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Status: Revised
Doc ID: MSK05-1125.1
Effective Date: 11/15/2025
Last Review Date: 01/30/2025

Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Musculoskeletal

Appropriate Use Criteria: Sacroiliac Joint Fusion

Proprietary

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon. Use of the Guidelines by any external AI entity without the express written permission of Carelon is prohibited.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA-approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for ongoing services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Sacroiliac Joint Fusion

Description and Scope

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 sacroiliac (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 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 lifestyle changes including smoking cessation and weight loss.

Sacroiliac 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.

There are two general surgical approaches for SI joint fusion, open and minimally invasive. The open approach is used primarily for cases of infection, tumor, and fracture, or as part of a long spinal fusion. The minimally invasive surgical (MIS) approach is generally used for cases of chronic low back pain attributed to a degenerative SI joint.

The more commonly used MIS technique utilizes a transiliac or lateral approach, and an FDA approved or cleared compression screw or device to transfix the joint. A newer alternative method proposes to achieve fusion by insertion and distraction of the joint using a proprietary bone graft or device via a different posterior approach. Bone grafts (i.e., human cell and tissue products [HCT/Ps]) used in the posterior approach are regulated by the FDA's Center for Biologics Evaluation and Research. A hybrid model adds transfixation to the posterior approach products.

The majority of published studies support the transiliac or lateral approach, whereas the posterior and hybrid approaches have been much less studied.

These guidelines address SI joint fusion when performed as an **elective, non-emergent** procedure.

Clinical Indications

The following general requirements apply to all indications except where they differ from the specific requirements. The specific requirements take precedence over any stated general requirement.

General Information

The terms in this section provide operational definitions when they are referenced as requirements in the guideline.

Documentation supporting medical necessity and a clearly stated plan of care 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[1] must include a combination of strategies to reduce inflammation, alleviate pain, and correct underlying dysfunction, including physical therapy **AND** at least one complementary conservative treatment strategy.

- **Physical therapy requirement** includes **ANY** of the following:
  - Physical therapy rendered by a qualified provider of physical therapy services
  - Supervised home treatment program that includes **ALL** the following:
    - Participation in a patient-specific or tailored program
    - Initial active instruction by MD/DO/PT with redemonstration of patient ability to perform exercises
    - Compliance (documented or by clinician attestation on follow-up evaluation)
  - **Exception to the physical therapy requirement** in unusual circumstances (for instance, intractable pain so severe that physical therapy is not possible) when clearly documented in the medical record
- **Complementary conservative treatment requirement** includes **ANY** of the following:
  - Anti-inflammatory medications and analgesics[2]
  - Adjunctive medications such as nerve membrane stabilizers or muscle relaxants[2]
  - Intra-articular corticosteroid injection[2]
  - Sacroiliac support belt or other appropriate bracing
  - Alternative therapies such as acupuncture, chiropractic manipulation, massage therapy, activity modification, and/or a trial period of rest (e.g., from the aggravating/contributing factors), where applicable

[1] Additional condition or procedure-specific requirements may apply and can be found in the respective section of the guideline.

[2] In the absence of contraindications

Clinical reevaluation – In most cases, reevaluation should include a physical examination. Direct contact by other methods, such as telephone communication or electronic messaging, may substitute for in-person evaluation when circumstances preclude an office visit. Clinical reevaluation must be done in reasonable proximity to the anticipated date of service such that the patient's condition would be unlikely to change by the date of service.

Failure of conservative management requires **ALL** the following:

- Patient has completed a full course of conservative management (as defined above) for the current episode of care
- Worsening of or no significant improvement in signs and/or symptoms upon clinical reevaluation
- More invasive forms of therapy are being considered

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 associated impact on activities of daily living (ADLs) and instrumental ADLs (IADLs) are key factors in determining the need for intervention. For purposes of this guideline, significant pain and functional impairment refer to pain that is at least 3 out of 10 in intensity and is associated with inability to perform at least two (2) ADLs and/or IADLs.

General Recommendations

Tobacco Cessation – Adherence to a tobacco-cessation program resulting in abstinence from tobacco for at least 6 weeks prior to surgery is strongly recommended.

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

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

When there are patient-specific modifiable comorbidities that may adversely impact patient-reported outcomes or health status, a shared decision-making discussion that covers these modifiable comorbidities is strongly recommended and should be documented.

Open Sacroiliac Joint Fusion

Open SI joint fusion may be considered medically necessary in **ANY** of the following scenarios:

- As an adjunct to sacrectomy or partial sacrectomy related to tumors involving the sacrum
- As an adjunct to the medical treatment of sacroiliac joint infection/sepsis (e.g., osteomyelitis, pyogenic sacroiliitis)
- For severe traumatic injuries associated with pelvic ring disruption (e.g., pelvic ring fractures, acetabular fracture, spinopelvic dissociation)
- During multi-segment spinal constructs (e.g., correction of deformity in scoliosis or kyphosis surgery) extending to the ilium as part of medically necessary lumbar spine fusion procedures

Open sacroiliac joint fusion procedures for indications not listed above, including but not limited to poorly defined low back pain and sacral insufficiency fractures, are considered **not medically necessary**.

Percutaneous/Minimally Invasive Sacroiliac Joint Fusion

Percutaneous/minimally invasive SI joint fusion with FDA approved structural fixation device*

***Limited to the insertion of usually more than one structural device traversing the SI joint intended to fuse to the bone or lead to the fusion of the joint itself**

Percutaneous/minimally invasive SI joint fusion* using a transiliac or lateral approach and an FDA approved structural fixation device may be considered medically necessary when **ALL** the following criteria are met:

- Pain persisting a minimum of 6 months that interferes with functional activities as documented by **BOTH** of the following:
    - Pain score (VAS) of 5 or greater
    - ODI 30 or greater
- Failure of at least 6 months of conservative management that includes a trial of at least one therapeutic intra-articular SI joint injection (i.e., corticosteroid injection)
- Confirmation of the SI joint as a pain generator as demonstrated by **ALL** the following:
    - Pain pattern consistent with SI joint pain (typically unilateral pain caudal to L5 vertebrae, localized over posterior SI joint)
    - Positive finger Fortin test (localized tenderness with palpation over the sacral sulcus)
    - Absence of tenderness of similar severity elsewhere in the pelvic region (e.g., greater trochanter, lumbar spine, coccyx)
    - Positive response from at least **THREE (3)** of the following provocative tests:
        - Long ligament test

        - Faber 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 test
    - Other sources of pain have been excluded as an etiology
- Diagnostic imaging studies that include **ALL** the following:
    - Imaging (plain radiographs and a CT) or MRI of the SI joint that excludes the presence of destructive lesions (e.g., tumor, infection) or inflammatory arthropathy that would not properly be addressed by percutaneous SI joint fusion
    - Imaging of pelvis (AP plain radiograph) to rule out concomitant hip pathology
    - 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
    - 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 on two (2) separate occasions

Revision minimally invasive SI joint fusion

Revision or replacement SI joint fusion may be considered medically necessary when **ANY** of the following conditions are present:

- Symptomatic pseudarthrosis (nonunion)
- Symptomatic implant/device malposition (with impingement of foramen by implant/device)
- Infection secondary to or involving implant/device
- Implant fracture/breakage/loosening

Exclusions (Percutaneous/Minimally Invasive SI Joint Fusion)

Indications other than those addressed in this guideline are considered **not medically necessary** including, but not limited to, the following:

- Infection or fracture (unrelated to implant)
- Tumor
- Acute traumatic instability of the SI joint
- Neural compression as seen on imaging that correlates with symptoms or other more likely source of pain
- Generalized pain behavior (e.g., somatoform disorder) or generalized pain disorders (e.g., fibromyalgia)
- Ankylosing spondylitis or rheumatoid arthritis
- Percutaneous or minimally invasive SI joint fusion procedures using a posterior approach for insertion of intraarticular allograft or devices combined with or without a transfixation device

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Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Medical necessity reviews are initiated by submitting the correct AMA CPT codes. Specific CPT codes for services should be used when available. The submitted codes must accurately identify the service or procedure to be performed. If no such code exists, contact the health plan directly and report the service or procedure using the appropriate unlisted procedure or Not Otherwise Classified (NOC) code (which often ends in 99). Do not submit a code that is “close to” the procedure performed in lieu of an unlisted code. Correct coding demands that the code reported is appropriate for the service provided (i.e., a code that most accurately represents the service provided), and not a code that is similar but represents another service. (*CPT® Assistant,* December 2010) Nonspecific or NOC codes may be subject to additional documentation requirements and review.

CPT/HCPCS

27278	Arthrodesis, sacroiliac joint, percutaneous, with image guidance, including placement of intra-articular implant(s) (eg, bone allograft[s], synthetic device[s]), without placement of transfixation device
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed
C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)

History

Status	Review Date	Effective Date	Action
Revised	01/30/2025	11/15/2025 except for Healthy Blue LA Medicaid, BCBS OH Medicaid	Independent Multispecialty Physician Panel (IMPP) review. Added discussion of newer surgical approaches to the guideline description. For minimally invasive technique, clarified use of transiliac or lateral approach and an FDA approved structural fixation device.

Status	Review Date	Effective Date	Action
Updated codes 01/01/2025	n/a	Unchanged	Added HCPCS code C1737.
Revised	01/23/2024	10/20/2024 except for Healthy Blue LA Medicaid	IMPP review. Added new criteria for open SI joint fusion and CPT 27280. Updated references.
Revised	07/18/2023	04/14/2024 except for Healthy Blue LA Medicaid	IMPP review. Revised exclusion for procedures that use a transfixing device with a posterior approach. Added required language per new Medicare regulations.
Updated	n/a	01/01/2024	Annual CPT code update. Removed 0775T and added 27278. Added guidance for correct coding to code section.
Revised	04/12/2023	09/10/2023; 11/05/2023 for Indiana Medicaid	IMPP review. Added clarifications and elements to required documentation and management.
Revised	01/24/2023	09/10/2023; 11/05/2023 for Indiana Medicaid	IMPP review. For Revision minimally invasive SI joint fusion, clarified symptomatic malposition and infection related to implant/device to distinguish from exclusions. Revised procedure description in exclusions to match that of new CPT 0775T.
Revised	11/11/2021	09/11/2022* *Not for Indiana Medicaid	IMPP review. Added requirement for a trial of at least one therapeutic intra-articular SI joint injection. New criteria for revision minimally invasive SI joint fusion. Added exclusion for posterior (dorsal) minimally invasive SI joint fusion procedures using only bone grafts and no internal fixation device.
Revised	11/11/2021	06/12/2022; 09/11/2022 for Anthem Medicaid except Indiana	IMPP review. Expanded indication for percutaneous/minimally invasive SI joint fusion to include any FDA approved structural device with fixation. Updated references.
Revised	12/03/2020	09/12/2021	IMPP review. Aligned conservative care definitions across musculoskeletal surgery and extremity/spine imaging guidelines. Added a more rigorous definition of the supervised home PT requirement.
Reaffirmed	02/03/2020	Unchanged	IMPP review. Guideline reaffirmed.
Revised	07/11/2018	03/09/2019	IMPP review. Added the General Clinical Guideline.
Created	12/12/2017	11/19/2018	IMPP review. Original effective date.