Coverage Guidelines

Sacroiliac Joint (SIJ) Fusion For Treatment of Low Back Pain

Disclaimer:
Please note that Baptist Health Plan Coverage Guidelines may be updated throughout the year. A printed version may not be most up to date version available. The health plan reserves the right to review and update this policy as needed. Refer to the website to ascertain that you are utilizing the most current available version. Clinical guideline policies are not intended to serve as treatment guidelines or treatment recommendation. Treating providers must use their own clinical judgment in rendering care to their patient population.

DEFINITION

Sacroiliac joint (SIJ) fusion describes several types of open surgical techniques that facilitate the fusion of the SIJ as a treatment option for low back pain. Many surgical techniques have been developed using different approaches and may be performed with or without hardware. The most common types of SIJ fusion techniques include an anterior or posterior approach, which may be performed with and without screws or plates, percutaneous screw fixation, and a posterior midline fascial splitting approach. SIJ fusion procedures are performed in an inpatient setting by a neurosurgeon. Depending on the technique, the procedure takes one to three hours and the inpatient hospital recovery time ranges from two to five days. SIJ fusion might be a consideration for patients with functional impairment for whom conservative interventions failed. The iFuse Implant System is a minimally invasive spinal fusion procedure targeting the sacroiliac joint. It was developed for patients with lower back pain who have failed nonsurgical management options. The iFuse procedure involves the implantation of titanium rods placed medial to lateral across the SIJ using fluoroscopic guidance.

The SImmetry SIJ fusion system is another recently developed, minimally invasive, procedure involving the implantation of titanium rods in a threaded pattern in order to promote long-term spinal fusion.

COVERAGE CRITERIA

Sacroiliac joint (SIJ) fusion performed as an open procedure or as a minimally invasive procedure including but not limited to iFuse or SImmetry is not currently considered medically necessary or is considered experimental / investigational because currently published peer-reviewed medical evidence does not demonstrate proven safety and efficacy.
MEDICAL BACKGROUND

Low back pain (LBP) is a very common yet potentially debilitating pain disorder that is reported to affect 60% to 80% of Americans. In fact, LBP is the second most common reason for patients to visit their primary care providers, second only to the common cold. In most cases, LBP is temporary and responds to conservative management interventions such as nonsteroidal anti-inflammatory drugs (NSAIDS), muscle relaxers, physical therapy and/or rest. In rare cases, LBP persists as a chronic and disabling condition that fails to improve with conservative management. In these cases, surgical interventions may be a consideration. The economic cost of LBP is estimated to be $60 billion in the US alone considering both productivity loss and healthcare costs.

Sacroiliac joint (SIJ) fusion is a surgical procedure used in an attempt to relieve LBP. However, the evidence that SIJ fusion is a safe and effective surgical option for these cases is currently inconclusive. According to a 2014 report published by Hayes Medical Technology, only six studies evaluating SIJ fusion were identified in peer-reviewed journals. The published evidence at that time consisted of one prospective study, two retrospective studies, three consecutive case series, and no clinical trials. Further, the 2014 report noted that the majority of evidence consisted of small sample sizes, short follow up periods, study endpoints that relied on patient reported pain scales and other anecdotal measures and results that were inconsistent across the studies and even within the studies.

In one retrospective study with a 23 year follow up, favorable results at one year dropped significantly at year 23. According to Hayes, additional studies were needed to determine whether SIJ fusion provided clinically significant, long-term benefits for patients with LBP. The 2016 updated report did not identify the quality evidence necessary to modify the assigned experimental rating. A literature review noted the publication of no new evidence following the update of the most recent report published by Hayes, Inc. Medical Technology.

Several important considerations exist for SIJ fusion. First, clinical outcomes following open surgery seem to vary significantly based on the approach as well as the experience of the surgeon and surgical team. For patients who do not respond to conservative management, it is possible that the right surgical technique coupled with an experienced surgeon and surgical team could yield a positive clinical outcome. But overall, open surgery is considered a complex procedure involving the open exposure of the bone, grafting, and hardware that carries a high likelihood of complications including blood loss, nerve injury, infection, disruption of musculoligamentous structures, long hospital stays and long recovery times.

Emerging literature has proposed the possible alternative of open SIJ fusion procedures with minimally invasive surgical approaches. Minimally invasive procedures are usually performed in an outpatient setting, involve less risk of nerve injury or other complications, and recovery times are usually almost immediate. As compared to open SIJ fusion, early data on minimally invasive procedures are promising but more independent high quality studies are necessary to establish safety, efficacy, and patient selection.

The iFuse system is a minimally invasive procedure designed specifically for the sacroiliac joint involving the placement of sterile, rigid titanium rods with a triangular cross section using drill bits and pins using fluoroscopic guidance. A systematic review of minimally invasive procedures involving separate cohorts of procedures that used either iFuse or a German product made up of hollow modular anchorage screws was conducted despite the low quality of evidence available. Outcomes overall were favorable, showing an average procedure length of less than one hour, 36.9 cc for estimated blood loss and a 1.7-day hospital stay. This review
recorded outcome measures at 6 months, 12 months and 24 months, noting a steady decrease in pain beginning at a baseline of 8, dropping to 5.2, 2.7 and 2.0, respectively. However, this study has several important limitations. For starters, this systematic review was limited by the low quality of data currently available in peer-reviewed literature consisting of one randomized study and three prospective studies. The authors note that even less data was available due to the overlap of cohorts that had to be considered and eliminated prior to data analysis. Also, this study involved the analysis of two different minimally invasive procedures noting outcome variation between the two without really offering a head to head comparison of against one another or against a control. Further, two of the three authors were employees and the third author worked as a consultant of the manufacturer of iFuse at the time of publication.\textsuperscript{13}

The only clinical trial evaluating iFuse that was also considered in the systematic review included a comparison of 102 patients undergoing iFuse against 46 patients receiving nonsurgical medical management. Outcome measures were pain, disability, and quality-of-life scores, which were collected at baseline and at 1, 3, 6, and 12 months. Polly and colleagues found better outcomes in the iFuse group at 1 year in relieving pain, improving function, and improving quality of life in patients, but more adverse events were also reported in this group.\textsuperscript{14}

Another study evaluated in the systematic review was a prospective, multicenter study of 172 patients with SIJ dysfunction due to degenerative sacroiliitis and SIJ disruption. Endpoints for this study relied heavily on patient satisfaction, noting an 80\% average satisfaction rating at 6 and 12 month follow-ups.\textsuperscript{15} Despite these promising results, a 2015 report from Hayes Medical Technology Directory assigned iFuse an investigational rating, noting the low-quality body of evidence leading to substantial uncertainty regarding longer-term efficacy and safety as well as the unavailability of comparison studies with other surgical approaches.\textsuperscript{16}

The Simmetry\textsuperscript{®} SIJ fusion system is another minimally invasive procedure that also involves the implantation of titanium. However, the titanium pieces in this procedure range in length and are inserted in a threaded design in order to promote long-term spinal fusion. Patients undergoing Simmetry SIJ fusion may be discharged same day, but post-operative pain control may result in one to two in-hospital days. A review of the literature identified one publication that specifically discusses Simmetry, noting that both authors have received compensation from the manufacturer.\textsuperscript{17} However, no validated studies or clinical trials are available for this procedure at this time.

Several professional organizations have evaluated the clinical importance of minimally invasive SIJ fusion procedures despite its lack of evidence. Following a report noting evidence to be moderate but largely industry sponsored, the North American Spine Society (NASS) recommended minimally invasive SIJ fusion following an especially vigilant patient selection process.\textsuperscript{18} The International Society for the Advancement of Spine Surgery (ISASS) also recommended minimally invasive spinal surgery for select patients when performed by an orthopedic or neurologic surgeon.\textsuperscript{19} In a subsequent policy statement, the ISASS note that the current evidence proves that minimally invasive SIJ fusion is safe effective based on consistent and replicable data; however, the recommendation does not extend to the endorsement of any specific SIJ technique.\textsuperscript{20}

Alternative procedures for the treatment of LBP may be medically necessary, please refer to Baptist Health Plan’s Coverage Guideline titled Spinal Surgeries, Pain Management Devices and Procedures and Injections for Pain Conditions.
REGULATORY INFORMATION

No legislative mandates were found for coverage of any spinal surgeries in either Kentucky or Indiana.

Baptist Health Plan Coverage Guidelines are created to provide members and providers with peer-reviewed, current medical information.

State and federal laws/mandates and contract language have priority over Coverage Guidelines and must be taken into consideration before eligibility for coverage is determined.

Baptist Health Plan Coverage Guidelines may or may not mirror Centers for Medicare & Medicaid Services benefits or coverage offered by any other health insurance company.

For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, http://www.cms.gov. Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

COVERAGE DETAIL

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING:

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
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<tbody>
<tr>
<td>27279</td>
<td>Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device</td>
<td>Is medically necessary when criteria are met</td>
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<tr>
<td>27280</td>
<td>Arthrodesis, open, sacroiliac joint including obtaining bone graft, including instrumentation, when performed</td>
<td>Is medically necessary when criteria are met</td>
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<td>0201T</td>
<td>Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed</td>
<td>Is medically necessary when criteria are met</td>
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<thead>
<tr>
<th>ICD.10 Procedure Codes</th>
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<th>Coverage Information</th>
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<tr>
<td>0SG734Z</td>
<td>Fusion of right sacroiliac joint with internal fixation device, Percutaneous approach</td>
<td>Is medically necessary when criteria are met</td>
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<tr>
<td>0SG83ZZ</td>
<td>Fusion of Right Sacroiliac Joint, Percutaneous Endoscopic Approach</td>
<td>Is medically necessary when criteria are met</td>
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<tr>
<td>0SG804Z</td>
<td>Fusion of Left Sacroiliac Joint with Internal Fixation Device, Open Approach</td>
<td>Is medically necessary when criteria are met</td>
</tr>
<tr>
<td>0SG807Z</td>
<td>Fusion of Left Sacroiliac Joint with Autologous Tissue Substitute, Open Approach</td>
<td>Is medically necessary when criteria are met</td>
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<tr>
<td>0SG80JZ</td>
<td>Fusion of Left Sacroiliac Joint with Synthetic Substitute, Open Approach</td>
<td>Is medically necessary when criteria are met</td>
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<td>0SG80KZ</td>
<td>Fusion of Left Sacroiliac Joint with Nonautologous Tissue Substitute, Open Approach</td>
<td>Is medically necessary when criteria are met</td>
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<td>0SG80ZZ</td>
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<tr>
<td>0SG834Z</td>
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<td>0SG837Z</td>
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<td>0SG83JZ</td>
<td>Fusion of Left Sacroiliac Joint with Synthetic Substitute, Percutaneous Approach</td>
<td>Is medically necessary when criteria are met</td>
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<td>Fusion of Left Sacroiliac Joint with Nonautologous Tissue Substitute, Percutaneous Approach</td>
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<tr>
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<td>0SG84JZ</td>
<td>Fusion of Left Sacroiliac Joint with Synthetic Substitute,</td>
<td>Is medically necessary when</td>
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Percutaneous Endoscopic Approach

| 0SG84KZ | Fusion of Left Sacroiliac Joint with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach | Is medically necessary when criteria are met |
| 0SG84ZZ | Fusion of Left Sacroiliac Joint, Percutaneous Endoscopic Approach | Is medically necessary when criteria are met |

REFERENCES


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**SEARCH TERMS**

Arthrodesis
Back
Fusion
Implant
Invasive
Joint
Minimally
Spinal
Spine
Surgery