Infuse™ Bone Graft for Spinal Indications

Infuse™ Bone Graft with Pivox™ Oblique Lateral Spinal System

OLIF25™ Procedures with certain sizes* of the Pivox™ Oblique Lateral Spinal System at a single-level from L2–L5

Infuse™ Bone Graft with Divergence-L™ Interbody Fusion Device

ALIF Procedures with certain sizes* of the Divergence-L™ Interbody Fusion Device at a single-level from L2–S1 or OLIF51™ Procedures with certain sizes* of the Divergence-L™ Interbody Fusion Device at a single-level from L5–S1

Infuse™ Bone Graft with PEEK Clydesdale™ Spinal System

OLIF25™ Procedures with certain sizes* of the PEEK Clydesdale™ Spinal System at a single-level from L2–L5

Infuse™ Bone Graft with PEEK Perimeter™ Interbody Fusion Device

ALIF Procedures with certain sizes* of the PEEK Perimeter™ Interbody Fusion Device at a single-level from L2–S1 or OLIF51™ Procedures with certain sizes* of the PEEK Perimeter™ Interbody Fusion Device at a single-level from L5–S1

Infuse™ Bone Graft with LT-Cage™ Lumbar Tapered Fusion Device

Infuse™ Bone Graft with Inter Fix™ Threaded Fusion Device and Inter Fix RP™ Threaded Fusion Device (Reduced Profile)

*Refer to the Infuse™ Bone Graft/Medtronic Interbody Fusion Device package insert for additional information.
SPINAL INDICATION

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. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or Grade 1 retrolisthesis at the involved level. Patients receiving the Infuse™ Bone Graft/Medtronic Interbody Fusion Device should have had at least six months of nonoperative treatment prior to treatment with the Infuse Infuse™ Bone Graft Bone Graft/Medtronic Interbody Fusion Device. The following interbody devices and surgical approaches may be used with Infuse™ Bone Graft:

- Certain sizes of the Pivox™ Oblique Lateral Spinal System, implanted via an OLIF approach at a single level from L2-L5.
- Certain sizes of the Divergence- L™ 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.
- Certain sizes of the Clydesdale™ Spinal System, implanted via an OLIF approach at a single level from L2-L5.
- Certain sizes of 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 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.

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

Physician Coding and Payment

Current Procedural Terminology Codes

Physicians use Current Procedural Terminology (CPT®) codes to report all of 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.

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>Total RVUs</th>
<th>2018 Medicare Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>22558</td>
<td>Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
<td>44.54</td>
<td>$1,603.42</td>
</tr>
<tr>
<td>+22853</td>
<td>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)</td>
<td>7.29</td>
<td>$262.44</td>
</tr>
<tr>
<td>+20930</td>
<td>Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)</td>
<td>0</td>
<td>$0</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0SG00A0</td>
<td>Fusion of Lumbar Vertebral Joint with Interbody Fusion Device, Anterior Approach, Anterior Column, Open Approach</td>
</tr>
<tr>
<td>0SB20ZZ</td>
<td>Excision of Lumbar Vertebral Disc, Open Approach</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>MS-DRG</th>
<th>Description</th>
<th>MDC</th>
<th>Relative Weight</th>
<th>2018 Medicare Payment*</th>
</tr>
</thead>
<tbody>
<tr>
<td>028</td>
<td>Spinal Procedures with MCC</td>
<td>01</td>
<td>5.5586</td>
<td>$33,498.79</td>
</tr>
<tr>
<td>029</td>
<td>Spinal Procedures with CC or Spinal Neurostimulator</td>
<td>01</td>
<td>3.2737</td>
<td>$19,728.89</td>
</tr>
<tr>
<td>030</td>
<td>Spinal Procedures without CC/MCC</td>
<td>01</td>
<td>2.1333</td>
<td>$12,856.29</td>
</tr>
<tr>
<td>459</td>
<td>Spinal Fusion Except Cervical with MCC</td>
<td>08</td>
<td>6.0381</td>
<td>$36,388.49</td>
</tr>
<tr>
<td>460</td>
<td>Spinal Fusion Except Cervical without MCC</td>
<td>08</td>
<td>4.0149</td>
<td>$24,195.71</td>
</tr>
</tbody>
</table>

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 453,454,455 and MS-DRGs 456,457,458; MS-DRGs 907, 908, 909; MS-DRGs 957, 958, 959; and MS-DRGs 981, 982, 983.

Source: FY2018 Medicare Hospital Inpatient Prospective Payment System, Final Rule. Federal Register, August 14, 2017. Updated with Correction Notice dated October 4, 2017. Assumes payment for a hospital with wage index and geographic adjustment factor of 1.000 and submitted quality data and is a meaningful EHR user.

* MCC – Major Complication and/or Comorbidity. CC – Complication and/or Comorbidity.
Outpatient Coding and Payment

HCPCS Codes and APC Assignment
Facilities use the Healthcare Common Procedure Coding System (HCPCS) to report outpatient services. Under Medicare’s methodology for outpatient payment, each HCPCS code is assigned to one Ambulatory Payment Classification (APC). Each APC has a relative weight which is multiplied by a conversion factor to determine the payment. An APC and payment amount are assigned to each significant service. Although some services are bundled and not separately payable, total payment to the facility is the sum of the APC amounts for the services provided during the outpatient encounter.

Many payers use Medicare’s APC methodology or a similar type of fee schedule to reimburse facilities for outpatient services. Other payers use a percentage of charges mechanism, depending on their contract with the facility.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
<th>APC</th>
<th>Status Indicator</th>
<th>CY'18 Medicare Payment</th>
<th>Payment Indicator</th>
<th>CY'18 Medicare Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>22558</td>
<td>Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar</td>
<td></td>
<td>C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+22853</td>
<td>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)</td>
<td></td>
<td>N</td>
<td>N1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+20930</td>
<td>Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)</td>
<td></td>
<td>N</td>
<td>N1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


NOTE: No specific HCPCS Level II code exists for the use of Infuse Bone Graft.

Status/Payment Indicators
Each HCPCS code in the Outpatient Prospective Payment System (OPPS) is assigned a status or payment indicator to provide payment information regarding covered procedures and services, as well as payment adjustments, applicable to the respective APC payment. The following indicators are applicable for this procedure:

- C  Inpatient Procedure (Not paid under OPPS. Admit patient.)
- N  Items and Services Packaged into APC Rates (No Separate APC Payment)
- N1 Packaged service/item; no separate payment made.

Coverage of Spinal Fusion in the Outpatient Setting
Medicare does not cover lumbar interbody spinal fusions in the outpatient setting. Commercial payers, however, may allow for the procedure to be performed in this setting. In these cases, hospitals will want to contact the payer and review their payer contracts to ensure that they provide adequate payment for this procedure in the outpatient setting.
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.

Will the hospital be reimbursed for this device? If not, the hospital will be resistant to use the product. Any suggestions?
In some cases hospitals have included contract terms that will allow for separate payment for devices. If there is no contract language that dictates the payment for devices some insurance companies will determine payment on a case by case basis while others will not allow payment. Our biggest suggestion to gain separate reimbursement for the device is to include a payment clause, commonly known as a “carve-out”, in future contract negotiations that will allow for payment.

Is there a CPT code for Infuse™ Bone Graft?
Yes, effective January 1, 2011 code 20930 should be reported when Infuse™ Bone Graft is used in a spinal indication. For detailed coding, please refer to the appropriate physician coding and payment section within this guide for the indication and procedure being performed.

How will it effect the hospital’s reimbursement if a spinal fusion is performed in an outpatient setting?
Medicare does not cover 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.

CODING AND REIMBURSEMENT ASSISTANCE

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

Phone: 877-690-5353
E-mail: (Physician) spinalcodingmd@medtronic.com
(Hospital) spinalcodinghospital@medtronic.com
Internet: www.medtronicspinal.com/spineline

Therapy Access Solutions (TAS)
Provides prior authorization and denial assistance.

Phone: 877-446-3873
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 1 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** 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 child-bearing 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.