Medtronic

## Infuse™ bone graft for TLIF

# Prior authorization guide

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# Overview

This document outlines resources available to support your efforts in obtaining prior authorization for Infuse™ bone graft. These requests should include patient-specific information, supportive clinical evidence and compliant billing/coding information.

The information provided is for consideration only. The provider is responsible for determining the medical necessity and submitting the appropriate codes with charges for the care provided. Please contact the payer for their prior authorization coverage requirements and workflows.

For healthcare insurers with established non-coverage a different process may need to be followed to request exception-based coverage. This is different from prior authorization processes and can be challenging to navigate. You will need to reach out to the patient's insurance plan to understand the process for this specific request. You may be able to leverage the data and references found within this document to pursue this approach.

**Supportive evidence, bibliography**

Click here

**Infuse™ bone graft Billing and Coding Guide**

Click here

**Sample prior authorization letter**

Click here

**Sample denial appeal letter**

Click here

## Contact

**For additional information, contact Medtronic Reimbursement Customer Support team by email at:**
**rs.cstusreimbursementsupport@medtronic.com**

# Prior authorization

Prior authorization is a utilization management mechanism requiring a provider to receive insurer approval before providing clinical services. Private payers require prior-authorization or pre-certification on most surgical and advanced diagnostic procedures. Numerous states have acted on specific prior authorization issues including transparency, timeline, process review, continuity of care and more. Follow state and national actions on approaches to reduce issues with prior authorization. Many private payers along with Medicare or Medicare Advantage plans will use artificial intelligence to guide the pre-authorization process. Ensuring your practice uses coverage policy key words in your authorization request, procedure documentation and appeals letter will help mitigate the risks involved with AI authorization processing.

The exception request process provides individuals with access to vital medical services that may not be standardly covered but are essential for their health and well-being. Review the payer policy to determine coverage status and if the payer does not cover Infuse™ bone graft, a request for exception-based coverage will be required. This includes medical records and supporting documentation with a letter of medical necessity and a patient-written advocacy letter. Obtain the exception request form from the health insurance plan.  The request will be approved or denied, but you can appeal if the latter is the case.  This process may take a few days to several weeks.

# Supportive evidence - bibliography

U.S. Food and Drug Administration. Infuse Bone Graft P000058/S096 Approval letter. February 13, 2026. https://www.accessdata.fda.gov/cdrh_docs/pdf/P000058S096A.pdf

U.S. Food and Drug Administration. Infuse Bone Graft P000058/S096 Summary of Safety and Effectiveness Data. February 13, 2026. https://www.accessdata.fda.gov/cdrh_docs/pdf/P000058S096B.pdf

Kim, S.-H. et al. Accelerated fusion dynamics by recombinant human bone morphogenetic protein-2 following transforaminal lumbar interbody fusion, particularly in osteoporotic conditions. *Spine J*. 24, 2078–2085 (2024).

White IK, Tuohy M, Archer J, Schroeder GD, Vaccaro AR, Mobasser JP. The Use of Bone Morphogenetic Protein in the Intervertebral Disk Space in Minimally Invasive Transforaminal Lumbar Interbody Fusion: 10-year Experience in 688 Patients. *Clin Spine Surg*. 2019 Jul;32(6):E272-E276.

Siddiqui MM, Sta Ana AR, Yeo W, Yue WM. Bone Morphogenic Protein Is a Viable Adjunct for Fusion in Minimally Invasive Transforaminal Lumbar Interbody Fusion. *Asian Spine J*. 2016;10(6):1091-1099. doi:10.4184/asj.2016.10.6.1091

For additional evidence and literature needs, please contact the Office of Medical Affairs at

**rs.cst-oma@medtronic.com**

# TLIF indication statement

- In an experimental rabbit study, rhBMP-2 has been shown to elicit antibodies that are capable of crossing the placenta. Reduced ossitication of the frontal parietal bones or the skull was noted intrequently (<3%) in fetuses ot 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 regnancy did not lead to an increase in antibodies in the rabbit study. Studies in genetically altered mice indicate that BMP-2 is critical to feta 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 vear 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.

**Brief summary of indications, contraindications, and warnings for Infuse™ bone graft**

Infuse™ bone graft with an FDA cleared intervertebral body fusion device and metallic screw-and-rod system is indicated for use in a transforaminal lumbar interbody fusion (TLIF) surgical approach at one or two adjacent levels from L2-S1 in the treatment of symptomatic degenerative disc disease (DDD) confirmed by patient history and radiographic studies and having at least six months of nonoperative treatment attempted prior to treatment with Infuse™ bone graft.

Infuse™ bone graft consists of two components – a recombinant human bone morphogenetic protein solution and a carrier/scaffold for the bone morphogenetic protein solution and resulting bone. These components must be used as a system. 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.

Infuse™ bone graft 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. An electronic version of the package insert may be found at **manuals.medtronic.com**.

*Date*
*Payer Name*

Attn: Utilization Management/Prior Authorization Department
RE: Prior Authorization for Infuse

Patient name: *Patient name*
Date of birth: *Date of birth*
Policy ID number: *Policy ID number*

Procedure code(s): *Procedure code(s)*
Diagnosis code(s): *Diagnosis code(s)*
Date(s) of service: *Date(s) of service*

To Whom it May Concern:
On behalf of my patient, *patient name*, I am writing to request a prior authorization for Infuse™ bone graft, recombinant human bone morphogenetic protein-2 (rhBMP-2), which has been deemed medically necessary to treat *symptomatic degenerative lumbar spinal disease* in a TLIF Spinal Fusion at *[Insert spinal levels impacted]*. Infuse is indicated for *[insert indication statement]*. The patient failed nonoperative management including *[Insert physical therapy, medications, injections, activity modification, bracing, etc]*. Now the patient requires interbody fusion to restore disc height, stabilize the motion segment, decompress the neural elements indirectly and/or directly, to obtain durable arthrodesis.

The patient has additional nonunion risk factors including *[age, diabetes, smoking history osteopenia/ osteoporosis, obesity, revision surgery, prior pseudoarthrosis, multilevel fusion, deformity, poor local autograft, inability to harvest adequate iliac crest autograft, chronic steroid use, inflammatory disease, renal disease, etc]* Failure to use an evidence-based osteoinductive graft strategy substantially increases this patient's risk of failed fusion, persistent pain, hardware failure, subsidence, and costly revision surgery.

*Explain clinical rationale leading to the decision to recommend this device. You may require one or more paragraphs to address the following:*

- *Patient's relevant medical history, diagnosis, date of diagnosis, and any diagnostic tests*
- *Current clinical presentation: symptoms, severity, impact on quality of life and activities of daily living, etc.*
- *Any significant risk factors, comorbidities, or other relevant history (e.g., hospitalizations, compliance with other therapies or treatments)*
- *Outcomes and limitations of previous treatments (e.g., surgeries, interventions)*
- *Reasons for procedure including why short-term monitoring did not work or would not be successful*
- *Include information from the payor policy if available*

In closing, I have determined that Infuse™ bone graft is medically necessary for my patient and provided the above and enclosed information to support this request. As such, I respectfully request prior authorization for coverage and reimbursement of all charges associated with this procedure, including physician professional fees, facility costs, device/supply charges, fees for follow-up care, and long-term monitoring.

Thank you for your review and consideration of coverage. If you have any questions, please contact me at *[phone number]*.

*Date*
*Payer Name*

Attn: Claims Appeals Department
RE: Appeal letter

Patient name: *Patient name*
Date of birth: *Date of birth*
Policy ID number: *Policy ID number*
Claim ID number: *Claim #*

Procedure code(s): *Procedure code(s)*
Diagnosis code(s): *Diagnosis code(s)*
Date(s) of service: *Date(s) of service*
Denial Code: *CARC & RARC codes*

To Whom it May Concern:
On behalf of my patient, *patient name*, I am writing to appeal a denial for Infuse™ bone graft, recombinant human bone morphogenetic protein-2 (rhBMP-2), which has been deemed medically necessary to treat *symptomatic degenerative lumbar spinal disease* in a TLIF Spinal Fusion at *[Insert spinal levels impacted]*. I respectfully request that this denial be reversed and reprocessed to pay. Infuse is indicated for *[insert indication statement]*. The patient failed nonoperative management including *[Insert physical therapy, medications, injections, activity modification, bracing, etc]*. Now the patient requires interbody fusion to restore disc height, stabilize the motion segment, decompress the neural elements indirectly and/or directly, to obtain durable arthrodesis.

The patient has additional nonunion risk factors including *[age, diabetes, smoking history osteopenia/ osteoporosis, obesity, revision surgery, prior pseudoarthrosis, multilevel fusion, deformity, poor local autograft, inability to harvest adequate iliac crest autograft, chronic steroid use, inflammatory disease, renal disease, etc]* Failure to use an evidence-based osteoinductive graft strategy substantially increases this patient's risk of failed fusion, persistent pain, hardware failure, subsidence, and costly revision surgery.

*Explain clinical rationale leading to the decision to recommend this device. You may require one or more paragraphs to address the following:*

- *Patient's relevant medical history, diagnosis, date of diagnosis, and any diagnostic tests*
- *Current clinical presentation: symptoms, severity, impact on quality of life and activities of daily living, etc.*
- *Any significant risk factors, comorbidities, or other relevant history (e.g., hospitalizations, compliance with other therapies or treatments)*
- *Outcomes and limitations of previous treatments (e.g., surgeries, interventions)*
- *Reasons for procedure including why short-term monitoring did not work or would not be successful*
- *Include information from the payer policy if available*

In closing, I have determined that Infuse™ bone graft is medically necessary for my patient and provided the above and enclosed information to support this request. As such, I respectfully request coverage and reimbursement of all charges associated with this procedure, including physician professional fees, facility costs, device/supply charges, fees for follow-up care, and long-term monitoring.

Thank you for your review and consideration of coverage. If you have any questions, please contact me at *[phone number]*.

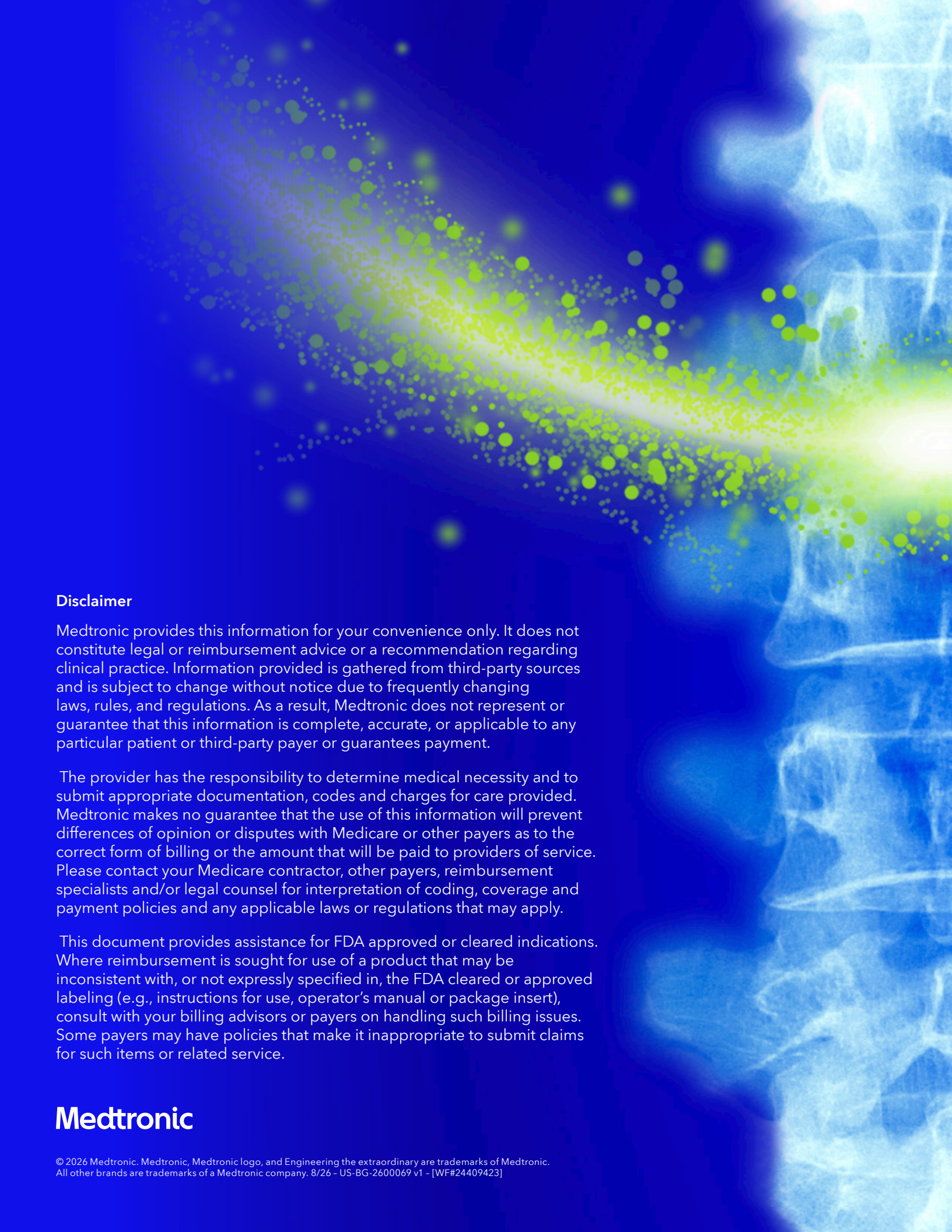
# Contact us

For additional information, contact the Medtronic Reimbursement Customer Support Team.

**rs.cstusreimbursementsupport@medtronic.com**

**SpineLine™ reimbursement website**

**Click here** **To access important disclaimer information**



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