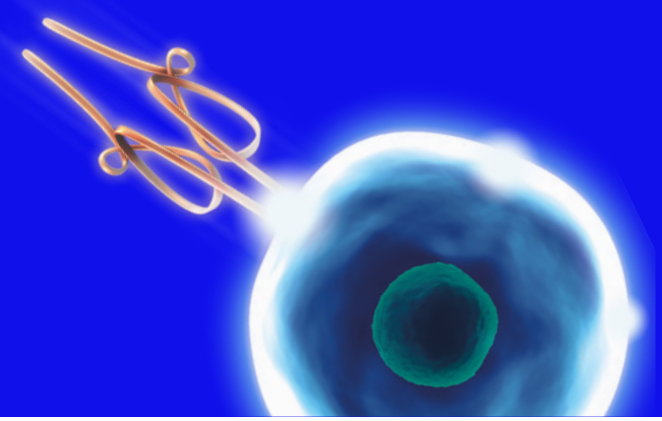
Medtronic

Billing and coding guide

Infuse™ Bone Graft

For spinal indications



The materials and information cited here are for informational purposes only and are provided to assist in obtaining coverage and reimbursement for health care services. However, there can be no guarantee or assurances that it will not become outdated, without the notice of Medtronic, Inc., or that government or other payers may not differ with the guidance contained here. The responsibility for coding correctly lies with the healthcare provider ultimately, and we urge you to consult with your coding advisors and payers to resolve any billing questions that you may have. All products should be used according to their labeling.

Refer to the Infuse™ bone graft/Medtronic interbody fusion device package insert for additional information.

Important information

- In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Reduced ossification of the frontal and parietal bones of the skull was noted infrequently (<3%) in fetuses of rabbit dams immunized to rhBMP-2; however, there was no effect noted in limb bud development. There are no adequate and well controlled studies in human pregnant women. Women of child-bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments.
- Women of child-bearing potential should be advised that antibody formation to rhBMP-2 or its influence on fetal development has not been completely assessed. In the clinical trial supporting the safety and effectiveness of the Infuse™ bone graft/LT-Cage™ lumbar tapered fusion device, 2/277 (0.7%) patients treated with Infuse™ bone graft component and 1/127 (0.8%) patients treated with autograft bone developed antibodies to rhBMP-2. The effect of maternal antibodies to rhBMP-2, as might be present for several months following device implantation, on the unborn fetus is unknown. Additionally, it is unknown whether fetal expression of BMP-2 could re-expose mothers who were previously antibody positive. Theoretically, re-exposure may elicit a more powerful immune response to BMP-2 with possible adverse consequences for the fetus. However, pregnancy did not lead to an increase in antibodies in the rabbit study. Studies in genetically altered mice indicate that BMP-2 is critical to fetal development and that a lack of BMP-2 activity may cause neonatal death or birth defects. It is not known if anti-BMP-2 antibodies may affect fetal development or the extent to which these antibodies may reduce BMP-2 activity.
- Infuse™ bone graft should not be used immediately prior to or during pregnancy. Women of childbearing potential should be advised not to become pregnant for one year following treatment with the Infuse™ bone graft/Medtronic interbody fusion device.
- The safety and effectiveness of the Infuse™ bone graft/Medtronic interbody fusion device in nursing mothers has not been established. It is not known if BMP-2 is excreted in human milk.

The Perimeter™, Clydesdale™, Divergence-L™, and Pivox™ devices must be used with any supplemental fixation system cleared for use in the lumbar spine.

Brief Summary of Indications, Contraindications, and Warnings for:

Infuse™ bone graft/LT-Cage™ lumbar tapered fusion device
Infuse™ bone graft/Inter Fix™ threaded fusion device
Infuse™ bone graft/Inter Fix™ RP threaded fusion device
Infuse™ bone graft/Perimeter™ interbody fusion device
Infuse™ bone graft/Clydesdale™ spinal system
Infuse™ bone graft/Divergence-L™ anterior/oblique lumbar fusion system
Infuse™ bone graft/Pivox™ oblique lateral spinal system
The Infuse™ bone graft/Medtronic interbody fusion device is indicated for spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one level from L2-S1, who may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level.

The following interbody devices and surgical approaches may be used with Infuse™ bone graft:

- The LT-Cage™ lumbar tapered fusion device, implanted via an anterior open or an anterior laparoscopic approach at a single level.
- The Inter Fix™ or Inter Fix™ RP threaded fusion device, implanted via an anterior open approach at a single level.
- The Perimeter™ interbody fusion device implanted via a retroperitoneal anterior lumbar interbody fusion (ALIF) at a single level from L2-S1 or an oblique lateral interbody fusion (OLIF) approach at a single level from L5-S1.
- The Clydesdale™ spinal system, implanted via an OLIF approach at a single level from L2-L5.
- The Divergence-L™ anterior/oblique lumbar fusion system interbody device implanted via an ALIF approach at a single level from L2-S1 or an OLIF approach at a single level from L5-S1.
- The Pivox™ oblique lateral spinal system implanted via an OLIF approach at a single-level from L2-L5.

The Infuse™ bone graft/Medtronic interbody fusion device consists of two components containing three parts – a spinal fusion cage, a recombinant human bone morphogenetic protein, and a carrier/scaffold for the bone morphogenetic protein and resulting bone. These components must be used as a system for the prescribed indication described above. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document. The Infuse™ bone graft component must not be used without the Medtronic interbody fusion device component.

NOTE: The Inter Fix™ threaded fusion device and the Inter Fix™ RP threaded fusion device may be used together to treat a spinal level. The LT-Cage™ lumbar tapered fusion device, the Perimeter™ interbody fusion device, the Clydesdale™ spinal system, the Divergence-L™ anterior/oblique lumbar fusion system, and the Pivox™ oblique lateral spinal system implants are not to be used in conjunction with either the Inter Fix™ or Inter Fix™ RP implants to treat a spinal level.

The Infuse™ bone graft/Medtronic interbody fusion device is contraindicated for patients with a known hypersensitivity to recombinant human Bone Morphogenetic Protein-2, bovine Type I collagen, or to other

components of the formulation and should not be used in the vicinity of a resected or extant tumor, in patients with any active malignancy, or patients undergoing treatment for a malignancy; in patients who are skeletally immature; in pregnant women; or in patients with an active infection at the operative site or with an allergy to titanium, titanium alloy, or polyetheretherketone (PEEK).

There are no adequate and well-controlled studies in human pregnant women. In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Women of child-bearing potential should be warned by their surgeon of potential risk to a fetus and informed of other possible orthopedic treatments. The safety and effectiveness of this device has not been established in nursing mothers. Women of childbearing potential should be advised to not become pregnant for one year following treatment with this device.

Please see the Infuse™ bone graft package insert for the complete list of indications, warnings, precautions, adverse events, clinical results, definition of DDD, and other important medical information. The package insert also matches the sizes of those sized devices that are indicated for use with the appropriate Infuse™ bone graft kit. An electronic version of the package insert may be found at www.medtronic.com/manuals.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician with appropriate training or experience.

Physician coding and payment

Current Procedural Terminology Codes

Physicians use Current Procedural Terminology (CPT®) codes to report all their services. Under Medicare's RBRVS methodology for physician payment, each CPT code is assigned a point value, known as the Relative Value Unit (RVU), which is then multiplied by a conversion factor to determine the physician payment. Many other payers use Medicare's RBRVS fee schedule or a variation of it. Industrial or work-related injury cases are usually reimbursed according to the official fee schedule for each state.

Use of CPT codes is governed by various coding guidelines published by the AMA and other major sources such as physician specialty societies. In addition, the National Correct Coding Initiative (NCCI), a set of CPT coding edits created and maintained by CMS, has become a national standard.

CPT Code	Description	RVUs	Medicare Payment
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	46.05	$1,507.68
+22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace (List separately in addition to code for primary procedure)	7.70	$252.10
+20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)	0	$0

Source: See references.

Hospital inpatient coding and payment

ICD-10-PCS

Hospitals use ICD-10-PCS codes to report inpatient services. Under ICD-10-PCS Coding Guideline B3.10c, interbody devices take precedence over other materials so Infuse™ Bone Graft (rhBMP-2) is included in the interbody device character and not separately reportable from the fusion. According to AHA Coding Clinic for ICD-10-CM and ICD-10-PCS First Quarter 2018, facilities may report a code for the placement of BMP if desired. When an open approach is used, assign 3E0U0GB - Introduction of recombinant bone morphogenetic protein into joints, open approach. The following is an example of codes that may be appropriate for the performance of a single level Oblique Lateral Interbody Fusion (OLIF) using Infuse™ bone graft and the Pivox™ oblique lateral spinal system:

Code	Description
0SG00A0	Fusion of Lumbar Vertebral Joint with Interbody Fusion Device, Anterior Approach, Anterior Column, Open Approach
0SB20ZZ	Excision of Lumbar Vertebral Disc, Open Approach

Diagnosis-Related Groups (DRGs)

Medicare uses the Medicare Severity-DRG (MS-DRG) payment methodology to reimburse hospitals for inpatient services. Each inpatient stay is assigned to one payment group, based on the ICD-10-CM and ICD-10-PCS codes assigned for the major diagnoses and procedures. Each DRG has a flat payment rate which bundles the reimbursement for all services the patient received during the inpatient stay. The following chart shows the estimated Medicare payment amounts for the MS-DRGs to which an anterior lumbar interbody fusion (ALIF) using Infuse™ bone graft/ LT-Cage™ lumbar tapered fusion device may group.

MS-DRG	Description	RVUs	Medicare Payment
028	Spinal Procedures with MCC	6.0261	$42,192
029	Spinal Procedures with CC or Spinal Neurostimulator	3.4282	$24,003
030	Spinal Procedures without CC/MCC	2.319	$16,237
459	Spinal Fusion Except Cervical with MCC	6.6323	$46,437
460	Spinal Fusion Except Cervical without MCC	3.6579	$25,611

Under the MS-DRG system, cases may be assigned to a number of other MS-DRGs, based on individual patient diagnosis and presence or absence of additional surgical procedures performed. Additional MS-DRGs include but are not limited to: MS-DRGs 907, 908, 909; MS-DRGs 957, 958, 959; and MS-DRGs 981, 982, 983.

* MCC – Major Complication and/or Comorbidity. CC – Complication and/or Comorbidity.

†Source: See references.

Frequently asked questions

Does Medicare cover Infuse™ bone graft?

Medicare has not issued a national coverage policy for Infuse™ bone graft. Therefore, local Medicare contractors are free to make coverage determinations based on their own medical necessity and evidence criteria.

How will it affect the hospital's reimbursement if a spinal fusion is performed in an outpatient setting?

Medicare does not cover anterior lumbar interbody spinal fusions in an outpatient setting. However, commercial payers may allow for the procedure to be performed in this setting. In these cases, hospitals will want to review their payer contracts to ensure they receive adequate reimbursement for this procedure in an outpatient setting.

Does Infuse™ bone graft have a HCPCS Level II C-Code?

No specific HCPCS II code exists for Infuse™ bone graft.

Coding and reimbursement assistance

SpineLine™

Provides coding, billing and reimbursement assistance for procedures performed using Medtronic products.

Email: RS.CSTreimbursementsupport@medtronic.com

Web: medtronic.com/SpineLine

References

CPT Changes 2017 American Medical Association.
Source: 2024 Medicare Fee Schedule, Final Rule, Federal Register. No geographic adjustments. Check bundling edits before applying and submitting codes for payment. 2/24

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Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat™* Reader with the browser.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

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