Clinical Policy Title: Sacroiliac joint fusion

Clinical Policy Number: CCP.1401

Effective Date: October 1, 2018
Initial Review Date: August 1, 2018
Most Recent Review Date: August 30, 2018
Next Review Date: September, 2019

Related policies:
CCP.1385 iFuse® Implant System
CCP.1010 Radiofrequency ablation for spine pain

Policy contains:
- Degenerative sacroiliitis.
- Minimally invasive sacroiliac joint fusion.
- Sacroiliac joint disruption.
- Sacroiliac joint fusion.

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ 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 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’ 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’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers open sacroiliac joint fusion to be clinically proven and, therefore, medically necessary in any of the following clinical scenarios:

1. As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum.
2. As an adjunct to the medical treatment of sacroiliac joint infection/sepsis.
4. During multisegment spinal constructs (for example, correction of deformity in scoliosis or kyphosis surgery) extending to the ilium (North American Spine Society, 2015).

AmeriHealth Caritas considers the use of sacroiliac joint fusion or arthrodesis in the following diagnoses: chronic pain related to sacroiliac joint disease, degenerative sacroiliitis, or sacroiliac joint dysfunction; or chronic lumbosacral and pelvic pain, to be investigational/experimental and therefore not medically
necessary. The efficacy of this procedure in the treatment of the diseases mentioned has not been established in peer reviewed medical literature.

Limitations:

None.

Alternative covered services:

- Activity modification.
- Bracing.
- Medication.
- Physical therapy.
- Sacroiliac joint injections.
- Therapeutic exercise.

Background

Sacroiliac joint disruption/degenerative sacroiliitis, or joint dysfunction, represents one source of lower back pain, affecting between 10 and 27 percent of such persons (Rupert, 2009). 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). The rising rate of spinal fusions in the past several decades accompanied by the relatively high rate of “failed back surgery” and the estimated 32 to 37 percent of failed cases associated with sacroiliac joint involvement has produced a more prevalent condition (Longo, 2014).

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/stabbing pain plus tingling in the buttocks in the back of the thigh, 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 percent of subjects in one study reported this type of pain (Dengler, 2016).

Treatment of the dysfunction, also known as sacroiliac joint disruption/degenerative sacroiliitis (Ledonio, 2014b), has been 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).

Sacroiliac joint fusion is also known as arthrodesis. It traditionally has been an open surgical procedure requiring a seven- to eight-inch incision to open muscle and tissue to access the sacroiliac joint. A bone
A graft from the pelvis is inserted into the joint, along with several screws to hold the fusion together. Surgery takes three hours or longer, and hospital stays can be up to five days (Wheeler, 2017).

Beginning in 2009, percutaneous and other minimally invasive sacroiliac joint fusion procedures were introduced into medical practice following clinical trials. While reports on their effectiveness are growing, and despite decisions of several insurers to cover these procedures under certain conditions, AmeriHealth Caritas considers these procedures to be investigational and experimental (see below):

- iFuse® Implant System (SI Bone).
- Rialto™ Joint Fusion System (Medtronic).
- SIJ-Fuse (Spine Frontier).
- Slimmetry® Sacroiliac Joint Fusion System (Zyga Technologies).
- Silex™ Sacroiliac Joint Fusion System (XTANT Medical).
- SambaScrew® (Orthofix).
- SI-LOK® Sacroiliac Joint Fixation System (Globus Medical).

It appears that the number of open sacroiliac joint fusion procedures is declining. A study of 121 surgeons who performed at least one open sacroiliac joint fusion from 2009 – 2012 found that during this time, the number of annual open procedures varied (152 – 191 – 202 – 123), while the number of minimally invasive procedures steadily increased (99 – 187 – 417 – 889). The percentage of open procedures performed in an ambulatory surgery center or hospital outpatient setting was just 1.78 percent, well below the 21.08 percent figure for minimally invasive procedures (Lorio, 2014).

As the shift to more minimally invasive sacroiliac procedures occurred, several conditions supporting open procedures still are considered necessary:

1. Adjunct to sacrectomy or partial sacrectomy related to tumors.
2. Sacroiliac joint fusion adjunct to medical treatment of sacroiliac joint infection/sepsis.
3. Sacroiliac joint fusion for severe traumatic injuries associated with pelvic ring fracture.
4. Sacroiliac joint fusion in multisegment spinal constructs extending to the ilium (Huang, 2018).

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

We conducted searches on June 18, 2018. Search terms were: “sacroiliac joint fusion,” “sacroiliac joint surgery,” “sacroiliac joint disruption,” “degenerative sacroiliitis,” and “sacroiliac joint dysfunction.”
We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Recommendations for diagnostic testing prior to undergoing open sacroiliac joint fusion include: 1) conservative treatments that must be performed, 2) identification of certain symptoms, 3) post-surgical results to be expected, and 4) diagnostic tests cited that must be performed with certain results. These are explained below.

1. Patients have undergone and failed 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.
2. Patients typically report unilateral pain that is caudal to the lumbar spine (L5 vertebra), localized over the posterior sacroiliac joint, and consistent with sacroiliac joint pain.
3. A thorough medical history and physical examination demonstrating localized tenderness with palpation over the sacral sulcus (Fortin’s point, that is, 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 that other obvious sources for their pain do not exist.
4. A positive response to a cluster of three provocative tests (e.g., thigh thrust test, compression test, Gaenslen’s test, distraction test, Patrick’s sign, posterior provocation test). Note that the thrust test is not recommended in pregnant patients or those with connective tissue disorders.
5. Absence of generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia).
6. Diagnostic imaging studies that include all of the following:
   a. Imaging (plain radiographs and computed tomography or magnetic resonance imaging of the sacroiliac joint that excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy that would not be properly addressed by percutaneous sacroiliac joint fusion.
   b. Imaging of the pelvis anteroposterior plain radiograph to rule out concomitant hip pathology.
c. Imaging of the lumbar spine (computed tomography or magnetic resonance imaging) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain.

d. Imaging of the sacroiliac joint that indicates evidence of injury and/or degeneration.

7. At least 75 percent reduction of pain for the expected duration of the anesthetic used following an image-guided, contract-enhanced intra-articular sacroiliac joint injection on two separate occasions.


In addition to the 2015 North American Spine Society guideline including indications for sacroiliac joint fusion using the traditional open procedure, the International Society for the Advancement of Spinal Surgery produced a similar guideline the same year. The only indication for open fusion is for pelvic ring fractures in the setting of trauma, due to the historically high incidence of complications, long recovery times, and prolonged courses of rehabilitation (International Society for the Advancement of Spinal Surgery, 2015).

A systematic review and meta-analysis of six studies of patients undergoing sacroiliac joint fusion for low back pain followed subjects for a mean of 17.6 months. All outcomes showed statistical and clinical improvement in average pain difference. Averages for the Visual Analog Scale, Oswestry Disability Index Pain Catastrophizing Scale, Short Form-36, and Majeed score were all significant at \( P < .001 \) (n = 380, 102, 140, 198, and 140) (Lingutla, 2016).

A prospective cohort study compared health status (using the EuroQOL-5D and Short Form-36 at baseline and six to 12 months after fusion surgery (n = 172). Before surgery, the group had a utility level significantly lower than that of a national representative sample of 3,844 (0.509 versus 0.789 for EuroQOL and 31.7 versus 49.2 for Short-Form 36). By 12 months after surgery, the study group had substantially increased scores to 0.625 for EuroQOL and 47.7 for Short Form-36 (Cher, 2016).

A systematic review comparing seven articles on sacroiliac fusion and five articles on sacroiliac injections found that most studies reported over 40 percent improvement in pain, but could not make a good comparison of effectiveness between the two treatments (Spiker, 2012).

Another systematic review compared six articles (n = 95) on sacroiliac fusion and five articles (n = 68) on denervation. Fusion patients had higher rates of complications (13.7 versus 7.3 percent) and infections (5.3 versus 0.0 percent) (Ashman, 2010).

A review of 16 journal articles (five consecutive case series, eight retrospective studies, and three prospective cohort studies) included 131 patients undergoing open surgery (followed an average of 60 months) and 299 undergoing minimally invasive surgery (followed an average of 21 months) for sacroiliac joint fusion. Sacroiliac degeneration/arthrosis was easily the most common pathology among patients undergoing surgical intervention, at 59.8 percent. Open surgical patients had much worse
outcomes, found in lower patient satisfaction (54 versus 84 percent), and higher reoperation rates (15 versus six percent). Ranges for radiographically confirmed fusion rates were similar, at 20 to 90 percent for open surgery and 13 to 100 percent for minimally invasive surgery (Zaidi, 2015).

A comparison of 149 patients who underwent open joint fusion and 114 treated with minimally invasive surgery for sacroiliac joint dysfunction showed minimally invasive patients had superior outcomes for estimated blood loss, operating time, and length of stay ($P < .001$). Pain relief was superior for the minimally invasive group, -6.2 versus -2.7 points ($P < .001$). However, nine authors were affiliated with the SI-BONE company (two as employees, five as consultants, and two as stockholders), which manufactures the iFuse® implant system, a commonly used in minimally invasive surgery (Smith, 2013).

A study following 63 patients for one year comparing 36 patients with sacroiliac joint fusion with 27 patients with minimally invasive surgery found the latter group to have significantly lower estimated blood loss, average surgical time, and average length of stay, all significant at $P < .001$. Postoperative disability scores were superior for the surgical group, although it fell short of statistical significant (47 versus 54 percent, or $P < .272$). None of the authors had any conflicts of interest (Ledonio, 2014a).

Ledonio presented a review of 39 patients with degenerative sacroilitis refractory to non-operative management, using the Owestry Disability Index to measure outcomes. A reduction in the index of 64 to 46 ($P < .0005$) in those who underwent fusion was significant, but those who underwent minimally invasive surgery had a more significant reduction ($P < .0002$). One of the authors was a paid consultant to SI-BONE, the company that manufactures the iFuse® implant minimally invasive system (Ledonio, 2014b).

Policy updates:

None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Lingutla (2016)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Improvements in low back pain after sacroiliac joint fusion</td>
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<tr>
<td>Cher (2016)</td>
<td><strong>Key points:</strong></td>
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</table>
Comparison of patients with sacroiliac joint fusion with national sample.

- Prospective cohort study compared health status before and six to 12 months after sacroiliac joint fusion for 172 persons with low back pain.
- Health status measured with the EuroQOL-5D and Short Form-36.
- Comparison made with national representative cross-sectional sample (n=3,844).
- Before surgery, patients had lower health status (0.509 versus 0.789 for EuroQOL and 31.7 versus 49.2 for Short-Form 36).
- At 12 months after surgery, the surgical group had substantially increased scores, from 0.509 to 0.625 for EuroQOL and 31.7 to 47.7 for Short Form-36.

Zaidi (2015)

Outcomes for open fusion surgery and minimally invasive surgery

Key points:
- Review of 16 journal articles (five consecutive case series, eight retrospective studies, and three prospective cohort studies) of patients with low back pain.
- Included 131 patients with sacroiliac joint fusion (followed an average of 60 months) and 299 with minimally invasive surgery (followed an average of 21 months).
- Sacroiliac degeneration/arthritis was easily the most common pathology among patients undergoing surgical intervention, at 59.8 percent (%).
- Open surgical patients had lower patient satisfaction (54 versus 84%).
- Open surgical patients had higher reoperation rates (15 versus 6%).
- Open surgical patients had lower rate of excellent satisfaction (54 versus 84%).
- Both groups had similar radiographically confirmed fusion rates 20 to 90% for open surgery and 13 to 100% for minimally invasive surgery.

Ashman (2010)

Complication and infection rates, open fusion surgery and denervation patients

Key points:
- A systematic review compared six articles (n = 95) on sacroiliac fusion and five articles (n = 68) on denervation for patients with low back pain.
- Open surgical patients had higher rate of complications (13.7 versus 7.3%).
- Open surgical patients had higher rate of infections (5.3 versus 0.0%).

References

Professional society guidelines/other:


Peer-reviewed references:


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

No National Coverage Determinations identified as of the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<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>
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<tr>
<td>27280</td>
<td>Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed</td>
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<td>M46.1</td>
<td>Sacroiliitis, not elsewhere classified</td>
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<td>Spinal instabilities, lumbar – sacral and sacrococcygeal region</td>
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<td>M53.3</td>
<td>Sacrococcygeal disorders, not elsewhere classified</td>
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