



Transitional Pass-Through Payment (TPT)

Frequently Asked Questions

CERAMENT® G & Transitional Pass-Through Payment (TPT) Payments in the Outpatient Setting

On November 1, 2023, Centers for Medicare and Medicaid Services (CMS) approved a new device category for CERAMENT® G to get a Transitional Pass-Through (TPT) Payment. CMS agreed that CERAMENT® G met all criteria for TPT category. The TPT is effective as of January 1, 2024.

What is a transitional pass-through (TPT) and what is it intended to do?

TPT is a pathway created by CMS to allow Medicare patients access to new and innovative technology while claims data is collected. The TPT is designed to reimburse for the incremental cost of a qualifying device (such as CERAMENT® G) when the cost of the device exceeds the current device-related portion of the Ambulatory Payment Classification (APC) for the associated procedure as determined by CMS. A TPT allows an HOPD or ASC to receive additional cost-based payment for the use of qualified technology for a period of 3 years.

What are the criteria to qualify for TPT?

There are four criteria: new technology that is surgically inserted or implanted; clinically reasonable and necessary; provides a substantial clinical improvement over the current standard of care; "not insignificant" cost.

Is CERAMENT G eligible for a separate transitional pass-through (TPT) payment? If so, when does the payment go into effect?

Yes, CMS has officially acknowledged that CERAMENT® G does meet the criteria to create a new pass-through device category and is eligible for a separate cost-based payment in the HOPD and ASC settings. The TPT payment for CERAMENT® G will be effective from January 1, 2024, and last for 3 years.

TPT was approved by CMS for procedures using CERAMENT G in the HOPD and ASC listed in Table 3 under their HCPCS code.

How long will the TPT payment last?

TPT payments will last until the end of 2026. When the pass-through payment expires, CMS will bundle the payment for the product into the relevant procedure APC. By design, CMS will rely on TPT claims data from this 3-year period to calculate the future rates.

When is the device eligible for TPT payments?

The CERAMENT® G TPT is effective January 1, 2024, and will last for 3 years.

Is there a specific HCPCS code that I will need to bill under?

Yes, CMS created a new HCPCS Level II code to define this TPT device new category:

C1602 - Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable).

This code will allow for billing and payment for CERAMENT® G when medically appropriate and billed with an associated procedure code. CMS has assigned this code an OPPS status indicator (SI) of "H" and an ASC payment indicator (PI) of "J7", meaning that the code is eligible to receive a separate payment in HOPD and ASC settings. According to CMS, this code must be paired with an associated procedure code.

How do I report the use of CERAMENT G?

CMS created a new device category and Level II HCPCS code (C1602) effective January 1, 2024. This device-category code should always be billed on the facility claim with an associated CPT procedure code that reflects the procedure performed. Medicare will only recognize the TPT payment with the specified CPT codes that pertain as shown in the billing guide and that pertain to treating bone infection.

Does the TPT payment apply to private payers?

No, the TPT payment applies only to fee-for-service Medicare patients. It does not apply to other payers, including Medicare Advantage. Private payer payment is based on a proprietary contract between 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 the payer and the provider. Facilities should check with private payers to determine if there is any supplemental reimbursement.

Does the Medicare TPT payment have any impact on the physician payment in any setting?

The TPT payment applies to facility payments under the Hospital Outpatient Prospective Payment System, including ASCs. TPT payment status for CERAMENT® G has no impact on the Medicare Physician Fee Schedule (MPFS) payment to the clinician for the associated procedure.

In the physician office setting, Medicare considers the costs of CERAMENT® G to be inherently part of the physician service and included as part of the MPFS "non-facility" payment amount. Some other payers might treat office-based use of CERAMENT® G differently, but that will depend on contracts between the plan and physicians.

CALCULATING BILLING AND PAYMENT AMOUNTS

Bonesupport can provide a TPT Calculator tool upon request.

How is the pass-through payment calculated?

The methodology for calculating the TPT payment amount in the HOPD or ASC is slightly different.

HOPD Payment Calculation⁴

For hospitals, the incremental pass-through payment is determined by taking the hospital's charges for CERAMENT G and converting that to "costs" based on the individual hospital's cost-to-charge (CCR) ratio.

* The HOPD receives payment for the non-device portion of the associated procedure's APC payment rate by subtracting the device offset as specified by CMS [CMS Transmittal 13033]. CMS has modified the device offset amounts for 2025. You can find the CY2024 and CY2025 device offset amounts in HOPD at <https://www.cms.gov/files/document/r13033cp.pdf> page 103. The device offsets can be found in the TPT Calculator Tool.

$$\begin{array}{c} \text{APC Payment for Primary} \\ \text{Procedure} \\ \text{(minus CMS Specified offset} \\ \text{amount*)} \end{array} + \begin{array}{c} [\text{Hospital charges}] \times \\ [\text{hospital-specific CCR}] \end{array} = \text{HOPD Payment}$$

ASC Payment Calculation⁵

For ASCs, the incremental pass-through payment is determined by Medicare Administrative Contractor (MAC) specific pricing, typically covering the acquisition cost of the device (e.g., invoice price).

The ASC receives payment for the non-device portion of the associated procedure payment rate. This device portion is usually a percentage of the payment, which is specified by CMS. (Transmittal 12439 (Table 2) and Transmittal 12559 released March 28, 2024; as well as the January and April 2024 ASC code-pair files.).

$$\begin{array}{c} \text{ASC Procedure Payment} \\ \text{(minus a device offset} \\ \text{amount)} \end{array} + \begin{array}{c} \text{MAC-specific pricing} \\ \text{for device (typically the} \\ \text{acquisition cost)} \end{array} = \text{ASC Payment}$$

How much should my hospital charge for CERAMENT® G?

Each hospital should determine its own charge for CERAMENT® G. However, it is important to understand that CMS will apply the hospital's cost-to-charge ratio (CCR) to the hospital charge to calculate an estimate of the cost of the device. Therefore, to be consistent with its billing practices, a hospital should submit the charges (accounting for their CCRs), not the invoice amount, to CMS on the claim with HCPCS C1602. Otherwise, CMS will calculate an incorrect payment amount for CERAMENT® G. CMS also relies on the charges on claims data for setting payment rates for related procedures when the TPT expires.

Where can a hospital find the relevant hospital outpatient operating cost-to-charge-ratio (CCR) used in the TPT payment calculation?

The CY 2025 CCRs by provider number are available at: FY 2025 Final Rule Impact File (ZIP).

References:

- 1) Ferguson, J et al., 'Radiographic and Histological Analysis of a Synthetic Bone Graft Substitute Eluting Gentamicin in the Treatment of Chronic Osteomyelitis', Journal of Bone and Joint Infection, 4.2 (2019), 76-84 <<https://doi.org/10.7150/jbji.31592>>
- 2) For indications, contraindications, warnings and precautions see Instructions for Use
- 3) Medicare CY2025 Final Rule --CMS-1809-FC and Addenda
- 4) <https://www.cms.gov/files/document/r13033cp.pdf> page 103.
- 5) (Transmittal 12439 (Table 2) and Transmittal 12559 released March 28, 2024; as well as the January and April 2024 ASC code-pair files.).

Additional references:

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CERAMENT® G with Gentamicin

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