

2024 Comprehensive Outpatient Coding & Billing Guide

CERAMENT® G with Gentamicin Synthetic Bone Void Filler

Device-drug matrix, Absorbable, Antimicrobial-Eluting Bone Void Filler

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PRODUCT OVERVIEW

PRODUCT DESCRIPTION

CERAMENT® G is the first combination bone graft substitute and antibiotic indicated as part of the management of osteomyelitis and open fractures. Unlike other treatment options, CERAMENT® G is injectable and can be delivered in a more patient-friendly single-stage procedure because of its unique ability to simultaneously remodel into bone and elute an antibiotic to protect bone healing. With a 96% success rate in reducing chronic osteomyelitis, healthcare resources and costs are reduced while clinical outcomes are improved¹.



FDA INFORMATION ON CERAMENT® G²

CERAMENT® G received “breakthrough device designation” from the FDA in March 2020 for the indication of bone infection and in June 2021 for trauma indications. This designation is reserved for therapies that provide effective treatment or diagnosis of life-threatening diseases or conditions (K090871).

INDICATIONS²

CERAMENT® G is a resorbable, gentamicin-eluting ceramic bone void filler intended for use in defects in the extremities of skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to a bone infection and open fractures. By eluting gentamicin, CERAMENT® G can reduce the occurrence and recurrence of bone infection from gentamicin-sensitive microorganisms in order to protect bone healing. CERAMENT® G can augment provisional hardware to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process. CERAMENT® G resorbs and is replaced by bone during the healing process

CONTRAINDICATIONS²

- Hypersensitivity to any amino-glycoside antibiotics
- Myasthenia gravis
- Severe renal impairment
- Pre-existing calcium metabolism disorder
- Pregnancy
- Breastfeeding

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

TRANSITIONAL PASS-THROUGH PAYMENT (TPT)

Effective January 1, 2024, CERAMENT® G is eligible for separate payment under the Medicare Hospital Outpatient Prospective Payment System (OPPS).

In the 2024 OPPS Final Rule, the 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 to qualify for this additional cost-based payment when billed with an associated procedure code, as defined by CMS. The TPT is effective January 1, 2024, and will last three years.

TPT was approved by CMS for procedures that are performed in the presence of infection. At this time, CMS has not approved additional payment for associated procedures that might be done for open fractures.

This payment is intended to reimburse hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs) for the incremental cost of a device (such as CERAMENT® G) 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., CERAMENT G) into the APC rates for the associated procedures.

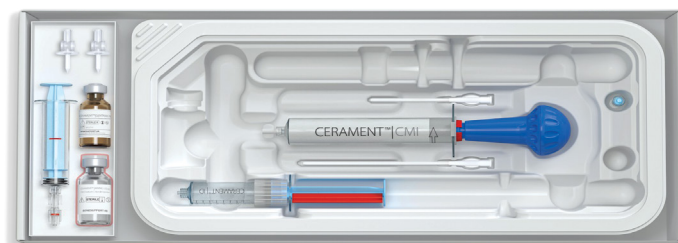
(Disclaimer: CMS makes it clear that Medicare TPT status and assignment of a HCPCS code does not imply or guarantee Medicare coverage. Medical necessity decisions will be made separately by the Medicare Administrative Contractors (MACs) based on the patient condition and service provided; the provider is responsible for submitting accurate claims for products and services rendered.)

MEDICARE COVERAGE DETERMINATIONS (NCD/LCD)

Currently, there is no National Coverage Determination (NCD) related to CERAMENT® G. Check with your local Medicare Administrative Contractor (MAC) regarding any Local Coverage Determinations (LCDs) related to CERAMENT® G. Medicare may cover CERAMENT® G on a case-by-case basis, with evidence of medical necessity. While traditional Medicare does not require or allow prior authorization or prior approval for procedures, Medicare Advantage plans are managed by commercial payers who may require prior authorization for Medicare Advantage patients. Check with your plan administrator for any prior authorization requirements.

PRIVATE PAYER COVERAGE DETERMINATIONS

Commercial insurance coverage policies vary, and many require prior authorization for any procedure. We encourage health care professionals (HCPs) to contact payer(s) directly with questions regarding coverage policies or guidelines for CERAMENT® G.



CODING AND PAYMENT IN THE HOPD AND ASC SETTINGS

When used in the hospital outpatient department (HOPD) or ASC, the facility may report certain devices by using the appropriate HCPCS Level II billing codes. This is true when a device is described by an eligible TPT category. Medicare will recognize the device codes for separate payment, as long as the device is billed in addition to a code recognized by CMS instructions for the associated procedure performed.

See Table 1: Effective January 1, 2024, Medicare established a unique HCPCS Level II code (C1602) to describe a new category of devices eligible for a cost-based transitional pass-through payment (TPT). This code is appropriate for billing CERAMENT® G in the HOPD and ASC settings.

The creation of this TPT will allow Medicare to provide adequate payment for CERAMENT® G so that patients can have access to new technology, while CMS gathers claims data for future payment system updates.

See Table 2: For each HCPCS code, CMS assigns a status indicator (SI) in the HOPD, or a payment indicator (PI) in the ASC, to indicate how that code will be paid by Medicare.

See Table 3: There are several CPT codes that may be applicable to procedures performed in cases for which CERAMENT® G is indicated. It is up to the provider to bill appropriately to reflect the procedures performed. Table 3 also includes the code descriptions, APC assignments, hospital SI, ASC PI, and the Medicare national unadjusted payment amounts³.

CMS specifies which CPT code pairs its claims-processing software will accept as an associated procedure to bill with C1602 (Transmittal #12421 (cms.gov)). The TPT will be denied if not paired with a recognized code from **Table 3**.

Note: Physician services are billed on a separate claim and paid under the Medicare Physician Fee Schedule (MPFS.) Although some of the less-intensive services can be performed in a physician office setting, the MPFS would consider bone-void fillers to be a practice expense and, therefore, not eligible for separate payment.

Payment may vary for private payers and Medicare Advantage plans.

HCPCS Code	Description	APC	SI	HOPD Payment	PI	ASC Payment
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	2043	H	"Costs" based on line-item charge X (CCR), minus a device offset.	J7	Contractor priced (e.g. invoice), minus a device offset.

3) Medicare CY2024 Hospital Outpatient PPS Final Rule. CMS-1786-FC and addenda

Table 2.	
Hospital Outpatient Status Indicators	
J1	Hospital part B services paid through a comprehensive APC
N	Packaged
E1	Not paid by Medicare when submitted on outpatient claims (any outpatient bill type).
C	Not paid under OPPTS. Admit patient, Bill as inpatient.
H	Pass through device category; separate cost-based pass-through payment
ASC Payment Indicators	
J7	OPPS pass-through device paid separately when provided integral to a surgical procedure on ASC list; payment contractor priced.
J8	Device-intensive procedure; paid at adjusted rate
N1	Packaged service/item; no separate payment made.
A2	Surgical procedure on ASC list in CY 2007; payment based on OPPTS relative payment weight
G2	Non office-based surgical procedure added in CY 2008 or later; payment based on OPPTS relative payment weight.
P3	Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs.

Table 3. POTENTIAL CPT CODES FOR RELATED PROCEDURES AND CORRESPONDING MEDICARE 2024 OPPTS PAYMENT						
HCPCS Code	DESCRIPTION	APC	SI	Unadjusted HOPD Payment	ASC PI	Unadjusted ASC Payment
Debridement (These are related codes but are not considered associated primary procedures eligible for TPT.)						
11012	Debridement including removal of foreign material at the site of an open fracture and/or an open dislocation (e.g., excisional debridement); skin, subcutaneous tissue, muscle fascia, muscle, and bone	5073	J1	\$2,716.18	A2	\$1,157.18
11044	Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); first 20 sq cm or less	5072	J1	\$1,546.35	A2	\$682.92
11047	Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed); each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)	N/A	N	N/A	N1	N/A
Shoulder/Clavicle						
23035	Incision, bone cortex (e.g., osteomyelitis or bone abscess), shoulder area	5112	J1	\$1,532.92	A2	\$819.05
23170	Sequestrectomy (e.g., for osteomyelitis or bone abscess), clavicle	5113	J1	\$3,087.24	J8	\$2,086.71
23172	Sequestrectomy (e.g., for osteomyelitis or bone abscess), scapula	5113	J1	\$3,087.24	A2	\$1,518.96
23174	Sequestrectomy (e.g., for osteomyelitis or bone abscess), humeral head to surgical neck	5114	J1	\$6,823.42	A2	\$3,393.01

HCPCS Code	DESCRIPTION	APC	SI	Unadjusted HOPD Payment	ASC PI	Unadjusted ASC Payment
Shoulder/Clavicle						
23180	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), clavicle	5114	J1	\$6,823.42	A2	\$3,393.01
23182	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), scapula	5114	J1	\$6,823.42	A2	\$3,393.01
23184	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), proximal humerus	5114	J1	\$6,823.42	A2	\$3,393.01
Arm/Elbow						
23935	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess), humerus or elbow	5113	J1	\$3,087.24	A2	\$1,518.96
24134	Sequestrectomy (e.g., for osteomyelitis or bone abscess), shaft or distal humerus	5114	J1	\$6,823.42	A2	\$3,393.01
24136	Sequestrectomy (e.g., for osteomyelitis or bone abscess), radial head or neck	5113	J1	\$3,087.24	A2	\$1,518.96
24138	Sequestrectomy (e.g., for osteomyelitis or bone abscess), olecranon process	5114	J1	\$6,823.42	A2	\$3,393.01
24140	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), humerus	5113	J1	\$3,087.24	A2	\$1,518.96
24145	Partial excision (craterization, saucerization, or diaphysectomy) bone (eg, osteomyelitis), radial head or neck	5114	J1	\$3,087.24	A2	\$3,393.01
24147	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), olecranon process	5113	J1	\$3,087.24	A2	\$1,518.96

HCPCS Code	DESCRIPTION	APC	SI	Unadjusted HOPD Payment	ASC PI	Unadjusted ASC Payment
Arm/Elbow						
25035	Incision, deep, bone cortex, forearm and/or wrist (e.g., osteomyelitis or bone abscess)	5114	J1	\$6,823.42	A2	\$3,393.01
25145*	Sequestrectomy (e.g., for osteomyelitis or bone abscess), forearm and/or wrist	5113	J1	\$3,087.24	A2	\$1,518.96
25150	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); ulna	5113	J1	\$3,087.24	A2	\$1,518.96
25151	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis);	5113	J1	\$3,087.24	A2	\$1,518.96
Hand/Fingers						
26230	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis); metacarpal	5113	J1	\$3,087.24	A2	\$1,518.96
26236*	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis); distal phalanx of finger	5112	J1	\$1,532.92	A2	\$819.05
Hip/Pelvis						
26992	Incision, bone cortex, pelvis and/or hip joint (e.g., osteomyelitis or bone abscess)	N/A	C	N/A	N/A	N/A
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); superficial	N/A	C	N/A	N1	N/A

HCPCS Code	DESCRIPTION	APC	SI	Unadjusted HOPD Payment	ASC PI	Unadjusted ASC Payment
Hip/Pelvis						
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); deep (subfascial or intramuscular)	N/A	C	N/A	N1	N/A
Knee/Leg						
27303	Incision, deep, with opening of bone cortex, femur or knee (e.g., osteomyelitis or bone abscess)	N/A	C	N/A	N1	N/A
27360	Partial excision (craterization, saucerization, or diaphysectomy) bone, femur, proximal tibia and/or fibula (e.g., osteomyelitis or bone abscess)	5113	J1	\$3,087.24	A2	\$1,518.96
27607	Incision (e.g., osteomyelitis or bone abscess), leg or ankle	5113	J1	\$3,087.24	A2	\$1,518.96
27640	Partial excision (craterization, saucerization, or diaphysectomy), bone (e.g., osteomyelitis); tibia	5113	J1	\$3,087.24	A2	\$1,518.96
27641	Partial excision (craterization, saucerization, or diaphysectomy), bone (e.g., osteomyelitis); fibula	5113	J1	\$3,087.24	A2	\$1,518.96
Foot/Toes						
28005	Incision, bone cortex (e.g., osteomyelitis or bone abscess), foot	5113	J1	\$3,087.24	A2	\$1,518.96
28120	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); talus or calcaneus	5113	J1	\$3,087.24	A2	\$1,518.96

HCPCS Code	DESCRIPTION	APC	SI	Unadjusted HOPD Payment	ASC PI	Unadjusted ASC Payment
Foot/Toes						
28122	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus	5113	J1	\$3,087.24	A2	\$1,518.96
28124*	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); phalanx of toe	5113	J1	\$3,087.24	P3	\$291.10
Manual Preparation and Insertion (These are related codes but are not considered associated primary procedures eligible for TPT.)						
20700	Manual preparation and insertion of drug-delivery device(s), deep (e.g., subfascial) (List separately in addition to code for primary procedure)	N/A	N	N/A	N1	N/A
20702	Manual preparation and insertion of drug-delivery device(s), intramedullary (List separately in addition to code for primary procedure)	N/A	N	N/A	N1	N/A
20704	Manual preparation and insertion of drug-delivery device(s), intra-articular (List separately in addition to code for primary procedure)	N/A	N	N/A	N1	N/A

CMS has specified a device offset amount for each associated CPT code when billed with the TPT; this is the amount that will be deducted from the total payment to reflect previous device costs. A TPT calculator tool can be made available upon request with the device offset amounts and showing how hospital charges are converted to cost by Medicare.

*HOPDs and ASCs who performed HCPCS C1602 with CPT code 25145, 26236, 28124 with dates of service from January 1, 2024 through March 31, 2024, may have had claims that were processed incorrectly, as these CPT codes were not included on the January 2024 ASC code pair file. Effected claims will be reprocessed by their Medicare Administrative Contractor (MAC).

Sources of the device offset amounts:

For HOPD Table 6a- see CMS transmittals 12421 (table 6a) and 12552 (table 2)

For ASC - see CMS transmittals 12421 (table 6a) and 12552 (table 2)

2024 ICD-10-CM DIAGNOSIS

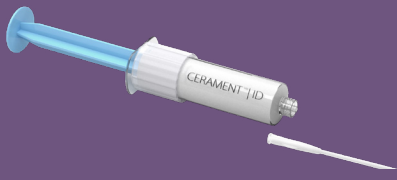
Diagnosis codes are assigned by the physician to accurately report the patient's condition as it relates to the procedure. Below are some examples of diagnosis codes that may be applicable for cases using CERAMENT® G based on the FDA approved indication of bone infection/osteomyelitis. This is only a list of possible codes that represent the typical diagnoses associated with the procedure and is not intended to be a complete list. No actual patient condition is represented by the examples provided.

In March 2024, CERAMENT® G received FDA clearance for an additional indication open fractures. Currently, TPT applies only to the bone infection indication.

ICD-10-CM Diagnosis Descriptions	Diagnosis Section it Maps to in ICD-10-CM
Acute hematogenous osteomyelitis	M86.00 - M86.09
Other acute osteomyelitis	M86.10 - M86.19
Subacute osteomyelitis	M86.20 - M86.29
Chronic multifocal osteomyelitis	M86.30 - M86.39
Chronic osteomyelitis with draining sinus	M86.40 - M86.49
Other chronic hematogenous osteomyelitis	M86.50 - M86.59
Other chronic osteomyelitis	M86.60 - M86.69
Other osteomyelitis	M86.8X0 - M86.8X9
Osteomyelitis, unspecified	M86.9

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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 that are performed in the presence of infection. At this time, CMS has not approved additional payment for associated procedures that might be done for open fractures.

How long will the TPT payment last?

We expect the TPT payment to last for 3 years. 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 OPSS 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 available 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 12552, released on March 21, 2024. <https://www.cms.gov/files/document/r12552cp.pdf>]

The device offsets can be found on the TPT Calculator Tool.

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

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.).

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

4) CMS Transmittal 12421, Table 6a, released December 21, 2023: r12421cp.pdf (cms.gov)

5) CMS Transmittal 12420, released December 21, 2023, r12420cp.pdf (cms.gov)

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 2024 CCRs by provider number are available at: FY 2024 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 CY2024 Hospital Outpatient PPS Final Rule. CMS-1786-FC and addenda
- 4) CMS Transmittal 12421, Table 6a, released December 21, 2023: r12421cp.pdf (cms.gov)
- 5) CMS Transmittal 12420, released December 21, 2023, r12420cp.pdf (cms.gov)

Sources of the device offset amounts:

For HOPD Table 6a- see CMS transmittals 12421 (table 6a) and 12552 (table 2)

For ASC - see CMS transmittals 12421 (table 6a) and 12552 (table 2)

Additional references:

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https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210044.pdf

CERAMENT® G with Gentamicin

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Phone: 1-866-903-2663

PRODUCT CODES

CERAMENT® G with Gentamicin 5ml	A0450-11
CERAMENT® G with Gentamicin 10ml	A0450-10
CERAMENT® G with Gentamicin 5ml (updated kit)	A0535-06
CERAMENT® G with Gentamicin 10ml (updated kit)	A0535-05
CERAMENT® BONE VOID FILLER 5ml	A0210-09
CERAMENT® BONE VOID FILLER 10ml	A0210-08
CERAMENT® BONE VOID FILLER 18ml	A0210-11
CERAMENT® Bead Tray	A0513
CERVOS Access/Delivery 11Ga x 110mm, Open Tip	CER-SUB-1111-OT
CERVOS Access/Delivery 8Ga x 250mm	CER-SUB-825
CERVOS Access/Delivery 15Ga x 60mm, Open Tip	CER-SUB-1560
BONESUPPORT Delivery Cannula 11Ga x 120mm, Closed Tip, Side Port Delivery	74389-01M
2-CAN Delivery Cannula 450mm	2CAN450B



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