Local Coverage Article:
Response to Comments: Facet Joint Interventions for Pain Management (A58613)

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Article Guidance

Article Text:

This article combines comments received from the above MACs in response to the LCD draft Facet Joint Interventions for Pain Management.

CGS Administrators, LLC received commented on proposed policy DL38773-Facet Joint Interventions for Pain Management from October 8, 2020 through November 22, 2020. Comments were received from the provider community. The notice period begins March 11, 2021 through April 25, 2021. The LCD becomes final on April 26, 2021.

Response to Comments



Response to Comments

NUMBER	COMMENT	RESPONSE
1	**Covered Indications Facet Joint Interventions** A letter with multiple comments was received from the American Society of Interventional Pain Physicians (ASIPP), American Society of Neuroradiology, and American Society of Spine Radiology and the state chapters for Kentucky, Ohio, Florida, Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia, Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, California, Hawaii, and Nevada Societies of Interventional Pain Physicians. The comment states they strongly support the evidence-based, medically reasonable and necessary criteria for facet joint interventions. The comment explains the ASIPP membership and role and states that within the LCD "multiple other organizations	Thank you for your support for evidence-based medically reasonable and necessary criteria for facet joint interventions. The goal of an LCD is not to represent specific specialties or organizations but to evaluate the body of literature and evidence on the topic from multiple different specialties and sources. The input from interventional pain providers is critical, and we thank you for your input. We also seek to include surgeons, primary care, and the full spectrum of providers involved in the multi-modality care of the Medicare patient. A review of the literature is not limited to United States publications. In the policy, we reference the 2020 ASIPP Guidelines, which includes international literature. The policy strives to include literature representing the full spectrum of the condition and not preferential to any specific societies, guidelines, or journals and focuses on a broad representation of the topic and quality of evidence.

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	which are prominently quoted in the evidence are not only international, but also interested in interventional pain management only peripherally. Their main goals are totally different being either surgical interventions, neuromodulation, or spinal injections with majority of practice by physicians without fellowship in pain medicine or without certification in pain medicine, either by American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA), American Board of Interventional Pain Physicians (ABIPP), or American Board of Pain Medicine."	
2	**Diagnostic facet joint procedures: (IA or MBB) -** The first sentence under this section is as follows: The primary indication of a diagnostic facet procedure is to confirm a clinical suspicion of facet syndrome. Intraarticular (IA) facet block(s) are considered reasonable and necessary as a diagnostic test only if medial branch blocks (MMB) cannot be performed due to specific documented anatomic restrictions. These restrictions must be clearly documented in the medical record and made available upon request. **ASIPP** comments that this will necessitate those individuals undergoing intraarticular injections to undergo medial branch blocks. If a physician desires to treat a patient with therapeutic intraarticular injections, utilization of intraarticular injections is appropriate for diagnostic purposes. Suggested language was provided.	In cases where therapeutic injections will be utilized, intraarticular injections, rather than medial branch blocks, are appropriate and the LCD has been changed accordingly.
3	**Diagnostic facet joint procedures: (IA or MBB) -** The second sentence under this section is as follows: Diagnostic procedures should be performed with the intent that if successful, radiofrequency ablation procedure would be considered the primary treatment goal at the diagnosed level(s). **ASIPP**- The commenter state that the decision between therapeutic blocks and radiofrequency ablation should be based on patient choice and medical condition with shared decision making. They state there is extensive evidence supporting	As explained in the LCD, this is an area of great controversy with differing opinions among subject matter experts and conflicting medical evidence. While there is published support for therapeutic injections, most of the evidence and guidelines do not support therapeutic intraarticular injections. This includes multiple studies, systematic reviews, and guidelines, including guidelines published by NASS, NICE, AHRQ, AANS, and CNS. In the multidisciplinary 2020 consensus guidelines, developed by representatives from a dozen pain societies including the US Department of Veterans affairs, multiple different specialties and with US and international representation states the use of therapeutic injections received a "D" rating consist

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	therapeutic facet joint nerve blocks, both MBB and IA. they recommend changing the language to allow treatment with either therapeutic blocks or radiofrequency ablation. They state based on the evidence, therapeutic facet joint procedures, both intraarticular injections and medial branch blocks are effective. With emerging evidence without overwhelming negative evidence, we believe that it would be inappropriate to issue a noncoverage policy for one or both procedures. This comment also discusses cost of the procedures.	with a recommendation against the intervention with moderate to high certainty evidence that the service has no net benefit or that the harm outweighs the benefit. The equates to the suggestion for practice to discourage the use of this service. This contrasts with the guidelines published in the 2020 ASCIPP Guidelines, which supports the use of therapeutic injection stating level II evidence of support based on three RCTs. Level II evidence requires at least one relevant, high-quality RCT or multiple moderate or low-quality RCTs per these guidelines. However, the evidence for therapeutic injections is largely based on three RCTs compared to RFA, where there are>10 RCTs. Also, there are at least eight RCTs and multiple observational studies that did not demonstrate the benefit of therapeutic injections.
	California Society of Interventional Pain Physicians comments that the third criterion of documentation of why the patient is not a candidate for RFA is too narrow. There are many reasons why a patient might prefer therapeutic injections beyond pseudarthosis or implants. Alternative language was provided.	The controversy is evident among the subject matter experts. In the contract advisory committee meeting, the experts were divided on this topic. While most experts did not support the routine use of therapeutic injections, it was clear the experts felt there is a clinically significant role in select patients. Based upon this feedback and emerging evidence without overwhelming negative evidence, we ensured access to care by allowing therapeutic injections for this population, allowing the provider to make that judgment if they can provide a rationale for their decision.
	A comment was received from American Academy of Physical Medicine and Rehabilitation, American Society of Neuroradiology, American Society of Spine Radiology, North American Spine Society, Society of Interventional Radiology, Spine Intervention Society which states intraarticular facet joint injections often include local anesthetic and steroid, thereby making the injection both diagnostic and therapeutic. Some patients will obtain at least 50% relief from a single intraarticular injection of steroid and pain relief can be reinstated every three months with a subsequent injection. Requiring documentation of why radiofrequency neurotomy should not be performed in patients being treated with therapeutic intraarticular facet injections creates unnecessary work for the physician that will not result in improved patient care	In terms of documentation of why a patient is not a candidate for RFA, it must be determined by the provider and patient. There are examples in the LCD, but this is not an inclusive or restrictive list. In all cases, we require documentation to explain the rationale for proceeding with therapeutic injections, which would be a standard part of shared decision-making discussions and expected in medical documentation.

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	(e.g. edematous joint/surrounding bone, whiplash injuries). A comment was received from **Abbott Neuromodulation** supporting the use of intra-articular injections as a useful therapeutic tool in carefully selected patients. Comment received from Dr. Josh Suderman, Vice President of Javery Pain Institute states concern regarding the possible elimination of therapeutic medial branch blocks and facet joint injections for the management of facet-joint mediated axial low back pain and changes to the requirements for radiofrequency ablation of the medial branch nerves to treat facet-joint mediated pain. A comment from Dr. Bryce Shellman about adding indications for intra-articular steroid-based facet joint injections for cervical acceleration-deceleration type injuries.	
4	**Diagnostic facet joint procedures: (IA or MBB) -** The second diagnostic procedure may only be performed a minimum of 2 weeks after the initial diagnostic procedure. **ASIPP-** This comment was in agreement with the 80% improvement and 2 week waiting period between diagnostic injections. This is followed by a review of the literature to support acute improvement in pain following local anesthetics alone that in some cases may be long lasting. **AMERICAN ASSOCIATION OF NURSE ANESTHETISTS** comments the draft LCD states, "[t]he second diagnostic procedure may only be performed a minimum of 2 weeks after the initial diagnostic procedure." Diagnostic injections done with local anesthetic only (i.e., Bupivacaine) can be expected to provide pain relief for the duration of the 1/2 life of the medication used. For a purely diagnostic procedure, it does not benefit the patient to wait two weeks for the second confirmatory injection as	Published literature by Manchikanti et al. describes the acute pain model vs. chronic pain models. In the acute model, pain relief is limited to the duration of the pharmacological action of local anesthetic. In chronic pain, model relief may last beyond the pharmacological duration of action, which challenges the concept that the pain relief achieved from local anesthetic alone is limited to the half-life of the anesthetic. They reported pain relief at ≥80% for six days for lidocaine alone and 11.86 for bupivacaine alone(1). They also reported long-term relief in many patients, serving as the basis for their support for therapeutic injections. However, relief is variable, with a duration of effect ranging from several hours to months in the literature. Due to the potential of continued pain relief, especially during the first two weeks after diagnostic injection, the duration between injections will remain at two weeks to provide the most accurate diagnosis. We recognize the concerns of extenuating circumstances, such as the need to reverse anticoagulation, to perform the procedure to increase the patient's clinical risk by waiting for the

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	waiting for two weeks only prolongs the patient's pain experience. two to three days is enough time to calculate the level of pain relief and improvement of daily activities of living. Therefore, we would recommend decreasing the time frame from two weeks to one week. This would result in the patient receiving pain relief in a shorter time frame. **The American Academy of Physical Medicine and Rehabilitation, American Society of Neuroradiology, American Society of Spine Radiology, North American Spine Society, Society of Interventional Radiology, Spine Intervention Society** requests that the duration between diagnostic procedures be revised from a minimum of two weeks to a minimum of 48 hours. There is no medical rationale for requiring two weeks between diagnostic injections. The diagnostic protocol simply requires enough time that the effect of the local anesthetic has worn off and that the index pain has returned to baseline. With the duration of effect of local anesthetics being significantly less than 48 hours, establishing 48 hours as the minimum will facilitate expeditious diagnosis and treatment, and will reduce hardships (e.g. lost wages, travel expenses, childcare) for patients who must travel a distance for treatment. **Florida Society of Interventional Pain Physicians** comments 2 weeks between blocks is unnecessary. We are unaware of any literature that requires a minimum of 2 weeks between blocks. Additionally, many physicians discontinue blood thinners for facet injection and ablation, and many more for any deep injection into the cervical spine, which will incur great risk to the patients. The current recommendations from the American Board of Anesthesiology include discontinuation of blood thinners for neuraxial blockade for 5 half-lives. Consequently, the patient would be off their blood thinners for 4 to 10 days at a time for weeks to accomplish a Radiofrequency Ablation. The potential complications of discontinuing blood thinners are serious.	two-week duration. Therefore, we will consider exceptions to the two-week duration under these extenuating circumstances. Comments regarding the percentage of pain relief and improvement required to define success are discussed in #5.

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	American Society of Regional Anesthesia and Pain Medicine recommends that the draft LCDs be revised to eliminate the requirement for a follow-up confirmatory diagnostic facet procedure, the requirement to wait two weeks when a second diagnostic procedure is medically necessary, and the limitation on use of facet joint procedures in patients with generalized pain conditions. ASRA is concerned that the proposed requirements for diagnosing facet syndrome are too restrictive and would limit access to effective treatments for individuals who may not meet the stringent criteria, but who nevertheless could benefit from facet joint interventions.	
	North American Neuromodulation Society & American Society of Anesthesiologists agrees that a second diagnostic facet procedure is considered medically necessary to confirm the validity of the initial diagnostic procedure when administered at the same level. However, we request that the duration between diagnostic procedures be revised from a minimum of two weeks to a minimum of 48 hours. There is no medical rationale for requiring two weeks between diagnostic injections. The diagnostic protocol simply requires enough time that the effect of the local anesthetic has worn off and that the index pain has returned to baseline. With the duration of effect of local anesthetics being significantly less than 48 hours, establishing 48 hours as the minimum will facilitate expeditious diagnosis and treatment, and will reduce hardships (e.g. lost wages, travel expenses, childcare) for patients who must travel a distance for treatment.	
	David M. Sibell, MD, Professor, Oregon Health &	

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	Science University, Anesthesiology & Perioperative Medicine Comprehensive Pain Center comments the requirement for a second diagnostic procedure to be done at a minimum of 2 weeks after the initial diagnostic blocks needs to be better explained. As the duration of action of the local anesthetic block is generally brief (hours), a repeat diagnostic block could be done sooner. There is no evidence to suggest a prolonged carryover analgesia from these blocks. Our patients frequently travel long distances and being able to repeat the diagnostic injection within a smaller window (i.e. one week), would greatly improve patient convenience. It is recommended that the guidelines are changed to allow repeating the diagnostic block 1 week after the first block.	
	California Radiological Society, Washington State Radiological Society agree wholeheartedly that a second diagnostic facet procedure is considered medically necessary to confirm the validity of the initial diagnostic procedure when administered at the same level. However, we request that the duration between diagnostic procedures be revised from a minimum of two weeks to a minimum of 48 hours. There is no medical rationale for requiring two weeks between diagnostic injections. The diagnostic protocol simply requires enough time that the effect of the local anesthetic has worn off and that the index pain has returned to baseline. With the duration of effect of local anesthetics being significantly less than 48 hours, establishing 48 hours as the minimum will facilitate expeditious diagnosis and treatment, and will reduce hardships (e.g. lost wages, travel expenses, childcare) for patients who must travel a distance for treatment.	
	Abbott Neuromodulation states_utilization of two medial branch blocks (MBBs) resulting in pain relief	

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	of 80% or higher is the best diagnostic tool to diagnose facet-mediated pain for any spinal region and is supported by Abbott. However, we do not support the two-week separation of the first block and the second block procedures, as the duration of pain relief should be consistent with the anesthetic used. Most anesthetics do not have a duration of two weeks and would have no other effect than delaying treatment for a patient needing pain management.	
5	**Therapeutic Facet Joint Procedures**– Patients with two (2) medically reasonable and necessary diagnostic facet joint procedures with each one providing a consistent minimum of 80% relief of primary (index) pain. **North American Neuromodulation Society & American Society of Anesthesiologists** comments with regard to the criteria for 80% relief of primary index pain, we recommend this be changed to 50% relief of primary index pain relief. **The University of Utah Department of Anesthesiology** requested modification of the percent of pain relief required to designate a diagnostic block as positive from 80% in the proposed policy to 50%. **Florida Society of Interventional Pain Physicians** comments in their jurisdiction greater than 50% relief of pain was the target to move forward with Radiofrequency Ablation. While the evidence may support 80% relief to avoid false positives, recognize that the literature predominantly includes patients of all ages and excludes patient with cognitive impairment. **North American Neuromodulation Society & American Society of Anesthesiologists** comments we fully support requiring at least two medically reasonable and necessary diagnostic medial branch blocks, with each providing a minimum of 50% relief of primary (index) pain.	There is significant controversy on the percentage of improvement to be a candidate for a diagnostic block to be considered successful. This is exemplified by the comments received. While there Is emerging data on the use of fewer diagnostic blocks and lower percentage for cut off, most studies on facet interventions utilize the 80% cut-off (at least 10 studies as reviewed in the 2020 ASIPP Guidelines[1]). Most societal guidance supports the 80% cut off and two diagnostic block criteria. In the literature to support a lower cut-off the authors acknowledges that the existing evidence does not adequately address the 50-80% group(2). The existing evidence is clear there is a high risk of false positives with a single block and 50% cut off, and that a dual block and higher cut-off (75-80%) improves diagnostic accuracy. The evidence also supports that improved diagnostic accuracy predicts greater improvement with RFA treatments. While there is high quality evidence that demonstrates patients with dual blocks using ≥80% relief are more likely to show a positive response to RFA and is consistent with several societal guidelines. While this must be balanced against excluding some patients for treatment who may potentially benefit, given the lack of supporting literature to define this population, current evidence supports dual blocks at 75-80% improvement is more strongly supported than the alternative less stringent approach. If additional literature can further define this population and provide support for a lower cut-off that can be considered through the reconsideration process.

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	Florida Society of Interventional Pain Physicians opposes dual block requirement, expresses concern the second block will extend the waiting period for Radiofrequency Ablation and offer alternative language. **North American Neuromodulation Society & American Society of Anesthesiologist** agree that a second diagnostic facet procedure is considered medically necessary to confirm the validity of the initial diagnostic procedure when administered at the same level. **California Radiological Society, Washington State Radiological Society s**tates we fully support requiring at least two medically reasonable and necessary diagnostic medial branch blocks, with each providing a consistent minimum of 80% relief of primary (index) pain with the duration of relief being consistent with the agent used. The benchmark studies of radiofrequency neurotomy used 80% to 100% relief thresholds following dual comparative local anesthetic blocks. The three studies achieved the best results heretofore reported in the literature. An impressive 55-60% of patients experience at least 80% pain relief lasting at least one year and that relief can be reinstated by repeating the procedure. References were included. **ASIPP** agreed with the 80% improvement and 2 week waiting period between diagnostic injections. **Abbott Neuromodulation** comments the utilization of two medial branch blocks (MBBs) resulting in pain relief of 80% or higher is the best diagnostic tool to diagnose facet-mediated pain for any spinal region and is supported by Abbott.	

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	The American Academy of Physical Medicine and Rehabilitation, American Society of Neuroradiology, American Society of Spine Radiology, North American Spine Society, Society of Interventional Radiology, Spine Intervention Society supports requiring at least 80% relief of index pain for the duration of relief consistent with the agent used in the first diagnostic block. Dual comparative blocks are advocated as a means of identifying true positive cases and excluding placebo responders and have been shown to have a sensitivity of 100% and a specificity of 65%. Evidence strongly supports reliance on 80-100% relief from dual diagnostic blocks to select patients for subsequent medial branch radiofrequency neurotomy. **The University of Utah Department of Anesthesiology** comments to the optimal number of diagnostic blocks performed prior to thermal RFA, as discussed in the consensus guidelines appropriately compromised on one diagnostic block required prior to thermal RFA to balance cost, access to care, and procedural risk. In regard to the cutoff of percent pain relief to consider a diagnostic block successful, the majority of published studies conducted for facet joint interventions have used a value of 50%. Additionally, as detailed in the consensus guidelines, several studies have directly compared cutoff vales of 50-70% or >80% and found no difference in efficacy outcomes after thermal RFA. They also requested the removal of the requirement for a second diagnostic block prior to initial thermal RFA based on the Cohen 2020 paper which recommends a single block. Dr. Helm and Dr. Snook of IMPAC: They expressed concern that the criteria for therapeutic facet injunctions is too narrow and provide alternative language.	
6	**Diagnostic facet joint procedures: (IA or MBB)** - at least 50% consistent objective improvement in the ability to perform activities of daily living (ADLs).	During the CAC meeting there was extensive discussion the use of functional measurement as part of evaluation of success with facet joint procedures. The panel agreed that measurement of function can provide valuable clinical input into

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	Abbott Neuromodulation support the medical necessity criteria of 50% improvement in activities of daily living (ADLs) for facet neurotomy procedures. However, additional clarity is required to establish a consistent standard for 50% ADL improvement. **The American Academy of Physical Medicine and Rehabilitation, American Society of Neuroradiology, American Society of Spine Radiology, North American Spine Society, Society of Interventional Radiology, Spine Intervention Society** states there insufficient evidence to support the new, alternate criteria proposed — "at least 50% consistent objective improvement in the ability to perform previously painful movements and activities of daily living (ADLs)". We encourage further consideration of how this improvement will be accurately quantified, measured, and reported. **California Radiological Society, Washington State Radiological Society** states there is insufficient evidence to support the new, alternate criteria proposed — "at least 50% consistent objective improvement in the ability to perform previously painful movements and activities of daily living (ADLs)" and offers alternative language. **California Society of Interventional Pain Physicians e**xpressed concern about the use of the criterion of 50% objective improvement. Inclusion of functional improvement was voted for however, when reviewing the discussion appended to the LCD, the concept had been expanded to mandate the use of specific tests of function. We suggest after the first diagnostic facet joint procedure, there must be a consistent positive response of at least 80% relief of	improvement such as the ability to stand, walk and do activities of daily living. There are multiple tools to measure function. However, these comments raise notable concerns that the clinical literature utilizes a percent improvement on VAS scales to measure response to diagnostic injections and to measure success of radiofrequency ablation. There are not standardized cut-off values for measurement of function in the published literature. We agree with the comments that we need a clear standard for measurement. Based on the current evidence functional measurement is appropriate for evaluation of long-term success with the procedure, but not for the initial diagnostic evaluation to determine if patient is an appropriate candidate for RFA procedure. Therefore, the functional assessment will be removed from the diagnostic section. The criteria for functional measure was already included in evaluation of success for therapeutic facet joint procedures and denervation procedures and will remain. As commenters suggested the language was revised from ADLs to provocative maneuvers to provide clarity. However, since the existing pain do not include provocative maneuvers and measure many aspects of ADLs, and we are no longer including under diagnostics we will retain ADLs. Also, the LCD requires pain and function to be measured and documented at baseline, and at each follow-up using the same pain or disability scale for each assessment. Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OSW), Quebec Back Pain Disability Scare (QUE), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the PROMIS profile domains are several functional scales that can be used to access function used to measure if the required 50% improvement from baseline is achieved.

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	primary (index) point (with the duration of relief being consistent with the agent used) and improvement in the ability to perform previously painful movements. **Dr. Micheal Kenosh, Vermont Orthopaedic Clinic Spine Care:** "I wholeheartedly agree that functional improvement should be followed in our patients, with specifics instead of vague indices for improvement. In my experience, however, there is no reliable literature that uses stand-alone improved function on any assessment tool as a reliable indicator or predictor for clinical success with MBB and RF. The suitable ADL measurement/Disability scales that would be approved for use should not be used as primary inclusion criteria but should only be regarded as a supporting tool to judge the post-procedure VAS score. In other words, success with RF in the literature is best correlated with VAS ratings, not with improvement in various functional scales. I agree it may not be optimal, but in this day and age it is all that we have to go by. These scales should be reserved for managing our patients over time and judging eventual procedural success. They should not be used to exclude candidates in the short term from obtaining RF" ASIPP Expresses concern that the language surrounding function is vague and confusing and provide recommended change from ADLs to "previously painful movements or provocative maneuvers". **Dr. Hlem and Snook of IMPAC:** Expresses concern That there are not validated tools to measure the effectiveness of functional improvement as part of the diagnostic evaluation. They state that the current tools to measure disability are not standardized for this use and they are not aware of any supporting literature that test the presence or absence of functional improvement after diagnostic medial branch. They provide alternative language.	
7	**Facet Joint Denervation –** In the Limitations Section - Number of spinal levels that can be treated	A facet level is defined in the LCD definition section Facet Level- refers to the zygapophyseal joint or

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	with RFA per session. **ASIPP** objects to the limitation to one to two levels stating it may not be appropriate to limit to one or 2 joints, either unilateral or bilateral with suggested language. **Abbott Neuromodulation** request the final LCD provide clarification and definition regarding the number of spinal levels that can be treated with RFA per session and believe that the levels should be clarified as (one or two) spinal levels. They request a definition for level in the LCD. **AMERICAN ASSOCIATION OF NURSE ANESTHETISTS r**equest clarification regarding the policy on coverage of 4 spine injections. We would request clarification if the policy limits four injections total or four injections per region for a total of eight possible injections in a given year. **Florida Society of Interventional Pain Physicians** comments that the limit to one or two (2) joints, either unilateral or bilateral is overly restrictive and may significantly limit treatment options and request the language to include three (3) joints for diagnostic blocks and (4) four joints for Radiofrequency Ablation. Additionally, providing one side at a time either right side or the left for a three (3) joint diagnostic injection allows the contralateral side to serve as a control. **North American Neuromodulation Society & American Society of Anesthesiologists** disagree with limitation 6, which states "one to two levels,	the two medial branch (MB) nerves that innervate that zygapophyseal joint. Each facet level in the spinal region comprises bilateral facet joints (i.e., there are two facet joints per level, one on the right side and one on the left). A session is a period, which includes all procedures (i.e., medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RFA ablations) performed during one day. **Response:** A facet level is defined in the LCD definition section Facet Level- refers to the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint. Each facet level in the spinal region comprises bilateral facet joints (i.e., there are two facet joints per level, one on the right side and one on the left). A session is a period, which includes all procedures (i.e., medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RFA ablations) performed during one day. **Region-** The segments of the back involved will be define in this policy as two regions: Cervical/Thoracic region= C1-C7/T1-T12 and Lumbar/Sacral region= L1-L5/S1-S5. This means in one session (same day), a provider can inject a maximum of two levels bilaterally within one region. Facet joint interventions (both diagnostic and therapeutic) are limited to one spinal region per session. Limitations #3 in the policy states "It is not expected that patients will routinely present with pain in both cervical/thoracic and lumbar spinal regions. Therefore, we are referring to one region per session. This means a maximum of one injection on the right and one on the left in two separate joints for a **total of four injections in one region** (cervical/thoracic or lumbar-sacral) per session (same day). For unilateral injections, this means a maximum of two injection on the right or two on the left in two separate joints within one region for a **total of two injections.** Despite the support from the pain management

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	either unilateral or bilateral, are allowed per session per spine region"]. We believe this is inconsistent with the real world. Patients may have disease confined to one or two levels or may have disease at multiple levels. Degenerative spondylosis and facet disease frequently do not isolate to one or two levels. This limitation would negatively impact physicians' ability to optimize patient outcomes. We recommend this limitation be revised to three facet levels for unilateral or bilateral injections. **David M. Sibell, MD, Professor, Oregon Health & Science University, Anesthesiology & Perioperative Medicine Comprehensive Pain Center t**he term "level" is confusing in this setting and should be clarified. **Dr. Grahling member of ASIPP and President of CT Pain Society** states Limiting facet joint ablations to 1-2 levels will result in undertreatment of very treatable pain and lead to an increase in opioid prescriptions unnecessarily and inappropriate surgical interventions. Many patients have 3, even 4 level facet joint disease.	community demonstrated above to allow three or more levels routinely, this practice is not supported in the medical literature. No supporting literature was provided with the above comments that support the concept that the facet pain may extend routinely beyond 1-2 levels. During the CAC meeting, prevalence data was shared, demonstrating L4/L5 followed by L5/S1 levels comprise around 80% of the overall prevalence for lumbar spinal pain. In the cervical spine, C2/3 represents 50%, followed by C5/C6 and C6/7. This was correlated with Medicare national data, which demonstrates that most facet procedures involve 1-2 levels, with more than two levels being in the minority of procedures performed. If additional literature is published in peer-reviewed journals that provide evidence of the medical necessity for treating three or more levels in the same session, this can be considered on reconsideration.
8	**Repeat or additional diagnostic MBB or intraarticular injections after 24 months at the same site previously treated with facet joint injections** **ASIPP** commented repeat or additional diagnostic MBB or intraarticular injections after 24 months at the same site previously treated with facet joint injections is necessary, only when there is a significant change in pathophysiologic process. We believe that repeat or additional diagnostic medial branch blocks or intraarticular injections are not necessary and not appropriate.	This was not intended to repeat diagnostics for patients who were successfully treated with facet joint interventions. The intent of this limitation was for circumstances in which patients have not had any treatments in over two years to be re-revaluated to ensure correct diagnosis before treatment. The LCD has been revised to clarify this.

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	Abbott Neuromodulation does not agree that patients who received 24 months of relief from a RF neurotomy should be required to receive additional MBB's. Since the RFA treatment was effective and durable, additional diagnostic blocks should not be required to continue treatment. **A comment was received from American Academy of Physical Medicine and Rehabilitation, American Society of Neuroradiology, American Society of Spine Radiology, North American Spine Society, Society of Interventional Radiology, Spine Intervention Society** AND **California Radiological Society, Washington State Radiological Society** repeating medial branch blocks after 24 months of pain relief from radiofrequency neurotomy is not necessary. If patients experienced more than 24 months of relief from the procedure, a repeat neurotomy should be permitted at the same level to reinstate relief. Comment: I concur that it is not generally necessary to repeat MBBs where there has been a successful RFD. However, according to the rubric mentioned above, would they be required (and, thereby, not prohibited) if it had been more than 24 months since the last RFD? What is the directive on a patient who has pain relief longer than 24 months, but then has the same pain recurring later? Would you please clarify these requirements? **North American Neuromodulation Society & American Society of Anesthesiologists** recommend that number 6 under the not reasonable and necessary and therefore denied section, which states, "diagnostic injections or MMB at the same level as the previously successful RFA procedure," [page 6] be amended. It should instead state,	

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	"diagnostic injections or MMB at the same level as the previously successful RFA procedure unless it has been an extended period of time (greater than three years) since the last RFA and/or there is a question as to the source of the recurrent pain".	
9	**Limitations - Facet joint procedure performed at a fused posterior spinal motion segment.** **ASIPP** suggest the removal of Facet joint procedure performed at a fused posterior spinal motion segment from limitations. This seems to be unnecessary. Facet joint pain is not based on instability, rather it is an inflammatory mechanism, which may be somewhat related to the instability or fusion. **AMERICAN ASSOCIATION OF NURSE ANESTHETISTS** requests clarification regarding the rationale behind the policy not applying radiofrequency to the fused posterior elements. This does not address a fused anterior segment. Anterior Lumbar Interbody Fusion or ALIF) that does allow for movement and subsequent pain generated from the posterior segment. Our concern is with the heating of the fused metal within the pedicle. This is not a major consideration in the ALIF, but it is a fused lumbar segment. **Florida Society of Interventional Pain Physicians** comments facet joint pain is an inflammatory mechanism; patients that undergo fusion can proceed to neuroma formation and inflammation of the facet joint. Many patients who have undergone fusion respond favorably to Radiofrequency ablation. Removing this therapeutic option will drive patients to implantable therapy or repeat surgery, which may not be necessary.	There is a paucity of literature to address use of RFA in this region. We will remove this restriction for fused posterior segments and add the restriction for anterior lumbar interbody fusion where there is concern.
10	**Facet interventions represent an important**	Thank you for your comment. A comment was

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	conservative therapeutic tool for chronic pain patients A comment was received from Abbott Neuromodulation expressing their agreement that facet interventions represent an important conservative therapeutic tool for chronic pain patients, and it is critical that all MACs ensure proper coverage guidelines for this treatment modality. Alternative therapies may include the use of chronic opioids or other more expensive procedures that provide a marginal expectation of success.	received from Abbott Neuromodulation expressing their agreement that facet interventions represent an important conservative therapeutic tool for chronic pain patients, and it is critical that all MACs ensure proper coverage guidelines for this treatment modality. Alternative therapies may include chronic opioids or other, more expensive procedures that provide a marginal expectation of success.
11	**Facet joint interventions are reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet the following inclusion criteria (LCD Letter A)** A comment was received from **Abbott Neuromodulation** expressing their support that facet joint interventions are reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet the following inclusion criteria: 1. Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale* 2. *Pain assessment must be done at baseline, after diagnostic procedure and at each follow-up using the same pain or disability scale for each assessment 3. Pain present for minimum of 3 months with documented failure to respond to noninvasive conservative management (as tolerated) 4. Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by facet joint synovial cyst) 5. There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, including but not limited to fracture, tumor, infection, or significant deformity	Literature to support the requested coverage for facet joint procedures in the acute phase for traumatic facet joint pain and untreated radiculopathy or neurogenic claudication can be submitted and reviewed on reconsideration.

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	North American Neuromodulation Society & American Society of Anesthesiologists agree pain to be present for a minimum of three months with documented failure to respond to non-invasive conservative treatment (as tolerated). While we would note that this indication makes sense for patients with chronic pain that is slow in onset, it should not apply to patients with traumatic induced facet joint pain. This can occur from a fall, accident, lifting or other strenuous situation. In these circumstances, patients should be allowed to receive treatment as early as within one month of conservative treatment. We would also like to note that for indication 3- Absence of untreated radiculopathy or neurogenic claudication, many patients have multiple sources for their pain. Optimal results often require that more than one structure is treated. Patients with acute herniation and predominately lower extremity pain may need only an epidural steroid injection, but patients with degenerative facet disease that causes central or foraminal stenosis frequently have both radicular and facet related pain simultaneously. Proper treatment requires that both sources of pain be treated to maximize patients' pain relief and functional improvement.	
	David M. Sibell, MD, Professor, Oregon Health & Science University, Anesthesiology & Perioperative Medicine Comprehensive Pain Center comments the requirement involving radiculopathy is confusing "(Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by facet joint synovial cyst)." If a patient has pain in a radicular distribution, but the radiculopathy has been treated (e.g., by surgery, with medications, or other procedures), is that considered "treated radiculopathy," and therefore, is it permissible to treat painful facet arthropathy in these patients? This type of scenario represents a large number of patients who are currently denied treatment for painful facet arthropathy, so it is important to have clarity surrounding the meaning of	

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	this phrase. Please include the definition of "untreated" in the definitions list.	
12	**Request to include Grandfathering Provision in Provider Qualifications Section** A comment was received from **American Association of Nurse Anesthetists** requesting Grandfathering Provision in Provider Qualifications Section we note that the proposed LCD does not contain in the Provider Qualifications section a grandfathering clause allowing providers who have provided specific interventional pain management services on a regular basis (at least two times per month) over a significant period of time from being exempt from the meeting the training requirement. As opportunities for training may not have existed previously; pain providers may have developed their knowledge base over time and should be recognized for their preparation and training. **A comment was received from American Academy of Physical Medicine and Rehabilitation, American Society of Neuroradiology, American Society of Spine Radiology, North American Spine Society, Society of Interventional Radiology, Spine Intervention Society AND California Radiological Society, Washington State Radiological Society** while we appreciate that all healthcare professionals have a very important role to play in team-based care within our medical system, training provided to non-physicians does not provide requisite background and experience in accurately selecting patients; safely performing technically demanding procedures; and immediately recognizing, evaluating, and addressing potentially serious, life-altering complications. Recommend language changes were provided.	The scope of practice for non-physician providers (NPPs) and Certified Nurse Anesthetists (CRNAs) are established by State laws and not within the scope of this policy. However, we understand that facet joint injections carry risk and appropriate training is necessary. In order to ensure the safety of the Medicare beneficiaries, we will require all providers to have documentation of training as outlined in the LCD.

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13	**Removal of medial branch blocks from the Therapeutic Facet Joint Procedures section.** **A comment was received from American Academy of Physical Medicine and Rehabilitation, American Society of Neuroradiology, American Society of Spine Radiology, North American Spine Society, Society of Interventional Radiology, Spine Intervention Society AND California Radiological Society, Washington State Radiological Society and David M. Sibell, MD, Professor, Oregon Health & Science University, Anesthesiology & Perioperative Medicine Comprehensive Pain Center** Medial branch blocks are performed outside the joint, where the medial branch nerves are predictably located, and identify whether the source of pain is within the distribution of the medial branch nerves. These injections are purely diagnostic using only local anesthetic. They are not therapeutic procedures and do not provide extended pain relief. Therefore, medial branch blocks should be removed from the Therapeutic Facet Joint Procedures section.	Thank you the correction has been made.
14	**Limitations – Patients who routinely present with pain in Cervical, Thoracic and Lumbar Regions.** A comment was received from **Florida Society of Interventional Pain Physicians that** is not uncommon for a Medicare patient to have both cervical and thoracic pain and or cervical and lumbar pain and explain rationale and request Delete #3, or allow for Cervical, Thoracic and Lumbar Regions separately. **North American Neuromodulation Society & American Society of Anesthesiologists** We strongly disagree with limitation 3 [page 5], which states that, the "routine performance of facet	While we understand a single patient may have multiple pain sources, if the pain source is not diagnosed correctly, it is not possible to target appropriate treatment. This may put the patient at risk or repetitive and potentially unindicated procedures. Since facet joints require diagnostic injections to determine if facet syndrome is present and identify the level, other procedures performed simultaneously may make it difficult to perform accurate diagnostics. Therefore, we affirm multiple blocks on the same day could lead to improper or lack of diagnosis. If performed, the medical necessity of each injection (at the same or a different level[s]) must be documented in the medical record.

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	joint interventions (both diagnostic and therapeutic) to both spinal regions may trigger a focused medical review." Patients with degenerative spondylosis in one area are very likely to have it in other areas of their spine if it is degenerative in nature. If they have trauma, then it would depend whether both areas were injured by that trauma or just one. Traumatically injured facets would be confined to the area(s) of injury, but patients can sustain injuries in more than one area as well. We recommend this statement be removed.	
15	**Facet Joint Interventions Covered Indications – Inclusion of "thoracic spine"** A comment was received from **Florida Society of Interventional Pain Physician** the entire proposed LCD addresses the Cervical/Thoracic, and Lumbar spine. Thoracic spine is not included in this statement. Entry level policy staff may read this and not recognize that thoracic pain is covered in this LCD. **RECOMMENDED LANGUAGE:** 'cervical/thoracic and low back pain'	Thank you we have made this correction throughout the LCD where appropriate.
16	**Request for Provider-Neutral Language & for CRNAs to Order and Refer Services if Allowed Under State Law.** **Owner/President Quality Anesthesia & Pain Management Services LLC and Michael Brown** The current proposed LCD discriminates against certified registered nurse anesthetists by restricting services legally authorized per State Law. There is no distinction between "diagnostic" and diagnosis in the LCD. A diagnostic procedure does not constitute making a medical diagnosis. A patient presenting with an order for a diagnostic medial branch block and a diagnosis of low-back pain to evaluate for spondylosis can be referred to a CRNA in North Carolina and per NC Law, the CRNA would be implementing a treatment plan, not making a medical diagnosis. A patient presenting for MBB	Defining state's scope of practice is not within the scope of this policy. When a patient is referred for facet joint syndrome, the diagnosis is not yet established. To make the diagnosis, the patient must meet all criteria in Section A: Covered Indications Facet Joint Interventions, as outlined in the LCD. The first two facet joint injection services performed are clinically categorized as "diagnostic" because the agent being injected may wear off rapidly (see the response to comments #4) and is being injected as part of the provider's differential diagnosis. If the injections fail to relieve pain by at least 80% or 50% improvement in function (as per LCD), the diagnosis is not established. This requires **both** the procedural aspect of injection and the post-work of assessment of pain and function. The post-work assessment is considered part of the procedure per

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	would be evaluated at baseline by the referring provider, evaluated again using pain scales before and after the MBB procedure, and then followed-up again in 1-2 weeks by the referring provider in which the DIAGNOSIS would be made. The proposed LCD does not contradict the fact that the diagnosis would be made at a future date. In fact, the LCD supports this by stating "50% objective improvement in ability to perform previously painful maneuvers and ADLs". How is an improvement in ADLs confirmed the same day of a diagnostic medial branch block? They are not. They must allow the patient to utilize a pain diary and follow-up with their referring/ordering provider after time has passed to determine if an improvement in pain, function, and ADLs has occurred.	CPT. Based on this evaluation, the provider will exclude or confirm facet joint syndrome. Once the diagnosis has been confirmed, longer-lasting treatments would then be prescribed and provided.
17	**History, Background and/or General Information** A comment was received from **North American Neuromodulation Society & American Society of Anesthesiologists** recommending revision of the last paragraph in the History/Background and/or General Information section that refers to utilization growth for facet joint interventions. We recommend this section be deleted or amended to appropriately account for the increase in training for interventional pain physicians in the past twenty years and thus, the wider availability for patients to access evidenced-based pain treatments like facet joint injections. The section makes no mention of the increased quality of life for patients as a result of the dissemination of the technology nor does it recognize the reduced demand for spine surgery that is the result of increased use of facet joint injection procedures. This reduction in need for surgery is better for patients— avoiding multiple risks and possible complications, the need for further surgery such as occurs with 'adjacent level disease', as well as reducing costs for payers, such as Medicare and Medicaid. We recommend the document acknowledge these benefits and trends when addressing utilization growth rather than imply that most of the utilization growth is not medically appropriate or necessary.	Your concerns regarding utilization are recognized and this section has been removed. In terms a specific guideline we recognize and appreciate the important work in the 2020 Multi-Society Facet Guidelines. Please see comment #1 for the scope of the LCD.

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	NANS and ASA would also recommend the grading include and be driven by the 2020 Multi-Society Facet Guidelines by Cohen, et al. as this guideline was produced by a coalition of pain and interventional societies who determined the grading and recommendations. The document is referenced but we believe that document to be the most comprehensive and evidenced-based review of literature in this space as opposed to surgical driven evaluation and grading tools.	
18	From coding manager Jennifer Wright-Davis Please add M54.2 Cervicalgia and M54.5 Low back pain to Group 1 Paragraph to support the first two criteria: Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale* and Pain present for minimum of 3 months with documented failure to respond to noninvasive conservative management (as tolerated)	Low back pain and neck pain can be related to conditions unrelated to the spine, for which facet blocks would not be appropriate. Before the performance of a facet interventional procedure, the provider's differential diagnosis should be narrowed to a high suspicion of facet joint syndrome and other paraspinal process excluded. Therefore, these less specific codes will not be added.
19	Facet joint procedures in patients with generalized pain conditions (such as fibromyalgia) or chronic centralized pain syndromes is considered not reasonable and necessary. Individual consideration may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal. **North American Neuromodulation Society & American Society of Anesthesiologists** disagrees with the parenthetical listed in limitation 9, stating, "(such as fibromyalgia). We recommend this reference be deleted. Patients with fibromyalgia (FM) can have other pathology that may be amenable to treatment. We believe this unfairly discriminates against patients with FM. We also know that many patients are misdiagnosed with FM when they actually have other potentially more treatable conditions. **American Society of Regional Anesthesia and Pain Medicine** states the limitation that facet joint procedures in patients with generalized pain conditions (such as poorly controlled fibromyalgia) or	We agree that there are some instances where individuals with centralized pain syndrome have legitimate facet joint pain that is separate from their central pain condition. This limitation is not intended not to allow access to patients with centralized pain syndromes, such as fibromyalgia, who meet the full diagnostic criteria for facet syndrome but require they meet the full diagnostic criteria per the LCD for facet joint syndrome and achieve appropriate improvement with intervention. The limitation is that facet joint procedures are not used to treat centralized pain syndrome, which is not considered reasonable and necessary. The language in the LCD was modified for clarity.

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	chronic centralized pain syndromes are considered not reasonable and necessary. There are some instances where such individuals have legitimate facet joint pain that is separate from their central pain condition. And while we appreciate that the proposed LCD allows for potential exceptions to the broad prohibition against the use of facet joint procedures in patients with generalized pain conditions, we are concerned that this broad limitation will result in an overall chilling effect on treatment of patients with fibromyalgia or other generalized pain conditions, particularly given that the opportunity for coverage would only be made available upon appeal. Indeed, the proposed language would create significant burden and uncertainty for those physicians willing to follow their judgement to furnish facet joint interventions to patients with fibromyalgia, with such care virtually guaranteed to be denied at first pass. We therefore do not believe a blanket statement excluding these individuals from effective treatment except through appeal is appropriate, and we urge the Medicare contractors to eliminate the statement in the final LCDs. **David M. Sibell, MD, Professor, Oregon Health & Science University, Anesthesiology & Perioperative Medicine Comprehensive Pain Center** the guidelines suggest restricting facet joint procedures in patients with generalized pain conditions such as fibromyalgia. Although there is some early evidence to support this notion, we believe that it is a topic that should be re-evaluated once we understand these syndromes better. There is insufficient evidence to support an across-the-board ban on this population of patients; for example, the one study referenced in the rationale only looked at cervical facet procedures. We strongly urge the panel to allow facet joint procedures in patients with fibromyalgia and centralized pain on a case-by-case basis, as deemed necessary by the physician. We recommend that those patients are actively engaging in therapies to treat their fibromyalgia/centralized pain, or that there is documentation describing their treatment course and being in remission. We agree that facet procedures should not be offered to patients with active, untreated fibromyalgia/centralized pain.	

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	We agree that trying to do focal procedures, such as medial branch block or RFD, on patients with poorly controlled hypersensitivity and myofascial pain is often counterproductive. But patients may be treated effectively for fibromyalgia, and have improvement in their hypersensitivity, while still having the diagnosis of fibromyalgia. They may then be able to improve with RFD. Are we to reward patients who put in the work on physical therapy and other treatments by telling them that they are now *not* eligible to be treated for painful facet arthropathy that may underlie some of their fibromyalgia symptoms? Currently, RFD can be a powerful tool that facilitates continued improvement in patients who have partially improved fibromyalgia. This policy would shut the door on those patients.	
20	North American Neuromodulation Society & American Society of Anesthesiologists states implanted electrical devices, the document should include a requirement to follow manufacturer instructions and highlight that implanted electrical stimulated devices are not a contraindication to radiofrequency denervation (RFD) but require extra planning. Thousands of patients with a SCS implant or a cardiac implantable device have been treated safely with RFD.	We appreciate your comment, and this has been added to the policy.
21	Angie Martin Great Plains Health Alliance/CBO: Please add allowed revenue codes 036X- Operating room- Some providers, especially rural hospitals, use the OR room for all procedures. Many times this is the only available space even when the procedure does not require anesthesia. 0761- OP Treatment room - This area is used for many scheduled services, especially in rural hospitals	The revenue codes will be added.
22	In any region of the spine (cervical/thoracic and/or lumbar), if the need for bilateral joint treatment is medically necessary, a physician may perform each side separately, limiting to 2 radiofrequency sessions per year per side if performed separately. Many physicians perform bilateral procedures on two separate dates of service for multiple reasons (patient tolerance, concerns for local anesthetic toxicity, OR scheduling). This reasonable and	There was no supporting literature provided to support the necessity of performance of the procedures in separate sessions per side. It makes clinical sense to perform both sides in the same session to optimize onset of pain relief (avoiding having to wait longer for the other side), less visits for the patient, ability to perform assessments on both sides in single visit, reduce radiation exposure and time in the procedure room or OR. In case

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	medically appropriate practice needs to be protected by this LCD.	there is medical necessity to perform procedures separately the reason should be documented and may be considered on appeal.

Associated Documents

Related Local Coverage Document(s)

LCD(s)

L38773 - Facet Joint Interventions for Pain Management

Related National Coverage Document(s)

N/A

Public Version(s)

Updated on 03/10/21 with effective dates 03/18/2021 - N/A

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