Reimbursement Guide

AUGMENT® Regenerative Solutions

New Device Pass-Through Category Established for AUGMENT® Bone Graft and AUGMENT® Injectable

On November 1, 2019, CMS published its final rule to update the Medicare hospital OPPS for CY 2020. Based on Wright's application, CMS agreed that AUGMENT® demonstrated substantial clinical improvement and approved AUGMENT® Bone Graft and AUGMENT® Injectable for device pass-through payment status as of January 1, 2020. In assessing of substantial clinical improvement, CMS seeks to determine whether the device will substantially improve the treatment of an illness or injury compared to available treatment.

With respect to AUGMENT®, CMS concluded:

- "AUGMENT® provides a substantial clinical improvement by significantly reducing, or eliminating, chronic pain (measured at > 20mm on VAS) associated with the autograft donor site with the elimination of the donor site procedure, at 6 months and 12 months."
- "We also note that in subjects 65+, AUGMENT® was more than twice as likely as autograft to result in fusion"
- "Finally, after analyzing the additional data provided through public comment, **we believe that AUGMENT® will provide a substantial clinical improvement by reducing chronic pain and also reducing complications."** (emphasis added)

This payment is intended to reimburse hospitals and ambulatory surgical centers for the incremental cost of a device (such as AUGMENT® Bone Graft and AUGMENT® Injectable) when the cost of the device exceeds the current device-related portion of the Ambulatory Payment Classification (APC) payment for the associated procedure as determined by CMS. This incremental payment helps to support access to a new technology while the claims-based cost data are collected to incorporate the cost for the device (i.e., AUGMENT® Bone Graft and AUGMENT® Injectable) into the APC rates for the associated procedures.

New HCPCS Code Effective January 1, 2020

HCPCS Code	Description	APC	Hospital Outpatient Payment	SI	Ambulatory Surgical Center Payment	PI
C1734	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	2026	Based on Facility's cost-to-charge ratio*	H	Contractor priced**	J7

*For hospitals, the incremental pass-through payment is determined by taking the hospital's charges for the AUGMENT® Bone Graft and AUGMENT® Injectable and converting to costs based on the individual hospital's cost-to-charge (CCR) ratio **for the cost center "Implantable Devices Charged to Patients" (07200) if available**. This cost is then reduced by an amount calculated by CMS which CMS determines to be the amount already included in the payment for the associated procedure to cover device costs (the device offset amount) to determine the additional payment

** For ambulatory surgical centers, CMS determines the amount differently. The ASC receives payment for the service portion of the underlying procedure – the portion of the payment not attributed to the device – by subtracting the "device offset" percent for the associated procedure (determined by HCPCS code) from the total ASC payment for that code. CMS then adds to that service portion a payment for the device itself – i.e., AUGMENT® Bone Graft and AUGMENT® Injectable – based upon MAC-specific pricing.

Physician Reimbursement

Medicare reimburses physicians according to the Medicare Physician's Fee Schedule (MPFS) which is based on Relative Value Units (RVUs).

CY 2020 FINAL PHYSICIAN PAYMENT

CPT® CODE[1]	Description	Facility (POS 21, 22 or 24)		Non-Facility (POS 11)	
		RVUs	Medicare National Average Payment[2]	RVUs	Medicare National Average Payment[2]
27870	Arthrodesis, ankle, open	29.51	$1,065	NA	NA
28705	Arthrodesis; pantalar	35.47	$1,280	NA	NA
28715	Arthrodesis, triple	27.12	$979	NA	NA
28725	Arthrodesis, subtalar	22.47	$811	NA	NA

POS=Place of Service

Outpatient Facility Reimbursement

Hospital outpatient services are reimbursed under Medicare's Outpatient Prospective Payment System (OPPS) based on the associated Ambulatory Payment Classification (APC). Procedures requiring similar resources are grouped into APCs and facilities are paid a lump sum payment for the services provided.

The device in the category described by HCPCS code C1734 should always be billed with one of the following CPT® codes[3].

CY 2020 FINAL HOSPITAL OUTPATIENT AND AMBULATORY SURGERY CENTER PAYMENT

CPT® CODE[1]	Description	Hospital Outpatient (POS 22)		Ambulatory Surgical Center (POS 24)		
		APC	Medicare National Average Payment[4]	SI	Medicare National Average Payment[4]	PI
27870	Arthrodesis, ankle, open	5115	$11,899	J1	$8,448	J8
28705	Arthrodesis; pantalar	5116	$15,944	J1	$11,578	J8
28715	Arthrodesis, triple	5115	$11,899	J1	$8,838	J8
28725	Arthrodesis, subtalar	5115	$11,899	J1	$8,118	J8

Additional HCPCS Codes for Wright Medical's Products

Medicare uses C-codes to track device cost information for future APC rate-setting purposes. No additional payment will be provided to the facility. All appropriate C-codes should be added to the hospital's chargemaster to report device costs used in the outpatient setting. CMS will return a hospital claim if the appropriate tracking code is not identified on the claim when a device-dependent procedure is performed.

HCPCS Code	Description
C1713	Anchor/screw for opposing bone-to-bone or soft tissue-to-bone (implantable):

Inpatient Facility Reimbursement

ICD-10-PCS Procedure Codes

ICD-10-PCS procedure codes are used by hospitals for inpatient procedures beginning October 1, 2015. This list groups codes together by root operations representing procedures performed with AUGMENT® Bone Graft and AUGMENT® Injectable. The ICD-10-PCS root operation is cited by the third digit. Root operations identify the general objective of the procedure using the ICD-10-PCS system. The code variances represent the body part or anatomy as well as left or right side of the body.

Root Operation Title	Objective
Fusion	A fixation device, bone graft, or other to render body part immobile
ICD-10-PCS Code	**ICD-10-PCS Description**
0SGF0KZ	Fusion of Right Ankle Joint with Nonautologous Tissue Substitute Open Approach
0SGG0KZ	Fusion of Left Ankle Joint with Nonautologous Tissue Substitute Open Approach
0SGH0KZ	Fusion of Right Tarsal Joint with Nonautologous Tissue Substitute Open Approach
0SGJ0KZ	Fusion of Left Tarsal Joint with Nonautologous Tissue Substitute Open Approach

MS-DRGs

Medicare assigns a hospital inpatient stay to a Medicare Severity-Diagnosis Related Group (MS-DRG) based on the reported ICD-10 diagnoses and procedure codes. Hospitals generally receive a fixed, predetermined payment for each MS-DRG, which includes all costs associated with the patient's hospital stay. Private payers may have carve-outs for implants.

FY 2020 FINAL HOSPITAL INPATIENT PAYMENT

MS-DRG	Description	Relative Weight	Medicare National Unadjusted Payment
492	Lower Extremity and Humerus Procedures Except Hip, Foot, Femur with MCC	3.4453	$21,564
493	Lower Extremity and Humerus Procedures Except Hip, Foot, Femur with CC	2.3020	$14,408
494	Lower Extremity and Humerus Procedures WO CC/MCC	1.8114	$11,337
503	Foot Procedures W CC	2.7166	$17,003
504	Foot Procedures W CC	1.7365	$10,869
505	Foot Procedures WO CC/MCC	1.6815	$10,524
509	Arthroscopy	1.3917	$8,711
515	Other Musculoskeletal System and Connective Tissue OR Procedures W MCC	3.1540	$19,741
516	Other Musculoskeletal System and Connective Tissue OR Procedures W CC	1.9391	$12,137
517	Other Musculoskeletal System and Connective Tissue OR Procedures WO CC/MCC	1.4153	$8,858

CC=Complications or Comorbidities MCC=Major Complications or Comorbidities

References:

1. Current Procedural Terminology 2020. CPT® copyright 2019 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS apply.
2. Calendar Year 2020 Medicare Physician Fee Schedule, Final Rule [CMS-1715-F]. Federal Register, November 15, 2019. Medicare national average physician payment rates listed in this document are based on the conversion factor of $36.0896. No geographic adjustments have been made to the reported payment rates.
3. https://www.cms.gov/files/document/r4494cp.pdf
4. Calendar Year 2020 Medicare Outpatient Prospective Payment System, Final Rule [CMS-1717-FC], Federal Register, November 12, 2019 and its associated addenda posted on the Centers for Medicare and Medicaid Services web site on November 1, 2019.
5. Fiscal Year 2020 Medicare Inpatient Prospective Payment System, Final Rule [CMS-1716-F], Federal Register, August 16, 2019. Rates were calculated with a hospital Medicare base rate of $6,258.96.
6. Haddad SL, et al. "Impact of Patient Age and Graft Type on Fusion Following Ankle and Hindfoot Arthrodesis." Combined Australia & New Zealand Orthopaedic Foot & Ankle Societies Conference, 2019; DiGiovanni C et al, JBJS, 2013; Daniels TR et al, FAI, 2015; Daniels TR et al, FAI, 2019

Status Indicator (SI) Definitions: H - Separate cost-based pass-through payment; not subject to copayment. **J1 -** Hospital Part B services paid through a Comprehensive APC.

Payment Indicator (PI) Definitions: J7 - OPPS pass-through device paid separately when provided integral to a surgical procedure on ASC list; payment contractor-priced. **J8 -** Device-intensive procedure added to ASC list in CY 2008 or later; paid at adjusted rate.

Brief Summary of Important Product Information

Indications for Use

AUGMENT® Bone Graft and AUGMENT® Injectable are indicated for use as an alternative to autograft in arthrodesis (i.e., surgical fusion procedures) of the ankle (tibiotalar joint) and/or hindfoot (including subtalar, talonavicular, and calcaneocuboid joints, alone or in combination), due to osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, psoriatic arthritis, avascular necrosis, joint instability, joint deformity, congenital defect, or joint arthropathy in patients with preoperative or intraoperative evidence indicating the need for supplemental graft material.

Contraindications

AUGMENT® Bone Graft and AUGMENT® Injectable should not:

- be used in patients who have a known hypersensitivity to any of the components of the product or are allergic to bovine collagen (AUGMENT® Injectable only) or yeast-derived products.
- be used in patients with active cancer.
- be used in patients who are skeletally immature (<18 years of age or no radiographic evidence of closure of epiphyses).
- be used in pregnant women. The potential effects of rhPDGF-BB on the human fetus have not been evaluated.
- be implanted in patients with an active infection at the operative site.
- be used in situations where soft tissue coverage is not achievable.
- be used in patients with metabolic disorders known to adversely affect the skeleton (e.g. renal osteodystrophy or hypercalcemia), other than primary osteoporosis or diabetes.
- be used as a substitute for structural graft.

Warnings

As with all therapeutic recombinant proteins, there is a potential for immune responses to be generated to the rhPDGF-BB component of AUGMENT® Bone Graft and AUGMENT® Injectable. The immune response to rhPDGF-BB was evaluated for AUGMENT® Injectable in two studies, and for AUGMENT® Bone Graft (which contains the identical rhPDGF-BB) in two pilot and one pivotal study for ankle and hindfoot arthrodesis procedures. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to AUGMENT® Bone Graft or AUGMENT® Injectable with the incidence of antibodies to other products may be misleading.

Women of childbearing potential should avoid becoming pregnant for one year following treatment with AUGMENT® Bone Graft or AUGMENT® Injectable. The implantation of rhPDGF-BB in women and the influence of their development of anti-PDGF-BB antibodies, with or without neutralizing activity, on human fetal development are not known.

The safety and effectiveness of AUGMENT® Bone Graft or AUGMENT® Injectable in nursing mothers has not been established. It is not known if rhPDGF-BB is excreted in human milk.

The safety and effectiveness of AUGMENT® Bone Graft or AUGMENT® Injectable has not been established in anatomical locations other than the ankle or hindfoot, or when combined with autologous bone or other bone grafting materials.

The safety and effectiveness of repeat applications of AUGMENT® Bone Graft or AUGMENT® Injectable have not been established.

The safety and effectiveness of AUGMENT® Bone Graft or AUGMENT® Injectable in pediatric patients below the age of 18 years have not been established.

AUGMENT® Bone Graft or AUGMENT® Injectable do not have any biomechanical strength and must be used in conjunction with standard orthopedic hardware to achieve rigid fixation.

The β-TCP component is radiopaque, which must be considered when evaluating radiographs for the assessment of bridging bone. The radiopacity may also mask underlying pathological conditions. Over time, the β-TCP is intended to be resorbed at the fusion site and replaced by new bone. Under such circumstances, it would typically be indistinguishable from surrounding bone.

Please refer to the full package insert for more information.

ACCESS WRIGHT™

For assistance with coding and reimbursement, please contact our

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