EVIDENCE-BASED UPDATES TO THE MEDICAL TREATMENT SCHECULE (MTUS)	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
General comment	Commenter has reviewed the proposed updates and has no comment at this time.	Sheila Monson, Claims Operations Manager State Compensation Insurance Fund April 25, 2019 Written Comment	Agree.	None.
General comment	Commenter has reviewed the proposed updates to the MTUS to incorporate the following updated guides by reference: Introduction to the Workplace Mental Health Guideline (ACOEM March 13,2019) Low Back Disorders Guideline (ACOEM March 7, 2019) Commenter supports the proposed updates to ensure that treatment for injured workers remains governed by evidence-based guidelines that are the most current available from ACOEM.	Stacy L. Jones Senior Research Associate California Workers' Compensation Institute (CWCI) May 6, 2019 Written Comment	Agree.	None.
9792.23.5 - Low Back Disorders Guideline	Commenter is a physician that has provided orthopedic and spine surgery care for injured workers within the state of California since 1988 from his practice in Los Gatos, California.	Randall Seago, MD May 3,2019 Written Comment	Disagree: David Polly's 2-year follow-up study from 2016 referenced by commenter was reviewed and referenced in the ACOEM Low Back Disorders Guideline. However, ACOEM	None.

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	Commenter states that he utilizes the iFuse Implant System for surgical treatment of the symptomatic sacroiliac joint. He states that this treatment has proven to be safe and effective with a minimally invasive percutaneous approach. Commenter opines that ACOEM has not kept up with generally accepted surgical practice and that this procedure is a supported treatment option by nationally recognized, evidence based medical guidelines. Commenter states that his multiyear experience with the iFuse device mirror those in the 2-year Level 1 RCT studies (iMia and INSITE). Commenter requests that the division update this guideline to follow NASS or ISASS published criteria.		points out several deficiencies with this RCT. The biggest deficiency is the failure to compare Sacroiliac Fusion Surgery (SI) with a quality rehabilitation program. SI is invasive, has adverse effects, is costly, but without quality trials addressing either sham or quality functional restoration-control, ACOEM does not give this a recommendation. In addition, SI-BONE, Inc. the manufacturers of the iFuse Implant System, is funding the iMia trial. Although that by itself is not considered undue bias, any potential conflict is always considered. Disagree: The NASS and ISASS recommendations should be submitted to ACOEM's stakeholder input web site for consideration: https://acoem.formstack.com/forms/stakeholderpatientinput These recommendations will	None.

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			be evaluated according to ACOEM's publicly available review process methodology which incorporates the high standards and criteria widely accepted by the US Institute of Medicine (IOM), the international GRADE Working Group, AGREE II, and AMSTAR. (See ACOEM's Low Back Disorders Guidelines footnotes 7 and for a summary see footnote 8). If these recommendations meet these standards and criteria, then they will likely be incorporated into ACOEM's guidelines.	
9792.23.5 - Low Back Disorders Guideline – Facet Interventions: Radiofrequency Neurotomy	Commenter would like to specifically comment on two section of ACOEM's updated guideline recommendations: radiofrequency neurotomy (RF) and spinal cord stimulation (SCS). Regarding the section on diagnostic and therapeutic facet joint procedures, commenter is in strong disagreement with the proposed guideline recommendations regarding RF. There is extensive high quality evidence	Timothy Maus, MD President Spine Intervention Society (SIS) April 19, 2019 Written Comment	Disagree: Radiofrequency neurotomy involves the use of radiofrequency electrode to create a heat lesion to coagulate the nerve supplying the joint. Radiofrequency lesioning is invasive because the nerves are permanently destroyed, has adverse effects, and is costly. The highest quality studies mostly suggest	None.

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	regarding the use of medial branch blocks and radiofrequency neurotomy for the evaluation and treatment of lumbar spine pain arising from the facet joints. Commenter opines that the ACOEM proposed guidelines reflect a significant misunderstanding of the current literature and he respectfully requests that the California Division of Workers' Compensation carefully review the cited evidence to ensure that appropriately selected patients are not denied access to valuable treatment for their facet-medicated pain. With his correspondence, commenter has enclosed a multi-medical society position statement signed by the Spine Intervention Society (SIS), American Academy of Pain, North American Spine Society, and American Academy of Physical Medicine and Rehabilitation. This position statement provides their summary of the RF evidence-base. The position statement opines the root of the problem lies not in the procedures, but rather in the inappropriate application of RF. The literature assessing medical		a lack of efficacy, the overall evidence base does not support this treatment. Additional quality research is needed in this area as it is currently an experimental procedure for purposes of treating acute, subacute, and chronic LBP, and radicular pain syndromes and/or "discogenic" LBP. (See more detailed response below). Disagree: Despite the thorough position statement submitted and signed by the multi-medical society, we disagree with its fundamental conclusion that there is high quality evidence that supports a recommendation for the use of RF neurotomy for the treatment of lumbar spine pain arising from the facet joints. The highest quality sham-controlled studies are largely negative and suggest a lack of	None.

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	branch blocks and facet RF neurotomy shows how these procedures can be performed in a disciplined, responsible manner, in order to achieve desirable outcomes that are clinically, socially, and economically worthwhile.		efficacy. Available systematic reviews also discuss significant methodological concerns. The evidence-base simply does not support a recommendation for RF neurotomy for treatment of patients with chronic low back pain confirmed with diagnostic blocks, but who do not have radiculopathy and who have failed conservative treatment. The evidence commenter and the position statement relies on are either lower level evidence or suffer from deficiencies that compromises their reliability as evidence. However, ACOEM's recommendation contains limited indications for RF. One procedure might be tried as an option after failure of non-invasive treatments including NSAIDs and a quality exercise program or as a means to help with participation in an active rehabilitation program. There is no recommendation for repeated procedures. It is reasonable to attempt a second	

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			lesion after 26 weeks in patients who had greater than 80% improvement in pain from first procedure for the first 8 weeks with a late return of pain. There is no recommendation for a third or for additional procedures. There is logically a limit as to how many times it is possible to permanently destroy the same nerve.	
	In order to address the true problem of the inappropriate application of these procedures, the following requirement should be applied: • At least 80% relief of index pain from medical branch blocks should be recognized as a pretext for further investigation. • Less than 80% relief of index pain should be regarded as non-positive; and further medical branch blocks at those levels should be produced. • At least 80% relief of index pain following comparative or placebo-		Disagree: Although an interesting finding in two studies reviewed and referenced by ACOEM (van Kleef footnote 1814 and Gallagher footnote 1816) is the possibility that patients with higher degree of successful blocks, (e.g.,>80%) as opposed to the 50% threshold that is more widely employed, have better outcomes. However, the van Kleef study used unconventional statistical testing with 90% confidence intervals, rendering it unusable and the Gallagher study had	None.

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	controlled blocks should become the only indication for facet RF neurotomy.		worrisome results in the placebo. Therefore, the better outcomes finding due to an 80% or higher degree of successful has not been proven and cannot be adopted as guidance at this time.	
	Recently published systematic reviews are flawed – not of the data published - but rather due to their lack of insight into to the details of the practices inherent in the procedures being assessed. The literature on facet RF neurotomy must be meticulously stratified. That stratification can be applied in each of three domains: selection, technique, and outcome. **Technique** – The orientation of the electrode is likely to be pivotal to clinical outcome. Perpendicular placements could be successful, but are likely to have lower success rates and shorter duration of effect, whereas parallel placements are more likely to have greater success rates for longer periods. The position statement then asserts 3 studies should be inadmissible as evidence of the effectiveness or efficacy or RF		Disagree: Commenter and the position statement concludes recently published systematic reviews are flawed because they lacked insight into the details of the practices inherent in the procedures being assessed. They contend that the literature on facet RF neurotomy must be meticulously stratified. First, they argue that correct placement of the electrode must be near the target nerve. In addition, they argue that placement of the electrode should be parallel to the nerve not perpendicular to it. The position statement then censored all but three studies (Nath, Tekin, and van Kleef) eligible to provide evidence of	None.

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	(Gallagher, Leclarie, and van Wijk) because they used the Shealy technique which placed the electrodes nowhere within reach of the target nerve. The position statement then asserts 7 studies placed their electrodes within range of the target nerve but used perpendicular placements (Tzaan, Civelek, Son, Chakraverty, Kroll, van Klef, and Juch). Therefore, the clinical outcomes of these studies need to be interpreted carefully and with insight. Finally, 9 studies used what appears to be the correct technique: placement of the electrode parallel to the target nerve (Dreyfuss, MacVicar, Gofeld, Burnham Speldewinde, Schofferman, Rambaransignh, Nath, Tekin, and Lekemeier). The position statement then censored all but three studies (Nath, Tekin, and van Kleef) eligible to provide evidence of efficacy. Nath showed a difference in favor of facet RF neurotomy that was not significant for the relief of back pain at six months, but which was significant for relief of leg pain, global perceived effect, and consumption of analgesics. Van Kleef showed a difference in		efficacy. Interestingly, the van Kleef study placed the electrode perpendicular to the nerve not parallel to it, and thus, is not consistent with the position statement's conclusion of the correct technique that should be used. Nevertheless, the van Kleef study was also referenced and considered by ACOEM but it used unconventional statistical testing with 90% confidence intervals, rendering it unusable. The Nath study was also referenced and considered by ACOEM but it suffered an apparent randomization failure. ACOEM will only select the highest quality studies to support its treatment recommendations. As is widely accepted in the scientific community, randomized controlled trials (RCTs) are considered the gold standard. However, even RCT's vary in quality and are carefully scrutinized and critically appraised by	

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	favor of RJ neurotomy that was not significant statistically, but survival analysis showed a statistically significant greater success rate from three months to one year after facet RF neurotomy. Tekin showed statistically significant differences in favor of RF neurotomy at six months and at one year, for group scores for back pain, and for disability, with significantly greater proportion of patients reporting excellent outcome. **Outcomes** – Two studies have provided benchmarks for the optimal outcomes of facet RF neurotomy (Dreyfuss and MacVicar) Each used optimal technique, as discussed above. The first reported that 80% of patients could expect at least 60% relief of their back pain at 12 months, and that 60% could expect at least 80% relief. The second study reported the outcomes from two neighboring practices, in which 58% or 53% of patients respectively achieved complete relief of pain. A success rate of 55% may not seem impressive, but is compensated by the definition of success: complete relief of pain,		ACOEM's panel experts. Here, both the van Kleef and Nath RCTs contained critical methodological deficiencies. The Tekin trial is not a RCT and, therefore, was not considered in ACOEM's recommendation. Disagree: Again, the studies referenced as benchmarks for the optimal outcomes of facet RF neurotomy (Dreyfuss and MacVicar) are not RCTs and, therefore, were not considered by ACOEM when making their recommendation. Moreover, these benchmarks for the optimal outcomes of facet RF neurotomy are about 55% and as stated in the position statement "A success rate of 55% may not seem impressive but is compensated by the definition of success: complete relief of pain,	None.

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	restoration of function, and no other health care. The modest success rate, however, is mathematically consistent with the vicissitudes of diagnostic blocks.		restoration of function, and no other health care." However, this begs the question, relief of pain for how long? Dreyfuss reviewed a 12 month window. MacVicar reviewed a 17-33 month with the need for repeat treatment. ACOEM concludes, no procedure to date has been shown to be effective for the treatment of pain that involves cutting or ablating nerve fibers, perhaps due to pain fiber regeneration, alternate pathways for conduction, phantom pain, ongoing neurological stimulations, and/or conduction from the transected or ablated nerve fibers.	
	(Selection) Diagnosis – Diagnostic blocks are the only means of establishing a diagnosis, and providing an indication for treatment by facet RF neurotomy. A positive response is one in which the patient obtains at least 80% relieve of the index pain on each occasion. Although placebo-controlled, triple		Agree in part; Disagree in part: Agree: As part of ACOEM's limited indication for RF neurotomy a patient must have "a confirmed diagnosis by medial branch blocks." Disagree: As mentioned above, ACOEM's limited indication for RF neurotomy, a patient	None.

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	blocks have been used in research studies, they are regarded by many as too consuming of resources to be practical in conventional practice. The position statement concludes a suitable alternative to placebo-controlled, triple blocks is comparative local anesthetic blocks. Use of comparative local anesthetic blocks are the best available, most practical means of establishing an indication for facet RF neurotomy, if complete relief of pain is the desired outcome. Summary of recommendations: 1. Recognize as valid only those procedures performed in accordance with technique that have been validated. Optimal results have been achieved only when those techniques have been used.		must have "a confirmed diagnosis by medial branch blocks." However, ACOEM does not specify the type of block to be used. Disagree: As mentioned above, The highest quality sham-controlled studies are largely negative and suggest a lack of efficacy. Available systematic reviews also discuss significant methodological concerns. The evidence-base simply does not support a recommendation for RF neurotomy for treatment of patients with chronic low back pain confirmed with diagnostic blocks, but who do not have radiculopathy and who have failed conservative treatment.	None.

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	2. Adopt the SIS guidelines as the standard for the performance of medial branch blocks and RF neurotomy.		As results of RF neurotomy are permanent destruction of the nerve, there should be good evidence of long-term benefit prior to recommending this procedure. Permanently denervated joints in the appendicular skeleton are called Charcot joints, and over long-term follow-up they do not do well; there are no long-term results reported for those potential adverse effects. Disagree: The SIS guidelines should be submitted to ACOEM's stakeholder input web site for consideration: https://acoem.formstack.com/forms/stakeholderpatientinput These recommendations will be evaluated according to ACOEM's publicly available review process methodology which incorporates the high standards and criteria widely accepted by the US Institute of Medicine (IOM), the	None.

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			international GRADE Working Group, AGREE II, and AMSTAR. (See ACOEM's Low Back Disorders Guidelines footnotes 7 and for a summary see footnote 8). If these recommendations meet these standards and criteria, then they will be incorporated into ACOEM's guidelines.	
	Furthermore, we recommend that payers regard as investigational any other techniques for facet RF neurotomy, or any other basis for the selection of patients for treatment by facet RF neurotomy.		Disagree: (See above response) Pursuant to Labor Code section 4604.5(a) only the guidelines adopted into the MTUS shall be presumptively correct on the issue of extent and scope of medical treatment.	None.
9792.23.5 - Low Back Disorders Guideline – Implantable Spinal Cord Stimulators	Commenter opines that spinal cord stimulation (SCS) is a well-established treatment for patients with refractory chronic pain.	Timothy Maus, MD President Spine Intervention Society April 19, 2019 Written Comment	Disagree: SCS are not recommended for treatment of acute, subacute, chronic low back pain, radicular pain syndromes or failed back surgery. (See more detailed response below). However, indications are provided for highly select circumstances when a worker has primarily	None.

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			radicular extremity pain, all other indicated treatments have failed, the patient has inadequate function, and the provider wishes to seek approval from a worker's compensation carrier for consideration of possible coverage despite the lack of quality evidence of efficacy in these patients.	
	Commenter offers the following evidence for "traditional" SCS: • The PROCESS study, a randomized controlled trial (RCT) of SCS in addition to conventional medical management (CMM) versus CMM alone, demonstrated that SCS patients with failed back surgery syndrome (FBSS) experienced significantly improved pain, function, quality of life, and high		Disagree: There are few quality studies evaluating SCS for the treatment of LBP, none of which compared SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or a sham procedure. This is the deficiency with the Kumar studies referenced by commenter.	None.

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	satisfaction with treatment at both 6[1] and 24[2] months. • An RCT by North and colleagues[3] compared SCS versus reoperation on the lumbosacral spine and demonstrated that for FBSS patients SCS was significantly more effective (as measured by pain relief and patient satisfaction). • The National Institute for Health and Clinical Excellence (NICE) final determination of the medical evidence on SCS concluded that SCS is recommended as a treatment option for adults with chronic neuropathic pain lasting at least 6 months despite		Disagree: Again, the deficiency with the North study referenced by the commenter fails to compare SCS with a non-surgical treatment such as a quality multi-disciplinary rehabilitation program or a sham procedure. Disagree: The NICE recommendations on SCS should be submitted to ACOEM's stakeholder input web site for consideration: https://acoem.formstack.com/forms/stakeholderpatientinput These recommendations will	None. None.

[1] Kumar K, et al. Spinal cord stimulation versus conventional medical management for neuropathic pain: A multicentre randomised controlled trial in patients with failed back surgery syndrome. *Pain* 2007;132:179-188.
[2] Kumar K, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: A 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. *Neurosurgery* 2008;63(4):762-770.
[3] North RB, et al. Spinal cord stimulation versus repeated lumbosacral spine surgery: a randomized controlled trial. *Neurosurgery* 2005;56(1):98-107.

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	appropriate conventional medical management.[4]		be evaluated according to ACOEM's publicly available review process methodology which incorporates the high standards and criteria widely accepted by the US Institute of Medicine (IOM), the international GRADE Working Group, AGREE II, and AMSTAR. (See ACOEM's Low Back Disorders Guidelines footnotes 7 and for a summary see footnote 8). If these recommendations meet these standards and criteria, then they will be incorporated into ACOEM's guidelines.	
	Commenter states that high frequency stimulation, specifically HF10, has also been studied, and that the safety and effectiveness of HF10 therapy has been demonstrated in an RCT by Kapural *et al*[5] and a prospective,		Disagree: The Kapural study referenced by the commenter also contained a methodological deficiency because it had no sham or functional restoration	None.

[4] http://www.nice.org.uk/

[5] Kapural L, et al. Comparison of 10-kHz high-frequency and traditional low-frequency spinal cord stimulation for the treatment of chronic back and leg pain: 24-month results from a multicenter, randomized, controlled pivotal trial. *Neurosurgery* 2016;79(5):667–677.

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	multicenter trial by Al-Kaisey *et al*[6]. Both studies reported 24-month results supporting the safety and effectiveness of HF10 SCS. In addition, commenter provided the SIS endorsed NASS coverage policy recommendations on spinal cord stimulation for consideration [Available upon request].		controlled arm, similar to the weaknesses of prior studies. ACOEM will only select the highest quality studies to support its treatment recommendations. As is widely accepted in the scientific community, randomized controlled trials (RCTs) are considered the gold standard. The Al-Kaisey *et al*. is not a RCT and is considered lower-level evidence.	
	Commenter opines that it is imperative that the California Division of Workers' Compensation carefully review the cited evidence in order to ensure that appropriately selected patients are not denied access to valuable treatment for their refractory chronic pain.		Disagree: The Low Back Disorders guidelines adopted into the MTUS contains a very limited indication for SCS when a worker has primarily radicular extremity pain, all other indicated treatments have failed, the patient has inadequate function, and the provider wishes to seek approval from a worker's compensation carrier for	None.

[6] Al-Kaisy A, et al. Sustained effectiveness of 10 kHz high-frequency spinal cord stimulation for patients with chronic, low back pain: 24-month results of a prospective multicenter study. *Pain Med* 2014;15:347–354.

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			consideration of possible coverage despite the lack of quality evidence of efficacy in these patients.	
General Comment – Labor Code 75.5(a) – CHSWC Study	Commenter notes that pursuant to Labor Code 75.5(a)(incorrect should be 77.5 as subsequently referenced), the Commission on Health and Safety and Workers' Compensation (CHSWC) is required to update their survey on the evaluation of evidence-based, peer-reviewed, nationally recognized standards of care, including existing medical treatment utilization standards, including independent medical review, as used in other states, at the national level, and in other medical benefit systems periodically. Commenter states that their last such update referencing this statute was done in April, 2006 -over 13 years ago. In the last update there is a reference to a joint commission between the DIR and CHSWC but the statute placed the non-delegable duty of updating the survey and evaluation on CHSWC given its nonbiased commission makeup. Commenter opines that another update is	Robert McLaughlin, Esq., APC May 6, 2019 Written Comments	Disagree: The proposed evidence-based updates to the MTUS are being made by the DWC through an Administrative Director (AD) order pursuant to Labor Code section 5307.27. Commenter references Labor Code 77.5 which specifically pertains to CHSWC. The DWC's AD has no authority over CHSWC and how it chooses to carry out its duties.	None.

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	mandated.			
General Comment – Labor Code 75.5(a) – CHSWC Study – ACOEM Low Back Disorders Guideline	As an example, commenter notes that the ACOEM guidelines on Low Back Disorders has multiple listings wherein the treatment recommendation states: "*Strength of Evidence* - **No Recommendation, Insufficient Evidence (I)** *Level of Confidence* - Low", "Moderate" or "High" or "*Strength of Evidence* - **Not Recommended, Insufficient Evidence (I)**" sometimes with citation to limited medical literature or no citation. Commenter opines that these decisions to recommend or not to recommend are based primarily on a consensus of the editors or contributors of the ACOEM guides. Commenter questions what internal biases for or against the treatment they may or may not have had. Is the ACOEM representation about there being insufficient evidence accurate? Why and under what standards are some treatments in which there is insufficient evidence recommended and others are not? Commenter opines that this is why CHSWC was tasked pursuant to Labor Code 77.5(a) to update their survey on the evaluation	Robert McLaughlin, Esq., APC May 6, 2019 Written Comments	Disagree: ACOEM's methodology is publicly available and incorporates standards and criteria widely accepted by the US Institute of Medicine (IOM), the international GRADE Working Group, AGREE II, and AMSTAR. The publicly available methodology (see ACOEM's Low Back Disorders Guideline footnotes 7 and for a summary see footnote 8) sets forth ACOEM's standardized process. Formulation of recommendations always begins with an exhaustive search of the literature on a given topic. ACOEM's research team critically appraises, grades, and critiques each study that meets their inclusion criteria. Studies are critiqued for methodological strengths and weaknesses and assessed for robustness and validity of conclusions derived from presented data. Tables A-	None.

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	of evidence-based, peer-reviewed, nationally recognized standards of care, periodically. For example in the section on Low Back Disorders, General Treatment Approach pages 209 through Rehabilitation for Delayed Recovery on page 682, there are approximately 96 references to there being "**Insufficient Evidence (I)**" regarding a treatment. Of those, approximately 52 are "**Not Recommended, Insufficient Evidence (I)**", 26 are "**No Recommendation, Insufficient Evidence(I)**" and approximately 18 are "**Recommended, Insufficient Evidence (I)**" Commenter states that this is the reason CHSWC was mandated to periodically update their survey and evaluation of treatment guidelines. Commenter questions whether the ACOEM Low Back Disorders Guideline and Workplace Mental Health Guideline are evidence-based, peer-reviewed, nationally recognized standards of care or just a consensus of the small group of contributors to ACOEM.		F published in ACOEM's methodology (see footnote 7) establishes the standards and criteria used by ACOEM to evaluate the evidence base and to formulate recommendations. These recommendations are guided by the existing evidence-base that have met their written "Study Inclusion Criteria". ACOEM panel unanimity is nearly always achieved primarily through iterative drafts. Failing attainment of unanimity, consensus is sought for all recommendations and rationales in each guideline. When consensus is not possible, a vote is taken. Minority statements may be included. A good example of this is the recommendation for the limited indication for Radiofrequency Neurotomy on page 525 of the Low Back Disorders Guideline. Commenter misunderstands evidence-base medicine. Not all medical interventions have	

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			been vigorously evaluated. For those that have, it is possible to develop guidelines or conclusions regarding treatment and causation that are wholly based on scientific evidence. For others, the final decision regarding the implications of results or lack thereof is the consensus opinion of the authors/collaborators. The key is to make sure that the methodology applied is transparent and adheres to widely accepted standards and criteria. Disagree: See above response.	None.
	Commenter opines that the adoption of the ACOEM guides into the MTUS regulations §§ 9792.23.5 and 9792.23.8 are more than likely not in compliance with Labor Code §§ 77.5(a) and 5307.27(a) and adoption of them may exceed the Administrative Director's authority under the enacting Labor Code statutes.			
General Comment – Labor Code	Commenter stats that the proposed guidelines inappropriately confuse	Robert McLaughlin, Esq., APC	Disagree: The proposed guidelines make no distinction	None.

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sections 4600 and 4620	medical-legal care under Labor Code § 4620, such as diagnostic testing, and care to cure or relieve an industrial injury under Labor Code § 4600. In addition the care noted in the guidelines are aimed at curing and do not adequately address relieving as required by Labor Code § 4600. Labor Code § 4600 (a) states the injured worker shall receive all medical services that are "reasonably required to ***cure or relieve*** the injured worker from the effects of his or her injury". Cal. Labor Code §4600(a). In addition, subsection (b) of that Code section also provides that medical treatment that is reasonably required to cure or relieve the injured worker from the effects of his or her injury means treatment that is based upon the Guidelines adopted by the Administrator Director. Labor Code § 4620 provides a definition of what constitutes medical-legal expenses. That statute states: (a) For purposes of this article, a medical-expense means any cost and	May 6, 2019 Written Comments	between medical-legal care versus medical care to cure or relieve. These guidelines are designed to provide health care providers, the primary target users of this guideline, with evidence-based guidance on the evaluation and treatment of working-age adults with low back disorders whether acute, subacute, chronic or post-operative or who have mental and behavioral health disorders impacting on and/or arising from the workplace. Disagree: These guidelines adequately address “relieving” as evidence by the numerous recommendations for prescription pain killers to pain relieving interventions such as manipulation. Disagree: Although commenter accurately describes Labor Code § 4620, he opines that the inclusion of diagnostic testing within the	None. None.

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	expenses incurred by or on behalf of any party, the Administrative Director, or the Board, which expenses may include X-rays, laboratory fees, other diagnostic tests, medical reports, medical records, medical testimony for the purpose of proving or disproving a contested claim. Cal. Labor Code §4620(a). Until a definitive diagnosis is made by a treating physician, with supporting diagnostic testing, the medical treatments necessary to cure or relieve the symptoms of the diagnosis and the diagnosis are in dispute. For example, in the Low Back Disorders Guideline, Spinal Fusion is recommended for treatment of Isthmic Spondylolisthesis under certain conditions many of which require X-Rays or MRI's to confirm the diagnosis and appropriateness of the treatment. Until the X-Rays or MRI are completed, the medical care to treat the Isthmic Spondylolisthesis is legally disputed as is it's a diagnosis and thus are not covered as medical treatment under Labor Code § 4600 but as diagnostic testing under Labor		ACOEM guidelines confuses the lines between Labor Code §§ 4600 and 4620. Again, The proposed guidelines make no distinction between medical-legal care versus medical care to cure or relieve. These guidelines are designed to provide health care providers, the primary target users of this guideline, with evidence-based guidance on the evaluation and treatment of working-age adults with low back disorders whether acute, subacute, chronic or post-operative or who have mental and behavioral health disorders impacting on and/or arising from the workplace. Commenter insists that the ACOEM guidelines should make the distinction between medical treatment under Labor Code § 4600 and medical-legal diagnostic testing under Labor Code § 4602. The DWC disagrees. In order to properly treat an injury or condition, it must first be properly	

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	Code § 4620. Commenter states that many physicians have commented to him over the years, "What has an X-Ray or MRI ever cured or relieved? Answer, nothing." Commenter notes that the Low Back Disorders Guideline address the need for Diagnostic Testing and Other Testing commencing on page 33 through 122. These diagnostic testing and other testing are just that, testing and not treatment meant to cure or relieve the injured workers' symptoms or diagnosis and therefore the inclusion of diagnostic testing within the ACOEM Guidelines confuses the lines between Labor Code §§ 4600 and 4620. Commenter opines that such failure to delineate the difference between medical treatment under Labor Code § 4600 and medical-legal diagnostic testing under Labor Code § 4620 brings into question whether the Administrative Director has the authority under Labor Code §§ 4600 and 5307.27 to adopt the Diagnostic Testing and Other Testing as set forth in the Low Back Disorders Guideline.		diagnosed. To use commenter's example, an X-ray or MRI would be considered part of an injured worker's medical care under Labor Code § 4600 if there were no legal dispute. Here, commenter is making a legal distinction, not a medical distinction. Therefore, inclusion of diagnostic testing within the ACOEM Guidelines is appropriate.	

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	Commenter notes that the ACOEM Low Back Disorders Guidelines emphasizes curing of the symptoms and not relief of the symptoms as indicated in their comments on each provided treatment, the strength of evidence and the level of confidence noted for each proposed treatment reviewed. Commenter opines that the use of the ACOEM Low Back Disorders Guidelines fails to adequately take into account the medical treatment to relieve as required by Labor Code §4600. Commenter notes that when adopted these Guidelines will be presumed correct. Commenter opines that as a result, injured workers will be effectively precluded from receiving a large portion of medical care meant to relieve the effects of their injuries, under Labor Code §4600, unless the doctor recommending the treatment is able to effectively rebut the presumption of correctness of the MTUS, which fail to adequately address treatment to relieve from the effects of the industrial injury.		Disagree: The ACOEM Low Back Disorders Guideline addresses "relieving" as evidence by the numerous recommendations for prescription pain killers to pain relieving interventions such as manipulation. Agree in part; Disagree in part: Agree: When these ACOEM guidelines are incorporated by reference into the MTUS, they will be presumed correct. Disagree: If treatments or medications are not recommended it is because the evidence-base simply does not support it. Also, these guidelines adequately address "relieving" as evidence by the numerous recommendations for prescription pain killers to pain relieving interventions	None. None.

			such as manipulation.	
General Comment – Labor Code section 5307.27(a)	Commenter states that the guidelines are reversed from what would be the best approach as set forth in Labor Code 5307.27(a) which provides the guidelines "shall address, at a minimum, the frequency, duration, intensity, and *appropriateness* of all treatment procedures and modalities commonly performed in workers' compensation cases." Commenter states that many of the treatments have insufficient evidence to support a conclusion one way or the other on the 'appropriateness' of the treatment. In addition, some treatment modalities have a strength of evidence ranking of either C, B or A. Quite often a physician will recommend medical treatment which receives a B ranking when there is also available a treatment with an A ranking. Utilization Review ('UR') and Independent Medical Review ('IMR') will often deny the recommended treatment with the B ranking on the grounds there is a treatment modality with a higher ranking of A. But what is lost is that both treatments are found	Robert McLaughlin, Esq., APC May 6, 2019 Written Comments	Disagree: Commenter equates "appropriateness" with a treatment recommendation supported by some evidence, irrespective of the studies deficiencies. In these guidelines, treatments that are considered "appropriate" are treatments that are recommended. Under commenter's hypothetical the treatment requested by the treating physician would not be considered appropriate because the evidence against the requested treatment is supported by stronger evidence. Therefore, commenter's conclusion that "both treatments are found to be appropriate" is simply incorrect and would not be found in these guidelines. Commenter fails to account for many of the nuances taken into consideration when appraising the strength of evidence. (See response beginning on page 19	None.

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	to be appropriate for the diagnosis and symptoms of the injured worker, just the strength of evidence is higher for one versus the other. This increases the frictional costs in obtaining medical care and increases the likelihood of an application for Independent Medical Review being filed. Commenter opines that a better reasoned Guideline would divide the care into three groups: (1) Those treatments found pursuant to evidence-based, peer-reviewed, nationally recognized standards of care to be effective and hence appropriate for the diagnosis or symptoms regardless or rankings (A, B or C); (2) Those treatments determined pursuant to evidence-based, peer-reviewed, nationally recognized standards of care to have insufficient evidence on the effectiveness and hence the appropriateness of the treatment for the diagnosis or symptoms; and (3) Those treatments found pursuant to evidence-based, peer-reviewed, nationally recognized standards of		to page 21). A treatment recommendation supported by a RCT loses credibility if it contains material methodological deficiencies. Accordingly, in commenter's hypothetical the treatment should be denied. Disagree: Again, commenter fails to account for many of the nuances taken into consideration when appraising the strength of evidence. (See response beginning on page 19 to page 21). We agree with the third group as this is already in place with our current regulations. However, groups one and two are problematic. First, group one would allow treatments that are evidence-based, peer-reviewed, nationally recognized standards of care to be effective and hence appropriate. Treatment efficacy is not as easy to define as commenter suggests. If the evidence-base suggests that a	None.

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	care to not be effective and hence inappropriate for the diagnosis or symptoms. All medical treatment falling under Category 3 should be listed in the MTUS as not appropriate and will not be approved unless the requesting physician can rebut the presumption of correctness of the MTUS. All other treatments should be approved as the treatment falling under Categories 1 and 2 are appropriate regardless of rank of Strength of Evidence (A, B, or C) as being appropriate. (All medical treatment falling under Category 2 should also be approved as there is insufficient evidence one way or the other on the appropriateness of the treatment and therefore the injured worker should be given the benefit of the doubt as to the appropriateness of the treatment, especially in light of Labor Code §3202.) Commenter opines that such an approach guarantees the injured worker only obtains the medical treatment appropriate for the diagnosis and injury while avoiding the costs to the workers compensation industry of treatment found to not be effective for		treatment may be effective but in only a small percentage of patients, commenter infers this treatment would be appropriate. However, if the potential harms are permanent and the evidence only shows short-term efficacy, then this treatment may not be appropriate. This is the type of nuance that commenter's conclusion misses. Second, group two would allow treatments with insufficient evidence on the effectiveness and hence the appropriateness of the treatment for the diagnosis or symptoms, but the injured worker should be given the benefit of the doubt as to the appropriateness of the treatment. Commenter's group 2 suggestion poses no standard. It is essentially a free-for-all that potentially subjects injured workers' to undue pressure to subject their bodies into experimental procedures that have not be scientifically proven to be	

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	the diagnosis and injury suffered by the injured worker unless the physician can rebut the presumption of correctness of the MTUS.		effective and; therefore, is not appropriate.	
9792.23.5 – Low Back Disorders Guideline	Commenter is addressing "Standing or Weight-bearing MRI for Back or Radicular Pain Syndrome Conditions" (p. 45.) Commenter notes that in addition to this being a diagnostic test not covered by Labor Code § 4600, the conclusions of the guidelines are contrary to the medical evidence cited. The Guidelines indicate such a diagnostic test is not recommended for back or radicular pain syndrome. However, the rationale for the recommendation notes studies have noticed a higher prevalence rate of disc herniations with upright-sitting examinations and an overall estimation of superiority for detection of spine abnormalities. A superiority in detecting spine abnormalities is an important test to assist the physician in correctly diagnosing the injured workers' symptoms and developing a treatment plan for those symptoms to cure or relieve the worker. Commenter	Robert McLaughlin, Esq., APC May 6, 2019 Written Comments	Disagree: (See response in pages 22-24 above). As ACOEM stressed it is important to note the sensitivity and specificity of CT or MRI are difficult to define as they require a 'gold standard' that is difficult to define in back pain since the final diagnosis often is based on the same imaging modality being tested; therefore, these clinical studies may be prone to incorporation bias, artificially inflating the sensitivity and specificity with some assuming MRI has 100% sensitivity and specificity. Disc degeneration, disc bulging and herniation, and endplate changes are widely prevalent in asymptomatic people on MRI have been shown to either not correlate, or correlated poorly with symptoms. This tremendously high prevalence	None.

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	opines that this is a diagnostic test and not treatment designed to cure or relieve the injured worker and should not be covered by the MTUS.		of abnormalities are essentially "false positives" in otherwise normal people resulting in higher overall costs and increased morbidity through the performance of some unnecessary procedures and/or surgeries. By loading the spine via standing or sitting, it increases the prevalence of disc bulging; thus increasing the false positives in otherwise normal people.	
9792.23.8 – Workplace Mental Health Guideline	Commenter opines that this guideline provides very little, if any, recommendations for treatment or reference to evidence based reports indicating the appropriateness of treatment for various mental health diagnosis. The Guideline addresses how a physician should make an initial assessment (spotting red flags, taking a good patient history, maintaining privacy under HIPAA et al & the use of a workplace questionnaire), how to perform a clinical examination (including screening tools, standardized psychological tests and use of mental health diagnostic systems), return to	Robert McLaughlin, Esq., APC May 6, 2019 Written Comments	Disagree: The Introduction to the Workplace Mental Health Guideline is part of the Workplace Mental Health Guideline that is being incorporated into the MTUS in separate parts as it is being published by the Reed Group (ACOEM's publisher). This guideline, contains evidence-based recommendations pertaining to Return-to-Work Programs for Mental Health Disorders that represent current evidence-based standards of care.	None.

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	work standards, risk and causation, work-relatedness and follow up visits. Commenter notes that the only true treatment modality addressed in the Guideline is the follow up visit section which consists of no more than 1page in a 71 page document (without the reference section). While the other sections are important for purposes of providing psychological reports which are substantial medical evidence, they do not address treatments to cure or relieve the injured worker from the effects of their psychological work related injury nor do they address the appropriateness of treatment for various mental health diagnosis. Commenter opines that adoption of this Guideline, with the exception of the 1 page on follow up visits, more than likely exceeds the Administrative Director's authority under Labor Code §§ 4600 and 5307.27 as the balance of the Guides do not address the appropriateness of treatment for various mental health diagnosis. Commenter states that the use of this Guideline by utilization review and		Disagree: These are evidence-based updates to the MTUS as indicated above. Moreover, this guideline is similar to the General Approaches Guidelines set forth in the California Code of Regulations, title 8, section 9792.22 that have already been reviewed and approved by the Office of Administrative Law.	None.

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	independent medical review will increase frictional costs as some will deny recommended care based on the report not complying with the standards set forth in the Guideline, and not address the treatment recommended. This will lead to increased legal challenges to the Guideline. Commenter opines that the use of this Guideline is misguided and emphasizes again why an updated survey and evaluation by CHSWC is required.		The General Approaches Guidelines have been incorporated by reference into the MTUS since 2007 and those guidelines have not increased frictional costs as described by commenter. Disagree: See response provided on page 18.	None.
9792.23.5. – Low Back Disorders Guideline	Commenter's company, SI-BONE manufactures the iFuse Implant System, an FDA-cleared medical device system used by surgeons to perform minimally invasive surgical (MIS) sacroiliac joint (SIJ) fusion (MIS SIJF). During this procedure, triangular titanium implants are placed across the SIJ to permanently stabilize the joint for patients with chronic SIJ dysfunction. Commenter would like to address the proposed adoption of the recent draft ACOEM Low Back Pain guidelines,	Daniel Cher, MD Vice President of Clinical Affairs SI-BONE April 26, 2019 Written Comment	Agree. Disagree: The DWC has adopted the ACOEM guidelines in its entirety since 2017 when the MTUS Drug	None. None.

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	specifically as they relate to the SIJF procedure. In the past, DWC has not adopted the ACOEM guidelines in their entirety, specifically as they relate to SIJF. Commenter encourages the division to continue this practice, for the following reasons: • We believe the ACOEM review does not take into account the full weight of evidence for the iFuse Implant System in that it only considers Level I evidence. ACOEM could recommend or find "confidence" in the MIS SIJF procedure based on Level I evidence alone – however as we note below, we also find the review lacking in that it does not consider any of the rest of the now 68 published, peer-reviewed Level I-IV papers found in the clinical literature on this topic.		Formulary was implemented. The MTUS Drug Formulary uses the ACOEM guidelines adopted into the MTUS as its foundation. Piece-meal adoption of various guidelines would render the MTUS Drug Formulary, as currently adopted, unusable. Disagree: There are no quality trials comparing SI joint fusion with a quality rehabilitation program. There are two moderate quality RCTs (Polly and Duhon) suggesting improved pain and function, but the comparison groups' treatments are ill-defined exercise and neither routinely incorporated a functional restoration program with progressive aerobic and strengthening exercises combined with CBT or sham-control. ACOEM will only select the highest quality studies to support its treatment recommendations. As is widely accepted in the	None.

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	• Many Health Technology Assessment groups, specialty benefits and guidelines development companies, as well as spine professional societies have all undertaken very similar, rigorous review of the literature on MIS SIJF and have made favorable recommendations or conclusions for this procedure. • Many have determined the exclusive use of the iFuse Implant System (titanium triangular implants) for these procedures is most appropriate. Just to name a few, **AIM Specialty Health** (exclusive to iFuse), **eviCore** (exclusive to iFuse), **BCBSA** Evidence Street (exclusive to iFuse), **NICE** (exclusive to iFuse), the **HAS** in France (exclusive to iFuse), **ISASS** and **NASS**,		scientific community, randomized controlled trials (RCTs) are considered the gold standard. Disagree: ACOEM's methodology incorporates the high standards and criteria widely accepted by the US Institute of Medicine (IOM), the international GRADE Working Group, AGREE II, and AMSTAR. A similarly rigorous review should result in similar recommendations or conclusions. Disagree: ACOEM's methodology incorporates the high standards and criteria widely accepted by the US Institute of Medicine (IOM), the international GRADE Working Group, AGREE II, and AMSTAR. A similarly rigorous review should result in similar recommendations or conclusions.	None. None.

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	among others, all have issued favorable recommendations, guidelines and policies for the procedure. Commenter states that there are issues of industry bias and there are iFuse study design considerations. Commenter opines that the ACOEM draft guidelines notes a potential for conflict of interest and ostensibly bias in results from the US randomized trial of SI joint fusion vs. non-surgical management (INSITE). While unclear exactly what study design consideration or bias issue resulted in the lack of confidence by ACOEM, questions typically range from blinding, control decision of conservative management as opposed to sham or other procedure, placebo, and the issue of our 6-month patient cross-over to surgery.		Agree in part; Disagree in part: Agree: ACOEM found issues with bias and study design deficiencies with the sacroiliac fusion surgery evidence-base. Disagree: It is clear the primary deficiency ACOEM had with sacroiliac fusion surgery is that there are no quality trials comparing SI joint fusion with a quality rehabilitation program. There are two moderate quality RCTs (Polly and Duhon) suggesting improved pain and function, but the comparison groups' treatments are ill-defined exercise and neither routinely incorporated a functional restoration program with progressive aerobic and strengthening exercises combined with CBT or sham-control.	None.

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	Blinding. One study design consideration, blinding, was not possible in this study since implants are radiopaque; it was deemed too easy for participants to gain access to their X-rays or CTs, which clearly show the presence/absence of our highly radiopaque implants.		Disagree: Although RCTs of surgical interventions are frequently more difficult to blind than RCTs of medications, which typically achieve blinding with placebo, imaginative techniques could possibly have been used such as digitally altering radiographs to mask the type of implant. Finally, researches should always strive to blind participants, surgeons, other practitioners, data collectors, outcome adjudicators, data analysts involved in the trial. While in this case it would have been impossible to blind the surgeons, researchers can always blind the individuals performing the statistical analysis by simply labelling the groups with non-identifying terms (such as A and B).	None.
	Sham surgery as control. Moreover, in 2012 when INSITE was designed, investigators refused to do sham		Disagree: Sham surgery has been used to study treatments for a variety of conditions,	None.

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	surgery as unethical. It is unclear whether IRBs would have approved such a study. Moreover, it is unclear whether patients participating in such a study would be representative of all patients in general. Commenter states that he would not participate in such a study.		including Parkinson's disease, osteoarthritis, compression fractures, and treatment depression. The Institutional Review Board (IRB) is an administrative body charged with the responsibility of reviewing, prior to its initiation, all research involving human participants. The IRB is supposed to protect from allegations of unethical behavior and has the authority to approve, disapprove, or require modifications in the study. If the IRB deemed sham surgery unethical it would have at least required a modification. There is no indication this control was even proposed to the IRB.	
	Commenter notes that sham is not necessarily a requirement for evaluation; no other spine surgical procedure has been subjected to a sham-control trial and most insurers cover it without requiring such. Why does ACOEM require it? Is sham-control an absolute requirement?		Agree in part; Disagree in part: Agree that sham is not necessarily a requirement, but is important and will impact the strength of evidence evaluation. Disagree: Again, many factors are considered by ACOEM (see response	None.

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	Commenter opines that it would be of interest to read the rest of this document to see if any treatment is recommended without sham... if yes, he states that they are being hypocritical. On **page 667** of the ACOEM guidelines, ACOEM states that trials should have included a "quality rehabilitative program", drawing an analogy to a single trial in lumbar fusion that showed that rehabilitation was effective in that population. There is no proven physical therapy for SIJP(F), so individual practitioners did what they believed was best for individual patients. **INSITE** (US RCT) and **iMIA** (Europe RCT) were therefore real-world, and showed that PT didn't work. iMIA had functional endpoints (e.g., active straight leg raise). The ACOEM guidelines reference to a "functional restoration program", was already delivered in INSITE/iMIA. ACOEM (as his investigators) defined such a program as:		provided above in pages 16-19) and an evidence rating is established by considering the totality of published criteria. Disagree: ACOEM's criticism with SIJF's evidence-base is that there are no quality trials comparing SI joint fusion with a quality rehabilitation program. The two moderate quality RCTs (Polly and Duhon) suggesting improved pain and function, but the comparison groups' treatments are ill-defined exercise. Commenter's statement, "so individual practitioners did what they believed was best for individual patients" is indicative of the vagueness involved with these trials. Neither routinely incorporated a functional restoration program with progressive aerobic and strengthening exercises combined with CBT or sham-control.	None.

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	Functional Restoration: Functional restoration is a blend of various techniques and programs (both physical and psychosocial), rather than one specific set of active exercises, processes or therapies. The basic principle for all of these individually tailored programs is to help LBP patients cope with pain and return to the functional status required for their daily needs and work activities.(37) The term functional restoration program frequently refers to a full-day multidisciplinary, medically-directed program typically lasting from 3 to 6 weeks, employing an interdisciplinary team often consisting of therapists, psychologists, case managers, and nurses.		Disagree: Although Functional Restoration Programs are individually tailored to the needs of each patient, all FRPs aim to restore physical function through targeted increases in physical performance. Again, the comparison groups' treatments are ill-defined exercise. Neither routinely incorporated a functional restoration program with progressive aerobic and strengthening exercises combined with CBT or sham-control.	None.
	Placebo effect. The bottom line is that large effect sizes were seen in INSITE. While some placebo effect might be present, the sheer size of the effect speaks against all of the observed effect being due to placebo. From a payer perspective, it may not be important to determine the proportion of the observed effect that is directly attributable to the device as		Disagree: From a scientific perspective, it is always important to determine the effect of the intervention as opposed to any placebo effect. If the study contains deficiencies with study design or with potential bias as a result of industry sponsorship, it impacts the trustworthiness	None.

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	opposed to placebo. Treated patients feel and perform better.		of the results.	
	Cross-over to surgery. Additionally, investigators were still able to draw conclusions after 6 months due to high crossover. While it is true that INSITE has high crossover, the crossover rate in iMIA was substantially lower. Analyses published at 1 year [7] and 2 years[8] in the *Journal of Bone and Joint Surgery* show that the superiority of SI joint fusion persists at 2 years. Moreover, there is very little evidence that chronic SIJ pain resolves on its own. Thus, the expectation in the control group is continued pain and disability.		Disagree: The control group described by INSITE is described as "non-surgical management" and for iMIA "conservative management." In both cases, they are vaguely defined exercise and neither routinely incorporated a functional restoration program with progressive aerobic and strengthening exercises combined with CBT or sham-control.	None.
	Industry sponsorship and bias. The table of references in the ACOEM document refer to studies being industry-sponsored (and therefore potentially suspect). Commenter points out that the vast majority of		Disagree: It is problematic that there are studies of interventions conducted in clinical settings where there is significant bias to support the organization's clinical business	None.

[7] Dengler J, Kools D, Pflugmacher R, et al. 1-Year Results of a Randomized Controlled Trial of Conservative Management vs. Minimally Invasive Surgical Treatment for Sacroiliac Joint Pain. Pain Physician 2017;20:537–50.
[8] Dengler J, Kools D, Pflugmacher R, et al. Randomized Trial of Sacroiliac Joint Arthrodesis Compared with Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint. J Bone Joint Surg Am 2019;101(5):400–11.

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	high-quality trials of spine surgery-related devices are industry sponsored.[9] Academics have little interest in or expertise to run clinical trials of devices used during spine surgery. Academic-sponsored trials are often made uninterpretable by early massive crossover.[10]		as is the case here. However, industry sponsorship does NOT by itself render a trial biased and untrustworthy. Thus, it is critical that industry sponsored trials apply a strong study design. Here, the issue is with the comparison group that may have been sub-optimally treated. The trials fail to compare SI joint fusion with a quality rehabilitation program.	
	Please note that the commenter has provided comprehensive medical literature supporting why the Division should cover SI joint fusion by supplying a clinical evidence summary and specialty group recommendations. Commenter claims that his material clearly demonstrates that the published clinical literature supporting SI joint fusion is very large and growing. It includes 2 randomized clinical trials, a large multicenter prospective cohort study,		Disagree: Beginning with the most recent RCTs referenced by commenter, the first one is the Polly RCT and the Sturesson RCT were both considered and evaluated by ACOEM and share the same methodology deficiencies that have already been extensively covered in the previous responses. The large prospective cohort study and the independent case series	None.

[9] Cher D. Industry Sponsorship of Spine Device Trials Is the Norm: Neurosurgery 2016;78(3):E475–6.
[10] Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus Nonsurgical Treatment for Lumbar Degenerative Spondylolisthesis. N Engl J Med 2007;356(22):2257–70.

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	long-term follow-up and several independent case series, all of which he opines suggest large and superior improvements in SI joint pain and dysfunction due to low back pain. [Information is available upon request.]		studies are not RCTs and were not referenced in ACOEM's Low Back Disorder's Guideline that is being incorporated by reference into the MTUS. As previously mentioned, ACOEM will only select the highest quality studies to support its treatment recommendations. As is widely accepted in the scientific community, randomized controlled trials (RCTs) are considered the gold standard. Commenter is welcome to submit these lower level studies to ACOEM for consideration through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinput	
	Commenter believes ACOEM's overall conclusions do not take into account most recent data, which includes: • Published 2-year data from		Disagree: See Polly footnote 2432 in the ACOEM Low Back Disorders Guideline. Disagree: Commenter incorrectly references Dengler when the reference should be	None. None.

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	INSITE • 2-year data from iMIA[11] (recently published) that show sustained responses to SI joint fusion. • Published individual-patient pooled analysis[12], showing high levels of consistency of effect size across studies		to Duhon BS. Although ACOEM did not reference the Duhon BS study entitled "Triangular Titanium Implants for Minimally Invasive Sacroiliac Joint Fusion: 2-Year Follow-Up from a Prospective Multicener Trial" this study evaluates the subjects in the iMIA trial that failed to compare SI joint fusion with a quality rehabilitation program. Disagree: The Dengler study referenced as footnote 2439 in ACOEM's Low Back Disorders Guideline was taken into account by ACOEM and did not change its conclusion because of the methodology deficiencies extensively discussed.	None.

[11] Dengler J, Kools D, Pflugmacher R, et al. Randomized Trial of Sacroiliac Joint Arthrodesis Compared with Conservative Management for Chronic Low Back Pain Attributed to the Sacroiliac Joint. J Bone Joint Surg Am 2019;101(5):400–11.
[12] Dengler J, Duhon B, Whang P, et al. Predictors of Outcome in Conservative and Minimally Invasive Surgical Management of Pain Originating from the Sacroiliac Joint: A Pooled Analysis. Spine 2017;42(21):1664-1673 [Epub 2017 Mar 27].

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	• Published 4-year prospective data[13] showing sustained responses		Disagree: As previously mentioned, ACOEM will only select the highest quality studies to support its treatment recommendations. As is widely accepted in the scientific community, randomized controlled trials (RCTs) are considered the gold standard. Commenter is welcome to submit these lower level studies to ACOEM for consideration through the following web address: https://acoem.formstack.com/forms/stakeholderpatientinput	None.
	Commenter states that the following information illustrates the amount of coverage and use of iFuse: • More than 260 million covered lives in US • Of the last 30 commercial payer plans to publish		Disagree: ACOEM will only select the highest quality studies to support its treatment recommendations. This insistence on meeting a rigorous standards that incorporates criteria by the US	None.

[13] Darr E, Cher D. 4-year outcomes after minimally invasive transiliac sacroiliac joint fusion with triangular titanium implants. Med Devices Evid Res 2018;11:287–9.

EVIDENCE-BASED UPDATES TO THE MEDICAL TREATMENT SCHECULE (MTUS)	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	coverage policies, all but 2 only cover iFuse ONLY because of the superior clinical evidence • We are also seeing many plans write in surgeon ONLY coverage so there is not overutilization by pain doctors and to ensure that there are optimal results as this is a real surgery albeit it is a minimally invasive surgery • ODG is also working on coverage according to the Managing Director, Phil LeFevre. • French National Authority for Health (HAS) recommends exclusive coverage • NICE exclusive recommendation to the UK healthcare system		Institute of Medicine (IOM), the international GRADE Working Group, AGREE II, and AMSTAR, coupled with the transparency of its methodology, is an important reason why the DWC continues to select the ACOEM guidelines for incorporation into the MTUS.	
9792.23.5 – Low Back Disorders Guideline	Commenter is Vice President of Clinical Affairs at SI-BONE. SI-BONE is a device manufacturer of the iFuse Implant System. Commenter notes that sacroiliac joint	Daniel Cher, MD Vice President of Clinical Affairs SI-BONE May 6, 2019 Oral Comment	Agree. Agree.	None. None.

EVIDENCE-BASED UPDATES TO THE MEDICAL TREATMENT SCHECULE (MTUS)	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	pain is a medical condition that comprises 15 to 30 percent of all chronic low-back pain. Commenter states that this condition has been studied for years and that the first surgical procedure on chronic sacroiliac joint pain was performed in 1908 and that was 24 years before the first lumber spine surgery procedure was performed. Commenter states that currently, there are both non-surgical and surgical treatments for sacroiliac joint pain. Non-surgical treatments consist of rest, medication, physical therapy, SI joint steroid injections, RF ablation of the lateral branches of the sacral nerve roots. Commenter notes that none of these procedures has been proven in high quality clinical trials to effect chronic SI joint pain. Commenter states that surgical treatments for SI joint pain include both open surgery and minimally invasive surgery. He notes that open surgery is no longer commonly performed, but typically requires a large incision and is a long surgery		Disagree: For patients with proven rheumatologic inflammatory disease of the sacroiliac joints (e.g., ankylosing spondylitis), SIJ injection has evidence of efficacy and is commonly managed successfully with corticosteroid injection therapy. Agree.	None. None.

EVIDENCE-BASED UPDATES TO THE MEDICAL TREATMENT SCHECULE (MTUS)	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	with substantial blood loss. Recovery from such a surgery takes many months and the results have been less than impressive.			
	Commenter notes that minimally invasive SI joint surgery was started in 2008 with the implant that his company manufactures. Since then, his company has done two prospective randomized controlled clinical trials against the non-surgical treatment.		Agree.	None.
	Commenter states that the ACOEM guidelines have mentioned one of those SI joint randomized clinical trials, but that they did not reference the other randomized clinical trial, so from his perspective their evaluation of the procedure is somewhat incomplete.		Disagree: The two SI joint randomized clinical trials (INSITE, iMIA) are referenced in ACOEM's Low Back Disorders Guideline.	None.
	Commenter states that to date, the ACOEM guidelines have considered only that one published randomized trial. He states that there are over 60 publications of SI joint fusion using his company's device and that these publications generally show that patients derive substantial benefit		Disagree: See above response. There are no quality trials comparing SI joint fusion with a quality rehabilitation program. There are two moderate quality RCTs (Polly and Duhon) suggesting improved pain and function,	None.

EVIDENCE-BASED UPDATES TO THE MEDICAL TREATMENT SCHECULE (MTUS)	RULEMAKING COMMENTS 30 DAY COMMENT PERIOD	NAME OF PERSON/ AFFILIATION	RESPONSE	ACTION
	from this procedure. He states that there is now a prospective five year follow-up and that the four year follow-up has been published. The five year follow-up is nearing completion and should be published this summer. He notes that in general, all of the publications show marked homogeneity with marked prolonged and sustained responses to SI joint fusion.		but the comparison groups' treatments are ill-defined exercise and neither routinely incorporated a functional restoration program with progressive aerobic and strengthening exercises combined with CBT or sham-control. ACOEM will only select the highest quality studies to support its treatment recommendations. As is widely accepted in the scientific community, randomized controlled trials (RCTs) are considered the gold standard.	
	Commenter states that the ACOEM guidelines note that the clinical trials supporting SI joint fusion did not include a Sham procedure. In February 2012, commenter was discussing SHAM surgery with physicians who could participate in this study. He notes that they all uniformly rejected that as unethical, unlikely to be approved by their IREs, and unlikely to be accepted by patients. After hearing this,		Disagree: Sham surgery has been used to study treatments for a variety of conditions, including Parkinson's disease, osteoarthritis, compression fractures, and treatment depression. The Institutional Review Board (IRB) is an administrative body charged with the responsibility of reviewing, prior to its initiation, all research	None.

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	commenter decided that the next best option would be to do a non-surgical treatment control – a real-world trial that compared their surgical procedure versus maximal non-surgical therapy, which included medications, physical therapy, SI joint steroid injections, and RF ablation. Commenter notes that both trails showed that non-surgical therapy in this particular condition was ineffective, whereas, the surgery procedure resulted in large improvements of pain, disability, and quality of life. For these reasons, commenter encourages the division to continue its support of SI joint fusion surgery.		involving human participants. The IRB is supposed to protect from allegations of unethical behavior and has the authority to approve, disapprove, or require modifications in the study. If the IRB deemed sham surgery unethical it would have at least required a modification. There is no indication this control was even proposed to the IRB. The primary deficiency, as already mentioned, is the ill-defined non-surgical treatment control. The comparison groups' treatments are ill-defined exercise and neither routinely incorporated a functional restoration program with progressive aerobic and strengthening exercises combined with CBT or sham-control.	
	Commenter states that positive health technology assessments are available from multiple other organizations, specifically with respect to the iFuse Implant System, for which the vast		Disagree: ACOEM's methodology incorporates the high standards and criteria widely accepted by the US Institute of Medicine (IOM),	None.

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	majority of the literature covers. Those technology assessments are from NICE in the UK, the French Health Authority, eviCore, the Blue Cross/Blue Shield Association, MCG, NASS, for the National Association of Spinal Surgeons, and ISASS, the International Association of Spinal Surgeons, and ISASS, The International Society for the Advancement of Spine Surgery.		the international GRADE Working Group, AGREE II, and AMSTAR. A similarly rigorous review should result in similar recommendations or conclusions.	