Fiscal Year (FY) 2026 Medicare Severity Diagnosis Related Group (MS-DRG) Reassignment Request: Cases using iFuse Bedrock Granite

Meeting with the Centers for Medicare & Medicaid Services (CMS)
October 31, 2024

Today's Speakers

SI-BONE Speakers

W. Carlton Reckling, MD | Chief Medical Officer

Jeff Zigler | VP, Market Access & Reimbursement

Jessamyn Carino | Assoc. Dir., Reimb. Policy

Subject Matter Experts

Dr. Isador Lieberman, MD | Texas Back Institute

Mark Domyahn, MBA | Principal, JD Lymon

Beth Roberts, JD | Partner, Hogan Lovells

Dr. Lieberman is a fellowship trained Orthopaedic and Spinal Surgeon. He is board certified by the American Board of Orthopaedic Surgery and holds specialist certification from the Royal College of Physicians and Surgeons of Canada. He completed medical school and residency at the University of Toronto and completed Spine surgery and Trauma surgery fellowships at the Toronto Hospital in Canada and at Queen's Medical Center in Nottingham, England.

Dr. Lieberman specializes in the surgical treatment of spinal disorders. His clinical interests include adolescent and adult scoliosis, deformity reconstruction, spinal tumors, minimally invasive/robotic/endoscopic spinal surgery, treatment of vertebral compression fractures, cervical and lumbar degenerative disorders and trauma.

Dr. Lieberman established the Uganda Charitable Spine Surgery Mission which provides services to the less fortunate in Uganda who are afflicted with spinal ailments, including tuberculosis and scoliosis.

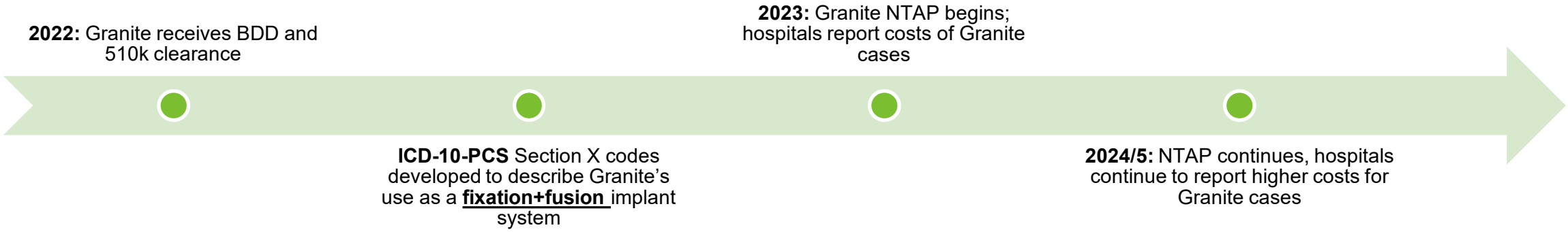
Reason for Today's Meeting

- **SI-BONE iFuse Bedrock Granite** received a Breakthrough Device Designation from FDA, and 510k clearance in May 2022
  - May 2022: Granite technology first available to U.S. patients
  - FY 2023: NTAP+ for inpatient procedures for Medicare patients
  - Hospital-reported costs show a much higher cost for cases using Granite
- Need for reassignment in FY26, to reimburse hospitals appropriately and help ensure patient access after NTAP ends
  - Submitted three MS-DRG reassignment requests:

Cases with Granite (X-codes)	Current cases mapping to (MS-DRGs):	Move cases to (MS-DRGs):
360 spine fusions	427, 428	426
Posterior-only spine fusions	448	447
Curvature / extensive spine fusions	457	456
	458	457

+ New Technology Add-on Payment

Timeline of Events and Unique PCS Coding



Unique ICD-10-PCS Codes to Describe Granite (Hospitals Use at Least 1 Code)

	Percutaneous	Open
Fixation	• **XNH7358**: Percutaneous insertion, internal fixation device with Tulip connector into left pelvic bone, New Technology Group 8 • **XNH6358**: Percutaneous insertion, internal fixation device with Tulip connector into right pelvic bone, New Technology Group 8	• **XNH7058**: Open insertion, internal fixation device with Tulip connector into left pelvic bone, New Technology Group 8 • **XNH6058**: Open insertion, internal fixation device with Tulip connector into right pelvic bone, New Technology Group 8
Fusion	• **XRGF358**: Percutaneous left sacroiliac joint fusion with internal fixation device with Tulip connector, New Technology Group 8 • **XRGE358**: Percutaneous right sacroiliac joint fusion with internal fixation device with Tulip connector, New Technology Group 8	• **XRGF058**: Open left sacroiliac joint fusion with internal fixation device with Tulip connector, New Technology Group 8 • **XRGE058**: Open right sacroiliac joint fusion with internal fixation device with Tulip connector, New Technology Group 8

Three Separate Applications for MS-DRG Reassignment

- Reassignment requests based on MS-DRG groupings (FY25 logic)
- ~560 cases impacted in FY23 claims (actual mapping)
- 1,825 estimated cases impacted in FY26 (SI-BONE projections)

MEARIS Application	Procedure Type	Current Assignment (FY25 MS-DRG Logic)	Requested Reassignment	Annual Cases Impacted (FY23 MedPAR)
1	"360" anterior / posterior spinal fusion with Granite	• MS-DRG 427 ("CC") • MS-DRG 428 ("no CC/MCC")	• DRG 426 ("MCC")	337 cases
2	Posterior-only spinal fusion with Granite	• MS-DRG 448 ("no CC/MCC")	• DRG 447 ("MCC")	143 cases
3	Curvature / extensive spinal fusion with Granite	• MS-DRG 457 ("CC")	• DRG 456 ("MCC")	73 cases
		• MS-DRG 458 ("no CC/MCC")	• DRG 457 ("CC")	<11 cases

426 MULTIPLE LEVEL COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION EXCEPT CERVICAL WITH MCC OR CUSTOM-MADE ANATOMICALLY DESIGNED INTERBODY FUSION DEVICE
427 MULTIPLE LEVEL COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION EXCEPT CERVICAL WITH CC
428 MULTIPLE LEVEL COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION EXCEPT CERVICAL WITHOUT CC/MCC
447 MULTIPLE LEVEL SPINAL FUSION EXCEPT CERVICAL WITH MCC OR CUSTOM-MADE ANATOMICALLY DESIGNED INTERBODY FUSION DEVICE
448 MULTIPLE LEVEL SPINAL FUSION EXCEPT CERVICAL WITHOUT MCC
456 SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITH MCC
457 SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITH CC
458 SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITHOUT CC/MCC

CC = complication and/or comorbidity; MCC = major complication and/or comorbidity

iFuse Bedrock Granite | Key Features & Highlights

INDICATIONS FOR USE

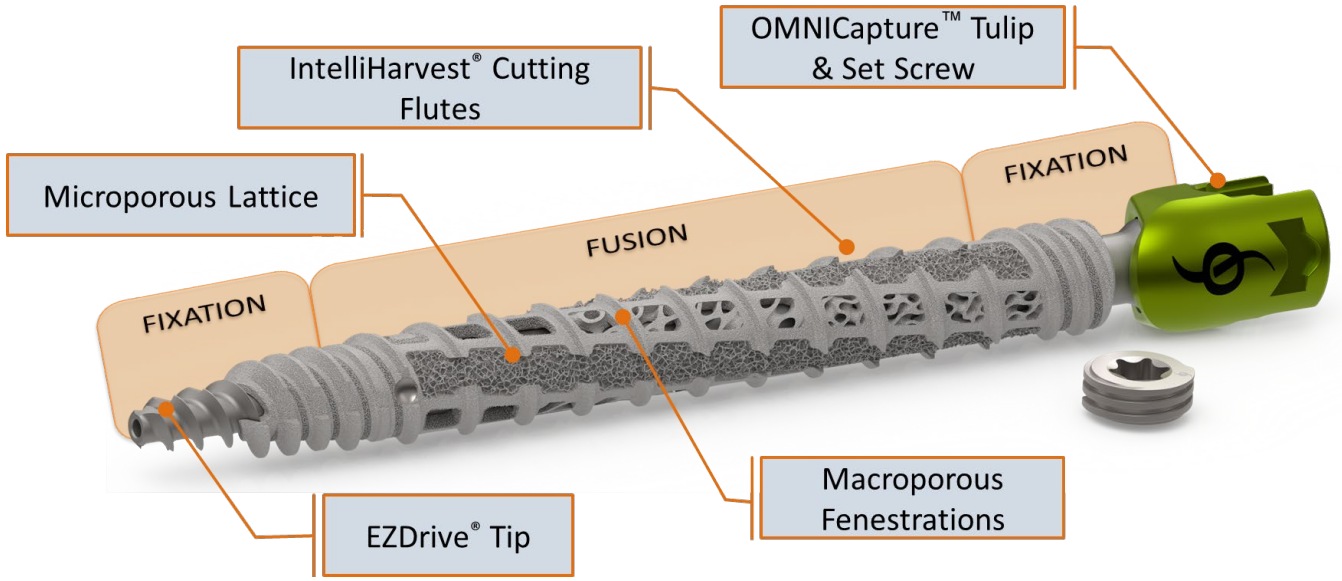
The iFuse Bedrock Granite Implant System is intended for sacroiliac joint fusion in skeletally mature patients for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

When connected to compatible pedicle screw systems with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Spinal tumor
- Pseudarthrosis
- Failed previous fusion

https://si-bone.com/label



ADVANTAGES:

- ***Intelliharvest Fenestrations*** *– Graduated fenestrations designed for optimal bone self-harvesting*
- ***FuSion 3D Surface*** *– 3D-printed microporous lattice surfaces that mimic native cancellous bone for enhanced bone fixation*
- ***EZDrive Tip*** *– Tapered tip designed to reduce insertion force and offer more controlled Implant placement*
- ***OMNICapture System*** *– Designed to mitigate tulip splay, set screw disassociation, Implant neck fracture, and cross-threading while providing higher locking torque. Larger degree of tulip angulation for improved rod approximation*
- *Designed specifically for foundational fixation of multilevel long constructs and to fuse the heavily loaded SI joint*

Clinical Rationale (in MEARIS application)

Challenges, Prior to Granite

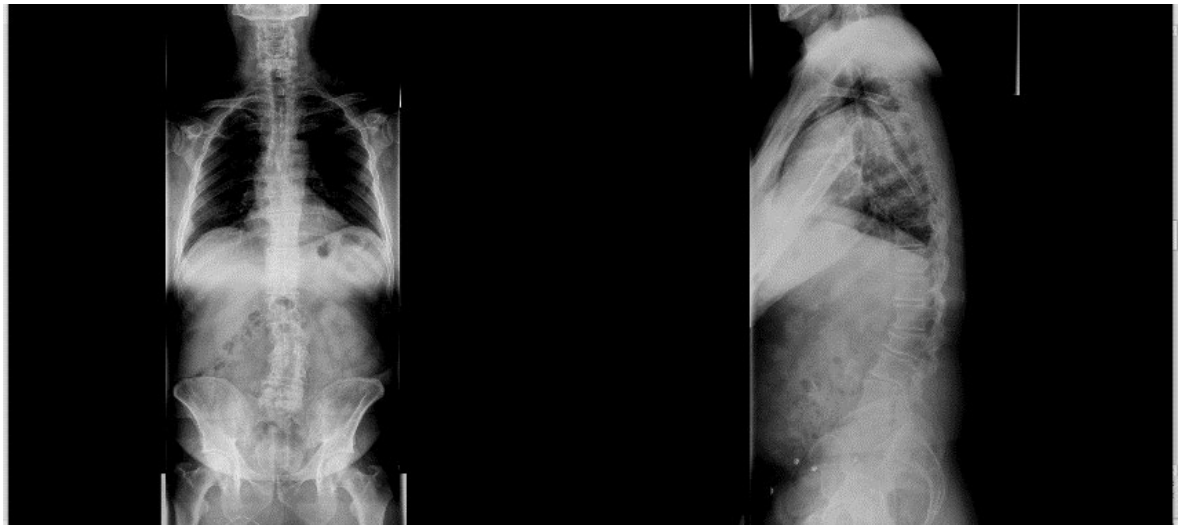
- **Biomechanics** of the lumbosacral junction (L5-S1) create specific challenges for fusion
- **Prior technologies and historical challenges** required further evolution of pedicle screw-based methods, improving on a 23% complication rate, even with more contemporary screws
- **Evolution of clinical practice and pelvic fixation** result in increased biomechanical loads on spinopelvic constructs due to longer fusions, deformity corrections, and patients with higher BMI or poor bone quality.

Opportunities for Granite's Use in Surgery

- **Hospitals and surgeons need Granite**, as it is a larger screw than most, offering multiple pelvic fixation points and implants, designed for both pelvic fixation and SI joint fusion

- **Advantages of Granite for hospitals and patients:**
  - Granite provides immediate stability, reduces breakage risk, and promotes long-term SI joint fusion
  - Granite offers multiple fixation options without altering physician workflow, or patient stays
  - Granite has shown strong performance with no reported breakages in over 8,500 cases

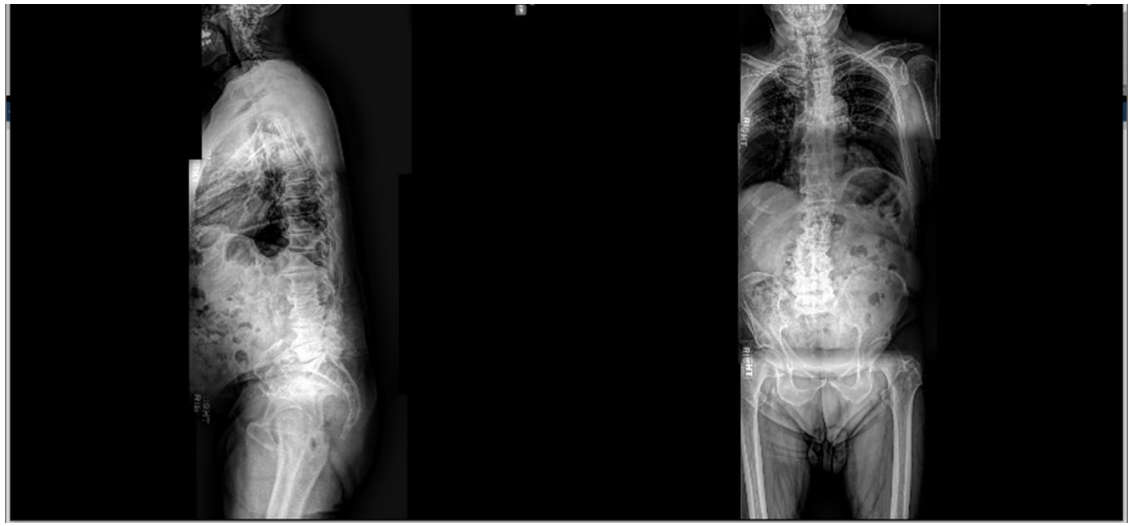
Case 1



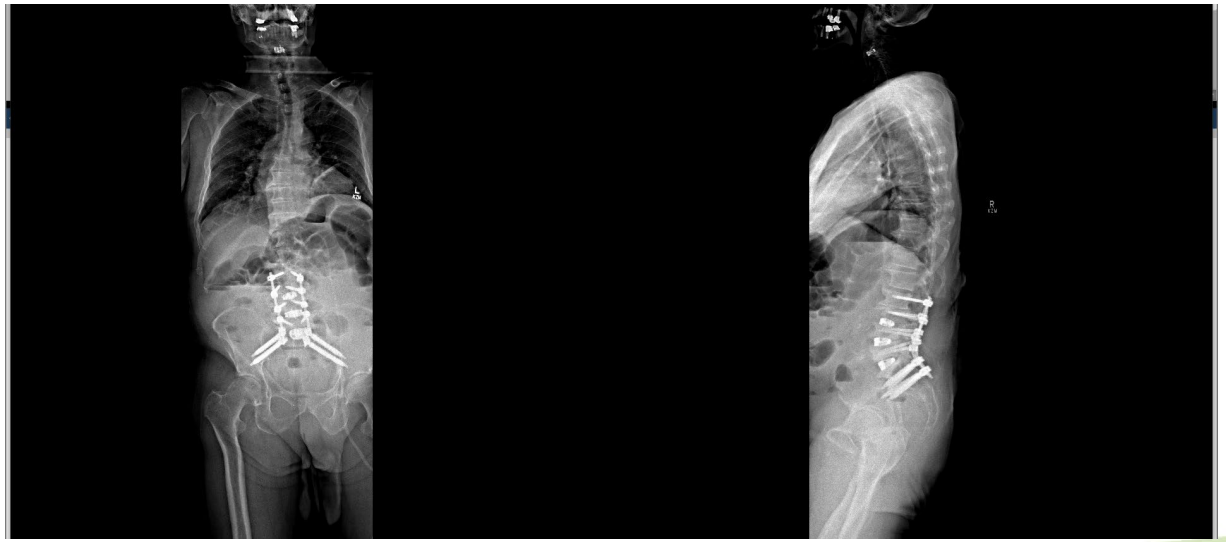
Procedure: Bilateral Single **Granite**

- 74 year young active rancher
- 3 year history of mechanical back pain and claudication symptoms
- Previous traumatic L2 compression fracture
- 2 previous decompressions at L4/5 and L5/S1
- On exam, kyphotic posture, right leg L5 weakness

Case 2



Procedure: Bilateral “Stacked” **Granite**



- 73 year young male
- 2 year history of mechanical back pain and stenotic symptoms
- 6 month history of myelopathic symptoms and hand weakness
- On exam, sagittal imbalance, myelopathic gait, weak handgrip

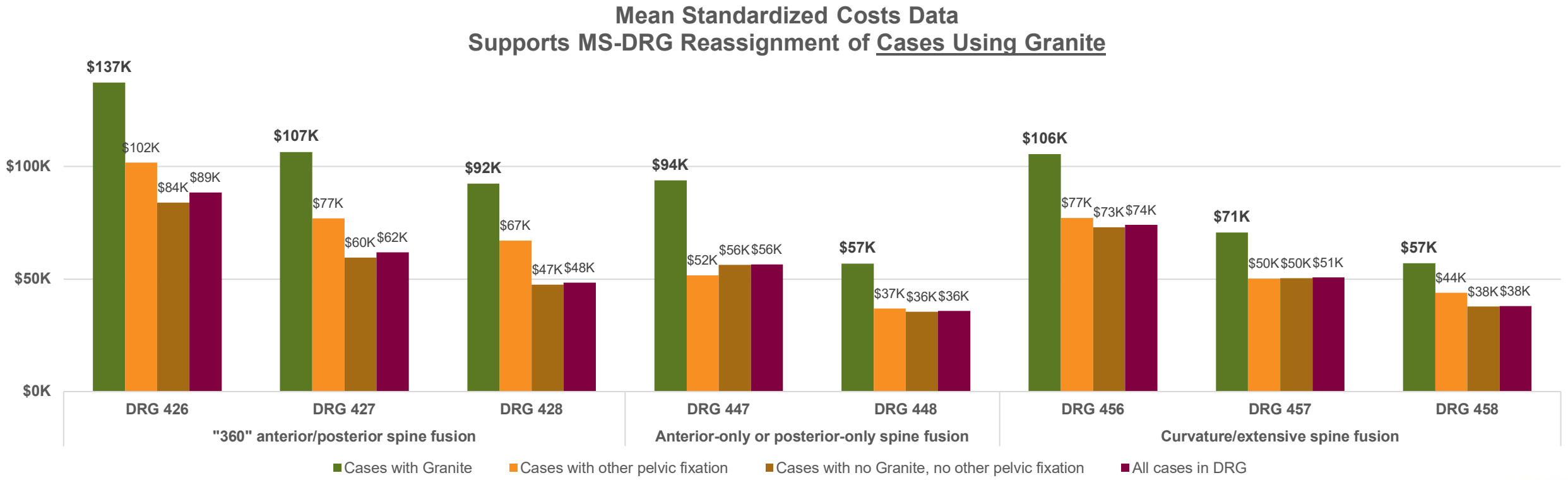
iFuse Bedrock Granite (Granite) Overview

- Initial review of MedPAR data for five consecutive quarters (all DRGs) supports our DRG reclassification requests:
  - An increase in cost and hospital resources of Granite vs non-Granite cases
  - Average LOS remained generally consistent between both case types
  - Granite cases primarily fell into three main spinal fusion DRG families:
    - **DRGs 426-8** (anterior/posterior “360” spinal fusions)
    - **DRGs 447-8** (posterior-only spinal fusions)
    - **DRGs 456-8** (curvature/extensive spinal fusions)
  - Prompted additional claims analysis provided in this presentation

ICD-10-PCS = International Classification of Diseases, Tenth Revision, Procedure Coding System

Granite cases are higher-cost, compared with all others

- Focused examination of Granite cases vs. all other pelvic fixation
- Narrowing analysis to eight MS-DRGs of interest (per MEARIS applications):



Cost Analysis - MedPAR FY2023

- Based on analysis of FY2023 Final MedPAR data, as used in modeling of FY2025 Final IPPS rule

- Using only the ICD-10-PCS codes developed to describe the use of Granite, compared with all other cases in the respective DRG, we modeled:
  - Number of discharges
  - Mean total charges
  - Mean standardized cost
  - Mean length of stay

- Analysis included:
  - FY23: total annual cases which would have been impacted
  - FY26: total annual projected cases impacted, per SI-BONE internal estimates

Request 1: Cost Analysis - MedPAR FY2023

MEARIS Confirmation Code DRG241018EVEFN

DRG 428 – anterior / posterior fusion no CC/MCC	Granite	No Granite	% diff
Number of discharges	66	8,290	
Mean standardized cost	$ 92,425.32	$ 48,005.85	*92.5%*

a

DRG 426 - anterior / posterior fusion MCC	All Cases
Number of discharges	2,952
Mean standardized cost	$ 88,504

DRG 427 - anterior / posterior fusion fusion CC	Granite	No Granite	% diff
Number of discharges	271	12,926	
Mean standardized cost	$ 106,506.30	$ 60,968.68	*74.7%*

b

DRG 426 - anterior / posterior fusion MCC	All Cases
Number of discharges	2,952
Mean standardized cost	$ 88,504

- Based on hospital-reported cost data from FY23:
  a) Move Granite cases mapping to DRG 428, **to DRG 426** and
  b) Move Granite cases mapping to DRG 427, **to DRG 426**

Proposed Modified Description:
DRG 426: "MULTIPLE LEVEL COMBINED ANTERIOR AND POSTERIOR SPINAL FUSION EXCEPT CERVICAL WITH MCC OR CUSTOM-MADEANATOMICALLY DESIGNED INTERBODY FUSION DEVICE OR INTERNAL FIXATION DEVICE WITH TULIP CONNECTOR FOR SACROILIAC JOINT FUSION AND/OR PELVIC FIXATION"

Request 2: Cost Analysis - MedPAR FY2023

MEARIS Confirmation Code DRG241018UL19G

DRG 448 - posterior fusion no CC/MCC			
	Granite	No Granite	% diff
Number of discharges	143	15,401	
Mean standardized cost	$ 56,813.90	$ 35,559.49	*59.8%*

a

DRG 447 - posterior fusion MCC	
	All Cases
Number of discharges	2,248
Mean standardized cost	$ 56,475

- Based on hospital-reported cost data from FY23:
  a) Move Granite cases mapping to DRG 448, **to DRG 447**

Proposed Modified Description:
DRG 447: MULTIPLE LEVEL SPINAL FUSION EXCEPT CERVICAL WITH MCC OR CUSTOM-MADE ANATOMICALLY DESIGNED INTERBODY FUSIONDEVICE OR INTERNAL FIXATION DEVICE WITH TULIP CONNECTOR FOR SACROILIAC JOINT FUSION AND/OR PELVIC FIXATION"

Request 3: Cost Analysis - MedPAR FY2023

MEARIS Confirmation Code DRG241018K14K1

DRG 458 – curvature / extensive fusion no CC/MCC	Granite	No Granite	% diff
Number of discharges	*	*	
Mean standardized cost	$ 56,980.79	$ 37,941.03	*50.2%*

a

DRG 457 - curvature / extensive fusion CC	All Cases
Number of discharges	3,989
Mean standardized cost	$ 50,690

DRG 457 - curvature / extensive fusion fusion CC	Granite	No Granite	% diff
Number of discharges	73	3,916	
Mean standardized cost	$ 70,644.68	$ 50,317.81	*40.4%*

b

DRG 456 - curvature / extensive fusion MCC	All Cases
Number of discharges	1,567
Mean standardized cost	$ 74,026

- Based on hospital-reported cost data from FY23:
  a) Move Granite cases mapping to DRG 458, **to DRG 457**
  and
  b) Move Granite cases mapping to DRG 457, **to DRG 456**

Proposed Modified Description:
DRG 456: "SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVEFUSIONS WITH MCC OR INTERNAL FIXATION DEVICE WITH TULIP CONNECTOR FOR SIMULTANEOUS SACROILIAC JOINT FUSION AND PELVIC FIXATION"
DRG 457: "SPINAL FUSION EXCEPT CERVICAL WITH SPINAL CURVATURE, MALIGNANCY, INFECTION OR EXTENSIVE FUSIONS WITH CC OR INTERNAL FIXATION DEVICE WITH TULIP CONNECTOR FOR SACROILIAC JOINT FUSION AND/OR PELVIC FIXATION"

Estimated Cases Impacted Analysis – 1,826 cases in FY 2026

- ~560 cases impacted in FY23 claims (actual mapping)
- 1,826 estimated cases impacted in FY26 (SI-BONE projections)

MS-DRG 427 and 428 growth (reassign to MS-DRG 428)

FY23 BRG cases in MS-DRG family (from MS-DRGs 427 and 428)	337
FY24 projected MCR cases	573
FY25 projected MCR cases	853
FY26 projected MCR cases	**1093**

MS-DRG 448 growth (reassign to MS-DRG 447)

FY23 BRG cases in MS-DRG family (from MS-DRG 448)	143
FY24 projected MCR cases	243
FY25 projected MCR cases	362
FY26 projected MCR cases	**464**

MS-DRG 457 growth (reassign to MS-DRG 456)

FY23 BRG cases in MS-DRG family (from MS-DRG 457)	73
FY24 projected MCR cases	124
FY25 projected MCR cases	185
FY26 projected MCR cases	**237**

MS-DRG 458 growth (reassign to MS-DRG 457)

FY23 BRG cases in MS-DRG family (from MS-DRG 458)	10
FY24 projected MCR cases	17
FY25 projected MCR cases	25
FY26 projected MCR cases	**32**

MCR = Medicare

FY26 Request and Next Steps

Cases using iFuse Bedrock Granite for simultaneous pelvic fixation and SI joint fusion have higher costs

Concerned that hospitals will be underpaid for procedures that adopt new technology to benefit Medicare patients once NTAP expires

For FY 2026, CMS should reassign any spinal fusion cases using iFuse Bedrock Granite (identified by specific ICD-10-PCS codes) to more appropriate MS-DRGs to ensure continued patient access to this innovative technology

We are happy to provide any additional analysis that may be helpful in CMS' evaluation, and we look forward to CMS' comments in the FY 2026 Proposed Rule