

## Who participates in an appeals process?

Several parties are frequently involved in the appeals process: you (the patient), the treating physician, your employer and your authorized representative (Relevant Patient Access Team).

## The Relevant Team

The Relevant Patient Access Team will assist you throughout the appeals process by working with your physician to track and move your appeal forward in a timely manner with the most up-to-date literature to support the Intracept Procedure.

## Detailed records

During the appeals process the Relevant Patient Access Team will assist you and your physician with the interactions with your insurance company. We will monitor the timeliness of the insurance company's response. If a deadline passes without a response, you may lose your right to appeal your insurance company's decision.

## Additional details on the appeals process can be found in the following resources:

- Your insurance company website
- [www.healthcare.gov](http://www.healthcare.gov)
- Your state Insurance Department



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### Indications:

The Intracept Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change).

### Risks:

The information provided by Relievable Medsystems, Inc. is not intended to be a substitute for professional medical advice. The Intracept Procedure, as with any surgical procedure, has risks that should be discussed with your medical professional.

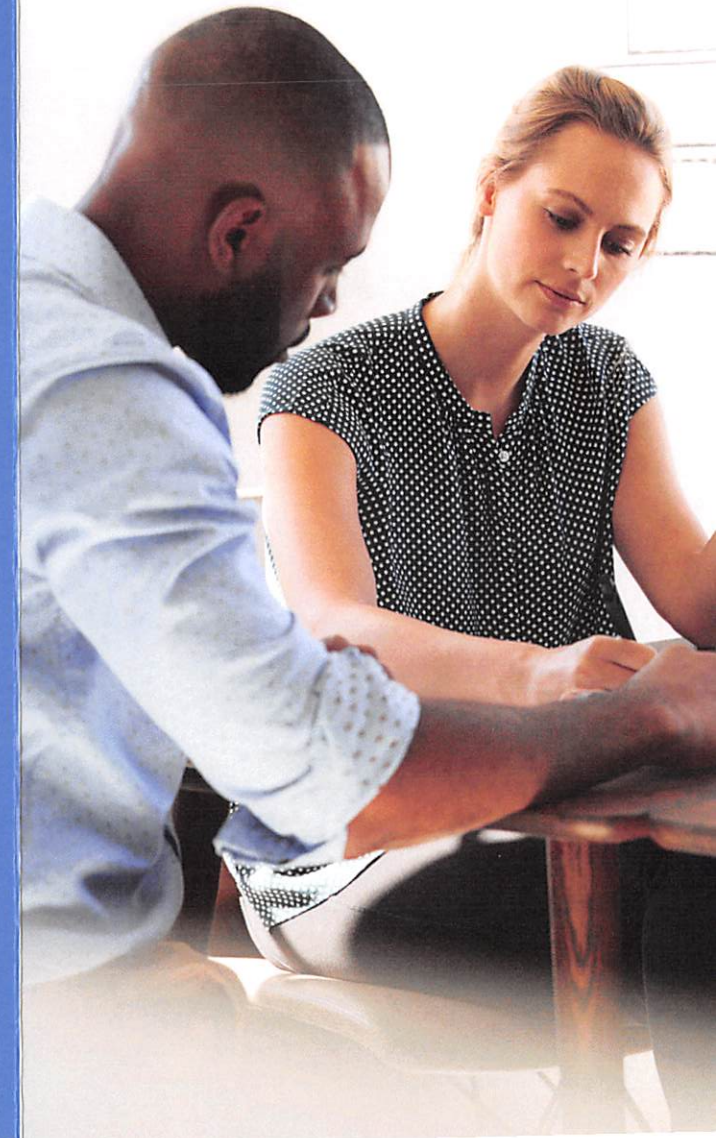
Relievable Medsystems Inc. is pleased to provide general information on the appeals process. This information is not intended to be legal or financial advice. Nothing in this brochure should be construed as a guarantee by Relievable of coverage or payment for Intracept Procedures.

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MKT 0077, Rev C

# Intracept<sup>®</sup>

## PATIENT ACCESS PROGRAM





# The Program Process

Once your physician has determined that the Intracept Procedure is the best treatment to address your chronic low back pain, obtaining prior authorization and approval for payment from your insurance company may require multiple steps.

## These steps will be explained in greater detail:

- Prior Authorization
- Internal Appeal(s)
- External Appeal

The Relievable Patient Access Team will continuously work with you and your physician to obtain the necessary documents that must be submitted to your insurance company in an attempt to obtain approval for the Intracept Procedure.

As a patient, you have the right to appeal a denial by your insurance company. You may have the right to multiple levels of appeal.\*

Your insurance company addresses the first two steps internally and makes the decision to approve or deny your request.

If you exhaust your internal review(s) without an approval, you may have the right to an external appeal, performed by an Independent Review Organization (IRO).

\* Appeal rights and actual time frames will depend upon your specific insurance policy.

## Step 1 Prior Authorization

You will be asked to sign a patient consent form. This will allow the Relievable Patient Access Team to be your Authorized Representative.

Your physician will provide the clinical documentation that demonstrates medical necessity. This documentation is then submitted to your insurance company requesting approval (prior authorization) for the procedure.

If your insurance company provides approval, the Relievable team will contact you and your physician. At that point you can begin scheduling your procedure.

**Step 1** Allow up to 30 days\* once all paperwork is submitted.

## Step 2 Internal Appeal(s)

If your insurance company does not approve your prior authorization for the Intracept Procedure, the Relievable Patient Access Team will assist your physician in submitting appeal letters, along with additional materials, to assist in demonstrating medical necessity.

If your insurance company provides approval, the Relievable team will contact you and your physician. At that point you can begin scheduling your procedure.

**Step 2** Allow an additional 30–60 days\* once all paperwork is submitted.

## Step 3 External Appeal

If your insurance company does not approve the procedure after internal appeal(s), you may have the right to request an external review with an Independent Review Organization (IRO). The Relievable Patient Access Team will assist you throughout this process.

The decision of the Independent Review Organization is binding.

**Step 3** Allow an additional 45-90 days\* once all paperwork is submitted.





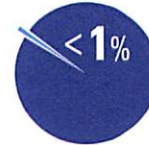
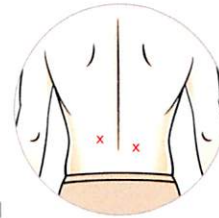
# Intrasept Key Patient Benefits

- Minimally invasive, implant free
- Same-day procedure
- Strong safety profile
- Sustained pain relief
- Improved function
- Decreased patient opioid and injection use
- Proven clinical evidence



## Minimally invasive, same-day procedure, implant-free that preserves future treatment options

- Performed through two small **1 centimeter incisions**
- Strong safety profile – **less than 1%** serious device-related or procedure related events



## Sustained Pain Relief and Improved Function

- The majority of patients experienced pain relief **within the first 6 weeks** posttreatment<sup>1</sup>
- **Improvement in pain and function** sustained for more than five years<sup>3</sup>
- Nearly **8 out of 10** patients indicated they would have the Intrasept Procedure again for the same condition<sup>3</sup>



## Decreased Patient Opioid and Injection Use

- **73% decrease** in the number of patients taking opioids five years post treatment<sup>3</sup>
- **93% decrease** in the number of patients receiving injections five years post treatment<sup>3</sup>



## Proven Clinical Evidence

- The Intrasept Procedure is **FDA-cleared**
- Proven in multiple clinical studies to be **safe, effective and durable**.



## Indications and Risks

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The information provided by Relieva Medsystems, Inc. is not intended to be a substitute for professional medical advice. The Intrasept Procedure, as with any surgical procedure, has risks that should be discussed with your medical professional. Risks include, but are not limited to, temporary leg pain. Severe risks such as nerve injury or fracture are rare.



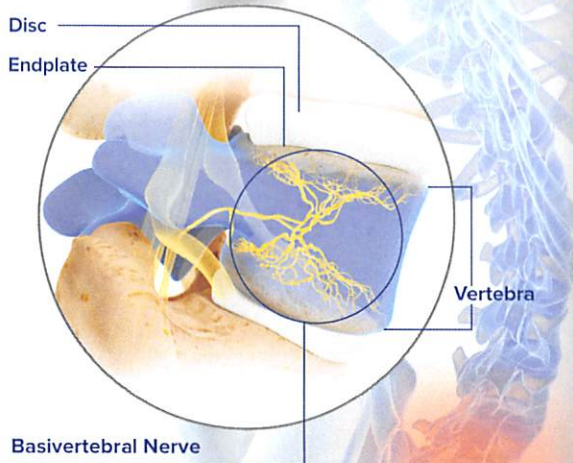
## TALK WITH YOUR DOCTOR

If you have:

- experienced chronic low back pain for more than 6 months, and
- have not received adequate pain relief through conservative treatment (i.e. physical therapy, chiropractic care, injections, medications, opioids)

You may be suffering from pain inside the bones of the spine called the vertebrae. Research now suggests the vertebral endplates are the source of pain in many patients previously diagnosed with disc pain and this pain is transmitted via a nerve inside the vertebra called the Basivertebral Nerve.

The Intracept<sup>®</sup> Procedure is a minimally invasive treatment that stops pain signals from the Basivertebral Nerve using radiofrequency energy.



To learn more about the Intracept Procedure and important safety information, please visit [www.Intracept.com](http://www.Intracept.com)



1. Fischgrund JS, Rhyne A, Franke J, et al. Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain: a Prospective Randomized Double-Blind Sham-Controlled Multi-Center Study. *European Spine Journal*. 2018. Clinical evidence on file.
2. Khalil J, Smuck M, Koreckij T, et al. A Prospective, Randomized, Multi-Center Study of Intraosseous Basivertebral Nerve Ablation for the Treatment of Chronic Low Back Pain. *The Spine Journal* (2019),spine.2019.05.598
3. Fischgrund JS, Rhyne A, Macadaeg K, Moore G, Kamrava E, Yeung C, et al. Long-term outcomes following intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 5-year treatment arm results from a prospective randomized double-blind sham-controlled multi-center study *Eur Spine J*. epub May 25, 2020.

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MKT 0060, Rev E

# GET BACK TO LIVING

FIND RELIEF FROM  
**CHRONIC LOW BACK PAIN**

intracept