral for ablation in young patients with newly diagnosed paroxysmal atrial fibrillation." *Pacing and Clinical Electrophysiology* 45.3 (2022): 348-356.

<sup>15</sup> Bunch TJ, May HT, Bair TL, et al. Increasing time between first diagnosis of atrial fibrillation and catheter ablation adversely affects long-term outcomes. *Heart Rhythm*. 2013;10(9):1257-1262. doi:10.1016/j.hrthm.2013.05.013.

<sup>16</sup> De Greef Y, Schwagten B, Chierchia GB, De Asmundis C, Stockman D, Buyschaert I. Diagnosis-to-ablation time as a predictor of success: Early choice for pulmonary vein isolation and long-term outcome in atrial fibrillation: Results from the Middelheim-PVI Registry. *Europace*. 2018;20(4):589-595. doi:10.1093/europace/euw426.



management, and other activities encompassed by this code. Allowing physicians to bill these new codes for the management of existing patients, in addition to new patients, creates an equitable care environment.

We additionally suggest that the CPM codes be added to the Telehealth Services List, given many chronic pain patients may not have the time or need for a face-to-face visit monthly. This provides greater flexibility and access to care versus requiring an in-person visit monthly.

While patients earlier in their journey managing chronic pain may have care primarily coordinated by a primary care practitioner, others progressing to high-impact chronic pain may have their care mainly coordinated via a Pain Management physician. We support the allowance to have codes billed at a maximum twice per month to account for the difference in specialty primarily managing a patient's care. As a suggestion, when describing the care coordination provided in the description of code GYYY1, the addition of "Pain Management Specialists" would create a more complete list: "ongoing communication and care coordination between relevant practitioners furnishing care (e.g., physical therapy and occupational therapy, community-based care, and pain management specialists)".

In response to comments on appropriate valuation of codes, we defer to physician societies on this item on specifically what care should be factored into the RVU levels.

Finally, given the many questions around appropriate billing of this code, we respectfully suggest that a MedLearn article or Educational Transmittal would be useful to providers with information on appropriate documentation for billing, who can bill the code, and what potential restrictions are based on overlap with other CCI bundles and potential procedures billed on the same visit (or within the same month).

### **Non-Face-to-Face Services/Remote Therapeutic Monitoring (RTM) Services**

AdvaMed would first like to thank CMS for responding to stakeholder concerns about new RTM codes over the past two years and working to find solutions to policy issues raised in prior rules to ensure beneficiary access to services that are part of the transformation of the delivery of care through digital health technologies.

We do, however, have two major concerns with the four HCPCS G codes for RTM treatment management services (GRTM1 and GRMT2) and RTM treatment assessment services (GRTM3 and GRMT4) described in the Proposed Rule. Our first concern is CMS' including in the descriptors of the new G codes two requirements: (1) that CPT codes for RTM (98975 and 98976 or 98977) must be billed prior to reporting the codes, and (2) that at least 16 days of data must be reported for GRMT1 and GRMT3.

In the case of the first requirement, remote physiologic monitoring treatment management service codes (CPT codes 99457 and 99458) do not have similar requirements tying these work services codes to the CPT device codes, e.g., CPT code 99454. Providers may bill either the work service codes or the device codes on any



given month separately without requiring a device code being reported before the billing of the treatment management code. We do not understand why this requirement would be proposed to be included for RTM services. With regard to the second requirement of reporting at least 16 days of data, we question whether 16 days of data are really necessary for a provider to make clinical decisions based on the information provided from remote therapeutic monitoring. We assume that CMS is aware that the CPT Editorial Panel will be considering a proposal to establish new codes to report monitoring of less than 16 days. In fact, we urge CMS to reconsider this first requirement and move to establish a code for less than 16 days of monitoring. These proposals, designed to improve access to these important medical technologies, will instead negatively affect the ability of practitioners to provide RTM services and potentially exacerbate health inequities.

A second concern we have with the RTM proposals is the significant difference in value CMS would assign to GRTM3/4 when performed by nonphysician qualified health care professionals--physical therapists (PTs) and occupational therapists (OTs), in particular--as compared to physicians. We understand that qualified nonphysician healthcare practitioners cannot bill for services provided incident to their own services. However, as a practical matter, no difference exists in the complexity or time of RTM services provided by therapists and physicians. And we understand that PTs and OTs do use Physical Therapy Assistants and Occupational Therapy Assistants who represent clinical staff expense to the PT and OT. We ask that CMS increase the values for RTM services provided by nonphysician qualified health care professionals to accurately reflect the costs associated with these new G codes.

#### Review of New RTM Device Code: Cognitive Behavioral Therapy Monitoring

AdvaMed appreciates CMS' acknowledgement of cognitive behavioral therapy (CBT) as part of remote therapeutic monitoring (RTM) codes and its review of the newly established RTM device supply code for CBT monitoring, CPT code 989X6.

With regard specifically to CBT being included in the RTM codes, our concerns with the proposed G codes are they do not include the new CBT code 989X6 or mention CBT. As we have discussed in the previous section, CMS has included in the descriptors of the new G codes two requirements: (1) that CPT codes for RTM (98975 and 98976 or 98977) must be billed prior to reporting the codes; and (2) that at least 16 days of data be reported for GRMT1 and GRMT3. As we noted above, providers should be able to bill either work codes or device codes on any given month separately, without requiring a device code to be billed before the billing of the treatment management code. These requirements will unnecessarily limit the new GRTM work codes to only respiratory and musculoskeletal work which is clearly not a limitation intended by CPT.

Remote physiologic monitoring codes (CPT codes 99457 and 99458) do not have similar requirements tying these work codes to CPT device codes, e.g., CPT code 99454. Regarding the second requirement of reporting at least 16 days of data, we reiterate our concern that 16 days of data are not necessary for a provider to make



clinical decisions based on the information provided from remote therapeutic monitoring. Again, we assume that CMS is aware that the CPT Editorial Panel will be considering a proposal to establish new codes to report monitoring of less than 16 days; and we urge CMS to reconsider this first requirement and establish a code for less than 16 days of monitoring. These proposals, which CMS intended to improve access to this important medical technology, will instead negatively affect the ability of practitioners to provide RTM services and potentially exacerbate health inequities.

### Moving Forward on RTM and Other Digital Devices

As noted above, we appreciate CMS' adoption of the RPM and RTM family of codes. We also appreciate CMS' proposal to create G codes to clarify that physician and non-physician practitioners could engage auxiliary personnel to furnish RTM treatment management services under general supervision, and to clarify that qualified non-physician health care professionals such as occupational therapists, physical therapists, and others could furnish RTM treatment management services directly. These codes—along with CMS' proposed changes—enable clinicians to leverage digital health technologies to track patients outside the four-walls of the practice.

However, these codes should not be viewed as a catch-all for all digital devices that may be used incident-to a physician's service and may be reasonable and necessary for the treatment of illness or injury. That is, there are other digital devices that are grounded in clinical evidence and are reasonable and necessary for the treatment of conditions that are common in the Medicare population, but where RPM and RTM codes fall short of describing the device and associated service. ***Given the ongoing crisis in access to behavioral health services and growing evidence that supports use of this technology, we urge CMS to consider ways to account for these types of therapeutic devices, specifically digital therapeutics, that are not described by the existing RTM code set but nonetheless hold promise for expanding access to care and would be appropriately paid under the physician service benefit category.***

### Request for Information on Remote Therapeutic Monitoring

RTM is a new, evolving technology and CMS needs to develop flexible payment policies that evolve with the technology and health benefits to patients. The same points we made above about AI, SaaS, and SaaD in the context of practice expenses is relevant here as well. RTM with its different designs and intended uses makes it difficult to generalize about the impact these technologies will have on specific uses. Costs can be expected to vary by patient cohort, physician specialty, and how clinical information is used for the treatment of specific conditions. The lengths of episodes of care can vary from weeks following a procedure or illness to ongoing in the case of chronic conditions and diseases. The kind of data collected is expanding from cardio-pulmonary measures to include wound healing and gait improvement, and the clinical conditions for which remote monitoring can bring value is expanding constantly. All of this points to the



need for CMS's remote monitoring policies to take a flexible approach to allow payment for new applications as the technology evolves.

## Payment For Skin Substitutes

### Changing the Terminology of Skin Substitutes

CMS aims to clarify policies for skin substitute products and believes that improving how these products are referenced will address confusion on how these products are defined and ultimately paid. CMS is proposing to replace the term "skin substitutes" with the term "wound care management" or "wound care management products" and solicits feedback on this proposal. CMS also expresses interest in other possible terms that could be used to "more meaningfully and accurately describe" the suite of products currently referred to as skin substitutes.

AdvaMed opposes the proposal to replace the term "skin substitutes" with "wound care management" or "wound care management products." As a foundational issue, AdvaMed does not believe the term "skin substitutes" is problematic or confusing. Indeed, what seems most confusing is to depart from the phrase "skin substitute" that has been in use for years and remains in pertinent Current Procedural Terminology (CPT) codes, such as 15271-15278. CMS' only stated reason for replacing the terminology is that skin substitutes "do not actually function like human skin that is grafted onto a wound." While CMS' statement may be accurate such as it is, AdvaMed is unaware that the use of the term "skin substitutes" has ever been conflated with human skin that is grafted onto a wound, commonly referred to as "skin graft".

Indeed, use of the term "wound care management product" is far more likely to create a problem rather than solving one that we do not believe exists today. AdvaMed believes "wound care management product" does not sufficiently distinguish skin substitutes from wound care dressings or bandages that are also used to treat wounds but without a mechanism of action that stimulates the host to regenerate lost tissue. CMS itself distinguishes wound care dressings and bandages from skin substitutes (87 FR 46028) yet proposes new nomenclature that—when considering that CMS intends to treat all products as incident to supplies—could easily be misinterpreted to include both types of products as opposed to the term "skin substitutes" where the distinction between skin grafts, skin substitutes and wound care dressings or bandages is clear.

CMS acknowledges in the proposed rule potential issues with the use of the term "care management" and its likely conflation with AMA CPT evaluation and management (E/M) codes. AdvaMed agrees that by adopting these terms, there is likely to be confusion and believes that this concern is significant enough to not support the use of the terms "wound care management" or "wound care management products." Instead, AdvaMed recommends the term "Cellular and/or tissue-based products (CTPs)" as a replacement term for "skin substitutes." We believe this term will better achieve CMS' goal of more accurately describing the entire suite of products but without the possible misinterpretation as other medical products or services. Not only would this term



better align with FDA categorization, and review process for these products, it would align with the ASTM International definition of a CTP, which is "*CTPs are defined primarily by their composition and comprise of cells and/or the extracellular components of tissue. CTPs may contain cells (viable or nonviable), tissues, proteins, and other materials for which there is a rationale for benefit beyond that achievable with conventional wound coverings. CTPs may additionally include synthetic components.*"<sup>17</sup>

**AdvaMed opposes the proposal to replace the term "skin substitutes" with the term "wound care management" or "wound care management products," and instead recommends CMS replace the term "skin substitutes" with the term Cellular and/or tissue-based products (CTPs)"**

#### Revising Payment for Skin Substitutes

CMS proposes that effective January 1, 2024, all skin substitute products furnished in the physician office be considered as incident to supplies, and CMS would no longer pay separately for skin substitute products under the average sales price (ASP)+6 percent payment methodology as of that date. Rather, CMS indicates that, starting in CY 2024, it would contractor price skin substitutes as separately payable medical supplies while it researches bundling them into Medicare's physician fee schedule (PFS) payment using the practice expense (PE) methodology over an unspecified time period. AdvaMed notes that CMS had a consistent policy for skin substitutes across the PFS and OPPS prior to CY 2014 when all these products were paid separately using the same methodology as biologicals. Beginning in CY 2014, CMS began a policy of packaging skin substitutes under the OPPS while continuing separate payment under the PFS. CMS could reestablish that consistent policy by reverting to separate payment for skin substitutes as CMS did prior to 2014. Such consistency would actually be improved today relative to 2014 as section 1847A(f)(2) of the Act requires ASP reporting effective January 1, 2022 for "products that are payable under this part as a drug or biological."

Under the PFS, CMS determines the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. For skin substitutes to be paid as "incident to" supplies that are bundled into the Medicare PFS payment requires CMS to establish proposed PE relative value units (RVU) for skin substitute application procedure codes 15271-15278. Absent these PE RVUs, the public is not in a position to provide meaningful comment on CMS' proposal. Until such time as CMS can propose PE RVUs for procedure codes 15271-15278 inclusive of skin substitutes, explain how it

<sup>17</sup> Standard Guide for Classification of Cellular and/or Tissue Based Products (CTPs) for Skin Wounds. ASTM International. Current edition approved Feb15, 2022. Published March 2022 Last previous edition approved in 2016 as F3163-16DOI:10.1520/F3163-22



would develop those RVUs in a step-by-step fashion, and make the supporting information available to the public, AdvaMed recommends that CMS delay its proposal.

Deployment of the PE methodology to determine the costs of the direct resources involves an assessment of a “typical service.” It would be incredibly difficult to accurately assess the cost of skin substitute products in this manner as the uses of these products vary immensely and would change based on the size of the wound, the intended use, and product type. Moreover, the incorporation of skin substitute products across the PFS could result in an unpredictable redistribution of funds to or from other unrelated PFS services merely as a result of how CMS decides to pay these products. Such dramatic changes in reimbursement will have a major impact on the ability of physicians to deliver these important services to Medicare beneficiaries.

If CMS does move forward with treating these products as incident to supplies that are bundled into payment for PFS services, CMS would be incorporating products that are currently paid separately and outside of PFS budget neutrality into a system with a fixed pool of funds. In this event, AdvaMed believes that aggregate expenditures for skin substitutes should be added to PFS pool of funds that are subject to budget neutrality. Otherwise, a fixed pool of PFS funding will be stretched over a larger volume of items and services and Medicare would realize savings merely from shifting the payment mechanism for skin substitute products.

As part of the process outlined in the proposed rule, in CY 2023, skin substitute products previously assigned Q codes will continue to be paid under the current ASP+6 percent payment methodology. CMS expects to retire all Q codes for skin substitutes by the end of 2023. Starting January 1, 2024, CMS will automatically assign A codes to those skin substitute products where the manufacturer has a Q code and is a 510(K) or PMA. All other HCT/P skin substitutes will need to apply and qualify for a code by January 1, 2024. The A code will be contractor priced. Pricing consistency is much easier established using ASP+6 percent. With contractor pricing, each Medicare Administrative Contractor (MAC) will be able to set its own price for a skin substitute, making inconsistent national pricing a virtual certainty. ASP+6 percent could instead be used to establish uniform national pricing based on overall market pricing reported to CMS if the agency was to include ASP pricing for all skin substitutes on its quarterly ASP pricing files. As indicated above, section 1847A(f)(2) requires ASP reporting for all products treated as drugs and biologicals under Part B. If CMS were to make all reported ASP pricing publicly available, this provision enables CMS to have the information needed to establish ASP+6 percent rates for all products, which would improve pricing consistency rather than detract from it as would occur under CMS’ current proposal.

AdvaMed opposes interim pricing by MACs and recommends instead ASP+6 percent pricing continue on an interim basis—with all ASP reported pricing being made publicly available—until CMS first proposes how it would incorporate skin substitute products into the procedural payment. Should these proposals prove unworkable, we would



encourage CMS to continue to allow ASP+6 percent pricing for skin substitutes on a permanent basis. Many skin substitutes are priced using the methodologies that apply under section 1847A of the Act to drug and biologicals. Leaving pricing to the MACs risks inaccurate pricing determinations as MACs are not provided any direction on the methodology to be used to price these services. Under section 1847A(f)(2)(A) of the Act, ASP must be reported for items, services, supplies, and products that are payable under this part as a drug or biological effective January 1, 2022. If CMS were to post all ASP pricing reported on its Part B drug files, paying for all skin substitutes at ASP+6% immediately advances CMS policy objectives of reducing Medicare spending and lowering out-of-pocket copayments for beneficiaries, as CMS would cease paying for skin substitute products at list or invoice price. This would mean paying for all skin substitutes on the basis of an audited and vetted sales price, inclusive of discounts, rather than instructing each MAC to develop their own pricing, which leaves open the possibility of continued payment at list or invoice price.

In the CY 2023 outpatient prospective payment proposed rule, CMS references the PFS proposed rule policy indicating that "if [CMS'] proposed policy is finalized, manufacturers would not report ASPs for skin substitute products starting in CY 2023" (87 FR 44651). However, AdvaMed notes that this would result in a gap in data if skin substitute products with existing Q codes were to be priced via the ASP+6 percent methodology for the entirety of 2023. AdvaMed recommends that CMS continue ASP reporting through at least the 2<sup>nd</sup> calendar quarter of 2023 (April through June) such that these ASP prices continue to be available through the 4<sup>th</sup> quarter of 2023 (October through December). Changing this requirement as AdvaMed requests will ensure no data gaps prior to a new pricing methodology being deployed for these services.

- **AdvaMed recommends that CMS not bundle skin substitute products under the PFS.**
- **AdvaMed recommends that CMS display reported ASP pricing for skin substitutes, as applicable, on its Part B drug files on the CMS website.**
- **However, if CMS does move forward with this proposal, AdvaMed recommends:**
  - **CMS delay bundling skin substitute products under the PFS until CMS can propose PE RVUs for procedure codes 15721-15278 inclusive of skin substitutes, explain how it would develop those RVUs in a step-by-step fashion, make the supporting information available to the public, and allow time for the public to provide meaningful comment.**
  - **Aggregate expenditures for skin substitutes be added to the PFS pool of funds that are subject to budget neutrality.**
  - **CMS continue current ASP reporting for the 2<sup>nd</sup> calendar quarter of 2023 (April through June) such that these ASP prices continue to be available through the 4<sup>th</sup> quarter of 2023 (October through December).**



### General Coding Proposal for all Wound Care Management Products

With the objective of streamlining coding for wound care management products, CMS proposes assignment of A codes to all wound care management products (that are not drugs or biological products eligible for separate payment under section 1847A of the Act) would continue with respect to products for which a HCPCS Level II code is requested for the first time, as well as for wound care management products previously assigned a Q code. AdvaMed continues to advocate that consistent with prior policy, CMS provide all skin substitutes with product specific Q-codes<sup>18</sup>.

As part of its proposal, CMS plans to discontinue all existing Q codes for wound care management products and assign those products an A code. This process would require the manufacturer of any HCT/P product that has not already been provided with a recommendation from the Food and Drug Administration's (FDA) Tissue Reference Group (TRG) to submit a HCPCS Level II re-application within 12 months of the effective date of the final rule (that is, January 1, 2023). Additionally, for applicants with products described as a 361 HCT/P, a recommendation letter from the TRG is also needed for submission of the HCPCS Level II application. CMS notes that as of May 2022, there are approximately 150 unique HCPCS Level II codes that describe wound care management products. AdvaMed is concerned about the ability of FDA to accommodate this timeline to provide applicants with the required TRG letter of recommendation. To ensure that FDA can work within this timeframe, AdvaMed recommends CMS assess FDA's progress in advance of next year's PFS rulemaking and report that data in the CY 2024 proposed rule. At that time, CMS should consider whether timelines need to be adjusted to best accommodate the resources at FDA and the applicant to ensure no discontinuation or gap in products available to Medicare beneficiaries. It is important to note that CMS could still ensure 361 compliance by requiring the TRG recommendation letter within a certain period of time without transitioning to A codes (i.e., keeping the product specific Q-codes). This would reduce the administrative work required to submit a new HCPCS II application for an A code.

Additionally, the two MACs, First Coast Service Options and Novitas, recently released draft local coverage determinations (LCD) (DL36377 and DL35041). The LCDs do not explicitly mandate the certification of 361 compliance, but strongly imply that proposed covered products (Group 2 codes) could be removed from coverage if 361 compliance is not demonstrated, perhaps as early as the September 24<sup>th</sup> comment deadline<sup>19</sup>. This deadline is not only unworkable, it interferes with CMS' proposed policy. These LCDs

<sup>18</sup> See 78 FR 74932 "...HCPCS Q-codes are typically assigned to drugs and biologicals and are used to describe skin substitutes..." and 86 FR 63563 "The CY 2014 OPPS/ASC final rule with comment also described skin substitutes as "...a class of products that we treat as biologicals..."

<sup>19</sup> See corresponding article DA57680 and DA52117 "It is recommended that the manufacturer of the particular skin substitute graft or CTP product obtain the appropriate information for FDA regulatory compliance and send to the MAC along with evidence-based literature, if available. Once this information has been received by the MAC, the product will be considered for coverage and placed into the appropriate Code Group"



are effectively requiring a TRG letter on a far more expedited basis than CMS would be requiring in regulation if it finalizes the above policy. AdvaMed recommends that CMS instruct the MACs to remove this recommended/mandated requirement from these LCDs to allow CMS national policy makers to decide when and if to mandate 361 compliance. We are concerned that multiple requirements could cause needless confusion among providers and potential disruption in patient care.

- ***AdvaMed continues to advocate that CMS provide all skin substitutes with product specific Q-codes.***
- ***If CMS moves forward with transitioning to A codes for these services, AdvaMed recommends CMS assess FDA's progress in advance of next year's PFS rulemaking and report that data in the CY 2024 proposed rule.***
- ***AdvaMed recommends that CMS instruct Novitas and First Coast Service Options to remove the requirement from their LCDs to allow CMS to consider their proposal.***

### **Rebasing and Revising the Medicare Economic Index (MEI)**

AdvaMed supports CMS' proposal to rebase and revise the MEI. The current MEI is based on 2006-based costs and the cost weights should reflect current market conditions. The 2017 weights for the proposed rebased and revised MEI are significantly different than the 2006-based current weights reflecting changes in the cost of providing physician services. The practice expense share of overall physician costs, for example, increased by 6.5 percentage points from 44.8 percent to 51.3 percent, while the share of physician work and malpractice declined. These data indicate that specialties and services with higher PE costs have been undervalued relative to other services in the PFS and that an update to the MEI weights is long overdue. This update is also necessary to bring fairness and equity to payments for physician services to, and stability to these payments given the significant revisions the PFS during the last several years.

These changes have included 2020 E/M updates resulting in a budget neutrality adjustment of -10.2% to the PFS conversion factor when implemented in 2021, even though the impact has been partially offset and delayed by legislation on a year-to-year basis. In 2021, the update of clinical wages also resulted in significant decreases to practice expense values, particularly for those codes with high supply or equipment costs; over 325 codes had declines of practice expense relative value units of 18 percent or more. Even with a four-year phase-in, many office-based procedures will see further reductions over the remaining three years of the four-year phase-in. These policy changes have occurred over a span where the PFS conversion factor has not kept pace with overall changes in price inflation, which has significantly reduced the purchasing power of providers. We also point out the annual physician fee schedule MEI update has consistently been less than inflation for every year going back to



2012. For these reasons, the MEI should be updated after CMS takes into consideration comments provided by stakeholders to its current proposal.

***AdvaMed thus supports CMS' approach to delay implementation of these adjustments to the PE calculation until the public has commented on the data sources and methodology of the rebased and revised MEI.*** A multi-year transition is appropriate given the large specialty-specific impacts of fully implementing the proposed rebased and revised MEI in one-year. Such a transition would also be consistent with other significant payment changes in the PFS including how CMS updated prices of supply and equipment inputs and its current transition of clinical labor updates for use in its PE methodology.

### **Clinical Laboratory Fee Schedule (CLFS): Revised Data Reporting Period and Phase-in of Payment reductions, and Proposals for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests**

#### Revised Data Reporting Period and Phase-in of Payment Reductions

In accordance with section 4(b) of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA), CMS is proposing to make certain conforming changes to the data reporting and payment requirements for tests paid under the Clinical Laboratory Fee Schedule (CLFS) to reflect the statutorily-mandated delays in private payer data reporting under PAMA (the Protecting Access to Medicare Act of 2014). Specifically, PMAFSCA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2023 through March 31, 2023. No changes were made to the data collection period, which remains January 1, 2019 through June 30, 2019.

Additionally, CMS is also proposing to make conforming changes to payment requirements for tests paid under the CLFS. Section 4 of PMAFSCA further amends the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extends the statutory phase-in of payment reductions resulting from private payor rate implementation through CY 2025. It further amends the Act to specify that the applicable percent for each of CY 2021 and 2022 is 0 percent, and that 15 percent will apply for CYs 2023 through 2025, instead of CYs 2022 through 2024.

AdvaMed urges CMS to use its authority to implement reductions of 0 percent in CY 2023 for clinical diagnostic laboratory tests (CDLTs) whose weighted medians have not been implemented fully. Sec. 1834A(b)(3) states that payment amounts "shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of greater than" the applicable percent. Congress limited CMS' authority to impose a rate reduction that exceeds 15 percent in CY 2023, but Congress did not restrict the agency's ability to impose a rate reduction that is less than that amount, and it did not tell CMS exactly the amount that it must reduce a CLFS rate.



Using its authority to institute a reduction of 0 percent for CLFS rates in CY 2023 would help to mitigate the harm done by the 2016 final rule. Beginning in 2018, CLFS rates have been adversely impacted by the agency's definition of "applicable laboratory" in the 2016 rule. CMS did make a change to the definition of "applicable laboratory" in the CY 2019 Physician Fee Schedule final rule, to include hospital outreach laboratories that bill Medicare Part B on the CMS 1450 under bill type 14x<sup>20</sup>. However, many of the private payor rates that will be reported by applicable laboratories in future data reporting periods already have been affected by the faulty CLFS rates established after the 2017 data reporting period, as those private payor rates are derived from the low Medicare rates. By implementing a reduction of 0 percent, CMS would help to avoid further underpayments for CDLTs under the CLFS.

- ***AdvaMed urges CMS to use its authority to implement reductions of 0 percent in CY 2023 for CDLTs whose weighted medians have not been implemented fully. AdvaMed also supports legislative efforts to improve accurate and sustainable Medicare rates in the future and we encourage CMS to work with Congress to achieve this goal.***

#### Proposals for Specimen Collection Fees for Clinical Diagnostic Laboratory Tests

CMS proposes to codify a number of its manual provision for specimen collection fees for clinical diagnostic laboratory tests. Throughout the COVID-19 pandemic, CMS encouraged access to diagnostic testing through its coverage and increased payment for specimen collection using HCPCS codes G2023 and G2024. AdvaMed supports permanent expansion in the use of these codes beyond the Public Health Emergency (PHE) to promote access to all medically necessary testing, not just COVID-19 testing. We encourage CMS to modify the proposed regulation to permit specimen collection fees for all patients (using G-codes or otherwise) rather than limiting access to homebound or non-hospital inpatients and, at minimum, for patients undergoing diagnostic testing and monitoring for infectious disease conditions (e.g., HIV, hepatitis). Nothing in the authorizing statute (42 U.S.C. (h)(3)(A)) requires CMS to limit specimen collection fees to a specific patient population—in fact, it seems to require the fee more broadly ("the Secretary shall provide for and establish...")—and the pandemic has shown that the availability of at-home or decentralized specimen collection is critical to overall access to care, particularly for vulnerable patient populations.

- ***AdvaMed supports the codification of these CMS payment policies but recommends that CMS expand patient access to specimen collection at decentralized locations.***

#### Expansion of Coverage for Colorectal Cancer Screening and Reducing Barriers

AdvaMed supports CMS' proposal to expand Medicare coverage of certain colorectal cancer (CRC) screening tests by reducing the minimum age payment limitation to 45

<sup>20</sup> 83 Fed. Reg. 59452, 60074 (Nov. 23, 2018).



years, citing updated CRC screening guidance from the CDC, relevant medical societies, and a revised recommendation from the United States Preventive Services Task Force (USPSTF) issued in May 2021. In fact, high rates of colon cancer in African American patients led to recommendations for screening at age 45 for these patients beginning in 2005—16 years before the 2021 U.S. Preventive Services Task Force announcement of a screening age of 45 for all people at average risk for colon cancer.<sup>21,22</sup> Alignment of CMS coverage guidelines for colorectal cancer screening with those of the USPSTF, CDC, and other cancer groups is critical in ensuring that the Agency's coverage policies keep pace with the changing science and advance health equity for the populations of patients who need these screenings the most.

Early detection and treatment of colorectal cancer is critical in ensuring the best possible patient outcomes and can help lower costs associated with treating advanced disease. Lowering the age to receive covered screening will greatly expand access to care for this disease and will aid in improving screening rates for the patients who need them. CMS adoption of this coverage change will also facilitate access to these important screening tests by patients who might otherwise defer needed care at the recommended age due to insurance and other access concerns.

AdvaMed applauds the Agency for including within this proposal barium enema tests and blood-based biomarker tests, two tests that were not recommended in the revised USPSTF recommendation, but that are Medicare covered screening tests and important alternatives to the stool-based and direct visualization tests, especially for individuals with medical complexity and those in rural and underserved communities. We agree with the Agency that consistent coverage and payment policies are important in promoting CRC screening and will result in expanded prevention, early detection, and improved health outcomes.

- ***AdvaMed supports CMS' proposal to expand Medicare coverage of certain CRC screening tests by reducing the minimum age payment limitation to 45 years.***
- ***AdvaMed urges CMS to continue to be flexible in modifying and changing the requirements for these important screening tests over time and as needed to keep pace with the changing science related to the appropriate age for screening, including modifications to the screening age to accommodate specific groups of patients if necessary.***

CMS also proposes to exercise authority under section 1861(pp)(1)(D) of the Act to expand coverage of CRC screening tests to include a follow-on screening colonoscopy after a Medicare covered non-invasive stool-based CRC screening test returns a positive result. CMS proposes to waive the frequency limitations that would otherwise

<sup>21</sup> Agrawal S, Bhupinderjit A, Bhutani MS et al. Colorectal cancer in African Americans. Am J Gastroenterol 2005; 100: 515–523; discussion 514.

<sup>22</sup> Screening for Colorectal Cancer US Preventive Services Task Force Recommendation Statement. JAMA 2021;325(19):1965-1977. doi:10.1001/jama.2021.6238 Corrected on August 24, 2021.



apply for CRC tests for the follow-on screening colonoscopy test when furnished as part of its proposed new complete colorectal cancer screening benefit. Beneficiary cost sharing for the initial screening stool-based test and the follow-on screening colonoscopy test would not apply, and thus Medicare payment for both tests would be at 100 percent.

Non-invasive CRC screening provides flexible care options to accommodate patients for whom a traditional colonoscopy may not be feasible for reasons including the time and expense of prep, time off work, transportation to and from the procedure, and other factors. Historically, a follow-on screening, triggered by a positive non-invasive CRC test result, has meant incurring additional out-of-pocket costs/co-pays to have a diagnostic colonoscopy to either confirm or rule out the non-invasive test findings which may impact the decision, by some patients, to follow-up and to receive an appropriate final diagnosis.

Covering and paying for a follow-up screening colonoscopy at 100 percent, following a positive non-invasive CRC test result, is a positive step in ensuring that patients are completely screened for this disease.

- ***AdvaMed supports the recommendation to cover a follow-up screening colonoscopy at 100 percent following a positive result for a non-invasive CRC screening test.***

CMS also proposes to, over time, reduce the beneficiary co-pay associated with removal of tissue and additional related services rendered during the same clinical encounter as the follow-on colonoscopy from 15 percent to 10 percent beginning in CY 2027 through CY 2029 and to zero percent from CY 2030 and thereafter. The costs associated with receiving care can be a barrier to patients receiving important recommended screening services. Reducing and alleviating these payment obligations may incentivize patients to take advantage of screening without concerns regarding affordability thereby improving access and health equity. Given the importance of colonoscopy in detecting and preventing costly and potentially deadly cancer, the decision to reduce and eventually phase out the beneficiary co-pay obligation is a good one.

- ***AdvaMed supports the decision to reduce the co-pay obligation associated with tissue removal and other services associated with a follow-on screening colonoscopy from 15 percent to 10 percent for CY 2027-CY 2029 and to zero percent for CY 2030 and later.***
- ***AdvaMed further recommends that the agency investigate and share information regarding the ability to further reduce and or phase-out these co-pays at an earlier date if feasible.***

When proposing to reduce the age requirement for CRC screening, CMS included stool-based testing. CMS stated that its rationale for including stool-based testing was that stool-based CRC screening is a category of Medicare-covered CRC screening tests



within NCD 210.3. However, while recognizing the need to cover blood-based biomarker tests for screening and to subsequently reduce the screening age for these tests to 45, CMS does not propose to cover a follow-up screening colonoscopy test after blood-based CRC testing. AdvaMed believes the same logic should be expanded to this section and CMS should finalize a policy that includes coverage of a follow-on screening colonoscopy after a covered blood-based CRC test returns a positive result, similar to the policy for stool-based testing. This would further CMS' goal of consistent coverage and payment policies to promote CRC screening for patients and would also help advance health equity for the populations of patients who need these screenings the most.

- ***AdvaMed recommends CMS also extend this policy to cover a follow-on screening colonoscopy after positive blood-based testing, as it proposes following stool-based testing.***

### **Removal of Selected National Coverage Determinations**

CMS states that it periodically identifies and proposes to remove National Coverage Determinations (NCDs) that are obsolete, no longer reflect current medical practice, or that involve items and services that are used infrequently by beneficiaries.

AdvaMed has long supported coverage policies that enhance appropriate patient access based on advancements in technology and the medical landscape. We further support efforts by CMS to review outdated or obsolete NCDs for items and services when new evidence becomes available or results in inconsistency with current medical practice. Medicare's coverage policies should be nimble and able to reflect those changes, and we appreciate the opportunity to comment on proposals to remove or revise outdated NCDs.

In the proposed rule, CMS requests comment on a proposal to remove NCD 160.22, Ambulatory EEG Monitoring. AdvaMed does not have a position on the proposal to remove the NCD, other than reiterating that Medicare coverage process should include a process for removing obsolete policies, when necessary, or revising them to be consistent with the current state of the evidence.

A related issue is the lack of transparency surrounding CMS' methods for managing NCD requests, prioritizing topics, and the provision of information to the public regarding the waiting list. We often hear from our members that a formal NCD request was submitted to CMS, but because there is no specified timeline for CMS to respond to such requests or to provide information regarding the waiting list, requestors have no visibility into the process or timeline for action on their requests.

We urge CMS to provide greater transparency regarding the status of NCD requests, prioritization of those requests and the status of the current waiting list.

We were pleased to see, in September of 2020, that CMS had posted on its website a dashboard (<https://www.cms.gov/files/document/ncd-wait-list.pdf>) of NCD requests



under review, requests that had been reviewed but not yet opened (referred to as the NCD Wait List), opened with a national coverage analysis (NCA) underway, or finalized within the previous 12 months. The NCD Wait List described complete, formal NCD requests that had been accepted by CMS that CMS noted it intends to open at some future date.

This dashboard represents a positive step forward toward transparency of NCD processes. However, the dashboard did not provide complete details regarding the NCAs that were underway or the NCDs that had been finalized, and it has not been updated since it was posted to the website in 2020.

**AdvaMed recommends CMS:**

- ***Update the NCD Dashboard, at least annually; and***
- ***Provide additional detail on the dashboard listing the NCDs in each category, rather than only listing NCDs on the waiting list.***

**Establishing a National Payment Rate for 0583T, an In-Office Tympanostomy Procedure Using the Tula System that Allows Patient Access to an FDA-Approved Breakthrough Technology**

AdvaMed appreciates CMS' willingness to continue its consideration of the Tula System--based on its clinical evidence, the importance of setting a national rate, the potential cost savings to the healthcare system, and the promise of this procedure to support rural and vulnerable populations.

We continue to ask that CMS assign national RVUs for 0583T (tympanostomy procedure using the Tula System). We believe that assigning national RVUs for 0583T would also advance health equity by enabling access to an FDA-approved breakthrough technology for Medicare and Medicaid-covered children. This procedure is currently priced by the Medicare Administrative Contractors (MACs) based on an individual claim consideration basis, so there are no MAC or national payment rates that state Medicaid agencies or commercial payers can use to set a rate for this procedure.

The need for a Medicare rate to serve as signal to Medicaid was highlighted in the February 2017 Issue Brief<sup>23</sup> released by the Medicaid and CHIP Payment and Access Commission (MACPAC), at <https://www.macpac.gov/wp-content/uploads/2017/02/Medicaid-Physician-Fee-for-Service-Payment-Policy.pdf>. This report reinforces the importance of Medicare rates, as 38 states use Medicare rates as a benchmark to set procedure reimbursement rates.

Without a national Medicare physician payment rate, Medicaid state agencies establish crosswalks to non-comparable services that effectively block access to this less invasive procedure for thousands of vulnerable children covered by Medicaid. While we were disappointed that the CY 2023 rule did not include a proposed physician rate for

<sup>23</sup> "Medicaid Fee-For-Service Payment Policy" February 2017 Issue Brief, The Medicaid CHIP Payment and Advisory Commission



0583T, we appreciate the many complex policy issues CMS grappled with in the proposed rule, and sincerely hope CMS will develop a national rate for this procedure in the future.

A national rate would support patient access to a procedure performed in an office versus an OR, significantly reducing costs by not involving a facility fee and offering patients an alternative to address their unmet needs.

***AdvaMed therefore strongly encourages CMS to set a rate for 0583T in the final rule. Alternatively, we urge CMS to propose national RVUs in next year's proposed rule for CY 2024. This would leverage Medicare's leadership as a national payer and support access to this breakthrough device that helps children with recurrent ear infections.***

Once again, we appreciate this opportunity to provide our input and recommendations for CMS' consideration in the CY2023 PFS final rule. If you have any questions or need additional information, please contact Richard Price ([rprice@advamed.org](mailto:rprice@advamed.org)).

Sincerely,

Chandra N. Branham, JD  
Senior Vice President and Head of Payment & Health Care Delivery Policy

