

Percutaneous Sacroiliac Joint Fusion



**DEFINING APPROPRIATE
COVERAGE POSITIONS**

Introduction

North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy.

Methodology

The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

[NASS Coverage Policy Methodology](#)

Scope and Clinical Indications

While the reported incidence of pain arising from the sacroiliac joint (SIJ) varies depending on the diagnostic criteria utilized, the sacroiliac joint is an established source of chronic low back and buttock pain. Anatomic data has demonstrated nociceptive innervation of the sacroiliac joint by the dorsal rami of the distal lumbar nerve roots and the lateral branches of the sacral nerve roots. Additionally, clinical improvement in patients undergoing sacroiliac fusion for infection demonstrates that pain can originate from the sacroiliac joint. Pathologic conditions that may result in pain arising from the sacroiliac joint include degenerative and inflammatory arthritis, post-traumatic arthritis, post-partum instability, post-infectious arthritis, joint degeneration related to previous lumbar spinal fusion, joint damage from previous posterior iliac crest bone graft harvesting, and neoplastic processes affecting the sacroiliac joint.¹³

Studies have reported the source of chronic lower back and buttock pain is from disorders of the sacroiliac joint in 10% to 26% of cases.^{3,7} Unfortunately, there is no single clinical, imaging, or provocative test that definitively confirms the sacroiliac joint as a primary source of pain.¹¹ Physical examination should include a combination of several provocative maneuvers to help identify pain arising from the sacroiliac joint. Diagnostic imaging studies have not been shown to reliably predict pain arising

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from the SI joint, but are necessary to identify other pathologic conditions that may be the source of a patient's back pain. A critical step in confirming the sacroiliac joint as the source of pain involves diagnostic block of the sacroiliac joint with local anesthetic.⁴ This must be performed under contrast-enhanced image guidance (fluoroscopy or CT) and with a relatively low volume of injectate to minimize leakage onto surrounding structures. Intraarticular confirmation of contrast spread should be confirmed and hard copies or digital images saved in the medical records. A positive response is one in which a patient experiences a substantial reduction in their pain, defined as at least 80 percent pain reduction, while the anesthetic is in effect. An hourly pain log should be kept by the patient and reviewed by the provider upon follow-up evaluation. The duration of pain relief should be consistent with the expected duration (i.e. long-acting or short-acting) of the anesthetic used. The pain log should also be stored in the medical records. A negative response excludes an intraarticular source of sacroiliac pain. Due to a potential placebo effect, a second diagnostic block is required to further confirm the diagnosis in patients who report substantial (albeit temporary) pain reduction from an initial injection.⁶

Previous work has evaluated the diagnostic validity of three specific criteria (developed by the International Association for the Study of Pain) for the diagnosis of SIJ pain (Szadek, 2009). From analysis of these data, one could reasonably support a diagnosis of SIJ-mediated pain in the presence of pain and tenderness over the SIJ, positive findings to a thrust test, compression test or 3 or more provocative tests (additionally including the Gaenslen test, Patrick test, and compression test), and at least 50 percent pain reduction from diagnostic infiltration of the SIJ using contrast-enhanced anesthetic that lasts at least 1 to 4 hours on two separate occasions. The patient's history should be consistent with pain localized to the sacroiliac joint.

Traditional care for the treatment of pain arising from the sacroiliac joint not due to an infectious or neoplastic process begins with physical therapy and activity modification. Analgesic medication including NSAIDs, acetaminophen, or opioids could be considered depending on each patient's medical history and symptom severity. Alternative treatments such as sacroiliac support belts and chiropractic care may be considered as well. It is important to note that while these treatments are utilized routinely, no comparative effectiveness study has been published to establish their efficacy. Fusion of the sacroiliac joint was initially described as a treatment option in 1925 (Smith-Peterson 1926). Given the depth and anatomic location of the SI joint, significant morbidity was associated with open fusion approaches and limited usage of these procedures. Over the past few decades, techniques utilizing trans-iliac approaches to fuse the sacroiliac joint have been developed. Minimally invasive technology has been applied to these approaches and has resulted in the development of percutaneous SIJ fusion procedures in recent years.

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Percutaneous SIJ fusion (e.g. insertion of a metallic device across the SIJ that is intended to fuse to the bone or lead to fusion of the joint itself, in distinction from insertion of screws without bone graft across the SIJ which are intended to stabilize but not fuse the joint) is indicated for the treatment of SIJ pain for patients with low back/buttock pain who meet ALL of the following criteria:

- a) Have undergone and failed a minimum six months of intensive nonoperative treatment that must include medication optimization, activity modification, and active physical therapy
- b) Patient's report of non-radiating, unilateral pain that is caudal to the lumbar spine (L5 vertebrae), localized over the posterior SIJ, and consistent with SIJ pain
- c) Localized tenderness with palpation of the posterior SIJ 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
- d) Positive response to the thigh thrust test OR compression test AND 2 of the following additional provocative tests: Gaenslen's test, distraction test, Patrick's sign)
- e) Absence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorders (e.g. fibromyalgia)
- f) Diagnostic imaging studies that include ALL of the following:
 1. 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 be properly addressed by percutaneous SIJ fusion
 2. Imaging of the ipsilateral hip (plain radiographs) to rule out osteoarthritis
 3. Imaging of the lumbar spine (CT or MRI) to rule out neural compression or other degenerative condition that can be causing low back or buttock pain
- g) At least 80 percent reduction of pain for the expected duration of the anesthetic used following an image-guided, contrast-enhanced SIJ injection on two separate occasions

Percutaneous SIJ fusion for SIJ pain is **NOT** indicated in ANY of the following scenarios:

- Any case that does not fulfill ALL of the above criteria
- Presence of systemic arthropathy such as ankylosing spondylitis or rheumatoid arthritis
- Presence of generalized pain behavior (e.g. somatoform disorder) or generalized pain disorder (e.g. fibromyalgia)
- Presence of infection, tumor, or fracture
- Presence of acute, traumatic instability of the SIJ
- Presence of neural compression as seen on an MRI or CT that correlates with the patient's symptoms or other more likely source for their pain.

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Coverage Recommendations

Within the limits of a weak body of evidence, the Coverage Committee **recommends coverage** for percutaneous SIJ fusion when the criteria outlined above are met. Due to the relatively weak evidence, it is particularly critical that inclusion criteria are scrutinized and patient selection is executed with vigilance. The procedure itself has proven to be relatively safe. There is a valid concern for bias in that the overwhelming majority of the data produced so far has been industry-sponsored and generally composed of case series. However there are some data on five-year outcomes that demonstrate sustained benefit that does not appear to degrade from 1 year to 5 year time-points. The committee will revisit the quality of forthcoming evidence as it is produced in re-evaluations of the indications and coverage of this procedure.

Rationale

As percutaneous fusion techniques addressing the SIJ have become available, multiple clinical studies have evaluated the results of these procedures. A prospective study by Al-Khayer in 2008 reported results of nine patients undergoing percutaneous sacroiliac fusion using a hollow modular anchorage screw filled with demineralized bone matrix and local bone that was obtained during drilling.¹ The mean follow up was 40 months (range, 24 – 70 months). The mean ODI value dropped from 59 (range: 34 to 70) preoperatively to 45 (range: 28 to 60) postoperatively ($P < 0.005$), which we would interpret as a modest clinical improvement. The mean VAS value also modestly dropped from 8.1 (range: 7 to 9) preoperatively to 4.6 (range: 3 to 7) postoperatively ($P < 0.002$). All of the patients reported that they would have the procedure again given the same circumstances. The average estimated blood loss was less than 50 ml. There was one complication consisting of a deep wound infection that healed with debridement and intravenous antibiotics. At one-year follow up, no non-unions were identified on radiographs.

In 2009 Khurana prospectively also reported on fifteen consecutive patients treated with percutaneous fusion using a hollow modular anchorage screws in combination with demineralized bone matrix.⁵ The mean follow-up in this study was 17 months (range, 9 to 39 months). The mean SF-36 scores improved from 37 (23 to 51) to 80 (67 to 92) for physical function and from 53 (34 to 73) to 86 (70 to 98) for general health ($p = 0.037$). Thirteen of 15 patients reported “good to excellent” results. The authors reported that residual pain in these two patients was potentially due to concurrent lumbar pathology. The average estimated blood loss was less than 50ml and there were no complications. Fusion was obtained in all patients.

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Wise and Dall published a prospective study in 2008 on 13 consecutive patients who underwent percutaneous SI fusion using threaded fusion cages filled with rhBMP-2.¹² The mean follow-up period for all 13 patients was 29.5 months (range, 24 to 35 months). Significant improvements were seen in final low back pain score on a visual analog scale with an average improvement of 4.9, ($P < 0.001$). Leg pain improved an average of 2.4 points ($P = 0.013$) and dyspareunia pain improved an average of 2.6 point ($P = 0.0028$). The mean estimated blood loss was less than 100 ml; there were no infections or neurovascular complications. The overall fusion rate was 89% (17/19 joints) as assessed by postoperative CT scan obtained six months following the procedure. One patient was revised to an open arthrodesis secondary to nonunion and persistent pain.

In 2012 Rudolph reported a retrospective study of 50 consecutive patients who underwent percutaneous SI fusion using triangular, porous, plasma-coated, titanium implants.⁹ The mean follow up was 40 months (range, 24 to 56 months). Outcomes were assessed using the SF-36 Health Survey and the Oswestry Disability Index. At the 3, 6 and 12 month assessments, 78%, 85%, and 71% of the patients respectively, had experienced clinically-significant improvement in pain and function from this fusion procedure. At all post-operative assessments, significant improvements had occurred in the mean numerical rating scale scores of the functional assessment questionnaire for pain ($P < 0.0001$), light activities ($P < 0.0001$), moderate activities ($P < 0.0001$), vigorous activities ($P = 0.0081$), sleep ($P < 0.0001$), overall happiness ($P = 0.0022$), and pain effect on social interest ($P < 0.0001$). Satisfaction with this fusion procedure was reported by 91% of the patients at 3 months and 82% of the patients at 6 and 12 months.

There were 10 complications in Rudolph's series of 50 patients. Three patients had a superficial wound cellulitis that resolved following treatment with oral antibiotics. One patient developed a deep wound infection that was successfully treated with six weeks of intravenous antibiotics. Two patients had a large buttock hematoma that gradually resolved. Two patients had implant penetration of the sacral foramen discovered on post-operative CT scan associated with nerve root irritation and radicular pain without neurological deficits. In both cases the implants were retracted surgically with complete resolution of symptoms. In one patient an implant had been placed too cephalad resulting in L5 nerve compression. The implant was retracted surgically with complete resolution of symptoms. One patient had a non-displaced fracture of the ilium adjacent to the sciatic notch at the edge of the lowest implant. The fracture healed without implant loosening. One late complication was reported. This involved recurrence of SI joint pain three years after surgery. CT scan identified that the two caudal implants were showing signs of motion and had been misplaced too posteriorly. Two additional implants were able to be placed anterior to the loosened implants with complete pain resolution.

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Rudolf and Capobianco (2014) reported five-year outcomes of 17 patients. It is unclear if these patients were part of the 2012 publication. In addition, it should be noted that there were a total of 21 consecutive patients, though only 17 were available for follow-up. One of these patients was truly lost to follow-up, two had passed away and one had become quadriplegic after cervical trauma. The percentages of patients who achieved substantial clinical benefit were 77%, 82%, and 88% at the 12, 24, and 60 month time points. The authors used an unvalidated outcome score (termed SI joint survey instrument) which was comprised of parts of both the ODI and SF-36. Improvement was seen in 6 of 8 domains at final follow-up. Patient satisfaction was 82 percent at 1 and 5 years. Fusion was noted in 87% of cases. No intraoperative complications were noted, though the authors did report a case of hematoma, wound infection, and two cases of cellulitis.

In 2012, McGuire retrospectively reviewed and reported on 37 consecutive patients treated with 38 minimally invasive elective SIJ fusions using dual fibular allografts filled with local autograft obtained during drilling.⁸ Patients were followed-up for a mean of 52 months (range, 24–62 months). Visual Analog Scale (VAS) was used to monitor clinical pain improvement and fusion was deemed to be present when bone bridging trabeculae could be seen crossing the SIJ on either oblique x-rays or by computed tomographic scan. Thirty-four patients (89.5%) achieved a solid arthrodesis; this group had substantial improvement in mean VAS pain scores from preoperative 9.1 to postoperative 3.4 ($P < .001$). This improvement in VAS occurred over a 6-month period and was sustained with subsequent follow-up. Nonunion occurred in four patients (10.5%). All four nonunions were successfully treated by secondary autogenous bone grafting and compression screw fixation.

A retrospective study by Sachs and Capobianco in 2012 reported on 11 consecutive patients treated by a single surgeon with a percutaneous SI joint using triangular, porous, plasma-coated, titanium implants.¹⁰ The baseline VAS pain score average was 7.9 (± 2.2) and the mean pain score average at the 12 month follow-up interval was 2.3 (± 3.1), resulting in an average improvement of 6.2 points from baseline ($p=0.000$). Patient satisfaction was very high with 100% of patients indicating that they would have the same surgery again for the same result. The estimated blood loss was less than 50ml, there were no operative complications reported, and no revision surgeries were needed.

In 2013, this same group published one year outcomes of 40 patients undergoing percutaneous SIJ fusion. Again, it is unclear if this included patients from the 2012 report. The indications and inclusion criteria of this study resemble those outlined in the coverage recommendation above. All patients indicated they would have the surgery again. A clinically significant improvement in pain was noted in all but one patient.

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Comparison to Open SIJ fusion

While current interest is clearly focused on percutaneous SI fusion techniques, in 2005 Buchowski et al reported a retrospective review of 20 patients undergoing open sacroiliac joint arthrodesis using a modified Smith Peterson approach with direct curettage of the joint.² Internal fixation was then applied using plates and screws. Preoperative and postoperative general health and function were assessed via the 36-item Short-Form (SF-36) Health Survey and the American Academy of Orthopaedic Surgeons (AAOS) Modems Instrument, which were collected prospectively. Medical records and plain radiographs were reviewed retrospectively to determine the clinical and radiographic outcome. The average estimated blood loss was 290ml and seventeen patients (85%) achieved a solid fusion. The three non-unions required treatment with an open anterior sacroiliac joint fusion procedure. Fifteen patients (75%) completed preoperative and postoperative SF-36 forms. Significant ($p < .05$) improvement occurred in the following categories: physical functioning, role physical, bodily pain, vitality, social functioning, role emotional, and neurogenic and pain indices. Improvement (not statistically significant) was also noted in general and mental health. Most patients (60%) indicated they would choose to have the surgery again, and only one patient definitely would choose not to have the surgery again.

Smith et al (2013) compared results of open versus percutaneous SIJ fusions. Importantly, the open fusions were performed at different centers and by different surgeons than the percutaneous procedures. Though both groups seemed to improve, there was reportedly an average of 3.5 points less pain in the percutaneous group. With an attempt to match the patients for age, gender and other parameters, this difference decreased to 3 points.

To our knowledge, the largest series of patients undergoing percutaneous SIJ fusions was recently published in 2014 by Sachs et al. This was a review of 144 patients who underwent the procedure with a mean follow-up of 16 months. Mean pain scores improved from 8.6 preoperatively to 2.7 postoperatively. Though there were no intraoperative complications noted, one patient presented with nerve root impingement from implant malposition that required revision surgery. It should be noted that the authors of this study had previously published multiple other case series on this subject in prior years. Although it not clearly defined, it is likely that some of the patients in this study were included in the other published studies. It should also be noted that this study, as well as many of the studies listed above, have been co-authored by industry employees and pain consultant. This underscores the need to consider both industry and non-industry sponsored studies on this topic as well as reserve the right to amend recommendations as future data evolves.

In a post-market analysis performed by one of the manufacturers (SI Bone, San Jose, CA, USA), co-authored by company employees (Miller et al, 2013), the safety profile of 5319 patients who underwent

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the procedure was analyzed. They noted complaints reported in 3.8 percent of patients. Pain, nerve impingement, and recurrent SIJ pain were the most common. Improper device placement occurred in 72 cases (1.4 percent). There were 96 revision surgeries performed in 94 patients. Various other parameters were listed. What is unclear from the study is a comparison to a benchmark of safety and complication rates of other surgical procedures.

Though the low level of evidence is comprised of primarily level IV case series data, the outcomes of SIJ fusion for non-infectious, non-traumatic related pain are relatively consistent. Both open and percutaneous SIJ fusions seem to produce improvement in pain scores. Considering that percutaneous SIJ fusions seem to be associated with less blood loss and fewer complications than open fusions, which has been a previously covered procedure, it seems reasonable to extend coverage to percutaneous procedures. The most contentious part of the procedure admitted by each of the papers reviewed is the reliability and accuracy of diagnosing SIJ mediated pain. Thus, in reviewing the IASP's recommendations and evaluative study of the criteria for the diagnosis, we propose the above listed criteria for coverage. These criteria are not only consistent with diagnostic recommendations made by others but also with indications for other procedures for pain-based diagnoses (e.g. medial branch nerve blocks in the diagnosis of facet-mediated pain and other diagnostic blocks). Because the evidence is low and subject to significant bias, for now it is particularly important to maintain scrupulous adherence to strict indications for surgical management of these patients. Future research and analysis must continue in order to further understand and refine the indications for this percutaneous SIJ fusion.

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Boakye, Maxwell: Nothing to Disclose.

Cho, Charles: Nothing to Disclose.

DePalma, Michael: Consulting: Vertiflex, Inc (Financial); Trips/Travel: Medtronic (Financial); Board of Directors: International Spine Intervention Society (Financial), Virginia Spine Research Institute, Inc (Financial); Scientific Advisory Board: Medtronic; Kimberly Clark (Financial); Other Office: Secretary, International Spine Intervention Society (Financial); Research Support (Investigator Salary): Relieva (B), SI Bone (B), Mesoblast, Inc (B); Research Support (Staff/Materials): Relieva (B), Mesoblast (B), SI Bone (B); Relationships Outside the One Year Requirement: AOI Medical (Upcoming Committee Meeting [Clinical Guidelines]), Stryker Interventional Spine (B), St. Jude Medical (NASS Annual Meeting, Consulting), Stryker Biotech (NASS Annual Meeting), ATRM (NASS Annual Meeting)

Dietze, Donald: Stock Ownership: Globus Medical Consulting: Globus Medical (Financial)

Easa, John: Stock Ownership: Janus Biotherapeutics

Ghiselli, Gary: Private Investments: DiFusion; Consulting: Biomet (B); Scientific Advisory Board: DiFusion (Nonfinancial, Stock options in company).

Glaser, John A.: Grants: SI Bone (D)

Harrop, James: Consulting: Depuy Spine (C); Board of Directors: Jefferson Medical College Physician Board (Nonfinancial); Scientific Advisory Board: Axiomed (Nonfinancial); Other Office: Bioventus (B), Asterias (B); Grants: AO Spine/ NREF (A); Other: Tejin (B)

NASS coverage recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. **The coverage recommendations do not represent a "standard of care,"** nor are they intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside these criteria will sometimes be necessary. This document should not be seen as prescribing the type, frequency or duration of intervention. Treatment and accompanying payment should be based on this information in addition to an individual patient's needs as well as the doctor's professional judgment and experience. This document is designed to function as a guide and should not be used as the sole reason for denial of treatment and services. It is not intended to supersede applicable ethical standards or provisions of law. This is not a legal document.

Lapinsky, Anthony: Royalties: RTI Surgical (B); Consulting: Orthofix (Financial)

Lebl, Darren: Nothing to Disclose.

Matz, Paul: Speaking and/or teaching arrangements: AO Spine North America (B); Trips/Travel: NASS (A)

O'Brien, David: Speaking and/or Teaching Arrangements: NASS; Trips/Travel: ISIS & AAPMR; Other Office: ISIS & AAPMR (Nonfinancial).

Patel, Alpesh: Royalties: Amedica (B); Stock Ownership: Amedica, Cytonics, Nocimed, Vital5; Consulting: Amedica (B), Stryker (Financial), Biomet (B), Depuy (B); Board of Directors: Cervical Spine Research Society (Nonfinancial); Fellowship Support: OREF (D), Omega (B); Other: Amedica (Financial, Private investment)

Reiter, Mitchell: Private Investments: CreOsso

Reitman, Charles: Trips/Travel: NASS - BOD (Financial), AAOS - Evidence Based Committee (Financial); Scientific Advisory Board: Clinical Orthopedics And Related Research - Deputy Editor (B)

Riley, Lee: Stock Ownership: Spinal kinetics; Speaking and/or teaching arrangements: AOSNA (B); Trips/Travel: DePuy Spine (B); Board of Directors: Lifenet Health (C); Other Office: CSRS (A); Grants: DePuy Spine (B)

Sharan, Alok: Consulting: Paradigm Spine (B); Speaking and/or teaching arrangements: Synthes Spine (B)

Summers, Jeffrey: Stock Ownership: MedWorx ; Private Investments: Morris Innovative (2000 Shares); Board of Directors: International Spine Intervention Society (ISIS) (Nonfinancial)

Tontz, William: Stock Ownership: Phygen; Consulting: Medtronic (C); Speaking and/or teaching arrangements: SpineArt (B); Trips/Travel: Medtronic (B); Scientific Advisory Board: Medtronic (Financial)

Toton, John: Nothing to Disclose.

Tromanhauser, Scott: Stock Ownership: Soteira, Inc.

Truumees, Eric: Royalties: Stryker Spine (C); Stock Ownership: Doctor's Research Group (D); Board of Directors: North American Spine Society (Nonfinancial); Other Office: AAOS Communications Cabinet

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(Financial); Research Support (Investigator Salary): Relievant (B) Globus (B); Other: Stryker Biotech (Nonfinancial)

Villavincencio, Allen: Stock Ownership: Lanx; Board of Directors: Junstin Parker Neurological Institute (Nonfinancial); Other Office: Boulder Neurosurgical Associates, LLC (Nonfinancial); Research Support (Investigator Salary): Profibrix, Medtronic (F)

Zindrick, Michael: Royalties: OrthoFix (C), Biomet (B); Stock Ownership: VTI; Scientific Advisory Board: Orthofix

Comments

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.

NASS coverage recommendations should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific procedure or treatment is to be made by the physician and patient in light of all circumstances presented by the patient and the needs and resources particular to the locality or institution. **The coverage recommendations do not represent a "standard of care,"** nor are they intended as a fixed treatment protocol. It is anticipated that there will be patients who will require less or more treatment than the average. It is also acknowledged that in atypical cases, treatment falling outside these criteria will sometimes be necessary. This document should not be seen as prescribing the type, frequency or duration of intervention. Treatment and accompanying payment should be based on this information in addition to an individual patient's needs as well as the doctor's professional judgment and experience. This document is designed to function as a guide and should not be used as the sole reason for denial of treatment and services. It is not intended to supersede applicable ethical standards or provisions of law. This is not a legal document.