Frequently asked questions on the Augment® device transitional pass-through payment

On November 1, 2019, CMS published its final rule to update the Medicare hospital OPPS for CY 2020. Based on Stryker'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 (e.g., Augment Bone Graft and Augment Injectable) into the APC rates for the associated procedures.

FAQs on the Augment device transitional pass-through payment

What is a device transitional pass-through payment?

The transitional pass-through payment is an incremental payment for devices under the Medicare Hospital Outpatient Prospective Payment System (OPPS). This payment is a pathway for new and innovative technologies, should they qualify, to receive additional payment in addition to the ambulatory payment classification (APC) payment for the primary procedure for a period of up to three years.

For a device to qualify for transitional pass-through payment, it must meet the following criteria:

- New technology that is surgically inserted or implanted
- Clinically reasonable and necessary
- Substantial clinical improvement over the current standard of care
- "Not insignificant" cost

As part of the CY 2020 annual rule-making cycle for OPPS, CMS approved Augment Bone Graft and Augment Injectable for device pass-through payment status.

What is the transitional pass-through payment intended to do?

The program is intended to reimburse hospitals and ambulatory surgical centers for the incremental cost of a device (such as Augment) when the cost of the device exceeds the current device-related portion of the 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 (e.g., Augment) into the APC rates for the associated procedures.

How do I report the use of the Augment Bone Graft and Augment Injectable? What is the appropriate code?

CMS created a new HCPCS code after approving Augment for device transitional pass-through payment. The applicable device category code is C1734 orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to-bone (implantable).

Is this new HCPCS code specific to, or exclusive for, the Augment products?

When CMS issues new HCPCS codes for device transitional pass-through payment, they create codes describing device categories. These codes are not intended to be specific to a particular product or brand. These new codes are added to the List of Device Category Codes for Present or Previous Pass-Through Payment published annually on the CMS website. (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Complet-list-DeviceCats-OPPS.pdf). Device category codes on the list that are current (have not expired) are intended solely for product categories that have been approved by CMS for transitional pass-through payment through the quarterly evaluation and annual OPPS rule-making process. In the CY 2020 OPPS Final Rule, **CMS specifically approved Augment for transitional pass-through payment for arthrodesis procedures of the ankle and/or hindfoot** based on data submitted by Stryker.

In order to be eligible for transitional pass-through payment, a product must be described specifically by the long descriptor of the new code and be billed with one of the arthrodesis of the ankle and/or hindfoot CPT codes noted below. The code description for **C1734 is orthopedic/device/drug matrix** for opposing bone-to-bone or soft tissue-to-bone (implantable). **At this time, Augment is currently the only product that fits squarely under the long descriptor of C1734, as it is the ONLY orthopedic product approved by the FDA as a device/drug combination product for ankle and hindfoot arthrodesis and approved by CMS for transitional pass-through payments.**

Does the pass-through payment apply to all Augment formulations and kit sizes?

As discussed above, the code is not specific to the Augment brand but, rather, describes a device category. However, any product or formulation as well as kit sizes that would be described by the new code and fits any additional instructions would be eligible for transitional pass-through payment. This may include single or convenient kits of Augment Bone Graft or Augment Injectable in either 1.5cc or 3.0cc kit sizes.

When is the device eligible for transitional pass-through payments and how long is the device eligible for pass-through?

Augment is eligible as of January 1, 2020. The device category (C1734) is eligible for pass-through for at least two years and no more than three years.

Are there any limitations on which associated procedures should be billed with C1734?

Augment (HCPCS C1734) is eligible for transitional pass-through payment when billed with one of the following CPT codes:

- 27870 arthrodesis, ankle, open
- 28705 arthrodesis; pantalar
- 28715 arthrodesis; triple
- 28725 arthrodesis; subtalar

FAQs on the Augment device transitional pass-through payment

To which settings does the transitional pass-through payment apply?

The transitional pass-through payment applies only to the hospital outpatient and ambulatory surgical center settings. It does not apply to the above associated procedures performed in the physician office or in an inpatient setting.

How much will the facility be reimbursed for Augment?

The pass-through payment will vary depending upon the following:

- Associated fusion procedure
- Costs for Augment based on the volume of Augment used, hospital's charges for Augment, and the hospital's relevant cost-to-charge ratio (CCR)

CMS will calculate the pass-through payment using the hospital's "implantable" devices charged to patients" (cost center 07200) CCR. If unavailable, CMS will defer to the hospital wide CCR.

While the payment rate will vary by patient and by hospital due to different cost-to-charge ratios, the intent of the transitional pass-through payment is to facilitate access to new and truly innovative devices by allowing for incremental payment for these new devices while the necessary cost data are collected to incorporate the costs for these devices into the associated procedure's APC rate.

How is the pass-through payment calculated?

The methodology for calculating pass-through payment differs for hospitals and ambulatory surgical centers.

For hospitals, the incremental pass-through payment is determined by taking the hospital's charges for Augment 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.

Hospital outpatient department

APC payment for primary procedure + [**Hospital charges for augment** × **Hospital cost-to-charge ratio (CCR)**] = **HOPD payment**

For ambulatory surgical centers, HCPCS code C1734 is priced at invoice and always requires that an invoice price be entered in item 19 on the CMS-1500 claim form or its electronic equivalent.

Ambulatory surgical center

ASC payment rate for primary procedure + **Device payment rate (contractor priced)** = **ASC payment**

Does the transitional pass-through payment apply to private payors?

The transitional pass-through payment applies to original Medicare Part B. Facilities should check with Medicaid, Medicare Advantage, and commercial payors to determine if there is coverage and supplemental reimbursement for Augment.

What impact does the transitional pass-through payment have on the payment to surgeons?

The transitional pass-through payment applies to facility payments under the hospital outpatient prospective payment system. Transitional pass-through payment status for Augment has no impact on the payment to the surgeon for the associated procedure.

Note:

These frequently asked questions will be updated as additional information and/or instructions are released by CMS or the local contractors.

Stryker's reimbursement
helpline 800 698 9985

For assistance with coding and reimbursement, please contact:
Toll-free: 800 698 9985, option 2
Fax: 949 449 8699
Email: orthoreimbursement@stryker.com
8:30am EST – 7pm EST, Monday through Friday
(except holidays and unexpected closures)

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 orAugment 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.

References

1. https://www.cms.gov/files/document/r4494cp.pdf
2. 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 website on November 1, 2019.
3. 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.
4. Haddad SL, et al. "Impact of Patient Age and Graft Type on Fusion Following Ankle and Hindfoot Arthrodesis." Combined Australia and 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

Disclaimer: This information is for educational/informational purposes only and should not be construed as authoritative. The information presented here is based upon publicly available source information. Codes and values are subject to frequent change without notice. The entity billing Medicare and/or third party payors is solely responsible for the accuracy of the codes assigned to the services or items in the medical record. When making coding decisions, we encourage you to seek input from the AMA, relevant medical societies, CMS, your local Medicare Administrative Contractor and other health plans to which you submit claims. Items and services that are billed to payors must be medically necessary and supported by appropriate documentation. Wright Medical does not promote the off-label use of its products. It is important to remember that while a code may exist describing certain procedures and/or technologies, it does not guarantee payment by payors.
Please contact your local Stryker representative for product availability.

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