SI-BONE® | iFuse Implant System®
Minimally Invasive Sacroiliac Joint Surgery

Patient Insurance Authorization Workbook

Patient Name .....

Surgeon Name .....

Member ID .....

Reference Number .....

Insurance Company Name .....

Insurance Company Phone Number .....

Contact SI-BONE's Reimbursement Support Team for assistance with the authorization process by phone at (800) 710-8511 or email at PICS@SI-BONE.com

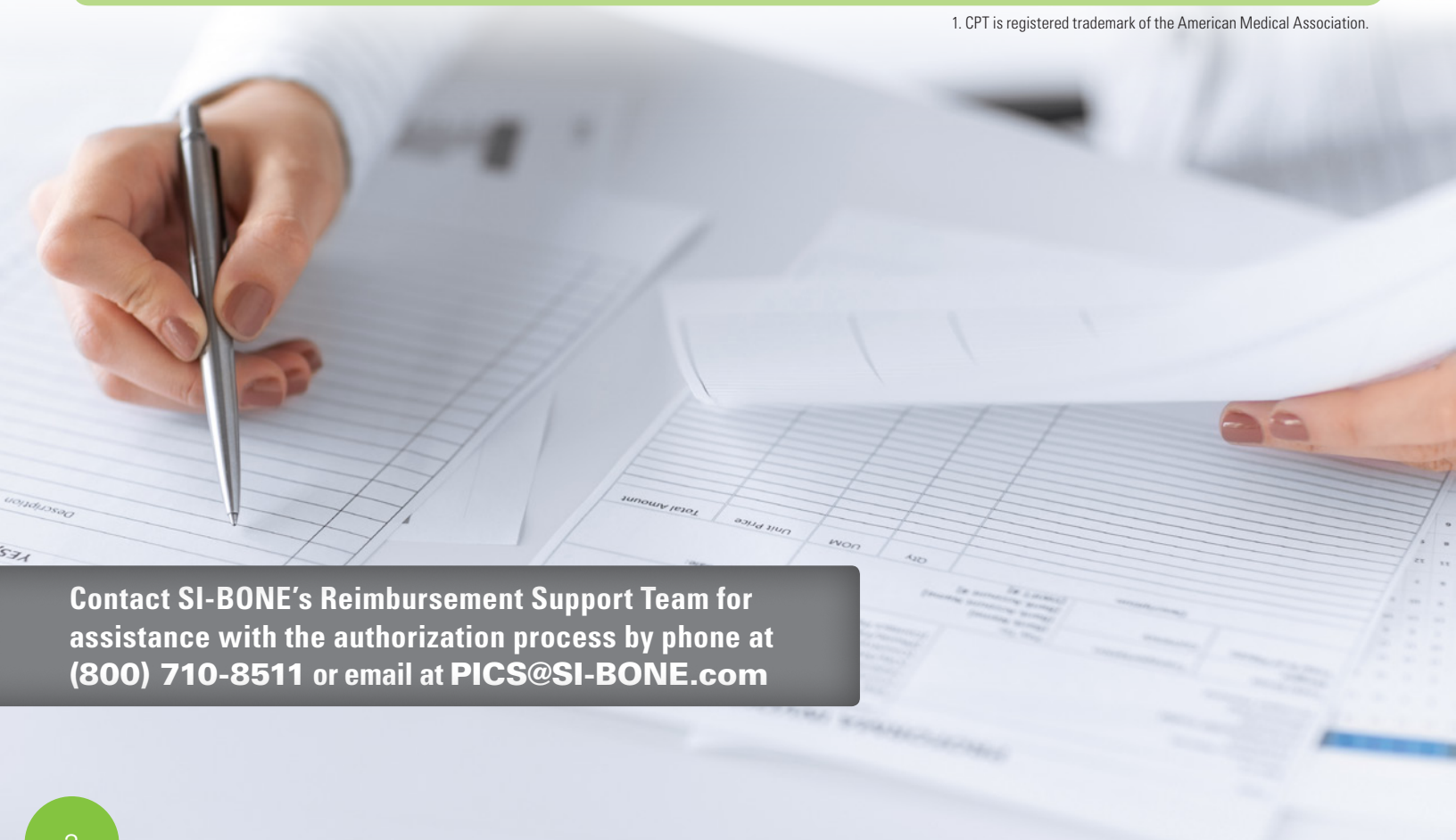
Table of Contents

SI-BONE believes patients should be informed, empowered and active participants in their decisions affecting their healthcare.

- This workbook is designed to help you navigate the insurance authorization process for your iFuse Procedure™.
- If your health plan does not provide coverage for the iFuse Procedure, our Patient Insurance Coverage Support (PICS) team can help you better understand your appeal options. This service is provided at no cost to you.
- Many health plans will allow members several levels of appeal to request coverage for a procedure.
- By partnering with your surgeon, and sometimes your employer, you can help impact the outcome of the insurance company.

- **Please note that SI-BONE is unable to:**
- Provide assistance for a procedure reported with any code other than CPT® (Current Procedural Terminology)[1] 27279
- Assist with matters relating to an "off label" indication
- Represent a physician or patient in the prior authorization or appeal process
- Offer or give legal advice, guarantee coverage or payment
- Support the ERISA appeal process
- For more information, refer to the following link: *http://si-bone.com/providers/reimbursement/*

1. CPT is registered trademark of the American Medical Association.



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Getting Started: The Prior Authorization Process for Surgery Approval

Your surgeon will likely request a written authorization from your insurance company prior to scheduling surgery. The authorization request typically includes details about your condition, your medical history, and information about the iFuse Procedure.

Since physicians and insurance companies communicate by using medical codes (called Current Procedural Terminology or CPT codes) to describe procedures, your surgeon will provide the insurance company with the following information when requesting an authorization:

CPT Code	CPT Code Description
CPT 27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device.

Prior Authorization Packet:

Typically, the initial prior authorization packet submitted to your insurance company includes:

- A letter of medical necessity describing your sacroiliac joint condition, including the treatments that you have tried but failed to resolve the condition, and the surgeon's recommendation for surgery
- Copies of your medical records from your surgeon, pain management physician, chiropractor, and other providers who may have been involved in treating your sacroiliac joint condition
- A Prior Authorization Form (if applicable)
- Imaging studies (e.g., pelvis, hip, and/or lumbar spine)

To obtain copies of templates of the resources listed above, please access the following link:
http://si-bone.com/providers/reimbursement/

How Will I Know If My Request For Surgery Is Approved Or Denied?

When your insurance carrier makes a decision to approve or deny a request for surgery, typically you and your surgeon will receive a letter in the mail. If your request is approved, contact your surgeon's office to schedule your procedure.

Initial Pre-Surgery Request Denial (Before Surgery)

- If your request is denied, you and your surgeon will receive a denial letter in the mail from your insurance plan. Details regarding the denial reason, as well as the next steps in the appeal process, will be included.
- Use this workbook as a roadmap to develop an effective appeal plan to request an approval for surgery.
- Contact SI-BONE's Patient Insurance Coverage Support (PICS) program for assistance with your appeal online at *http://sijpc.org/insurance-coverage-support/insurance-assistance-program/* , by phone at **(800) 710-8511**, or by email at **PICS@SI-BONE.com**

Payment for Surgery Denied (After Surgery)

- If you had surgery and your claim is denied, contact our PICS program for assistance with your appeal online at *http://sijpc.org/insurance-coverage-support/insurance-assistance-program/* , by phone at **(800) 710-8511**, or by email at **PICS@SI-BONE.com**
- This workbook will be helpful during the appeal process to request an approval for payment.

Why Do Insurance Plans Sometimes Deny a Surgery Request?

Some insurance plans may not consider the iFuse Procedure to be a covered benefit under your plan. Reasons include lack of understanding about certain SI joint conditions and available treatment options including:

- Lack of awareness that the standard of care for treatment has evolved in the past several years (i.e., your plan may consider the procedure "experimental and investigational").
- The plan's medical policy does not yet incorporate the available peer reviewed clinical literature.
- Your insurance plan has requirements for additional long term data or additional clinical evidence.
- Lack of understanding on the diagnostic pathway for SI joint conditions for surgery.

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Throughout the appeal process, keep in mind that by remaining consistent, determined, and polite in all interactions with your insurance company, you have the best chance of influencing a successful appeal.

Questions To Ask Your Health Plan Representative About Coverage

To determine if the iFuse Procedure is a covered benefit under your health plan, contact the Member Services number on the back of your insurance card and ask the following questions:

Questions	Date and Time	Insurance Co. contact, title, and phone No.	Details of the conversation
"Is minimally invasive sacroiliac joint fusion a covered benefit under my plan?"[2] *Be prepared to provide CPT code 27279 to describe the procedure.*			
"What are the specific steps to request an approval for my surgery?"			
If the procedure is not a covered service, be prepared to ask the following questions:			
"What is the reason the procedure is not covered (e.g., experimental, not medically necessary for my condition, or another reason)?" "If this procedure is considered experimental, does my policy include all recently published evidence?"			
"What are my available appeal options? How many levels of appeal will I have?"			
"Will my doctor have an opportunity to hold a peer review with a health plan physician if there is a denial to discuss why I need this surgery?"			
"How do I file a grievance with my plan to request access to the procedure?"			
"Who can I talk with the plan to help get this procedure approved? Is there an appeal case manager who can assist me through this process?"			

2. Review your health plan's website, policy manual, or your employer's Summary of Benefits and Coverage document to determine coverage. If necessary, call your health plan to find out where you can find this information on your plan's website or request a copy to be mailed to you.

Support Through the Appeal Process

Your *Health Insurance Policy Handbook* (sometimes called a *Summary Plan Description*) will explain your patient appeal rights in detail. Typically, most plans have a timeline of 7-14 days to respond to an initial request for a surgery authorization. If the surgery request is denied, in some cases, an expedited appeal option may be available.

Getting started with SI-BONE's Patient Insurance Coverage Support Team (PICS):

- When requesting insurance coverage support from SI-BONE, a Case Advocate will be assigned to help you develop an appeal strategy. If your request for surgery is initially denied by your insurance plan, below are the following steps to request assistance:
- Download a copy of the Patient Authorization Form (*http://si-bone.com/form/patient-authorization/*), read it carefully and sign it electronically. Upon completion, a Case Advocate will be in touch to discuss next steps. If you are not able to access the form via the internet, call 800-710-8511.
- Upon receipt of the Patient Authorization Form, your Case Advocate will take the following steps to support the authorization request:

  1. *Request copies of your medical records from your surgeon's office.*
  2. *Review the denial letter including:*
     - » *The specific denial reason provided by your health plan (e.g., "experimental and investigational" or "not medically necessary") and the criteria used to deny the request*
     - » *Instructions for next steps in the appeal process and the deadlines for submission*
  3. *Contact you and/or your health care provider to discuss next steps in the appeal process.*

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Depending on the laws in your state and your specific insurance plan, several levels of insurance appeal may be available, including:

PEER-TO-PEER REVIEW:

- If the initial request for surgery is denied by your insurance company, your surgeon may have an option to set up a phone call with the health plan's physician to discuss the medical necessity for your procedure in order to request an approval. During a peer review call, your surgeon can share critical, clinical and surgical information that the health plan reviewer perhaps has not seen previously.

1st LEVEL APPEAL:

If your health plan provides an unfavorable decision, you have the right to file an appeal with most health plans. Most plans are required to make an appeals process available to you, your surgeon, or a designated representative.

You will find details for your health plan's denial reason located in your denial letter, along with the plan's timeline for filing the appeal, and other key information. Be sure to follow your plan's appeals process closely. For example, denial of the first level appeal is often required prior to filing additional levels of appeal, when available.

Common denial reasons include:

- "Not medically necessary"
- "Experimental and investigational"

Based on the plan's denial reason, you can ask your surgeon to provide documentation to your health plan supporting the need for surgery to treat your SI joint condition (for example, your surgeon may write a letter of medical necessity and submit this information to your health plan for review along with your medical records, clinic notes, and peer reviewed clinical articles explaining the procedure and the results.

Two types of appeal options are typically available to appeal a denial by your health plan:

- **Internal Appeal**
  - » *First Level Appeal (informal review handled by your health plan)*
  - » *Second Level Appeal (formal review handled by your health plan)*
- **External Appeal**

  Independent Third Party Review Group Appeal (the reviewer(s) can either uphold the original decision or approve the request. Your health plan must abide by the reviewers decision).

During the appeals process, your health plan is required to review your appeal in a timely manner. The denial letter should tell you the timeframe in which you must make your request. Your plan must also provide a detailed explanation for the decision to deny the request, and include instructions for appealing the decision.

Support Through the Appeal Process (continued)

According to the Centers for Medicare and Medicaid Services' (CMS) Healthcare.gov website, "insurance companies in all states must participate in an external review process that meets the consumer protection standards of the health care law". The website indicates that your state "may have an external review process that meets or goes beyond these standards. If so, insurance companies in your state will follow your state's external review processes. You'll get all the protections outlined in that process".

Additionally, CMS also provides resources to help consumers with the appeal process. The links below may contain helpful information to help you understand your health plan's process.

https://www.healthcare.gov/contact-us/

https://www.cms.gov/CCIIO/Resources/Files/external_appeals.html

Additionally, the Patient Advocate Foundation has published a guide to help patients with the appeal process available by clicking on the following link.

http://www.patientadvocate.org/requests/publications/Guide-Appeals-Process.pdf

2nd LEVEL APPEAL:

- If the first level appeal is denied, the second level appeal request is normally reviewed by a medical director from your insurance plan. The reviewer typically one who was not involved in the initial denial decision. During your second level appeal, your physician can supply further details about your condition to the insurer to request that your surgery be considered for approval individually (not according to the plan's standard medical policy).

External Review:

- If the second level appeal is denied, the external appeal is typically conducted by an independent, third party reviewer in collaboration with a physician who is board certified in the same specialty as your physician. Specific steps in the appeal process may vary depending on whether your health plan is fully funded or self funded. With a fully funded health plan, the Department of Insurance may have oversight of your plan. With a self funded plan, you may have rights under the Employee Retirement Income Security Act of 1974 ("ERISA"). You should contact your attorney for additional information.

Expedited Appeal

- **Your plan may allow you to request an urgent or expedited appeal** if your healthcare provider believes a delay in treatment could seriously jeopardize your life or overall health, affect your ability to regain maximum function, or subject you to severe and intolerable pain. Details can be obtained from your insurance plan.

Contact SI-BONE's Reimbursement Support Team for assistance with the authorization process by phone at (800) 710-8511 or email at PICS@SI-BONE.com

NOTE:

At every level of your appeal our Case Advocate will work with you and your physician to include relevant medical clinical notes on your condition and peer-reviewed literature that was not previously submitted. For information on SI-BONE's PICS, please visit *http://sijpc.org/insurance-coverage-support/*

Patient Checklist for Your Appeal Submission

Throughout the appeal process, even if your insurance plan denies the initial request, your health plan's medical director and/or an external reviewer has discretion to deviate from a non-coverage policy based on individual consideration of your medical condition.

Step 1:

GATHER YOUR SURGEON'S CLINIC NOTES ASSESSING YOUR SI JOINT CONDITION

- ☐ Initial and subsequent visits to your surgeon related to this condition
- ☐ Notes containing your surgeon's decision that minimally invasive SI joint fusion surgery is appropriate for you
- ☐ Notes for your appointment after surgery (for post surgery denials)

GATHER YOUR OUTSIDE MEDICAL RECORDS (include copies of relevant records from):

- ☐ Primary care physician
- ☐ Pain management physician
- ☐ Physical therapist(s)
- ☐ Chiropractor
- ☐ Any other healthcare providers involved in your care for this condition
- ☐ Specific reports
- ☐ Injections: diagnostic, therapeutic, RF ablation, etc.
  - » *Operative reports (Hospital or ASC) (for post surgery denials)*
  - » *Clinic notes and discharge summary from related procedures*
- ☐ An updated medication list (prescription and non-prescription) that you are taking

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Step 2: FOLLOW THE STEPS OUTLINED IN THE PATIENT CHECKLIST BELOW

After you have gathered the preliminary information and have a basic understanding of your SI joint condition, as well as your insurance company's policy, you are ready to start the appeal process.

Some appeals are handled by the doctor's office or the clinic or the hospital. As the patient, you have the right to understand the steps in the process and should "oversee" the process. Obtain copies of all letters from your surgeon to the insurance company, as well as correspondence to you from the insurance company. To determine the next steps in the appeal process, below are some activities to consider:

Activity	Date & Time	Person contacted, title, and phone No.	Details of the conversation
Obtain a copy of your denial letter.			
Download and sign Patient Authorization form.			
Contact an SI-BONE Case Advocate by calling **(800) 710 8511** or by email at **PICS@SI-BONE.com**			
Contact your surgeon's office to ensure that all of your medical records from other providers are in your surgeon's chart and will be included in the appeal packet.			
When either you or your surgeon is submitting the appeal to your insurance plan, remember to include the following in the appeal packet: • A detailed appeal letter from your provider explaining why the procedure is medically necessary. The letter should address your specific medical condition and the plan's reason for denial. • Documentation (outlined above and as applicable to you) demonstrating that appropriate non operative treatments were attempted to resolve your SI joint condition prior to your surgeon's recommendation for surgery. • Copies of the clinical evidence supporting safety and efficacy of MIS SI joint fusion.* • International Society for the Advancement of Spine Surgery and/or North American Spine Society's *Patient Selection Criteria* for SI joint fusion.*			

* Available from SI-BONE's website at http://sijpc.org/insurance-coverage-support

Your Role in the Appeal Process: Be Proactive and Persistent

To keep the authorization process moving forward and help ensure success, consider taking the following actions:

- Use a note pad or binder that will help you stay organized during the appeal process. Bring this information with you to all appointments.
- Keep detailed records of all communications during the appeal process with your healthcare plan. Document everything. Note the date and time of your call or letter, the topics discussed, any next steps with due dates, and the outcome of the call or correspondence. Record names, titles, departments, and phone numbers.
- If the contact from the plan told you that a call will be returned by a certain date and time and the representative did not return the call, call that person back.
- Gather all medical records and other supporting documents as early in the process as you can. Obtain all records, including written diagnostic imaging reports that may include MRIs of your spine, X rays, CT scans, a list of medications, and any other documents related to your SI joint condition.
- Relevant at each appeal level, the various reviewers will need to have all copies of documentation to make an informed decision.
- Ask your health plan's Members Services representative to assign an Appeal Case Manager from your insurance plan to help you through the process.

- The more you know about your SI joint condition and the steps that your surgeon took to identify your SI joint as the source of your pain, the more confident you will be when interacting with your health plan in the appeal process.
- Be knowledgeable about your diagnosis, evaluation, and treatment options.
- Keep your Human Resources team and/or your Plan Administrator at your employer informed of your challenges with obtaining an authorization for surgery, including the impact on your quality of life and your family's life. Your Human Resources team may be able to offer guidance on requesting an approval for the procedure based on medical necessity.
- Be proactive, persistent, and willing to pursue your plan's appeal process until you receive a favorable outcome (file all levels of appeal available to you).

Important:

Know the deadlines that your insurance company has established for each appeal level. Failure to comply with the deadlines may result in the loss of the opportunity for an appeal.

Will an Appeal Always be Required for Surgery Approval?

Note: Once MIS SI joint fusion is added to your plan's coverage policy, an appeal will no longer be necessary. More insurance companies are adding the iFuse Procedure to their coverage policies as the clinical evidence has become available. There is nationwide Medicare coverage, 44 of 50 state Medicaid programs cover (as of January 2017), and a number of commercial plans cover the iFuse Procedure. Since 2009, more than 25,000 iFuse Procedures have been performed.

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Sample Patient Appeal Letter

Below is one method of organizing a patient appeal letter. Please remember that this letter should tell your story in your own words.

Notice to Patient: This sample letter is provided as a courtesy by SI-BONE, Inc.
Please do not include statements that do not apply. Remove yellow highlighting before printing.

Date
Name of Insurance Plan
Address
City, State, and Zip Code

Patient Name
Member ID
Member Group Number
Reference Number (if applicable)
CPT 27279
Diagnosis code from physician (if known)

Re: **Appeal request for minimally invasive SI joint fusion**

Dear Sir or Madam:

I wish to appeal the denial of my request for minimally invasive surgical sacroiliac (SI) joint fusion. The denial letter indicates that the procedure is considered "experimental and investigational." This procedure is not "experimental and investigational," but rather is an accepted standard of medical practice, supported by credible scientific evidence published in peer-reviewed, medical journals. Physician specialty societies have published comprehensive, evidence-based coverage recommendations that define patient selection criteria (diagnostic algorithm), and consensus treatment guidelines.

Furthermore, there is additional clinical evidence that was not considered in your medical policy that substantiates that minimally invasive sacroiliac joint fusion is now an accepted standard of care. Enclosed are the results of a recently published prospective, multicenter, randomized controlled trial (RCT), demonstrating that minimally invasive SI joint fusion using the iFuse Implant System® is more effective than non-surgical management in relieving pain, improving patient function and improving quality of life in patients with SI joint dysfunction due to degenerative sacroiliitis or SI joint disruption, (Polly et al., 2015).i This data has not yet been considered in your policy, nor have the 5-year outcomes published by Rudolf ii and outcomes from many other relevant clinical articles (see enclosed iFuse Clinical Evidence Summary).

Over the last [months or years], I have experienced persistent and unremitting SI joint pain, as well as short-term relief of my pain due to <insert number of SI joint therapeutic injection(s) or other conservative treatments tried and failed to resolve your condition>. My physician and my surgeon, have recommended minimally invasive SI **(Paint a picture of the condition in your own words. Add additional items if applicable and remove items that do not apply to you.)**

- **Share how/when the condition started.**

Continues

- **Describe the SI joint pain in your own words ("hurts when I …").**
- **Give a brief description of the impact of the condition on your quality of life (e.g., laundry, cooking, grocery shopping, gardening, playing with grandchildren, and taking care of family members and pets).**
- **Describe limits relating to participating in recreational, social, community and civic activities. How has this condition affected your relationships with others?**
- **Mention if you feel you have other treatment options to effectively control pain; does pain medication control the pain? Are you concerned with a possible risk of a possible risk of dependency?**

It is my physician's clinical opinion that I am an appropriate candidate for the minimally invasive SI joint fusion procedure using the iFuse Implant System. Please reconsider your earlier decision and provide coverage for the iFuse Procedure. I sincerely look forward to a timely review and favorable outcome so I may return to my life and my ability to function.

Sincerely,

[Your name]

Enclosure: iFuse Publications List

i Polly DW, *et al.,* "Randomized Controlled Trial of Minimally Invasive Sacroiliac Joint Fusion Using Triangular Titanium Implants Vs Nonsurgical Management for Sacroiliac Joint Dysfunction: 12-Month Outcomes." *Neurosurgery.* 2015 Aug 19. (Epub ahead of print).

ii Rudolf L."Five-Year Clinical and Radiographic Outcomes After Minimally Invasive Sacroiliac Joint Fusion Using Triangular Implants." *The Open Orthopaedics Journal.* 2014;8:375-383.

This letter was prepared using a sample letter provided by SI-BONE, Inc.

One or more of the individuals named herein may be past or present SI-BONE employees, consultants, investors, clinical trial investigators, or grant recipients. Research described herein may have been supported in whole or in part by SI-BONE.

Available Resources

Patient Support

- SI Joint Patient Community (SiJPC.org) PICS program, Patient Insurance Coverage Support Toll free: **1 800 710 8511** or **+1 408 207 0700, x3334** or email at **PICS@SI-BONE.com.**

Patient Selection Criteria

- International Society for the Advancement of Spine Surgery (December 2015)
  ISASS Policy Statement Minimally Invasive Sacroiliac Joint Fusion
  http://www.isass.org/public_policy/2015-03-19-coverage-criteria-for-minimally-invasive-si-joint-fusion-2015.html
- North American Spine Society (June 6, 2015)
  http://si-bone.com/uploads/documents/PercutaneousSacroiliacJointFusion.pdf

Appropriate documentation of medical necessity is important.

State Insurance Resources

- National Association of Insurance Commissioner: *www.naic.org*
- Insurance Commissioner by State: *http://naic.org/state_web_map.htm*
- National Association of Attorneys General: *www.naag.org*
- List of Attorneys General by State: *http://www.naag.org/ag/full_ag_table.php*
- National Conference of State Legislators: *http://www.ncsl.org/public/leglinks.cfm*
- House of Representatives: *http://www.house.gov*
- Senators: *http://www.senate.gov*

Notes

Date	Contact Name and Phone No.	Conversation details	Follow up activities/Next steps

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Notes

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The iFuse Implant System® is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than six months.

There are potential risks associated with the iFuse Implant System. It may not be appropriate for all patients and all patients may not benefit. For information about the risks, visit *www.si-bone.com/risks*

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