Clinical Review Criteria
Minimally Invasive Sacroiliac Fusion (SI Fusion)

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Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
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<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>None</td>
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<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
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<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
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<tr>
<td>GHC Medical Policy</td>
<td>In the absence of a NCD or a LCD use GHC Medical Policy</td>
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For Non-Medicare Members

A. Sacroiliac joint fusion is medically necessary when ALL of the following are met:
   1. Appropriate imaging studies demonstrate localized sacroiliac joint pathology
   2. The individual is a nonsmoker, or in the absence of progressive neurological compromise will refrain from use of tobacco products for at least 6 weeks prior to the planned surgery
   3. And ONE of the following:
      a. Post-traumatic injury of the SI joint (e.g., following pelvic ring fracture)
      b. As an adjunctive treatment for sacroiliac joint infection or sepsis
      c. Management of sacral tumor (e.g., partial sacrectomy)
      d. When performed as part of multisegmental long fusions for the correction of spinal deformity (e.g., idiopathic scoliosis, neuromuscular scoliosis)

B. Sacroiliac joint fusion is not covered for ANY other indication, including the following, because it is considered experimental, investigational or unproven:
   1. Mechanical low back pain
   2. Sacroiliac joint syndrome
   3. Degenerative sacroiliac joint
   4. Radicular pain syndromes

C. Percutaneous or minimally invasive sacroiliac joint stabilization (e.g., iFuse Implant System™, S1mmetry® SI Joint Fusion System) for sacroiliac joint fusion (CPT codes 0334T, 27279) are not covered for ANY indication because there is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
Lower back pain is extremely common and the sacroiliac (SI) joint has been implicated as one of the potential sources dating all the way back to the early 1900s. Formed by the connection of the sacrum and the right and left iliac bones, the SI joint lies at the junction of the spine and the pelvis. Held together by a collection of strong ligaments the SI joint only allows for limited rotation and translation. The SI joint plays a primary role in supporting the weight of the upper body. Pregnancy, gout, rheumatoid arthritis, psoriasis, ankylosing spondylitis, and other
conditions that cause abnormal wear may aggravate the joints by placing an increased amount of stress on the SI joints.

There are many different terms for SI joint problems, including SI joint dysfunction, SI joint syndrome, SI joint strain, and SI joint inflammation. With the most common symptoms being pain, stiffness and burning the diagnosis of SI joint conditions can prove difficult for a multitude of reasons. For starters, there are no widely accepted guidelines for diagnosis and treatment nor has any imaging modality established definitive symptoms that correlate with a visible pathology. These issues are further complicated by the large spectrum of different etiologic factors and variability that contribute to the pain. As a result, diagnosis of SI joint dysfunction relies on thorough history and physical examination.

Conventional treatments for SI joint dysfunction typically consist of non-operative interventions such as injections and anti-inflammatory oral medications. However, oral steroids and physical therapy can also be helpful. In the event that conservative interventions fail, SI joint fusion has been proposed as an additional treatment option. A variety of techniques have been described over the years without the wide acceptance of a single technique. Generally speaking, the surgery entails removal of the cartilage in the SI joints followed by an implant of plates or screws to hold the bones together. The technique may even employ the use of bone grafts to promote fusion. Ultimately, the surgery is designed to eliminate SI joint motion with the overall goal to relieve pain.

Medical Technology Assessment Committee (MTAC)
Sacroiliac Fusion (SI Fusion) for Sacroiliac Joint Dysfunction
12/08/2014: MTAC REVIEW

Evidence Conclusion: Lower back pain is extremely common and the sacroiliac (SI) joint has been implicated as one of the potential sources dating all the way back to the early 1900s (Goldthwait and Osgood 1905). Formed by the connection of the sacrum and the right and left iliac bones, the SI joint lies at the junction of the spine and the pelvis. Held together by a collection of strong ligaments the SI joint only allows for limited rotation and translation. The SI joint plays a primary role in supporting the weight of the upper body. Pregnancy, gout, rheumatoid arthritis, psoriasis, ankylosing spondylitis, and other conditions that cause abnormal wear may aggravate the joints by placing an increased amount of stress on the SI joints. There are many different terms for SI joint problems, including SI joint dysfunction, SI joint syndrome, SI joint strain, and SI joint inflammation. With the most common symptoms being pain, stiffness and burning the diagnosis of SI joint conditions can prove difficult for a multitude of reasons. For starters, there are no widely accepted guidelines for diagnosis and treatment nor has any imaging modality established definitive symptoms that correlate with a visible pathology. These issues are further complicated by the large spectrum of different etiologic factors and variability that contribute to the pain. As a result, diagnosis of SI joint dysfunction relies on thorough history and physical examination. Conventional treatments for SI joint dysfunction typically consist of non-operative interventions such as injections and anti-inflammatory oral medications. However, oral steroids and physical therapy can also be helpful (Ashman, Norvell et al. 2010). In the event that conservative interventions fail, SI joint fusion has been proposed as an additional treatment option. A variety of techniques have been described over the years without the wide acceptance of a single technique. Generally speaking, the surgery entails removal of the cartilage in the SI joints followed by an implant of plates or screws to hold the bones together. The technique may even employ the use of bone grafts to promote fusion. Ultimately, the surgery is designed to eliminate SI joint motion with the overall goal to relieve pain.

Articles: The literature search revealed just under 200 articles. No randomized control trials (RCTs) comparing MIS SI joint fusion with non-surgical treatment for the treatment of chronic low back pain due to sacroiliac joint dysfunction were identified. The only comparison studies were cohorts investigating MIS SI joint fusion versus open surgical techniques or SI joint denervation and were not selected because they did not include a nonsurgical group. Currently, there are numerous trials registered with the NIHCT set to compare MIS SI joint fusion with conservative management. The majority of the literature base was small and retrospective. The best available publications were two prospective cohorts with no comparison groups and a retrospective medical chart review of 18 patients who underwent MIS SI joint fusion surgery. The following publications were selected for critical appraisal: Wise, CL and Dall, B. Minimally invasive sacroiliac arthrodesis outcomes of a new technique. J Spinal Disord Tech 2008;21(8):579-584. [Evidence Table 1]. Cumming, J and Capobianco, RA. Minimally invasive sacroiliac joint fusion: one-year outcomes in 18 patients. Annals of Surgical Innovation and Research 2013;7(1):12-18. [Evidence Table 2]. Duhon BS, Cher DJ, Wine KD, et al. Safety and 6-month effectiveness of minimally invasive sacroiliac joint fusion: a prospective study. Medical Devices: Evidence and Research 2013;6:219-229. [Evidence Table 3]
Minimally invasive sacroiliac joint fusion, with or without bone grafts and other metal implant devices and does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

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<tr>
<th>Date Created</th>
<th>Date Reviewed</th>
<th>Date Last Revised</th>
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<tr>
<td>08/27/2014</td>
<td>09/02/2014 MPC, 11/03/2015 MPC, 09/06/2016 MPC, 07/11/2017 MPC</td>
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Revision History

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<tr>
<th>Date</th>
<th>Description</th>
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<tr>
<td>06/23/2016</td>
<td>Added NCD/LCD Medical Director review language</td>
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<tr>
<td>09/08/2015</td>
<td>Revised LCD L35008</td>
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<tr>
<td>09/06/2016</td>
<td>Added GH policy for Medicare members and new criteria for non-Medicare members</td>
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**Codes**

CPT: 27279