Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
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Plan: AmeriHealth Caritas Pennsylvania Community Health Choices	**Submission Date**: 8/1/2024
Policy Number: ccp.1385	**Effective Date:** 7/2018 **Revision Date:** July 1, 2024
Policy Name: IFuse implant system	

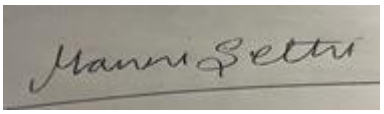
Type of Submission – Check all that apply:

New Policy
X Revised Policy*
Annual Review – No Revisions
Statewide PDL

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

Previously retired. Reactivated policy. See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

IFuse implant system

Clinical Policy ID: CCP.1385

Recent review date: 7/2024

Next review date: 11/2025

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

AmeriHealth Caritas Pennsylvania Community HealthChoices has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania Community HealthChoices' 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 AmeriHealth Caritas Pennsylvania Community HealthChoices on a case by case basis, 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. AmeriHealth Caritas Pennsylvania Community HealthChoices' 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. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania Community HealthChoices will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

The iFuse implant system minimally invasive surgery for sacroiliac joint dysfunction is clinically proven and, therefore, may be medically necessary when all of the following conditions are met (Lorio, 2020):

- Chronic sacroiliac joint pain (pain lasting at least six months).
- Significant sacroiliac joint pain that impacts quality of life or significantly limits activities of daily living.
- Sacroiliac joint pain confirmed with at least three physical examination maneuvers that stress the sacroiliac joint (see list provided above) and reproduce the patient's typical pain.
- Confirmation of the sacroiliac joint as a pain generator with ≥50% acute decrease in pain upon fluoroscopically guided diagnostic intra-articular sacroiliac joint block using a small volume (≤2.5 mL) of local anesthetic.
- Failure to respond to nonsurgical treatment consisting of non-steroidal anti-inflammatory drugs and a reasonable course (four to six weeks) of physical therapy. Failure to respond means continued pain that interferes with activities of daily living and/or results in functional disability.
- Additional or alternative diagnoses that could be responsible for the member's ongoing pain or disability have been considered. Physicians should consider that members can have multiple pain generators and addressing just one pain generator may not relieve all disability or all back pain.

Limitations

The iFuse system minimally invasive surgery for sacroiliac joint dysfunction is not clinically proven and, therefore, not medically necessary for members with any of the following (Lorio, 2020):

- Less than six months of sacroiliac joint pain and/or functional impairment.
- Failure to pursue conservative treatment of the sacroiliac joint (unless contraindicated).
- Pain not confirmed with a diagnostic sacroiliac block.
- Presence of other pathology that would substantially prevent the member from deriving benefit from sacroiliac joint fusion.

Alternative covered services

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

Background

Sacroiliac joint dysfunction represents a type of lower back pain that causes significant disability and impairs quality of life. It affects 15% to 30% of people with chronic, non-radicular pain (Chang, 2022). Factors that increase the risk for developing sacroiliac joint dysfunction include leg length discrepancy, older age, inflammatory arthritis, decreased mobility, previous spine surgery, pregnancy, and trauma (Cohen, 2013).

Sacroiliac joint dysfunction can also happen with too much or too little movement of the joint. The symptoms may include a dull ache of varying severity in the lower back; a sciatic-like hot or stabbing pain plus tingling in the buttocks or in the back of the thigh; a stiffness with reduced range of motion; worsened pain after increased pressure (e.g., while 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 study estimates that 43% of these surgeries are unsuccessful. (DePalma, 2011).

The limitations of fusion surgery have prompted the development of devices that perform minimally invasive procedures for sacroiliac dysfunction. 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 a 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 2017, Medicaid programs in 44 states and the District of Columbia covered minimally invasive sacroiliac joint fusion (SI-BONE, 2017). By February 4, 2019, 32 Blue Cross Blue Shield plans covered minimally invasive joint fusion; of those, 27 covered only the iFuse implant (SI-BONE, 2019).

In 2009, the first iFuse implants were conducted. By early 2019, 37,000 procedures had been performed worldwide (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 sacroiliitis. In all other countries in which the device is available commercially, iFuse is indicated only 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

Guidelines

In June 2015, the North American Spine Society produced a guideline defining the conditions that constitute medical necessity of minimally invasive surgery for sacroiliac joint fusion. The guideline found no evidence that minimally invasive surgery resulted in superior improvements in symptoms and functional outcomes, compared to open fusion techniques (North American Spine Society, 2015).

The National Institute for Health and Care Excellence produced a guideline recommending iFuse as an option for treating persons with a confirmed diagnosis of chronic sacroiliac joint pain due to degenerative sacroiliitis or sacroiliac joint disruption whose pain is inadequately controlled by non-surgical management. The Institute's guideline was based on a review of outcomes found in the medical literature (National Institute for Health and Care Excellence, 2022).

A position statement from the International Society for the Advancement of Spine Surgery, most recently updated in 2020, endorsed use of lateral minimally invasive surgery (including iFuse) for sacroiliac joint fusion, provided

several criteria on patient condition are met, along with indications that the patient is not a candidate for minimally invasive surgery; these are listed in the coverage section (Lorio, 2020).

Systematic Reviews and Meta-analyses

Several systematic reviews and meta-analyses have demonstrated the effectiveness of minimally invasive sacroiliac joint fusion, particularly using the iFuse Implant System, in reducing pain and improving function in patients with sacroiliac joint dysfunction. A review of 12 studies (n = 432) found that average pain scores fell from 8.1 at baseline to 2.7 at 12 months, with most improvement occurring in the first six months (Heiney, 2015). Another review of 20 studies showed that iFuse patients had significantly superior outcomes for pain ($P = .03$), disability/physical function ($P = .01$), and global/quality of life ($P = .04$) compared to screw-type surgery (Tran, 2019). A pooled analysis of three multi-center trials (n = 423) also found that the surgical group had greater reductions in sacroiliac pain and disability compared to nonsurgical management, both significant at $P < .0001$ (Dengler, 2017). A more recent systematic review of 42 studies confirmed that minimally invasive sacroiliac joint fusion using the iFuse system demonstrated larger improvements in pain relief and increased physical function compared to conservative management at six months, and similar outcomes at one- and two-year follow-ups (Chang, 2022).

The long-term durability and safety of the iFuse Implant System have also been established in several studies. A study of 11,388 iFuse patients found a four-year survivorship without implant revision of 96.46%, with the revision rate being lower for elderly patients (Cher, 2015). Another study of 312 patients treated from 2003 to 2015 documented four-year revision rates much lower for iFuse patients (5.7%) compared to those with sacroiliac joint screw fixation (30.8%) (Spain, 2017). A literature review of 10 studies (n = 740) of iFuse implant procedures found that 79% to 90% of patients achieved minimal clinically important differences in pain reduction (Amer, 2022).

Minimally invasive sacroiliac joint fusion has also been shown to be superior to open surgery and conservative management in several aspects. A systematic review of 16 studies (n = 430) found that minimally invasive surgery had a lower reoperation rate (6% versus 15%) and a higher percentage of patients who stated the care was excellent (84% versus 54%) compared to open surgery (Zaidi, 2015). A systematic review/meta-analysis of three studies (n = 388) revealed that compared to conservative management, the iFuse implant resulted in superior outcomes, including pain reduction ($P < .0001$), disability reduction ($P < .001$), and cost-effectiveness ($P < .001$), with low adverse event rates (Hermans, 2022).

Other minimally invasive techniques and implant designs have also been studied, although to a lesser extent than the iFuse system. A meta-analysis of seven studies (n = 240) on cooled radiofrequency found significant reductions in pain intensity (average of 3.8 points, $P < .001$) and disability ($P < .001$), with 72% of patients presenting positive results and only mild complications (Sun, 2018). While other implant designs such as SImmetry, SI-LOK, and RI-ALTO are available, little research comparing outcomes using each design has been performed (Joukar, 2020).

A recent systematic review and meta-analysis confirms that the lateral transiliac procedure, particularly using the iFuse Implant System, has the largest evidence base among minimally invasive sacroiliac joint fusion techniques. The review of 32 cohorts (n = 1637) found improvements in pain scores (average reduction of 4.8 points on a 0-10 scale) and Oswestry Disability Index scores (average improvement of 25.9 points) compared to

other procedures, while maintaining low safety event rates and accurate implant placement and fusion (Whang, 2023).

Furthermore, minimally invasive sacroiliac joint fusion using the iFuse system may be an effective treatment for sacroiliac joint dysfunction following lumbar fusion. A systematic review of 17 studies found that the incidence of sacroiliac joint dysfunction after lumbar fusion was 7.0% out of 4,329 patients. In two studies with a combined 117 out of 178 participants (66%) having a history of prior lumbar surgery, the iFuse procedure resulted in a 68-73% improvement in pain scores and 63-71% improvement in functional scores (Karimi, 2024).

In 2024, we condensed and reorganized the findings section thematically and added two new systematic reviews (Whang 2023 and Karimi, 2024).

References

On June 13, 2024, 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

5/2018: initial review date and clinical policy effective date: 7/2018

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

7/2020: Policy references updated.

7/2021: Policy references updated.

7/2022: Policy references updated.

7/2023: Policy references updated. Source of coverage changed to a 2020 International Society for the Advancement of Spine Surgery guideline.

7/2024:Policy references updated.