IFuse implant system

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Policy contains: iFuse implant system, minimally invasive sacroiliac joint fusion, sacroiliac joint dysfunction.

This policy is a Sandhills Center Clinical Coverage Policy adopted from AmeriHealth Caritas of North Carolina. These clinical policies are used to assist with making coverage determinations. Sandhills Center's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Sandhills Center when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Sandhills Center clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Sandhills Center's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Sandhills Center will update its clinical policies as necessary. Sandhills Center clinical policies are not guarantees of payment.

Coverage policy

The iFuse implant system for sacroiliac joint dysfunction is clinically proven and, therefore, medically necessary when all of the following conditions are met:

- The member has moderate to severe pain with functional impairment and pain persists despite a minimum of six months of intensive non-operative treatment that must include medication optimization, activity modification, bracing, and active therapeutic exercise targeted at the lumbar spine, pelvis, sacroiliac joint and hip, including a home exercise program.
- The member's record documents typically unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain.
- The member receives thorough physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin's point, i.e., at the insertion of the long dorsal ligament inferior to the posterior superior iliac spine in the absence of tenderness of similar severity elsewhere (e.g., greater trochanter, lumbar spine, coccyx), and other obvious sources for their pain do not exist.
- The member has a positive response to a cluster of three provocative tests (e.g., thigh thrust test, compression test, Gaenslen's test, distraction test, Patrick's test, posterior provocation test). The complete list of tests are as follows:

    - Cranial Shear Test

- Extension Test

    - Flamingo Test
    - Fortin Finger Test
    - Gaenslen's Test
    - Gillet's Test (One Legged-Stork Test)
    - Hibb's test
    - Patrick's Test (FABER)
    - Pelvic Compression Test
    - Pelvic Distraction Test
    - Pelvic Rock Test (Erichsen)
    - Resisted Abduction Test (REAB)
    - Sacral thrust (sacral apex
    - Sacroiliac Shear Test
    - Standing Flexion Test
    - Seated Flexion Test
    - Thigh Thrust Test (POSH)
    - Yeoman test

- There is an absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia).
- Diagnostic imaging studies that include **all** of the following are conducted:
    - Imaging (plain radiographs and a computed tomography or magnetic resonance imaging) of the sacroiliac joint that excludes the presence of destructive lesions (e.g., tumor, infection), fracture, traumatic sacroiliac joint instability, or inflammatory arthropathy that would not be properly addressed by percutaneous sacroiliac joint fusion.
    - Imaging of the pelvis (anterior and posterior plain radiograph) to rule out concomitant hip pathology.
    - Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) to rule out neural compression or another degenerative condition that could be causing low back or buttock pain.
- At least 75% reduction of pain for the expected duration of two anesthetics (on separate visits each with a different duration of action), and the ability to perform previously painful maneuvers, following an image-guided, contrast-enhanced intra-articular sacroiliac joint injection.
- A trial of at least one therapeutic intra-articular sacroiliac joint injection (i.e., corticosteroid injection) has been attempted (Centers for Medicare & Medicaid Services, Local Coverage Determination L36406).

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Conservative therapies, including manipulation, pelvic brace, and sacroiliac joint injections.

Background

Sacroiliac joint dysfunction represents one source of lower back pain, affecting between 15% and 30% of persons with chronic, non-radicular pain. Factors that raise risk for developing sacroiliac joint dysfunction include leg length discrepancy, older age, inflammatory arthritis, previous spine surgery, pregnancy, and trauma (Cohen, 2013).

Sacroiliac joint dysfunction is due to too much or too little movement of the joint. The disorder can be marked by a dull ache of varying severity in the lower back; a sciatic-like hot or stabbing pain plus tingling in the buttocks in the back of the thigh; a stiffness with reduced range of motion; worsened pain after increased pressure like climbing stairs; and instability in the pelvis and lower back (Yeomans, 2018). Referred pain to the leg is common; 76.2% of subjects in one study reported this type of pain (Dengler, 2016).

The disorder is typically diagnosed by a thorough medical examination that takes into account symptoms and/or pain-block injections of the joint or its nerve supply. The examination is considered the gold standard of the diagnostic process. X-rays, computed tomography scans, and magnetic resonance imaging scans are used, but are less helpful in diagnosing sacroiliac joint dysfunction (Yeomans, 2018).

Treatment is nonsurgical in most cases. Types of treatment include rest periods of one to two days; application of heat and/or ice to the painful area; over-the-counter pain medications; manual manipulations often administered by chiropractors or osteopaths; a pelvic brace; and sacroiliac joint injections. Short-term resolution of symptoms occurs in most cases (Yeomans, 2018).

If eight to 12 weeks of nonsurgical therapy fails to resolve symptoms, surgery can be considered. The procedure is a fusion that uses screws or rods with a bone graft across the joint. The decision of whether to perform fusion should be considered carefully, as recovery is slow (typically three to six months), and there is a risk that the patient may not recover at all (Yeomans, 2018). One estimate of this “failed back surgery” is 43% (DePalma, 2011).

The limitations of fusion surgery have prompted the development of devices that perform procedures for sacroiliac dysfunction that are minimally invasive. One of these is the iFuse sacroiliac joint infusion system, or iFuse Implant System®, developed by SI-BONE Inc., an international medical device company based in Santa Clara, California. The company received 510(k) premarket notification status from the Food and Drug Administration for the iFuse Implant System in November, 2008.

The iFuse procedure is performed in an operating room, under spinal or general anesthesia, and lasts about an hour. After a small incision of 2 – 3 centimeters is made on the side of one buttock, the bone is prepared and fluoroscopy is employed to guide the surgeon in properly placing the three implants. Each triangular-shaped implant, made of porous titanium, is small: 3 – 7 millimeters in diameter and 30 – 70 millimeters in length. The goal of the surgery is to stabilize and fuse the sacroiliac joint (SI-BONE, 2019).

In June 2017, SI-BONE received U.S. Food and Drug Administration clearance for full United States commercial launch of the iFuse-3D™ Implant, with a fenestrated design and enhanced porous surface that resembles the trabecular structure of cancellous bone, to provide enhanced osteo-integration and to promote intra-articular fusion. The announcement was based on a journal article (MacBarb, 2017).

By April, 2018, Medicaid programs in 44 states and the District of Columbia covered minimally invasive sacroiliac joint fusion (SI-BONE, 2021). By February 4, 2019, 32 Blue Cross Blue Shield plans covered minimally invasive joint fusion, 27 of which are exclusive to the iFuse implant (SI-BONE, 2019). In 2016, the Centers for Medicare & Medicaid Services issued Local Coverage Determinations detailing the conditions that would be required for covering minimally invasive sacroiliac joint fusion, including iFuse, a policy which was updated in 2019 (Centers for Medicare & Medicaid Services, 2019).

In 2009, the first iFuse implants were conducted. By early 2019, a cumulative worldwide total of 37,000 procedures was reported (SI-BONE, 2019). The SI-BONE company states that in the United States, iFuse is intended for sacroiliac joint fusion, including patients whose disorder is a direct result of sacroiliac joint disruptions and degenerative sacroiliiitis. In all other countries in which the device is available commercially, iFuse is indicated for sacroiliac joint fusion (Heiney, 2015).

In addition to iFuse, other minimally invasive procedures to address sacroiliac joint dysfunction have recently emerged. Among these are cooled radiofrequency, endoscopic sacroiliac denervation, joint fixation, and minimally invasive fusion using hydroxyapatite-coated screws.

Findings

In June, 2015, the North American Spine Society produced a guideline explaining the conditions constituting medical necessity of minimally invasive surgery for sacroiliac joint fusion (North American Spine Society, 2015). The guideline served as the basis for the Centers for Medicare & Medicaid Services' decision to cover the procedure several months later, and since updated in 2019 (Centers for Medicare & Medicaid Services, 2019).

The National Institute for Health and Care Excellence produced a guideline on safety and efficacy of minimally invasive sacroiliac joint fusion surgery for chronic pain. The guideline states that evidence "is adequate to support the use of this procedure" provided a diagnosis of sacroiliac joint dysfunction is confirmed and that the procedure only be performed by trained surgeons who regularly use image-guided surgery (National Institute for Health and Care Excellence, 2017). The Institute later published a Medical Technologies Guidance, which included summaries of clinical evidence, economic evidence, and patient selection for use of iFuse (National Institute for Health and Care Excellence, 2018).

An updated position statement from the International Society for the Advancement of Spine Surgery endorsed use of lateral minimally invasive surgery (including iFuse) for sacroiliac joint fusion, provided several criteria on patient condition are met, six months of conservative treatment have failed, and other conditions have been ruled out (Lorio, 2020).

A systematic review of 12 studies of patients with sacroiliac joint fusion from Italy, Spain, the United Kingdom, and the United States (n = 432) included 368 patients from 10 cohorts using triangular titanium coated implants (five of these were iFuse) and 64 patients from two cohorts using hollow modular anchorage screws. Average pain score fell from 8.1 at baseline to 2.7 in 12 months (almost all in the first six months); the 24-month average was slightly better (2.0). Disability score improved from 56.2 at baseline to 25.1 after 12 months; again, almost all of the improvement occurred in the first six months. The review showed significant variation across studies and between the types of implants used (Heiney, 2015).

A systematic review of 16 studies (n = 430) compared 131 patients with sacroiliac pain/dysfunction undergoing open surgery to 299 who were undergoing minimally invasive surgery. Outcomes were superior for minimally invasive surgery, i.e., a lower reoperation rate (6% versus 15%) and a higher percentage of patients who stated the care was excellent (84% versus 54%) (Zaidi, 2015).

A systematic review and meta-analysis of 20 studies compared minimally invasive (iFuse) joint fusion for sacroiliac dysfunction with screw-type surgery. Although iFuse patients had significantly superior outcomes for

pain (*P* = .03), disability/physical function (*P* = .01), and global/quality of life (*P* = .04), few studies of screw-type surgery were available (Tran, 2019).

A pooled analysis of three multi-center trials of persons with sacroiliac pain (n = 423) compared subjects with minimally invasive surgery with titanium implants (n = 326) and those with nonsurgical management (n = 97). The surgical group had greater reductions in sacroiliac pain and disability, both significant at *P* < .0001 (Dengler, 2017).

A trial comparing 263 patients undergoing sacroiliac joint fusion with open surgery (n = 149) or minimally invasive surgery/iFuse (n = 114) determined superior outcomes for the iFuse group. Lower averages for operating room time (70 minutes versus 163 minutes), estimated blood loss (33 cubic centimeters versus 288 cubic centimeters), and hospital length of stay (1.3 days versus 5.1 days), were each significant at *P* < .0001. The iFuse group had greater reductions in average pain score at 12 months (-6.2 versus -2.7) and at 24 months (-5.6 versus -2), both at *P* < .0001. Postoperative complications were slightly lower for the minimally invasive group (18% versus 21%) (Smith, 2013).

A study from 5,319 iFuse patients treated from 2009 – 2013 documented complaints reported in 204 (3.8%) of patients. The most common complaints were pain (2.2%, n = 119), followed by nerve impingement (0.9%, n = 48) and recurrent sacroiliac joint pain (0.8%). Revision surgeries were performed in 94 (1.8%) of patients, typically soon after surgery (Miller, 2013).

A study of 11,388 iFuse patients, using the SI-BONE internal database from 2009 – 2014, found four-year survivorship without implant revision was 96.46%, a figure that is increasing over time. The revision rate did not differ by sex and was lower for elderly patients. A total of 63.5% of revisions occurred within one year of initial treatment (Cher, 2015).

A study using two trials of 148 and 172 patients showed subjects who underwent iFuse had a 16% greater chance of returning to work than nonsurgical patients (difference not significant) (Saavoss, 2016).

A study of 312 patients treated from 2003 – 2015, 274 of whom received iFuse with triangular titanium implants and 38 patients with sacroiliac joint screw fixation, documented four-year revision rates much lower for iFuse patients (5.7% versus 30.8%) (Spain, 2017).

A literature review included 11 retrospective case series (n = 278) of level 4 evidence the iFuse reduces pain from sacroiliac joint fusion. Patients in each study were followed from 8 – 60 months (Martin, 2020).

One analysis of minimally invasive sacroiliac joint surgery, other than iFuse, reviewed cooled radiofrequency, which was the subject of a meta-analysis of seven studies (n = 240) that compared patient status before and after the procedure. Pain intensity decreased by an average of 3.8 points (*P* < .001) using two rating scales. Reduction in disability also declined significantly (*P* < .001), and 72% of patients presented positive results, measured by the Global Perceived Effect (*P* < .001). Only mild complications were observed (Sun, 2018).

References

On April 12, 2021, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “sacroiliac joint,” “minimally invasive,” “fusion,” “dysfunction,” “arthrodesis,” and “iFuse.” We included the best available evidence according to established

evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

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7/2019: Policy references updated; policy ID changed to CCP.1385; coverage section changed from CCP.1385

investigational to medically necessary.

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