Patient Guide To Insurance Coverage For **Bone Growth Therapy**

ORTHOFIX®

Coverage Information

Your physician has prescribed bone growth therapy, commonly known as bone growth stimulation, to improve your opportunity for a successful fusion. Bone growth therapy is a safe, non-surgical treatment that uses a Pulsed Electromagnetic Field (PEMF) to activate the body's natural healing process that may be impaired. You have the assurance of knowing that the Orthofix Bone Growth Therapy devices are FDA approved and widely accepted by health care professionals.

However, insurance coverage is complex and can vary widely with individual policies. For patients whose insurance provider may not fully cover these devices or for patients without insurance, this brochure describes Orthofix billing practices, which are based on insurance and government requirements.

What happens after my physician prescribes the device?

After your physician determines that you would benefit from bone growth therapy, he or she provides Orthofix with a written prescription and other information required by your insurance provider to determine whether the device is covered under your plan. Orthofix then works with your insurer to determine coverage before you receive the device. This process can take a few days or even several weeks.

What is "Medical Necessity?"

Health insurers, including Medicare, typically cover only those items and services which are determined by their policy to be "reasonable and necessary" for treating specific medical conditions. To determine medical necessity, health insurers require providers such as Orthofix to provide information about your diagnosis to determine whether the device is covered by your insurance plan.

Will my insurance company pay for the device?

Insurance policies are different depending on the plan you have chosen. If guidelines are met, the bone growth therapy device is accepted and approved by the majority of private and public health plans, including Medicare, Medicaid and workers' compensation plans.

Does Orthofix pre-authorize the bone growth therapy device with my insurance company?

In accordance with the patient's benefit plan, Orthofix will assist you in determining coverage by your health plan before you receive the device.

Is there financial responsibility for patients?

Even if an item is considered medically necessary and, therefore, covered by insurance, some health insurers require you to pay a portion of the cost. These costs could include a deductible, co-payment or other coinsurance amount. For Medicare patients, the coinsurance amount for a bone growth therapy device is generally 20% of the Medicare allowable amount. For patients with other health insurance, the coinsurance amount varies by insurer.

Can I pay my patient responsibility (coinsurance/deductible) online?

Yes. If your insurance has determined that you have a coinsurance/deductible, you will receive a bill with instructions for payment. Please visit BoneGrowthTherapy.com or contact a Patient Services Representative at 1-800-535-4492 for additional details.

For Medicare patients, what is an "ABN?"

An ABN is an Advance Beneficiary Notice of Noncoverage for Medicare patients. This document gives patients advance notice that Medicare may not pay for the item prescribed by the physician for their condition. The ABN informs you of your financial responsibility if you choose to receive the device. If an ABN is required for your specific situation, you will be asked to sign it before you receive the bone growth therapy device.

What if I don't have insurance?

Please contact our Patient Service Representatives at 1-800-535-4492 to discuss payment options. Orthofix also has a patient financial assistance program for people who demonstrate financial need based on established guidelines.

Is financial assistance available?

Patients with balances due resulting from limited or no insurance coverage may qualify for our patient financial assistance program. Upon request, an Orthofix Patient Service Representative will work with you to establish a payment plan, or use established guidelines to assess your eligibility for a financial hardship waiver or reduction of the amount owed. Full or partial eligibility is determined by documented household income and family size. If eligible, patients are required to complete a financial hardship application and return the signed application to Orthofix. A determination letter is then sent by Orthofix upon receipt of the completed application.

Can Orthofix waive my financial obligation?

Orthofix is required by law to collect a patient's coinsurance or other amount owed for the bone growth therapy device. Under specific and limited circumstances, such as when we have verified a patient's financial hardship, Orthofix may reduce a patient's financial obligation for the device.

Who do I call if I have any questions?

Orthofix Patient Service Representatives are trained to answer your financial questions. For more information, please call 1-800-535-4492.

Guarantee Program

*Orthofix Bone Growth Therapy is prescribed with a Guarantee Program which states that radiographic progress will be shown in fusion healing, or the fee paid for the unit will be refunded to the payer(s) of record or, at the direction of the originally prescribing physician, a one-time replacement unit can be provided.***

This permits physicians to prescribe and insurance providers to approve our bone growth therapy devices with confidence, and most importantly, to assure our patients will have the maximum opportunity to heal.

**Subject to eligibility requirements.

Spinal Fusion Therapy Products

Model 5212
SpinalStim™ device

Model 5505
CervicalStim™ device

Bone Healing Therapy Products

Model 5313
PhysioStim™ device

Model 5314
PhysioStim™ device

Model 5315
PhysioStim™ device

Model 5302
PhysioStim™ device

Model 5303
PhysioStim™ device

Brief Prescribing Information:

For all products, full prescribing information can be found in product labeling on our patient education website www.BoneGrowthTherapy.com or by calling Patient Services at 1-800-535-4492.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

PhysioStim™ device
The PhysioStim device is indicated for the treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

Use of this device is contraindicated where the individual has synovial pseudarthrosis. Demand type pacemaker operation may be adversely affected by exposure to pulsed electromagnetic fields. The safety and effectiveness of this device has not been established for individuals lacking skeletal maturity or individuals with a nonunion secondary to, or in connection with, a pathological condition. The safety of this device for use on patients who are pregnant or nursing has not been established. Rare instances of reversible minor discomfort have been reported.

SpinalStim™ device
The SpinalStim device is indicated as a spinal fusion adjunct to increase the probability of fusion success and as a nonoperative treatment of salvage of failed spinal fusion, where a minimum of nine months has elapsed since the last surgery.

Cardiac pacemakers may be adversely affected by exposure to pulsed electromagnetic fields. Use of this device is contraindicated where the individual has an implanted cardiac pacemaker. The safety and effectiveness of this device has not been established for individuals lacking skeletal maturity. The safety of this device for use on patients who are pregnant or nursing has not been established. Rare instances of reversible minor discomfort have been reported.

CervicalStim™ device
The CervicalStim device is indicated as an adjunct to cervical fusion surgery in patients at high risk for non-fusion; there are no known contraindications.

Do not use this device if you have a cardiac pacemaker or defibrillator. Remove the device prior to any imaging procedures. The safety of this device for use on patients who are pregnant or nursing has not been established. Adverse effects may include increased pain, numbness and tingling, headache, migraines and nausea; these effects may or may not be directly related to use of the device.

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