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AAHKS AMERICAN ASSOCIATION OF HIP AND KNEE SURGEONS

MEMORANDUM

To: AAHKS **From:** Epstein Becker & Green, P.C.

Date: August 6, 2024

Re: Summary of the Proposed 2025 Medicare Payment Rules: Physician Fee Schedule; Outpatient Prospective Payment System; and Ambulatory Surgical Centers

The Centers for Medicare & Medicaid Services (CMS) recently released both the CY 2025 Medicare Physician Fee Schedule (PFS) proposed rule and the CY 2025 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System (OPPS & ASC) proposed rule. Comments on the proposed rules are due September 9, 2024. The following is a summary of policies in the proposed rules that may affect AAHKS members.

PHYSICIAN FEE SCHEDULE

I. Conversion Factor

- CMS proposes a 2025 conversion factor, upon which all Medicare physician payments are based, of 32.3562, representing a reduction of 2.8% from 2024 levels.

- Reductions in the conversion factor are mandated according to the statutory PFS budget neutrality adjustment which requires across the board PFS reductions to offset increases in reimbursement for select services.

- The 2.8% reduction in 2025 consists of:
  - The expiration of a 2.93% temporary increase enacted by Congress.
  - A 0.05% adjustment to account for changes in the RVUs of select physician services.

II. Impact on Arthroplasty Rates

- CMS proposes to increase total RVUs for CPTs 27130 and 27447 very slightly due to small increases in the estimated practice expense and medical malpractice costs. **[*See* APPENDIX 1, ATTACHED]**

- The small increases in practice expense and malpractice insurance partially offset the 2.8% reduction in the conversion factor, leading to an approximate reduction in Medicare reimbursement for CPT codes 27130 and 27447 of 0.28% in 2025.

CPT	2023	2024	2025 (proposed)
27130	$1,300.92	$1,264.64	**$1,261.25**
27447	$1,299.57	$1,262.68	**$1,258.98**

- CMS estimates that the total value of all Medicare payments to all orthopedic surgeons for all claims (TJA and other services) will decrease by 1% in 2025.

III. Potentially Misvalued Services

- CMS is required by law to evaluate CPT codes as potentially misvalued at least once every five years. CMS considers "nominations" from the public on potentially misvalued codes and reviews each flagged code on an individual basis.

- **CPT 27279 –** *(ARTHRODESIS, SACROILIAC JOINT, PERCUTANEOUS OR MINIMALLY INVASIVE (INDIRECT VISUALIZATION), WITH IMAGE GUIDANCE, INCLUDES OBTAINING BONE GRAFT WHEN PERFORMED, AND PLACEMENT OF TRANSFIXING DEVICE)*
  - For the second year in a row, the 090-day global code CPT 27279 has been nominated as potentially misvalued due to the absence of separate direct PE inputs for this service in the non-facility office setting .
  - The nomination was submitted by the American College of Radiology, the Outpatient Endovascular and Interventional Society, and the Society of Interventional Radiology.
  - Currently, Medicare only prices CPT 27279 in the facility setting, at about $826.85 for the physician's professional services, but the nominators are seeking separate direct PE inputs for this service to better account for valuation when performed in the nonfacility/office setting.
  - CMS does not propose to revalue the code as nominated as CMS remains concerned about whether this service can be safely and effectively furnished in the non-facility/office setting. CMS instead seeks additional studies and comments from medical societies.

IV. Fracture Care Management

- As a part of an effort to identify barriers to access for "high-value, potentially underutilized services", CMS seeks public comments on "how often evidence-based care for persons with fractures is not provided and the reasons for this, and how recent or new PFS codes, or their revaluation, might help resolve specific barriers to its provision."

- Evidence-based care for fractures, according to CMS, includes transitional care management and other care management services, E/M visits (including the inherent complexity add-on for office/ outpatient visits), principal illness navigation services, community health integration services, and the social determinants of health risk assessment.

- CMS says "parties have indicated that orthopedic surgeons, [SNFs], and other practitioners and providers may not be providing comprehensive patient centered fracture management care for quality, payment, or administrative reasons, and that there is inadequate "hand-off" when post-discharge fracture care is transferred to practitioners in the community. They indicate a systemic disconnect on which provider and/or specialty is responsible for osteoporosis diagnosis and treatment, and that global surgical periods focus on acute fracture recovery rather than addressing osteoporosis." CMS wants to know if this is true and if this could be improved by billing for new global postoperative add-on code or new transitional care management codes, or other E/M codes.

V. 90-day Global Surgical Codes

- CMS proposes to "broaden the applicability of transfer of care modifiers" (-54, -55, and -56) for 90-day global services to require their use when a physician expects to furnish only preoperative management, surgical care only, or postoperative management only.

- CMS proposes to create a new code, GPOC1, for postoperative care services to more appropriately compensate time and resources rendered by a physician who was not involved in the surgical procedure.

    - Proposed GPOC1 Descriptor – *Post-operative follow-up visit complexity inherent to evaluation and management services addressing surgical procedure(s), provided by a physician or qualified health care professional who is not the practitioner who performed the procedure (or in the same group practice), and is of a different specialty than the practitioner who performed the procedure, within the 090-day global period of the procedure(s), once per 090-day global period, when there has not been a formal transfer of care and requires the following required elements, when possible and applicable:*
        - *Reading available surgical note to understand the relative success of the procedure, the anatomy that was affected, and potential complications that could have arisen due to the unique circumstances of the patient's operation.*
        - *Research the procedure to determine expected post-operative course and potential complications (in the case of doing a post-op for a procedure outside the specialty).*
        - *Evaluate and physically examine the patient to determine whether the post-operative course is progressing appropriately.*
        - *Communicate with the practitioner who performed the procedure if any questions or concerns arise. (List separately in addition to office/ outpatient evaluation and management visit, new or established)*

    - Proposed Valuation – CMS proposes RVU value of 0.17 for GPOC1.

VI. Expiring Telehealth Flexibilities

- CMS proposes to end flexibilities that began during the COVID-19 public health emergency that allow for reimbursement of telehealth claims that do not satisfy geographic location requirements. Starting Jan. 1, 2025, reversion to telehealth originating site rules would limit payable telehealth claims to services in which the is located in certain rural and underserved areas.

- Congress is considering legislation would extend or make such telehealth flexibilities permanent.

- For 2025 and beyond, CMS proposes to allow two-way, real-time audio-only communication to satisfy the requirement for an interactive telecommunications system, when appropriate.

- CMS also proposes to maintain cardiac rehabilitation services on the telehealth list provisionally through 2025.

VII. Quality Measures - Proposed Changes to the 2025 MIPS MVP Pathway: Improving Care for Lower Extremity Joint Repair

- Changes proposed for the 2025 Lower Extremity Joint Repair MIPS-MVP include:

    - (**NEW**) IA_AHE_9: Implement Food Insecurity and Nutrition Risk Identification and Treatment Protocols
        - CMS proposes to include this measure to better account for food insecurity, which it deems a priority issue.

    - (**NEW**) IA_ERP_6: *COVID-19 Vaccine Achievement for Practice Staff*
        - CMS proposes the addition of this measure to expand the focus and importance of vaccination status to drive improvement across the practice setting.

    - (**REMOVAL**) IA_PSPA_27: *Invasive Procedure or Surgery Anticoagulation Medication Management*
        - CMS proposes to remove as it is duplicative with the PSH Care Coordination activity (IA_CC_15).

    - (**REVISION**): Q470: *Functional Status After Primary Total Knee Replacement*
        - CMS is proposing to revise the numerator note by clarifying that if a tool other than the Oxford Knee Score (OKS) or Knee injury/Osteoarthritis Outcome Score Joint Replacement (KOOS, JR.) is used to assess a patient's functional status for this measure, it would result in a performance not met. The requirements for meeting this measure require use of the specific

tools referenced in the measure specification, as they have been tested, validated, and determined to be most appropriate for capturing the numerator action.

- (**REVISION**): Q376: *Functional Status Assessment for Total Hip Replacement*
  - CMS is proposing to revise initial patient population by changing the timing of the encounter to better align with the post-surgical assessment timeframe of 300 to 425 days after the original THA surgery. The new proposed encounter timeframe is from November of the year prior to August of the year prior. This is intended to also harmonize the timeframe of the patient encounter with the administrative claims measure "Hospital-Level RSCR Following Elective Primary THA and/or TKA" available for Hospital Inpatient Quality Reporting, thereby aligning timing specificity and patterns across similar measures.

VIII. Ambulatory Specialty Care Pathway

- CMS requests public input on the design of a new MIPS Value Pathways (MVPs) *Framework to Improve Ambulatory Specialty Care*. Through this MVP, CMS wishes to engage specialists in value-based payment for those procedures that currently lack alternative payment models (APMs). CMS also wishes to encourage specialist interaction with primary care providers.

- MIPS-eligible clinicians participating in this MVP would receive a payment adjustment according to their performance on a set of clinically relevant MVP measures and comparing the participant's final score against a limited pool of clinicians (other model participants of their same specialty type and clinical profile, who are also required to report on those same clinically relevant MVP measures).

- CMS proposes developing MVPs based on existing Specialty Measure Sets for specialties that do not have MVP coverage. This approach would serve as a bridge until new measures are available to support the creation of individual MVPs for clinicians without an MVP specific to their specialty, patient populations served, or the primary conditions treated.

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OUTPATIENT PROSPECTIVE PAYMENT SYSTEM & AMBULATORY SURGICAL CENTER PAYMENT SYSTEM

I. Arthroplasty Rates

- CMS is proposing a 2.6% increase to payment rates under the OPPS and ASC payment systems. This update is based on the projected hospital market basket percentage increase of 3.0%, reduced by a productivity adjustment of 0.4 percentage points

- 2025 OPPS rates:

CPT	2023	2024 (proposed)
27130 & 27447	$12,552.87	$12,755.58

- 2025 ASC rates:

CPT	2023	2024 (proposed)
27130	$9,244.39	$9,369.82
27447	$9,054.68	$9,183.77

- See details in **[See APPENDIX 1, ATTACHED]**

II. "Pass-Through" Payments Proposed for New Orthopedic Surgical Devices

a. *Overview of Transitional Device Pass-Through Payment*

- CMS seeks public comment on the public applications received for Medicare's "transitional device pass-through payment" pathway. Generally, CMS uses a transitional pass-through payment framework to provide additional payment for a period of at least two years but not more than three years for new devices, drugs, and biologicals used by providers in the delivery of services that are too new to have adequate cost data and that meet certain eligibility criteria. Granting additional pass-through payments is intended to allow patient access to innovative technologies while CMS gathers additional cost data to set an appropriate, updated OPPS payment rate for the underlying procedure. Pass-through status is a facility-specific payment that has no direct link on physician reimbursement.

- If status is approved, the formula to calculate pass-through reimbursement is the hospital's charge for the device, adjusted to the actual cost for the device, minus the amount included in the APC payment amount for the device. Devices approved for pass-through payments are eligible for such payments for a period of at least two but not more than three years. Once the pass-through payment period expires, payment for the device is packaged into the OPPS payment rate for the associated procedures.

- Medical devices must meet certain eligibility criteria and be described by a category of devices established by CMS regulations to qualify for transitional pass-through payment. CMS accepts applications for pass-through status on an ongoing basis and makes preliminary, subregulatory determinations on a quarterly basis. CMS outlines its analysis and solicits public comment for applications not preliminarily approved during the quarterly process during the next annual notice-and-comment rulemaking cycle.[1]

- A medical device must satisfy the following standards be eligible for pass-through payment:

    - Medical Device Eligibility Criteria
        - FDA premarket approval or clearance (as applicable) if the pass-through payment application is submitted within 3 years from the date of market availability.
        - Reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part.
        - An integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. "CMS interprets "integral" to mean that the device is necessary to furnish or deliver the primary procedure with which it is used.
        - Not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or a supply or material furnished incident to a service.

    - Criteria to Establish a Pass-Through Device Category
        - Not appropriately captured in any existing category
        - Substantial clinical improvement over available treatments and/or Breakthrough Device designation by the FDA.
        - A cost that is "not insignificant", meaning the three criteria are met:
            - The estimated average reasonable cost exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices.

[1]All applications that are preliminarily approved by CMS will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Through notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials, for consideration during the public comment process for the proposed rule.

- The estimated average reasonable cost exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent.
- The difference between the estimated average reasonable cost and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service.

b. Surgical Devices Proposed for Pass-Through Status

- CMS seeks stakeholder comment on the 10 device pass-through applications currently eligible for review. As summarized below and detailed in **APPENDIX 2**, two devices—(1) the CANTURIO™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System and (2) the iFuse Bedrock GraniteTM Implant System—may be relevant to AAHKS members. CMS invites public comment on whether the devices meet each aspect of the device pass-through payment criteria, including the cost criterion for device pass-through payment status. **[Criteria Outlined in APPENDIX 2]**

    - **CANTURIO™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System.** Canary Medical, Inc. applied for a new device category for transitional pass-through payment status for the CTE with CHIRP® System for CY 2025, but is only seeking a new device category for transitional pass-through payment status for the CTE component ("CTE") of the CTE with CHIRP® System. Notably, CMS questioned whether the CTE implant could be considered "integral", as CMS believed the device appeared purely additive and not necessary to furnish or deliver a TKA and did not believe that the data generated from the CTE implant post-procedure appeared necessary to furnish or deliver the primary service necessary to furnish or deliver TKA

    - **iFuse Bedrock GraniteTM Implant System.** SI-BONE applied for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System. Notably, although the device's application stated that no previous or existing device categories for pass-through payment appropriately described the device, CMS asserted its belief that codes C1713 and C1889 may appropriately describe the iFuse Bedrock GraniteTM Implant System. Additionally, CMS disagreed with the HCPCS codes used in the device application and found that the device did not satisfy all three cost-significant criteria

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APPENDIX 1
Medicare Payment Trends for Hip and Knee Surgeries in the United States

Code (DRG/CPT)	2020		2021		2022		2023		2024		2025 Proposed		% Change from 2024
	Weight/RVUs	Rate	Weight/RVUs	Rate	Weight/RVUs	Rate	Weight/RVUs	Rate	Weight/RVUs	Rate	Weight/RVU	Rate	
IPPS[1,2]													
469	3.1399	$18,200.84	3.0989	$18,530.61	3.0866	$18,952.62	3.2314	$20,602.57	3.3298	$21,636.27	3.3019	$22,010.80	**+1.73%**
470	1.9684	$11,410.09	1.9104	$11,423.69	1.9015	$11,675.76	1.9119	$12,189.78	1.8817	$12,226.85	1.9051	$12,699.59	**+3.87%**
521	--	--	3.0652	$18,329.99	3.0663	$18,827.97	3.0192	$19,249.63	2.9942	$19,455.62	2.9240	$19,491.68	**+0.19%**
522	--	--	2.1943	$13,121.34	2.1903	$13,449.08	2.1729	$13,853.85	2.1122	$13,724.59	2.1206	$14,136.13	**+3%**
OPPS													
27130	147.2988	$11,899.38	148.7344	$12,314.76	149.6049	$12,593.29	152.4576	$13,048.08	143.6551	$12,552.87	142.7134	$12,755.58	**+1.60**
27447	147.2988	$11,899.38	148.7344	$12,314.76	149.6049	$12,593.29	152.4576	$13,048.08	143.6551	$12,552.87	142.7134	$12,755.58	**+1.60**
ASC													
27130	--	--	180.4429	$8,833.04	180.8564	$9,027.63	183.3725	$9,508.60	172.7471	$9,244.39	171.3730	$9,369.82	**+1.36**
27447	180.3081	$8,609.17	179.2409	$8,774.20	179.6492	$8,967.37	179.7859	$9,322.62	169.2021	$9,054.68	167.9702	$9,183.77	**+1.43**
PFS													
27130	36.0896	$1,415.07	34.8931	$1,322.45	33.5983	$1,277.40	38.39	$1,300.92	38.63	$1,264.64[3]	38.98	$1,261.25[4]	**-0.27%**
27447	36.0896	$1,413.27	34.8931	$1,320.70	33.5983	$1,276.06	38.35	$1,299.57	38.57	$1,262.68	38.91	$1,258.98	**-0.29%**

[1] **National Payment Amount** – Projected by CMS of the baseline amount that will be paid nationally for the MS-DRG. This amount **DOES NOT INCLUDE** facility-specific calculation of teaching, disproportionate share, capital, and outlier payments for all cases. *See footnote 2.*

[2] Assumes hospital with wage index greater than 1.0 that reported quality data and is a meaningful EHR user.

[3] Final CY 2024 Conversation Factor, as amended by the *Consolidated Appropriations Act, 2023*: 32.7375.

[4] Proposed CY 2025 Conversion Factor: 32.3562.

NOTE: Rates have been rounded to the nearest hundredth decimal where applicable.

APPENDIX 2:
Summaries of the Relevant Applications for Transitional Device Pass-Through Payment Status in the CY 2025 OPPS Proposed Rule

I. CANTURIOTM Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System

Canary Medical, Inc. applied for a new device category for transitional pass-through payment status for the CTE with CHIRP® System for CY 2025, but is only seeking a new device category for transitional pass-through payment status for the CTE component ("CTE") of the CTE with CHIRP® System. According to the application summarized by CMS:

- The CTE implant is a physical implant that is attached to the tibial baseplate as part of a total knee arthroplasty (TKA) to form the patient's knee prosthesis and provide additional stability to the replacement knee joint. The CTE implant is single-use, intended to be used with one patient only, comes into contact with human tissue, and is implanted into the patient's knee prosthesis.
- The software and electronics within the CTE implant with CHIRP® system collects unprocessed 3-D accelerometer and 3-D gyroscopic sensor data using its Inertial Measurement Unit on the patient's functional movement and gait parameter post-surgery and transmits the encrypted data via the Home Base Station to the cloud platform.

The CTE implant with CHIRP® System is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

CRITERIA	ANALYSIS FROM THE PROPOSED RULE
CTE implant with CHIRP® System - ELIGIBILITY FOR TRANSITIONAL PASS-THROUGH PAYMENTS[1]	
(1) If required by the FDA, the device received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA, or meet another appropriate FDA exemption for premarket approval or clearance. CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability.	**FDA Breakthrough Device Designation + De Novo Classification.** • **FDA Breakthrough Device Designation:** Effective October 24, 2019. The CTE implant with CHIRP® System is indicated to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care and is indicated for use with the Zimmer Persona® Personalized Knee System (K113369) for TKA in patients with severe knee pain and disabilities, including: (1) rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis; (2) collagen disorders, and/or avascular necrosis of the femoral condyle; (3) post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy; (4) moderate valgus, varus, or flexion deformities; and (5) the salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery. • **De Novo Classification:** Granted by FDA on August 27, 2021, with the following indications for use: (1) to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. The kinematic data are an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery; (2) for use in patients undergoing a cemented TKA procedure that

[1] 42 C.F.R § 419.66(b)(2) has been omitted.

CRITERIA	ANALYSIS FROM THE PROPOSED RULE
CTE implant with CHIRP® System - ELIGIBILITY FOR TRANSITIONAL PASS-THROUGH PAYMENTS[1]	
	are normally indicated for at least a 58 mm sized tibial stem extension; (3) the objective kinematic data generated by the CTE implant with CHIRP® System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit; and (4) the CTE implant with CHIRP® System is compatible with Zimmer Persona® Personalized Knee System.
(3) The device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. "CMS interprets "integral" to mean that the device is necessary to furnish or deliver the primary procedure with which it is used.[2]	**CMS questions whether the CTE implant can be considered "integral", as it appears purely additive and not necessary to furnish or deliver a TKA and it does not appear that the data generated from the CTE implant post-procedure is necessary to furnish or deliver the primary service necessary to furnish or deliver TKA.** CMS stated the applicant did not indicate whether the CTE implant is integral to the service furnished. CMS raised the following points questioning whether the CTE implant is integral to the service furnished. • Indications for use of the CTE implant with CHIRP® System listed in the FDA DeNovo review letter states that the objective kinematic data generated by the CTE implant with CHIRP® System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit • A warning included in the device IFU for the CTE implant with CHIRP® System provides that the kinematic data obtained from this device have not been demonstrated to have clinical benefit. • It is not intended to be utilized for clinical decision-making, and no data have been evaluated by FDA regarding clinical benefits.
(4) The device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or a supply or material furnished incident to a service.	**Not indicated by applicant.** CMS stated the applicant did not indicate whether the CTE implant met this criteria.

[2] CY 2014 OPPS Final Rule, 78 Fed. Reg. 74826, 75005 (Dec. 10, 2013).

CRITERIA	ANALYSIS FROM PROPOSED RULE
CTE implant with CHIRP® System - CRITERIA FOR ESTABLISHING MEDICAL DEVICES	
(1) The device is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.	**CMS stated it has not identified an existing pass-through payment category that describes the CTE implant.** The applicant asserted that the CTE implant with CHIRP® System is the only device authorized by FDA with an indication to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care and that no previous or existing device categories for pass-through payment appropriately describe the CTE implant. The applicant explained that the device category code **C1776 (Joint device (implantable))** was created for older technology that performs the function of the joint and does not describe a device that captures activity and kinematic data but is not a substitute for the natural knee.
(2) The device is either a substantial clinical improvement criterion or that the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation.	**The CTE implant with CHIRP® system has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation** and therefore is not evaluated for substantial clinical improvement.
(3) The cost of the device is not insignificant, using three cost significance criteria. CMS calculates the device offset amount at the HCPCS/CPT code level instead of the APC level[3] and generally uses the lowest APC payment rate applicable for use with the nominated device.[4]	**CMS believes that the CTE implant meets the cost significance requirements.** In its calculation, CMS used APC 5115, which had a CY 2024 payment rate of $12,539.82 at the time the application was received. HCPCS code 27447 had a device offset amount of $5,659.22 at the time the application was received. According to the applicant, the cost of the CTE implant part of the CTE implant with CHIRP® System is $7,250.00.
1st Cost Significance Requirement: The estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices.	**CMS believes that the CTE implant meets the 1st cost significance requirement.** CMS calculated that the average reasonable cost of $7,250.00 for the CTE implant is 57.82 percent of the applicable APC payment amount for the service related to the category of devices of $12,539.82 (($7,250.00/$12,539.82) x 100 = 57.82 percent).
2nd Cost Significance Requirement: The estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list).	**CMS believes that the CTE implant meets the 2nd cost significance requirement.** CMS estimated the average reasonable cost of $7,250.00 for the CTE implant is 128.11 percent of the cost of the device-related portion of the APC payment amount for the related service of $5,659.22 (($7,250.00/$5,659.22) x 100 = 128.11 percent).
3rd Cost Significance Requirement: The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service.	**CMS believes that the CTE implant meets the 3rd cost significance requirement.** CMS calculated the difference between the estimated average reasonable cost of $7,250 for the CTE implant and the portion of the APC payment amount for the device of $5659.22 to be 12.69 percent of the APC payment amount for the related service of $12,539.82 ((($7,250 - $5,659.22)/$12,539.82) x 100 =12.69 percent).

[3] CY 2017 OPPS Final Rule, 81 Fed. Reg. 79562, 79657 (Nov. 14, 2016).
[4] CY 2005 OPPS Final Rule, 69 Fed. Reg. 65682, 65775 (Nov. 15, 2004).

II. iFuse Bedrock Granite™ Implant System

SI-BONE applied for a new device category for transitional pass-through payment status for the iFuse Bedrock Granite™ Implant System. According to the application summarized by CMS:

- The iFuse Bedrock Granite™ Implant System consists of iFuse Granite™ implants of various lengths and diameters and associated instruments sets and is intended to provide sacropelvic fusion of the sacroiliac joint (when placed in the sacral-alar-iliac (SAI) trajectory) and fixation to the pelvis when used in conjunction with commercially available pedicle screw fixation systems as a foundational element for segmental spinal fusion only when performing both a lumbar and sacroiliac joint (SIJ) fusion procedure in the same operative session. The applicant asserts that joint fusion occurs as a result of the device's porous surface and interstices and fixation occurs through the device's helical threaded design and traditional posterior fixation rod connection. The applicant asserts that the device can be placed into the pelvis in two trajectories: the SAI trajectory (i.e., into the sacrum, across the SIJ and into the ilium), or directly into the ilium.
- The applicant stated that the iFuse Bedrock Granite™ Implant System is only used when both a SIJ fusion procedure and a lumbar fusion procedure are performed in the same operative session and that the iFuse Bedrock Granite™ Implant System is not utilized when only a SIJ fusion procedure is performed (HCPCS code 27279) or when only a lumbar fusion procedure is performed (HCPCS code 22612, 22630 or 22633).

CRITERIA	ANALYSIS FROM THE PROPOSED RULE
iFuse Bedrock Granite™ Implant System - ELIGIBILITY FOR TRANSITIONAL PASS-THROUGH PAYMENTS	
(1) If required by the FDA, the device received FDA premarket approval or clearance (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by the FDA, or meet another appropriate FDA exemption for premarket approval or clearance. CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability.	**FDA Breakthrough Device Designation + 510(k) Clearance.** • **FDA Breakthrough Device Designation.** Effective November 23, 2021, as a treatment of the acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including: (1) degenerative disc disease (DDD), as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies; (2) severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra; (3) skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion; (4) spondylolisthesis; (5) trauma (i.e., fracture or dislocation); (6) spinal stenosis; (7) deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis); (8) spinal tumor; and (9) pseudarthrosis, and/or failed previous fusion. • **510(k) Clearance.** For the indications above one additional indication for use: SIJ dysfunction that is a direct result of SIJ disruption and degenerative sacroiliiitis, including conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. ○ **May 26, 2022**: The indications only addressed compatibility of the iFuse Bedrock GraniteTM Implant System with the SeaSpine Mariner Pedicle Screw System ○ **December 22, 2022:** Expanded the previously cleared indication of the iFuse Bedrock GraniteTM Implant System to include general compatibility with certain compatible pedicle screw systems
(3) The device must be an integral part of the service furnished, used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. "CMS	**CMS stated it did not have sufficient information.** CMS stated the applicant did not indicate if the Implant was integral to the services, but that the applicant stated the iFuse Bedrock GraniteTM Implant System is single-use, permanently implanted, and surgically inserted into the patient.

CRITERIA	ANALYSIS FROM THE PROPOSED RULE
iFuse Bedrock Granite™ Implant System - ELIGIBILITY FOR TRANSITIONAL PASS-THROUGH PAYMENTS	
interprets "integral" to mean that the device is necessary to furnish or deliver the primary procedure with which it is used.	
(4) The device is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or a supply or material furnished incident to a service.	**Not indicated by applicant.** CMS stated the applicant did not indicate whether the iFuse Bedrock GraniteTM Implant System met this criteria.

CRITERIA	ANALYSIS FROM PROPOSED RULE
iFuse Bedrock Granite™ Implant System - ELIGIBILITY FOR TRANSITIONAL PASS-THROUGH PAYMENTS	
(1) The device is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996.	**While CMS believes C1713 and C1889 may appropriately describe the iFuse Bedrock GraniteTM Implant System, the applicant states that no previous or existing device categories for pass-through payment appropriately describes the device.** The applicant explained why the following existing device categories are insufficient, and CMS described its position that C1713 and C1889 may appropriately describe the iFuse Bedrock GraniteTM Implant System: • **C1821 (Interspinous process distraction device):** The iFuse Bedrock GraniteTM Implant System is used to fixate and fuse, while the devices described in C1821 are interspinous spacers which, after implantation, are opened or expanded to distract the neural foramina and decompress the nerves. • **C1713 (Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable)):** The iFuse Bedrock GraniteTM Implant System allows for simultaneous fusion of the SIJ and fixation of the pelvis by connecting via Tulip Connector to the base of the stabilizing rods within the lumbosacral spinal construct, while C1713 includes implantable pins and/or screws that are used to oppose soft tissue-to-bone, tendon-to-bone, or bone-to-bone. ○ However, CMS questions whether a transfixing device utilizing the Tulip Connector is sufficiently distinguishable from traditional implantable pins or screws that it is meant to replace. Based on the description the applicant provided, CMS believes the device may be similar to the devices described by C1713. • **C1889 (Implantable/insertable device, not otherwise classified):** The does not describe any specific device category, and therefore does not uniquely describe the device category proposed for the iFuse Bedrock GraniteTM Implant System. However, CMS states that the category may be used to describe any implantable/insertable device that is not otherwise described by a more specific device category and is, therefore, sufficiently broad to include implantable devices that allow for simultaneous fusion of the SIJ and fixation of the pelvis and noted that CMS created[5] C1889 with the specific intent to recognize devices furnished during a device intensive procedure that are not described by a specific Level II HCPCS Category C-code.
(2) The device is either a substantial clinical improvement criterion or that the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation.	**The iFuse Bedrock Granite™ Implant System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation** and therefore is not evaluated for substantial clinical improvement.
(3) The cost of the device is not insignificant, using three cost significance criteria. CMS calculates the device offset amount at the HCPCS/CPT code level instead of the APC level and generally uses the lowest APC payment rate applicable for use with the nominated device.	**CMS disagreed with the HCPCS codes the applicant used in its cost criterion calculation.** In its calculation, CMS used APC 5116, which had a CY 2024 payment rate of $17,756.28, and HCPCS code 27279 due to CMS' understanding that 27279 is always reported when the iFuse device is used along with only one of the three specified lumbar fusion codes. HCPCS code 27279 in APC 5116 had a CY 2024 device offset amount of $12,264.26 at the time the application was received. According to the applicant, the cost of the iFuse Bedrock Granite™ Implant System is $11,689.00.

[5] CY 2017 OPPS/ASC Final Rule, 81 Fed. Reg. 79562, 79562 (Nov. 14, 2016).

	The applicant stated the iFuse Bedrock Granite™ Implant System device should be reported with the SIJ fusion procedure HCPCS code 27279 *and* a CPT code for lumbar fusion (HCPCS code 22612, 22630 or 22633), and that the selection of the primary lumbar fusion CPT code (HCPCS code 22612, 22630 or 22633) is dependent on the procedure performed. The applicant had utilized HCPCS code 22612 for the device offset amount for test two of the cost criterion. In the Proposed Rule, CMS stated it believed HCPCS code 22612, 22630, and 22633 were not appropriate to use for the cost criterion calculation.
• **1st Cost Significance Requirement:** The estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices.	**CMS believes the iFuse Bedrock Granite™ Implant System meets the first cost significance requirement.** CMS calculated that **t**he average reasonable cost of $11,689.00 for the iFuse Bedrock Granite™ Implant System is 65.83 percent of the applicable APC payment amount for the service related to the category of devices of $17,756.28 (($11,689.00/$17,756.28) x 100 = 65.83 percent).
• **2nd Cost Significance Requirement:** The estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list).	**CMS does not believe the iFuse Bedrock Granite™ Implant System meets the second cost significance requirement.** CMS estimated the $11,689.00 average reasonable cost for the iFuse Bedrock Granite™ Implant System to be 95.31 percent of the cost of the device-related portion of the APC payment amount for the related service of $12,264.26 (($11,689.00/$12,264.26) x 100 = 95.31 percent).
• **3rd Cost Significance Requirement:** The difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service.	**CMS does not believe the iFuse Bedrock Granite™ Implant System meets the 3rd cost significance requirement.** CMS calculated the difference between the estimated average reasonable cost of $11,689.00 and the portion of the APC payment amount for the device of $12,264.26 is negative 3.24 percent of the APC payment amount for the related service of $17,756.28 ((($11,689.00 - $12,264.26)/$17,756.28) x 100 = -3.24 percent).