Sacroiliac Joint Fusion

Policy # 00558
Original Effective Date: 08/01/2017
Current Effective Date: 05/30/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider percutaneous/Minimally Invasive Sacroiliac (SI) Joint Fusion with the iFuse system (titanium triangular implant) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered when ALL of the following criteria are met:

- Persistent pain greater than six (6) months' duration that interferes with functional activities as documented by all of the following: (See policy guidelines)
    - Pain score Visual Analogue Scale (VAS) of 5 or greater
    - Oswestry Disability Index (ODI) 30 or greater
- Failure of at least six (6) months of conservative management (See policy guidelines)
- Confirmation of the SI joint as a pain generator as demonstrated by ALL of the following:
    - Pain pattern consistent with SI joint pain (typically unilateral pain caudal to L5 vertebrae, localized over posterior SI joint); and
    - Positive finger Fortin test (localized tenderness with palpation over the sacral sulcus); and
    - Absence of tenderness of similar severity elsewhere in the pelvic region (e.g., greater trochanter, lumbar spine, coccyx); and
    - Positive response from at least three (3) of the following provocative tests:
        - Long ligament test
        - Faber's test/Patrick's sign
        - Active straight leg raise

        - Compression test
        - Distraction test
        - Thigh thrust test (not recommended for those who are pregnant or those with connective tissue disorder)
        - Gaenslen's test
    - Other sources of pain have been excluded as an etiology
- Diagnostic imaging studies that include ALL of the following:
    - Imaging (plain radiographs and a computerized tomography {CT}) or magnetic resonance imaging (MRI) of the SI joint that excludes the presence of destructive lesions (eg, tumor, infection) or inflammatory arthropathy that would not properly be addressed by percutaneous SI joint fusion; and
    - Imaging of pelvis (AP plain radiograph) to rule out concomitant hip pathology; and
    - Imaging of lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain; and
    - Imaging of SI joint that indicates evidence of injury and/or degeneration
- Diagnostic confirmation of the SI joint as the pain generator demonstrated by at least 75% reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced intra-articular SI joint injection (with anesthetic only) on two (2) separate occasions

When Services Are Considered Not Medically Necessary

Fusion/ stabilization of the sacroiliac joint for the treatment of back pain presumed to originate from the SI joint using any other devices not listed above (other than iFuse system) is considered **not medically necessary**.**

The use of percutaneous/Minimally Invasive SI Joint Fusion with the iFuse®‡ system (titanium triangular implant) for indications other than those addressed in this guideline including but not limited to the following is considered to be **not medically necessary:****

- Presence of infection, tumor, or fracture
- Presence of acute, traumatic instability of the SI joint
- Presence of neural compression as seen on imaging that correlates with symptoms or other more likely source of pain
- Presence of generalized pain behavior (eg, somatoform disorder) or generalized pain disorders

(eg, fibromyalgia)
- Presence of ankylosing spondylitis or rheumatoid arthritis

Policy Guidelines

Documentation supporting medical necessity should be submitted at the time of the request and must include the following information:
- Symptom duration and severity
- Specific functional limitations related to symptoms
- Type and duration of all therapeutic measures provided. If conservative management is not appropriate, the reason must be clearly documented.

Conservative management provided by a health professional(s) for this condition(s) should include a combination of strategies to reduce inflammation, alleviate pain, and improve function, including all of the following:
- Activity modification
- Physician-supervised therapeutic exercise program (home exercise program), physical therapy, or manual therapy
- Prescription strength anti-inflammatory medications and analgesics
- Corticosteroid injection
- Sacroiliac support belt or other appropriate bracing

Documentation of compliance with a plan of therapy that includes elements from these areas is required where conservative management is appropriate.

Reporting of symptom severity – Severity of pain and its impact on function are key factors in determining the need for intervention. For purposes of this guideline, significant pain refers to pain rated 5 or greater on the VAS scale and is associated with functional impairment involving the inability to perform at least two (2) age-appropriate daily activities.

The Visual Analogue Scale (VAS) consists of a straight line with the endpoints defining extreme limits such as “no pain at all’ and “pain as bad as it could be”. The patient is asked to mark his pain level on the line between the two endpoints. The distance between “no pain at all’ and the mark then defines the subject’s pain. This tool was first used in psychology by Freyd in 1923. If descriptive

terms like “mild”, “moderate”, “severe” or a numerical scale is added to the VAS, one speaks of a Graphic Rating Scale (GRS). A line-length of 10 or 15 cm showed the smallest measurement error compared to 5- and 20-cm versions and seems to be most convenient for respondents.

Oswestry Disability Index (ODI) was originally published in 1980 in *Physiotherapy*. The ODI is an outcome measure that was designed to assess function in activities of daily living for those with acute or chronic back pain. The ODI consists of 10 patient-completed questions in which the response options are presented as 6-point Likert scales. Scores range from 0% (no disability) to 100% (most severe disability).

Tobacco Cessation – Adherence to a tobacco-cessation program resulting in abstinence from tobacco for at least six (6) weeks prior to surgery is recommended. Documentation of nicotine-free status by laboratory testing (e.g., cotinine level or carboxyhemoglobin) is recommended. After six (6) weeks of tobacco cessation, labs should be performed with ample time afforded to submit this confirmation and complete the prior authorization process.

Diabetes – It is recommended that a patient with history of diabetes maintain hemoglobin A1C 8% or less prior to any joint replacement surgery.

Body Mass Index (BMI) – It is recommended that any patient with a BMI equal to or greater than 40 should attempt weight reduction prior to surgery.

Background/Overview

Low back pain is a global health issue and one of the top 3 causes of health degradation in highly developed countries. Goldwaith and Osgood first discussed the possibility that SI joint injury could cause low back pain as early as 1905. Since that time, there have been numerous studies looking at the prevalence of SI joint syndrome in persons with back pain, and the results of these vary widely. Recent studies have estimated that 15%–30% of chronic low back pain is of sacroiliac origin.

Identifying the SI joint as the pain generator is challenging due to the multifactorial nature of low back pain. Once confirmed, management may include physical or manual therapy with a focus on core and pelvic stability, external orthotics, periodic intra-articular injections, anti-inflammatory medications, and life style changes including smoking cessation and weight loss.

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SI joint fusion techniques were developed based on the assumption that movement across the joint was the primary source of pain. These techniques are not new, but their success has been limited by the extensive nature of the open fusion procedure and a lack of consistent outcome data. However, recent advances in minimally invasive techniques have shown some promise and are addressed here.

This document addresses SI joint fusion when performed as an elective, non-emergent procedure and not as part of the care of a congenital condition, acute or traumatic event such as fracture (excluding fracture of implant and periprosthetic fracture), malignancy or infection.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of radiofrequency generators and probes have been cleared for marketing by the U.S. FDA through the 510(k) process. In 2005, the SInergy®‡ (Halyard; formerly Kimberly-Clark), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. The intended use is in conjunction with a radiofrequency generator to create radiofrequency lesions in nervous tissue. FDA product code: GXD.

A number of percutaneous or minimally invasive fixation/fusion devices have been cleared for marketing by the FDA through the 510(k) process. They include the iFuse Implant System (SI Bone), the Rialto™‡ SI Joint Fusion System (Medtronic), SIJ-Fuse (Spine Frontier), the SImmetry®‡ Sacroiliac Joint Fusion System (Zyga Technologies), Silex™‡ Sacroiliac Joint Fusion System (XTANT Medical), SambaScrew®‡ (Orthofix), and the SI-LOK®‡ Sacroiliac Joint Fixation System (Globus Medical). FDA product code: OUR.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and

other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

For individuals who SIJ pain who receive SIJ fusion/fixation with a triangular implant, the evidence includes 2 nonblinded RCTs of minimally invasive fusion and 2 case series with more than 85% follow-up at 2 to 3 years. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Both RCTs reported superior short-term results for fusion, however, a preferable design for assessing pain outcomes would be independent, blinded assessment of outcomes or, when feasible, a sham-controlled trial. Longer term follow-up from these RCTs has indicated that the results obtained at 6 months persist to 2 years. An additional cohort study and case series, with sample sizes ranging from 45 to 149 patients and low dropout rates (<15%), have also shown reductions in pain and disability at 2 years. One small case series showed outcomes that persisted to 5 years. The cohort studies and case series are consistent with the durability of treatment benefit. Analysis of an insurance database reported an overall incidence of complications to be 16.4% at 6 months and cumulative revision rate at 4 years of 3.54%. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have SIJ pain who receive SIJ fusion/fixation with a cylindrical threaded implant, the evidence includes a prospective cohort. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The prospective cohort study will follow patients for 2 years following implantation of slotted screws filled with autologous bone. Results at 1 year are consistent with findings from the studies using a triangular implant. However, longer follow-up and controlled trials are needed to evaluate this type of implant. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

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4. Lingutla, KK, Pollock, R, Ahuja, S. Sacroiliac joint fusion for low back pain: a systematic review and meta-analysis. Eur Spine J. 2016;25(6):1924-31.
5. North American Spine Society, NASS coverage policy recommendations for percutaneous sacroiliac joint fusion (2015). Accessed November 20, 2017.
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Policy History

Original Effective Date: 08/01/2017
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05/04/2017 Medical Policy Committee review

05/17/2017 Medical Policy Implementation Committee approval. New policy.

02/01/2018 Medical Policy Committee review

02/21/2018 Medical Policy Implementation Committee approval. Coverage statement changed to track AIM guidelines.

03/07/2019 Medical Policy Committee review

03/20/2019 Medical Policy Implementation Committee approval. Criteria revised per AIM guidelines to state:

- Persistent pain greater than six (6) months' duration that interferes with functional activities as documented by all of the following: (See policy guidelines)
  - Pain score Visual Analogue Scale (VAS) of 5 or greater
  - Oswestry Disability Index (ODI) 30 or greater
- Failure of at least six (6) months of conservative management (See policy guidelines)

03/05/2020 Medical Policy Committee review

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03/11/2020 Medical Policy Implementation Committee approval. Added "(with anesthetic only)" to last bullet under patient selection criteria.
Next Scheduled Review Date: 03/2021

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2019 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	27279, 27299
HCPCS	No codes

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ICD-10 Diagnosis	M46.1, M47.898-M47.899, M48.08, M53.2X8, M54.18, M54.30-M54.32, M54.40-M54.42, M54.5, M54.6, S33.2, S33.6

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.