Breaking News Regarding the Transitional Device Pass-Through Payment for AUGMENT® Regenerative Solutions

Wright Medical is excited to notify you that CMS has approved AUGMENT® Bone Graft and AUGMENT® Injectable ("AUGMENT®") for transitional device pass-through payment under Medicare fee-for-service effective January 1, 2020. This payment 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 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®) into the APC rates for the associated procedures.

We are providing key details about the new transitional device pass-through payment below. As a strong advocate for this policy change, we would be happy to provide any other information you need regarding this important reimbursement development. **Our helpline is open from 8:30am EST to 7:00pm EST, Monday through Friday. You can call 800.361.2314 or email Reimbursement@wright.com with any questions.**

TRANSITIONAL DEVICE PASS-THROUGH PAYMENT FOR AUGMENT® AS OF JANUARY 1, 2020

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® 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 found that:

- 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.
- In subjects 65 years and older, AUGMENT® was more than twice as likely as autograft to result in fusion.

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.**[1] (Emphasis Added)

As noted above, this program is a pathway for new and innovative technologies, such as AUGMENT®, to receive incremental payment in addition to the APC payment for the primary procedure for a period of up to three years.[2] With its approval of AUGMENT® for pass-through status, CMS created a new code under which AUGMENT® should be reported – C1734 *orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable).*[3]

This change applies only to Medicare outpatient hospital and ambulatory surgical center cases. Private payer payment is based on a proprietary contract between hospital providers and payers. To the extent that a private payer offers carve-out payments for new technology or for implants, any additional payment and the requirements for such would be determined by the contract between payer and the provider.

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[1] *48 Fed. Reg. 61293 - 61294*

[2] *Note that potential incremental amounts vary from hospital to hospital. The change in payment for associated procedures will vary depending on a number of different factors: associated procedure; and 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).*

[3] Medicare Transmittal (R4494CP) – *January 2020 Update of the Hospital Outpatient Prospective Payment System* https://www.cms.gov/files/document/r4513cp.pdf

ABOUT WRIGHT MEDICAL

Wright Medical is a focused, specialty orthopaedic company that provides extremity and biologic solutions that enable clinicians to alleviate pain and restore their patients' lifestyles. We are a recognized leader of surgical solutions for the upper extremities (shoulder, elbow, wrist and hand), lower extremities (foot and ankle) and biologics (synthetic and tissue-based bone graft substitute materials) markets. Wright Medical is committed to finding and delivering the best possible solutions to patients, providers, and Medicare.

We would be pleased to help your hospital understand the new Medicare policy and answer any questions you may have. **For questions or for more information, please email Reimbursement@wright.com or call our helpline at 800.361.2314.**

This letter is presented for informational purposes only and is accurate as of its date of publication. It is the provider's responsibility to report the codes that accurately describe the products and services furnished to individual patients. Providers should contact the appropriate payer if they have questions and follow the payer's billing guidelines.

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.