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RE: Proposed Local Coverage Determination: Facet Joint Interventions for Pain Management (DL34892)

Dear Dr. Schafer:

On behalf of the Arkansas, Colorado, Delaware, Louisiana, Maryland, Mississippi, New Jersey, New Mexico, Oklahoma, Pennsylvania, and Texas Societies of Interventional Pain Physicians, the American Society of Interventional Pain Physicians (ASIPP), the American Society of Neuroradiology, and the American Society of Spine Radiology with their entire membership, we would like to thank you for all your hard work, along with other Medicare Carrier Advisory medical directors in developing local coverage determination (LCD) for Facet Joint Interventions for Pain Management (DL34892).

While we appreciate your hard work and trying to follow the mandate for the evidentiary content, there are some issues if addressed, will improve the LCD and maintain the access to these procedures to Medicare recipients. This LCD has a non-coverage policy for therapeutic facet joint nerve blocks and intra-articular injections, which may be purely based on lack of appropriate information.

Background Information:
Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain related disorders principally with the application of interventional techniques in managing sub acute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment (The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09. www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf).

Interventional pain management techniques are minimally invasive procedures including, percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic diskectomy, intrathecal infusion pumps and spinal

cord stimulators, for the diagnosis and management of chronic, persistent or intractable pain (Medicare Payment Advisory Commission. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December. 2001. http://medpac.gov/docs/default-source/reports/december-2001-report-to-the-congress-paying-for-interventional-pain-services-in-ambulatory-settings.pdf?sfvrsn=0).

ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States. ASIPP is comprised of 50 affiliated state societies, and the Puerto Rico Society of Interventional Pain Physicians.

In addition to having state societies throughout the country, ASIPP also has mandatory CAC membership (US Department of Health and Human Services. Centers for Medicare and Medicaid Services (CMS) Manual System. Pub. 100-08 Medicare Program Integrity. Inclusion of Interventional Pain Management Specialists on Carrier Advisory Committee (CAC) Membership. Change request 3721. March 4, 2005. www.cms.hhs.gov/transmittals/downloads/R106PI.pdf). In some states, this facility has been essentially eliminated with misinterpretation of 21st Century Cures Act.

In contrast, multiple other organizations 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.

However, American Society of Anesthesiology constitutes a large number of interventional pain physicians, even though they are only a fraction of the entire society. Similarly, American Academy of Physical Medicine and Rehabilitation also has a significant number of physicians practicing interventional pain management. Both of these organizations also provide ABMS board certification. Even then, their main goals are representation of anesthesiology and physical medicine and rehabilitation. Both these groups have membership on the CAC.

Application of the Language from Medicare Program Integrity Manual:
Chapter 13, Local Coverage Determinations, under evidentiary content, following is specified:

- The target Medicare population
- In conducting a review, MACs shall use the available evidence of general acceptance by the medical community, such as published original research in peer-reviewed medical journals, systematic reviews and meta-analyses, evidence-based consensus statements and clinical guidelines.
- MACs shall explain the rationale that supports their coverage determination of covered, noncovered, or limited coverage. The rationale is the reasoning leading to the coverage determination.

This manual also defines Medicare reasonable and necessary as follows:

> Contractors shall determine if evidence exist to consider an item or service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational; and
- Appropriate, including the duration and frequency that is considered appropriate for the item or service

Consequently, it is crucial that the studies are performed utilizing Medicare population, related to published original research in peer-reviewed medical journals, systematic reviews and meta-analysis are performed based on evidence-based principles with methodologic quality assessment and evidence synthesis. Similarly, guidelines must be prepared based on appropriate principles utilizing either existing systematic reviews or performing multiple systematic review and meta-analysis in the guidelines itself even if they are consensus statements. Further, once the procedure meets medical necessity criteria of safe and effective, appropriately performed with duration and frequency, MAC shall explain the rationale that supports their coverage, determination of covered, non-covered, or limited coverage. In this case, MACs are deciding to make it limited coverage despite performed in Medicare population, a large body of evidence is available, and has been covered all these years, with cost effectiveness (50% of the cost of radiofrequency neurotomy with 50% duration of relief, 3 months versus 6 months).

This will result access to care with their choice and shared decision making in approximately 50% of the patients. Ultimately, if these patients are moved to radiofrequency neurotomy, 30%-45% of patients will fail or do not like it, leading to access issues in at least 20% of FFS Medicare population who meet medical necessity criteria based on 2019 LCD, along with evidentiary basis.

It is also interesting to note that a recent study by the Office of Inspector General (OIG) (https://oig.hhs.gov/oas/reports/region9/92003003.pdf), showed the effect of appropriate LCDs compared to vaguely written LCDs. As an example, CGS LCD which differs from other LCDs developed in collaboration with Multi-Society Pain Workgroup (MPW), without ASIPP, had language which was confusing with limitation of 5 procedures per year, despite the requirement to be 3 months of relief with each injection. The data showed significant population receiving more than 5 procedures per year in all MACs, except CGS, which showed very small number of patients received such services. Consequently, it is important to appreciate the proposed language in the policies in reference to utilization which is similar to existing CGS policy with diagnostic phase and therapeutic phase. Ironically, the same groups are opposing the policy they approved a few years ago, North American Neuromodulation society (NANS) and Spine Intervention Society (SIS) with 2 separate opinions.

COVERAGE GUIDANCE

A. Covered Indications Facet Joint Interventions

We strongly support the evidence-based, medically reasonable and necessary criteria for facet joint interventions. There is extensive evidence to support these descriptions.

A. Diagnostic facet joint procedures: (IA or MBB)

1. 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, 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.

Comment/Solution

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.

Recommendation:

The primary indication of a diagnostic facet procedure is to confirm a clinical suspicion of facet syndrome. Intraarticular (IA) facet joint blocks are considered reasonable and necessary as a diagnostic test only, medial branch blocks cannot be performed due to specific documented anatomic restrictions or a shared decision is made to proceed with therapeutic intraarticular injections with or without steroids. These restrictions and decisions must be clearly documented in the medical record and made available upon request.

This will not only facilitate and improve patient care, but also reduce the costs savings. This will be appropriate since LCD permits 4 therapeutic facet joint intraarticular injections or medial branch block sessions per rolling 12 months.

2. 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).

Comment/Solution

The diagnostic procedures are performed to rule in or rule out facet joint pain. If successful a patient may receive radiofrequency ablation, intraarticular injections, or therapeutic facet joint nerve blocks based on their choice and medical condition with shared decision making.

As we discussed below, there is extensive evidence supporting therapeutic facet joint nerve blocks, both MBB and IA.

Language may be changed to diagnostic procedures should be performed with the intent that if successful, therapeutic management will be carried out either with radiofrequency ablation, therapeutic facet joint nerve blocks, or intraarticular injections.

3. A second diagnostic facet procedure is considered medically necessary to confirm validity of the initial diagnostic facet procedure when administered at the same level. The second diagnostic procedure may only be performed a minimum of 2 weeks after the initial diagnostic procedure.

Comment/Solution

This statement is evidence-based and well supported in the literature and previous LCDs. Many have been misled utilizing an acute pain model and less than 7 hours of relief with the first block and less than 23 hours of relief with the second block, or 45-90 minutes and 90-180 minutes. Based on this misguided information, without consideration of chronic pain. Consequently, some of them have recommended based on lack or misguided evidence that these procedures may be repeated the next day a patient undergoing almost 3 procedures with 2 diagnostic blocks and radiofrequency

neurotomy within one week. They made similar argument in the past that a person can have 2 diagnostic blocks on the same day along with radiofrequency neurotomy because it is supposed to have been only 90 minutes, 45 minutes, and 90 minutes. This will be not only risky, increases utilization, but will impact the quality of care without any scientific basis.

In contrast to the above concepts, we agree with the concepts developed by MACs with 80% improvement, 2 week waiting period between the procedures. Further, doing the procedures that frequently may not even be feasible in reference to pre-certifications, etc.

There is significant evidence from the United States, in Medicare population, for utilization a chronic pain model (1-3). The evidence which was derived from multiple studies and a recent prevalence study utilizing a chronic pain model in lumbar facet joint pain with diagnostic facet joint nerve blocks with 80% pain relief as the criterion standard showed average duration of pain relief greater than 80% was 6 days with lidocaine block and a total relief of greater than 50% of 32 days (2). Similarly, when bupivacaine was employed for the second block in the patients who were positive for lidocaine block, the average duration of pain relief greater than 80% was 13 days with total relief of greater than 50% lasting 55 days. This was also shown in the previous studies as shown in the guidelines.

In the cervical spine also the results were similar (Table 1). The recent publication of diagnostic accuracy study showed that in chronic cervical facet joint pain with diagnostic facet joint nerve blocks with a criterion standard of > 80% pain relief showed 6 days of relief with lidocaine block and total relief of > 50% for 31 days (3). Further, utilizing bupivacaine for the diagnostic purposes in patients who were positive for lidocaine block, the average duration of relief of 80% or greater was 12 days with a total relief of 50% or greater of 55 days (Table 2).

The argument that without steroids these blocks would not last long enough is not based on any evidence. Recently, Shanthanna et al (4) in a review of 69 studies spanning from epidural injections to various types of nerve blocks have shown that addition of corticosteroids to local anesthetic has only small benefit and a potential for harm. Injection of local anesthetic alone could be therapeutic beyond being diagnostic. They concluded that a shared decision based on patient preferences should be considered. Further, they stated if used, one must avoid high doses and series of steroid injections. Multiple other systematic reviews (5-9) and studies (10-20) have illustrated the same. In fact, all these systematic reviews and studies have shown mostly equal effects. Occasionally, better improvement with steroids on a short-term basis was seen as Shanthanna et al have shown. Overall, the evidence is overwhelming for long-acting response to local anesthetics similar to combined with steroids or sodium chloride solution.

As described in facet joint guidelines from ASIPP there is extensive literature showing diagnostic and therapeutic effect. To understand this, they simply need to use a chronic pain model other than acute pain model, as shown in Tables 1 and 2.

Table 1. *Duration of relief with controlled comparative local anesthetic blocks in the diagnosis of lumbar facet joint pain.*

Duration of Relief in days (average)							
		1% Lidocaine Block			0.25% Bupivacaine Block		
Outcome	N	50-79%	>=80%	Total Relief	50-79%	>=80%	Total Relief
False positive	101	24.89	5.95	30.83	23.58	3.02	26.60
Negative	96	9.63	0.02	9.65	0.00	0.00	0.00
Positive	102	26.04	6.07	32.11	42.47	12.96	55.44
Total	299	20.38	4.09	24.47	33.07	8.02	41.09

Source: Manchikanti L, Kosanovic R, Pampati V, et al. Low back pain and diagnostic lumbar facet joint nerve blocks: Assessment of prevalence, false-positive rates, and a philosophical paradigm shift from an acute to a chronic pain model. *Pain Physician* 2020;23:519-530 (2).

Table 2. *Duration of relief with controlled comparative local anesthetic blocks in the diagnosis of cervical facet joint pain.*

Duration of Relief in days (average)							
		1% Lidocaine Block			0.25% Bupivacaine Block		
Outcome	N	50-79%	>=80%	Total Relief	50-79%	>=80%	Total Relief
False positive	50	24.54	6.64	31.18	26.25	0.18	26.43
Negative	99	8.11	0.04	8.15	0.00	0.00	0.00
Positive	145	24.81	6.10	30.91	43.28	11.86	55.29
Total	294	19.14	4.15	23.29	38.71	8.82	47.64

Source: Manchikanti L, Kosanovic R, Cash KA, et al. Assessment of prevalence of cervical facet joint pain with diagnostic cervical medial branch blocks: Analysis based on chronic pain model. *Pain Physician* 2020; in press (3).

4, b, ii. After the first diagnostic facet joint procedure, there must be a consistent positive response of at least 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used) **or** at least 50% consistent objective improvement in the ability to perform previously painful movements and activities of daily living (ADLs).

The present language is as follows:

If, after the first medial branch block injection, the patients experiences ≥ 80% relief of their primary (index) pain, lasting a time period consistent with the local anesthetic used, the patient may undergo a second, confirmatory medial branch block. Since the technique of medial branch block relies on the patient's perception of pain relief to establish the diagnosis, the patient must have sufficient pain immediately prior to the injection (generally ≥ 3/10 NPRS) to be able to detect significant improvement following the injection. Additionally, provocative maneuvers or positions which normally exacerbate index or typical pain must be determined before the injection.

The Problem:

The problem with this language appears to be vague and somewhat confusing language. It will be difficult.

Recommended Language:

We recommend the language be changed which will conform to proposed language, as well as the present language with avoidance of confusion as follows:

After the first diagnostic facet joint procedure, there must be a consistent positive response of at least 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used) or at least 50% consistent objective improvement in the ability to perform previously pain**ful** movements **or provocative maneuvers** ~~and activities of daily living (ADLs)~~.

These revisions need to be made in all places.

B. Therapeutic Facet Joint Procedures (IA or MBB)

The document describes therapeutic facet joint procedures is considered medically reasonable and necessary for patients who meet all the following criteria. Among these, the following is of importance and requires revisions:

c. Documentation of why the patient is not a candidate for radiofrequency ablation (such as established spinal pseudoarthrosis, implanted electric device)

Adverse consequences of this treatment were alluded above as follows:

This will result access to care with their choice and shared decision making in approximately 50% of the patients. Ultimately, if these patients are moved to radiofrequency neurotomy, 30%-45% of patients will fail or do not like it, leading to access issues in at least 20% of FFS Medicare population who need medically necessary criteria based on 2019 LCD, along with evidentiary basis.

Evidentiary Basis:

Therapeutic facet joint nerve blocks are one of the well-studied procedures in Medicare population in the United States. As shown in comprehensive evidence-based guidelines for facet joint interventions from ASIPP (1), there is Level II evidence with moderate strength of recommendation for therapeutic lumbar facet joint nerve blocks with inclusion of 3 relevant randomized controlled trials, with long-term improvement as shown in Table 3 (10-12).

Similar to the lumbar spine, there is Level II evidence with moderate strength of recommendation for cervical therapeutic facet joint nerve blocks with inclusion of one relevant randomized controlled trial and 3 observational studies, with long-term improvement as shown in Table 4 (13-16).

In the thoracic spine also, the evidence is Level II with moderate strength of recommendation for thoracic therapeutic facet joint nerve blocks with inclusion of 2 randomized controlled trials and 3 observational studies as shown in Table 5 (17-21).

To emphasize, majority of these studies were performed in the United States and included a large proportion of Medicare patients. The evidence has improved since the previous publication of LCD, at which time there were less number of studies.

The guidelines and systematic reviews have assessed the quality of these studies and trials and have arrived at the conclusion that these studies of moderate to high quality, and showed Level II evidence, with moderate strength of recommendation. Consequently, neither therapeutic facet joint nerve blocks be eliminated, nor intraarticular injections be limited to 3 or 4 times a year based on relief of at least 3 months with first injection which is a criteria impossible to achieve.

The manuscript quoted North American Spine Society (NASS) (22) in the LCD. NASS coverage policy recommendation is no longer available on their website. Further, this was a recommendation from the

society whose primary practice is surgery, with improper assessment and biased evaluation. Reference 9 is not specific to interventional techniques. The results of NASS assessments are based on International Spine Intervention Society (ISIS), and their opposition to therapeutic interventions, other than radiofrequency neurotomy. They have been promoting radiofrequency neurotomy and trying to eliminate intraarticular injections and therapeutic facet joint nerve blocks. However, based on the evidence MACs were able to retain those procedures. Therapeutic facet joint nerve blocks have been studied in 11 studies, with 5 randomized controlled trial and 6 observational studies, with all of them showing positive results. One of the issues in this was that too many treatments have to be repeated; however, they are ignoring the fact that cost of facet joint nerve blocks is almost 50% of radiofrequency neurotomy, with 50% duration of relief and higher success rate (60% versus 80%). Further, none of the studies recommending radiofrequency in these guidelines were performed in Medicare population. Consensus guidelines developed by Cohen et al, neither invited, nor included ASIPP. The American Society of Anesthesiologists, neither approved, nor reviewed the guidance. Consequently, the only official organization of pain physicians, not necessarily interventional pain physicians was American Academy of Pain Medicine from so-called Multi-Society Pain Workgroup.

Table 3. *Effectiveness of lumbar therapeutic facet joint nerve blocks.*

Study Study Characteristic Methodological Quality Scoring	Patients	Interventions	Pain Relief and Function			Results			Comments
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	≥ 1 year	
LUMBAR FACET JOINT NERVE BLOCKS									
Civelek et al, 2012 (10) RA, AC Quality Scores: Cochrane = 9/13 IPM-QRB = 28/48	100	LA with steroid = 50 CRF = 50	NA	75% vs. 92%	69% vs. 90%	NA	P	P	Long-term effectiveness
Manchikanti et al, 2010 (11) RA, DB, AC Quality Scores: Cochrane = 12/13 IPM-QRB = 45/48	120	LA with steroid = 60 LA = 60	82% vs. 83%	93% vs. 83%	85% vs. 84%	P	P	P	Short- and long-term effectiveness
Manchikanti et al, 2001 (12) RA, AC Quality Scores: Cochrane = 6/13 IPM-QRB = 34/48	73	LA with steroid = 41 LA = 32	100% vs 100%	75% vs 80%	75% vs 80%	P	P	P	Positive short and long-term results

RA = randomized; DB = double-blind; AC = active control; ST = steroid; LA = local anesthetic; SAL = saline; SI = significant improvement; U = undetermined; NSD =no significant difference; NE = not effective; CRF – cooled radiofrequency; P = positive; N = negative; NA = not applicable

Source: Manchikanti L, Kaye AD, Soin A, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 2020; 23:S1-S127 (1).

Table 4. *Effectiveness of cervical therapeutic facet joint nerve blocks.*

Study Study Characteristic Methodological Quality Scoring	Patients	Interventions	Pain Relief and Function			Results			Comments
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	≥ 1 year	
CERVICAL FACET JOINT NERVE BLOCKS									
Manchikanti et al, 2010 (13) RA, DB, AC Quality Scores: Cochrane = 12/13 IPM-QRB = 45/48	120	Local anesthetic = 60 Local anesthetic with steroid = 60	83% versus 85%	87% versus 95%	85% versus 92%	P	P	P	Short- and long-term effectiveness
Manchikanti et al, 2004 (14) Prospective Quality Score: IPM-QRBNR = 37/48	100	Therapeutic medical branch blocks	92%	82%	56%	P	P	P	Long-term effectiveness
Hahn et al (15) A retrospective practice audit Quality Score: IPM-QRBNR = 31/48	178 patients were included.	Medial branch blocks	62.4%	62.4%	62.4%	P	P	P	Long-term effectiveness
Lee et al (16) Observational study Quality Score: IPM-QRBNR = 34/48	51 patients were positive for controlled diagnostic blocks	Therapeutic medical branch blocks	86%	86%	86%	P	P	P	Long-term effectiveness

RA = randomized; DB = double-blind; AC = active control; ST = steroid; LA = local anesthetic; U = undetermined; SI = significant improvement; RFTN = radiofrequency thermoneurolysis; P = positive; N = negative; NA = not applicable

Source: Manchikanti L, Kaye AD, Soin A, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 2020; 23:S1-S127 (1).

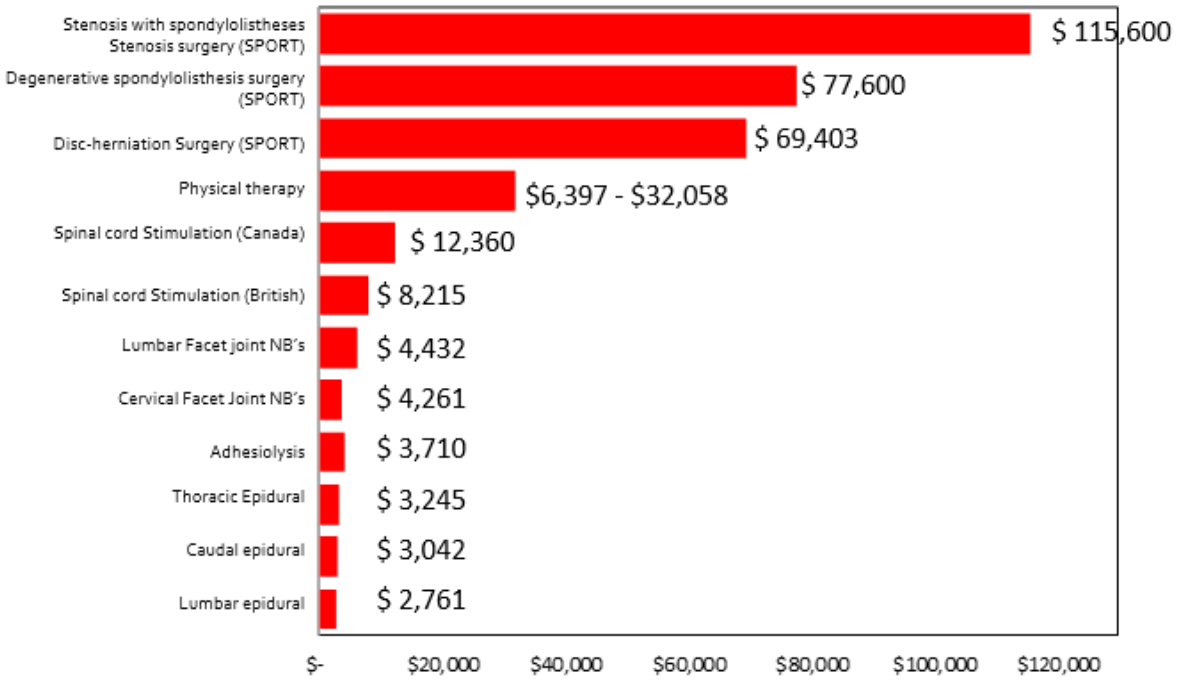
Table 5. *Effectiveness of thoracic therapeutic facet joint nerve blocks.*

Study Study Characteristic Methodological Quality Scoring	Patients	Interventions	Pain Relief and Function			Results			Comments
			3 mos.	6 mos.	12 mos.	Short-Term ≤ 6 mos.	Long-Term		
							> 6 mos.	≥ 1 year	
THORACIC FACET JOINT NERVE BLOCKS									
Manchikanti et al, 2012 (17) RA, DB Quality Scores: Cochrane = 11/13 IPM-QRB = 45/48	100 patients	Local anesthetic = 50 Local anesthetic with steroid = 50	79% vs 83%	79% vs 81%	80% vs 83%	P	P	P	Short- and long-term effectiveness
Manchikanti et al, 2006 (18) Prospective outcome study Quality Score: IPM-QRBNR = 37/48	55 consecutive patients, all meeting diagnostic criteria for thoracic facet joint pain	Thoracic facet joint nerve blocks	71%	71%	76%	P	P	P	Short- and long-term effectiveness
Lee et al, 2018 (19) Randomized, active controlled trial Quality Scores: Cochrane = 12/13 IPM-QRB = 39/48	40 patients • Intraarticular steroid injection = 20 patients • Medial branch blocks = 20 patients.	Thoracic facet joint nerve blocks	NA	40%	NA	P	NA	NA	Short- and long-term effectiveness
Park et al, 2013 (20) Observational study Quality Scores: Quality Score: IPM-QRBNR = 29/48	53 patients with axial back pain with chronic facet joint pain for osteoporotic compression fractures in thoracolumbar region. Majority of the patients included osteoporotic fractures at T12 and L1.	Facet blocks of the T11 and T12 medial branches and L1 and L2 medial branches	78.9%	78.9%	78.9%	P	P	P	Positive study
Chang, 2018 (21) Retrospective, observational data collected from 72 patients Quality Score: IPM-QRBNR = 31/48	20 patients underwent PRF thoracic medial branch blocks	Pulsed radiofrequency treatment	73%	73%	73%	P	P	P	Positive study Short- and long-term improvement

RA = randomized; AC = active control; SI = significant improvement; P = positive; N = negative; NA = not applicable

Source: Manchikanti L, Kaye AD, Soin A, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 2020; 23:S1-S127 (1).

The cost utility analysis has shown significant cost effectiveness of therapeutic medial branch blocks in cervical and lumbar spine and we expect the same in the thoracic spine (23,24). The cost effectiveness was shown to be per year of quality of life improvement $4,432 for lumbar facet joint nerve blocks and $4,261 for cervical facet joint nerve blocks. This quality of improvement is superior to physical therapy alone or multiple other treatments for other conditions as shown in Fig. 1.



Source: Manchikanti L, Kaye AD, Soin A, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 2020; 23:S1-S127 (1).

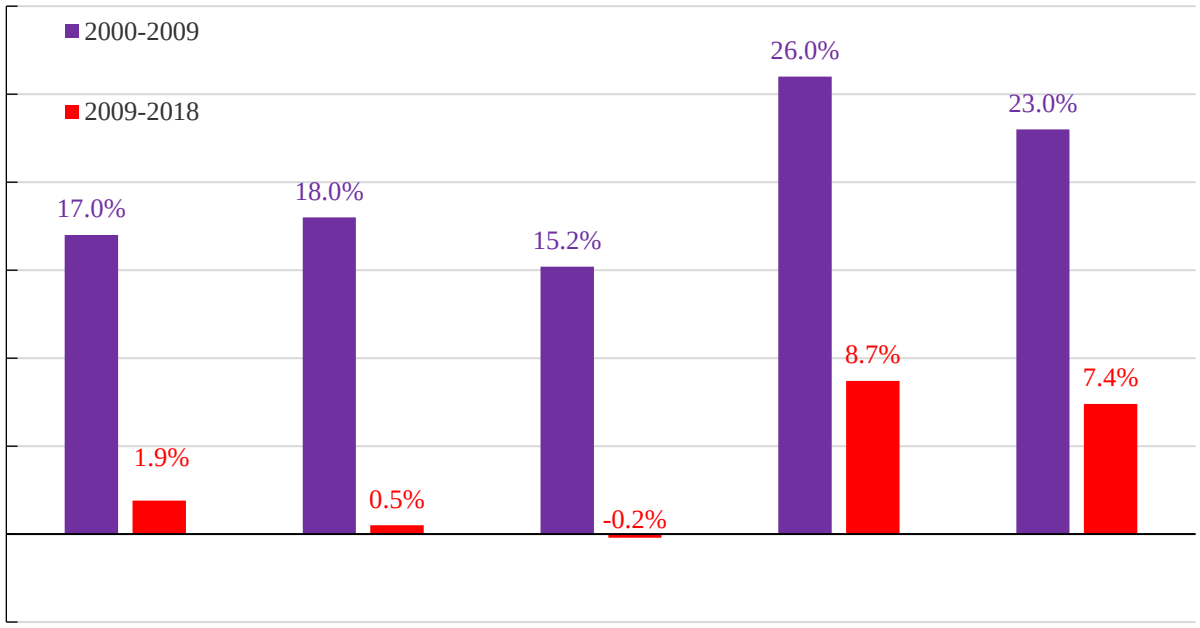
Fig. 1. *Cost effectiveness per quality-adjusted life-year (QALY).*

Utilization patterns of facet joint interventions shows that overall, these procedures have increased substantially over the years from 2000 to 2009, however from 2009 to 2018 in FFS Medicare population per 100,000, flattening for some and decline for others. Increases were reduced to 1.9% annually and 18.8% total per 100,000 FFS Medicare population compared with an annual increase of 17% and overall increase of 309.9% from 2000 to 2009. Figure 2 demonstrates these factors (1,25,26). As it is shown in this figure, facet joint nerve blocks in the lumbar spine actually declined 0.2% annually with cervical/thoracic facet joint nerve blocks increasing 0.5% annually. In contrast, cervical and thoracic facet neurolysis increased 8.7% annually and lumbar facet neurolysis increased 7.4%. We believe that this effect has been due to partially secondary to the MPW encouraging radiofrequency neurotomy and attempting to eliminate the other procedures.

Consequently, as alluded above, eliminating these procedures will result in the following:

> This will result access to care with their choice and shared decision making in approximately 50% of the patients. Ultimately, if these patients are moved to radiofrequency neurotomy, 30%-45% of patients will fail or do not like it, leading to access issues in at least 20% of FFS Medicare population who need medically necessary criteria based on 2019 LCD, along with evidentiary basis.

Trends of expenditures and utilization of facet joint interventions in FFS population shows increase for cervical and thoracic radiofrequency neurotomy and lumbar radiofrequency neurotomy at an annual rate of 12.3% and 11.6% (Table 6). Compared to this, the increases for cervicothoracic facet joint injections and lumbar facet joint injections, the increases were 3.5% and 3.3% (25).



Data source: Part B Carrier Summary Data Files.
https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-Carrier-Summary-Data-File/Overview

Source: Manchikanti L, Sanapati MR, Pampati V, Soin A, Atluri S, Kaye AD, Subramanian J, Hirsch JA. Update of utilization patterns of facet joint interventions in managing spinal pain from 2000 to 2018 in the US fee-for-service Medicare population. *Pain Physician* 2020; 23:E133-E149 (26).

Fig. 2. *Comparative utilization patterns based on an annual rate from 2000-2009 and 2009-2018.*

Table 6. *Total allowed charges by place of services by type of procedures.*

Total	C2009	C2010	C2011	C2012	C2013	C2014	C2015	C2016	C2017	C2018	Change	GM
C/T FJI	$81,588,618	$73,188,771	$82,671,292	$86,479,555	$93,008,461	$92,620,549	$99,268,335	$117,816,821	$104,027,503	$111,420,505	37%	3.5%
Lumbar FJI	$263,416,206	$230,506,997	$255,149,549	$284,530,647	$298,591,267	$288,637,018	$317,603,055	$378,174,199	$335,011,474	$354,354,129	35%	3.3%
C/T RFT	$30,438,563	$23,848,722	$28,661,723	$31,793,404	$34,516,390	$52,611,759	$59,944,653	$67,552,231	$75,119,880	$86,606,144	185%	12.3%
Lumbar RFT	$133,675,207	$149,136,570	$169,584,192	$198,709,779	$208,473,256	$228,136,999	$251,316,488	$280,591,435	$329,674,962	$359,946,245	169%	11.6%
Total	$509,118,597	$476,681,060	$536,066,755	$601,513,390	$634,589,374	$662,006,327	$728,132,533	$844,134,686	$843,833,820	$912,327,051	79%	6.7%
Total * (inflation-adjusted)	$595,668,758	$548,183,219	$600,394,766	$655,649,595	$685,356,524	$701,726,707	$771,820,485	$886,341,420	$860,710,496	$912,327,051	53%	4.9%
Per 100,000 Medicare beneficiaries *	$1,300,558	$1,168,485	$1,243,053	$1,303,478	$1,320,533	$1,311,639	$1,405,866	$1,568,746	$1,483,984	$1,530,750	18%	1.8%
Per beneficiaries*	$13	$12	$12	$13	$13	$13	$14	$16	$15	$15	18%	1.8%
Per facet joint patient*	$1,925	$1,752	$1,816	$1,841	$1,868	$1,772	$1,780	$1,911	$1,759	$1,785	-7%	-0.8%

Source: Manchikanti L, Pampati V, Soin A, Vanaparthy R, Sanapati MR, Kaye AD, Hirsch JA. Trends of expenditures and utilization of facet joint interventions in fee-for-service (FFS) Medicare population from 2009-2018. *Pain Physician* 2020; 23:S129-S147 (25).

Further analysis was performed for lumbar facet joint sessions and lumbar facet neurotomy sessions as shown in Tables 7 and 8. Overall, there was 0.2% reduction in the United States from 2009 to 2018 for facet joint injection sessions, which are performed for diagnostic and therapeutic purposes. The costs of these procedures are one half of radiofrequency neurotomy procedures. Overall, US total was $896 per 100,000 Medicare population compared to $913 in 2009. In contrast, utilization of lumbar facet neurolysis sessions as shown in Table 8, was an annual increase of 7.9% from 2009 to 2018. However, per 100,000 population, these procedures were performed at a rate of 240 in 2009 and 475 in 2018 (25).

Table 7. *Utilization of lumbar facet joint sessions rate per 100,000 Medicare beneficiaries (episodes) by 2016 Medicare carrier and state.*

State name	R2009	R2010	R2011	R2012	R2013	R2014	R2015	R2016	R2017	R2018	Change	GM
Cahaba												
Alabama	969	1,228	1,224	1,347	1,141	1,127	1,098	1,264	1,050	1,006	3.8%	0.4%
Georgia	1,099	1,107	1,087	1,175	1,131	1,154	1,246	1,235	1,116	1,210	10.1%	1.1%
Tennessee	1,187	1,138	1,195	1,157	865	847	808	902	873	809	-31.8%	-4.2%
Cabha Total	1,093	1,150	1,160	1,215	1,044	1,044	1,061	1,132	1,019	1,026	-6.2%	-0.7%
PCPY		5.2%	0.9%	4.7%	-14.1%	0.0%	1.7%	6.7%	-10.0%	0.7%		
CGS												
Kentucky	1,154	1,011	1,084	1,170	1,131	1,056	1,337	1,182	1,310	1,238	7.3%	0.8%
Ohio	814	802	911	971	923	879	966	965	896	910	11.8%	1.2%
CGS Total	911	861	961	1,028	983	930	1,073	1,027	1,014	1,003	10.2%	1.1%
PCPY		-5.4%	11.5%	7.0%	-4.4%	-5.4%	15.3%	-4.3%	-1.2%	-1.1%		
First Coast												
Florida	1,453	1,253	1,226	1,326	1,154	1,297	1,266	1,293	1,250	1,215	-16.4%	-2.0%
PCPY		-13.8%	-2.2%	8.2%	-13.0%	12.4%	-2.4%	2.2%	-3.4%	-2.8%		
NGS												
Connecticut	817	740	662	730	752	772	753	771	868	809	-1.0%	-0.1%
Illinois	914	639	729	783	765	761	750	762	810	829	-9.4%	-1.1%
Maine	648	680	650	673	743	722	973	751	720	719	10.8%	1.1%
Massachusetts	929	899	937	1,032	1,063	1,097	1,148	1,010	1,060	1,038	11.6%	1.2%
Minnesota	352	310	368	490	429	463	400	395	399	397	12.9%	1.4%
New Hampshire	727	1,003	1,048	985	718	898	783	947	932	958	31.8%	3.1%
New York	488	497	500	440	558	579	661	661	652	614	25.8%	2.6%
Rhode Island	877	907	894	796	1,045	904	926	846	586	795	-9.3%	-1.1%
Vermont	1,000	915	733	767	784	825	977	1,081	1,149	878	-12.3%	-1.4%
Wisconsin	682	674	713	778	765	724	771	794	724	684	0.4%	0.0%
NGS Total	682	623	649	670	705	716	752	740	746	727	6.7%	0.7%
PCPY		-8.7%	4.2%	3.3%	5.1%	1.7%	5.0%	-1.7%	0.8%	-2.5%	-100.0%	
Noridian												
Alaska	574	639	290	115	480	813	1,061	978	827	935	62.9%	5.6%
Arizona	1,047	1,107	998	1,095	1,042	1,061	1,151	1,149	1,236	1,258	20.2%	2.1%
California	836	682	687	664	611	552	574	581	588	630	-24.6%	-3.1%
Idaho	496	409	387	659	548	578	548	688	692	749	51.2%	4.7%
Montana	559	543	622	664	531	630	549	566	473	717	28.4%	2.8%
Nevada	1,026	965	1,076	1,279	1,008	786	1,081	1,020	971	1,106	7.8%	0.8%
North Dakota	389	238	254	361	773	460	260	421	484	642	65.1%	5.7%
Oregon	478	470	372	447	404	430	589	509	587	638	33.4%	3.3%
South Dakota	818	542	649	468	418	419	473	679	665	538	-34.2%	-4.5%
Utah	935	728	752	915	1,110	1,430	1,347	1,135	1,145	1,123	20.2%	2.1%
Washington	753	613	420	443	456	435	404	467	498	586	-22.1%	-2.7%
Wyoming	972	899	903	975	1,013	981	821	1,136	824	1,168	20.2%	2.1%
Noridian Total	814	702	670	695	656	630	666	673	689	744	-8.5%	-1.0%
PCPY		-13.7%	-4.5%	3.8%	-5.6%	-4.1%	5.8%	1.0%	2.5%	8.0%		

Table 7 (cont.). *Utilization of lumbar facet joint sessions rate per 100,000 Medicare beneficiaries (episodes) by 2016 Medicare carrier and state.*

State name	R2009	R2010	R2011	R2012	R2013	R2014	R2015	R2016	R2017	R2018	Change	GM
Palmetto GBA												
North Carolina	803	730	747	889	742	784	865	897	877	832	3.7%	0.4%
South Carolina	1,085	998	1,026	1,101	1,260	1,330	1,340	1,456	1,449	1,382	27.4%	2.7%
Virginia	867	726	731	851	1,025	1,029	1,100	1,113	1,101	1,186	36.9%	3.5%
West Virginia	636	597	741	821	820	1,127	1,023	1,233	1,262	931	46.3%	4.3%
Palmetto Total	862	770	799	914	941	1,004	1,050	1,111	1,101	1,065	23.5%	2.4%
PCPY		-11%	4%	14%	3%	7%	5%	6%	-1%	-3%		
Novitas												
Arkansas	1,172	1,099	967	1,173	1,219	1,111	1,365	1,500	1,519	1,424	21.5%	2.2%
Colorado	538	522	560	671	686	694	808	784	743	810	50.6%	4.7%
Delaware	1,034	522	963	750	1,106	1,076	1,253	1,318	1,384	1,323	27.9%	2.8%
District of Columbia	391	538	451	886	533	633	835	746	791	432	10.5%	1.1%
Louisiana	512	786	802	749	797	890	957	973	975	853	66.4%	5.8%
Maryland	1,008	841	907	1,035	1,010	1,259	1,319	1,183	1,051	1,216	20.7%	2.1%
Mississippi	1,041	990	1,200	1,343	1,187	1,018	1,196	1,228	1,265	1,303	25.1%	2.5%
New Jersey	600	668	691	720	755	831	943	893	966	964	60.8%	5.4%
New Mexico	698	759	819	879	796	740	773	880	937	903	29.4%	2.9%
Oklahoma	858	756	667	751	775	1,072	1,300	1,318	1,407	1,481	72.5%	6.2%
Pennsylvania	684	644	607	613	689	721	769	783	863	863	26.2%	2.6%
Texas	1,324	1,036	964	993	922	902	1,044	1,074	960	933	-29.6%	-3.8%
Novitas Total	906	816	806	854	854	890	1,006	1,015	1,003	1,000	10.4%	1.1%
PCPY		-9.9%	-1.3%	6.0%	-0.1%	4.2%	13.1%	0.9%	-1.2%	-0.3%		
WPS												
Indiana	952	1,034	974	1,106	942	1,052	1,179	1,259	1,107	1,123	18.0%	1.9%
Iowa	551	595	558	527	635	611	657	773	792	794	44.0%	4.1%
Kansas	574	605	578	808	596	530	549	620	675	787	37.3%	3.6%
Michigan	1,639	1,497	1,459	1,563	1,624	1,857	1,706	1,443	1,256	969	-40.9%	-5.7%
Missouri	767	866	812	934	975	997	961	947	952	1,082	41.1%	3.9%
Nebraska	581	394	248	466	525	541	593	606	838	887	52.9%	4.8%
WPS Total	1,048	1,035	985	1,103	1,099	1,199	1,175	1,115	1,040	985	-5.9%	-0.7%
PCY		-1.2%	-4.8%	12.0%	-0.4%	9.1%	-2.0%	-5.1%	-6.7%	-5.3%		
USA Total	901	826	820	859	822	849	896	907	911	906	0.6%	0.1%
PCPY		-8.3%	-0.7%	4.8%	-4.4%	3.4%	5.5%	1.2%	0.5%	-0.6%		

Source: Manchikanti L, Pampati V, Soin A, Vanaparthy R, Sanapati MR, Kaye AD, Hirsch JA. Trends of expenditures and utilization of facet joint interventions in fee-for-service (FFS) Medicare population from 2009-2018. *Pain Physician* 2020; 23:S129-S147 (25).

Table 8. *Utilization of lumbar facet neurolysis rate per 100,000 Medicare beneficiaries (episodes) by 2016 Medicare carrier and state.*

State name	R2009	R2010	R2011	R2012	R2013	R2014	R2015	R2016	R2017	R2018	Change	GM
Cahaba												
Alabama	111	144	160	231	221	254	257	362	341	381	243.2%	14.7%
Georgia	390	447	405	443	438	494	584	578	669	715	83.1%	7.0%
Tennessee	223	161	228	306	262	259	329	392	437	433	94.2%	7.7%
Cahaba Total	258	269	280	341	321	352	413	460	508	537	108.1%	8.5%
PCPY		4.2%	4.1%	21.8%	-5.7%	9.6%	17.4%	11.2%	10.5%	5.7%		
CGS												
Kentucky	336	374	402	509	501	517	649	640	799	853	153.5%	10.9%
Ohio	199	256	309	370	373	420	422	473	453	502	152.3%	10.8%
CGS Total	238	289	336	410	410	448	487	521	551	602	152.8%	10.9%
		21.6%	16.0%	22.2%	0.0%	9.2%	8.8%	6.9%	5.8%	9.1%		
First Coast												
Florida	392	334	329	387	378	470	488	580	617	627	60.1%	5.4%
PCPY		-14.6%	-1.6%	17.7%	-2.5%	24.5%	3.7%	18.9%	6.4%	1.6%		
NGS												
Connecticut	104	137	135	174	157	161	253	225	250	359	245.8%	14.8%
Illinois	220	194	231	286	310	326	366	382	425	415	88.3%	7.3%
Maine	239	159	214	152	241	241	302	222	279	205	-14.2%	-1.7%
Massachusetts	196	213	219	272	349	272	381	355	318	391	99.1%	8.0%
Minnesota	141	84	95	173	152	178	119	171	203	173	22.6%	2.3%
New Hampshire	340	394	629	458	257	363	400	466	498	558	64.0%	5.6%
New York	155	141	151	170	222	229	269	294	253	309	99.0%	7.9%
Rhode Island	166	131	86	53	110	22	74	118	104	157	-5.6%	-0.6%
Vermont	371	287	332	307	434	501	394	563	531	418	12.8%	1.3%
Wisconsin	229	222	204	306	301	313	353	394	387	417	82.1%	6.9%
NGS Total	186	172	190	226	255	257	298	317	313	344	84.6%	7.0%
PCPY		-7.9%	10.6%	19.2%	12.7%	0.7%	16.1%	6.1%	-1.1%	9.9%		
Noridain												
Alaska	128	61	174	260	226	325	440	477	479	520	307.3%	16.9%
Arizona	334	434	436	483	570	564	631	668	799	989	196.7%	12.8%
California	151	182	196	194	203	223	216	233	248	258	70.9%	6.1%
Idaho	189	218	194	222	211	323	339	326	333	300	58.4%	5.2%
Montana	316	236	150	124	173	126	224	149	158	314	-0.6%	-0.1%
Nevada	257	275	414	542	568	439	494	671	609	723	181.8%	12.2%
North Dakota	167	110	182	144	234	389	278	236	274	204	22.2%	2.3%
Oregon	139	187	153	174	180	178	215	204	233	251	79.9%	6.7%
South Dakota	193	161	260	255	111	176	145	282	230	269	39.2%	3.7%
Utah	453	452	465	594	720	915	1,139	921	941	968	113.8%	8.8%
Washington	200	185	129	130	123	157	138	151	194	267	33.0%	3.2%
Wyoming	486	475	464	262	230	89	216	358	451	490	0.8%	0.1%
Noridian Total	197	225	231	245	264	283	300	315	345	390	97.8%	7.9%
PCPY		14.1%	2.7%	5.9%	7.7%	7.4%	5.9%	5.1%	9.4%	13.1%		

Table 8 (cont.). *Utilization of lumbar facet neurolysis rate per 100,000 Medicare beneficiaries (episodes) by 2016 Medicare carrier and state.*

State name	R2009	R2010	R2011	R2012	R2013	R2014	R2015	R2016	R2017	R2018	Change	GM
Palmetto GBA												
North Carolina	331	314	350	318	305	276	349	356	430	415	25.2%	2.5%
South Carolina	251	313	333	336	431	420	513	582	624	625	148.8%	10.7%
Virginia	198	195	174	228	306	348	423	440	566	585	195.1%	12.8%
West Virginia	292	299	290	230	285	364	359	456	594	544	86.5%	7.2%
Palmetto Total	271	276	287	286	330	336	406	438	527	522	92.9%	7.6%
PCPY		2%	4%	-1%	16%	2%	21%	8%	20%	-1%		
Novitas												
Arkansas	688	696	557	623	791	809	1,034	1,271	1,331	1,354	96.8%	7.8%
Colorado	126	118	172	264	260	304	388	392	536	536	324.3%	17.4%
Delaware	207	80	182	114	209	165	330	410	393	577	178.9%	12.1%
District of Columbia	52	179	125	320	393	495	646	1,108	483	259	397.2%	19.5%
Louisiana	268	300	424	465	456	547	672	673	734	714	166.2%	11.5%
Maryland	377	319	421	459	542	478	668	621	606	704	86.7%	7.2%
Mississippi	238	298	391	395	451	367	396	400	445	660	177.6%	12.0%
New Jersey	163	181	181	212	249	344	422	428	394	461	183.4%	12.3%
New Mexico	197	274	360	315	289	373	372	553	519	493	149.6%	10.7%
Oklahoma	213	268	355	320	400	615	543	610	864	900	322.5%	17.4%
Pennsylvania	144	162	161	161	204	230	281	285	298	324	125.3%	9.4%
Texas	384	417	381	440	505	523	567	675	702	666	73.4%	6.3%
Novitas Total	272	293	307	339	393	430	500	554	586	607	123.2%	9.3%
PCPY		7.6%	4.9%	10.4%	15.9%	9.5%	16.3%	10.9%	5.6%	3.7%		
WPS												
Indiana	272	251	312	237	308	354	431	455	453	449	65.0%	5.7%
Iowa	121	201	203	207	244	228	305	276	435	359	196.4%	12.8%
Kansas	197	180	219	161	163	190	228	250	314	283	43.3%	4.1%
Michigan	269	327	275	353	379	388	406	406	428	407	51.4%	4.7%
Missouri	209	239	262	296	328	349	336	292	360	380	81.8%	6.9%
Nebraska	138	158	198	209	221	216	283	261	328	444	221.9%	13.9%
WPS Total	228	257	263	277	312	330	364	358	404	397	74.2%	6.4%
PCY		13.0%	2.2%	5.3%	12.8%	5.6%	10.5%	-1.8%	13.0%	-1.9%		
USA Total	240	250	262	286	308	332	375	411	452	475	97.7%	7.9%
		4.1%	4.5%	9.5%	7.4%	8.0%	12.8%	9.5%	10.2%	5.1%		

Source: Manchikanti L, Pampati V, Soin A, Vanaparthy R, Sanapati MR, Kaye AD, Hirsch JA. Trends of expenditures and utilization of facet joint interventions in fee-for-service (FFS) Medicare population from 2009-2018. *Pain Physician* 2020; 23:S129-S147 (25).

Thus, based on the evidence, therapeutic facet joint procedures, both intraarticular injections and medial branch blocks are effective. These have been covered ever since the first LCD was established for interventional pain management in early 2000s. With emerging evidence without overwhelming negative evidence, we believe that it would be inappropriate to issue a noncoverage policy for one or both procedures.

Other advantages of therapeutic medial branch blocks and intraarticular injections include: performance of bilateral procedures in one session, for radiofrequency procedures, in 2018, there were staged procedures of 23.9% in lumbar spine performing in more than one session on the same side, or 2 separately in separate sessions, and 19.6% in cervical spine. Similarly, more than 2 episodes were utilized in the lumbar spine in 6.9% of the patients and 5.1% of the patients in cervical spine (25).

Comments:

Further, changes such as this one not only affect Medicare patients, but the entire United States population in pain. Commercial insurers and Medicare Managed Care are adapting unpublished, non-evidence-based NASS guidance and denying coverage for therapeutic facet joint nerve blocks and intraarticular injections. In addition, some insurers, not only are mandating for radiofrequency neurotomy, but they would like to reimburse at the same level for facet joint nerve blocks and radiofrequency neurotomy, saving billions of dollars and costing taxpayers billions of dollars. Ironically, radiofrequency neurotomy is twice the cost of facet joint nerve blocks and effective for 6 months in 60% to 65% of the patients, whereas therapeutic facet joint nerve blocks and therapeutic facet joint nerve blocks are effective in over 80% of the patients at half the price, for over 3 months. Finally, cost utility analysis, if performed side by side, may show that therapeutic facet joint nerve blocks are more cost effective than radiofrequency neurotomy (Fig. 1). Table 9 shows 2020 Medicare fee schedules in various settings for radiofrequency neurotomy and facet joint nerve blocks.

It is also interesting to note the differential between the costs will only increase with radiofrequency neurotomy when they are performed in an office setting due to reimbursement for multiple levels in an office setting, even though in a facility setting, the differential remains the same and around 50%.

If Medicare is interested in finding out how many procedures are performed for therapeutic facet joint nerve blocks compared to intraarticular injections, please create a modifier for therapeutic facet joint nerve blocks and diagnostic and therapeutic intraarticular injections.

If you desire to get further information, you may also use with steroids and without steroids, 2 different modifiers, which will provide appropriate information in the future.

Table 9. *2020 Medicare fee schedules.*

CPT	Description	Physician fee	Office Overhead	ASC Facility	HOPD Facility
Facet joint injections (IA, MBB)					
64490	C/T facet joint injections, 1st Level	$109.71	$85.89	$410.32	$811.96
64491	C/T facet joint injections, 2nd Level	$62.44	$35.73		
64492	C/T facet joint injections, 3rd Level	$63.16	$35.73		
64493	L/S facet joint injections, 1st Level	$93.11	$84.81	$410.32	$811.96
64494	L/S facet joint injections, 2nd Level	$53.77	$37.53		
64495	L/S facet joint injections, 3rd Level	$54.50	$36.81		
Facet joint radiofrequency					
64633	C/T Facet joint nerve block w/radiofrequency neurolysis w/fluoroscopy	$233.14	$197.77	$796.79	$1,719.16
64634	C/T Facet joint nerve block w/radiofrequency neurolysis w/fluoroscopy - additional	$70.74	$121.98		
64635	L/S Facet joint nerve block w/radiofrequency neurolysis w/fluoroscopy	$229.89	$196.33	$796.79	$1,719.16
64636	L/S Facet joint nerve block w/radiofrequency neurolysis w/fluoroscopy - additional	$62.07	$113.68		

Source: https://www.cms.gov/Center/Provider-Type/Physician-Center ; https://www.cms.gov/Center/Provider-Type/Ambulatory-Surgical-Centers-ASC-Center; https://www.cms.gov/Center/Provider-Type/Hospital-Center

Solution:

Please revise and remove restrictions:

Option I: Return to old language (as published by CGS)

When dual medial branch blocks or intraarticular injections provide greater than 80% relief of the primary or index pain consistent with the expected physiological effects of the agents utilized index pain or 50% improvement in function with ability to perform previously painful maneuvers, consistent with the expected physiological effects of the agents utilized, followed by at least 50% improvement for 6 weeks with pain and function, therapeutic facet joint nerve blocks or intraarticular injections may be considered.

Option II: Expand indications

- Patient's choice
- Patient's comfort
- Patient's anxiety
- Patient's fear
- Obesity
- Cardiac and respiratory compromise
- Lack of response or inadequate response to radiofrequency
- Spinal pseudoarthrosis
- Implanted electrical device

C. Facet Joint Denervation

Frequency limitation: For each covered spinal region no more than two (2) radiofreqency sessions will be reimbursed per rolling 12 months.

Limitation of thermal RFA with at least 6 months of relief is appropriate. This is appropriate in most instances; however, if a person requires bilateral radiofrequency neurotomy involving higher anatomic levels in cervical spine, it may be associated with significant side effects. Similar difficulties may be observed in patients undergoing lumbar or thoracic radiofrequency neurotomy in some patients. In addition, it is a reasonably painful procedure and difficult to perform both sides at the same time. To show practical importance, First Coast Services has this option available; however, their increase utilization rates have been less than the rest of the United States. Consequently, this may not increase the utilization patterns since many of them already performed the staged procedures and more than 2 radiofrequency neurotomies per year.

Consequently, frequency limitation to be amended to state: "if bilateral need is documented and it is medically necessary, a physician may perform each side separately with limiting to 2 radiofreqency sessions per year per side if performed separately."

Limitations

Under the limitations, we have some issues which need to be addressed. We have a few comments and suggestions and requests for changes.

Proposed

6. One or two levels, either unilateral or bilateral, are allowed per session per spine region. The need for a three-level procedure may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal.

Present LCD

For each covered spinal region (cervical/thoracic or lumbar), no more than two (2) joints bilaterally thermal RF sessions will be reimbursed in any calender year, involving no more than four (4) joints per session.

It may not be appropriate to limit to one or 2 joints, either unilateral or bilateral. Consequently, we request the language to be revised as follows:

Comment/Solution

Please revise as follows:

6. Two ~~levels~~ joints ~~either unilateral~~ for bilateral procedures and 4 joints for unilateral are allowed per session per spine region. The need for a three or four-level procedure bilaterally may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal. A session is a time period, which includes all procedures (i.e., medial branch block (MBB), intraarticular injections (IA), faces cyst ruptures, and RFA ablations performed during one day.

Proposed

7. Repeat medically reasonable and necessary therapeutic intraarticular injections or RFA at the same site of a previously treated facet joint may be done without additional diagnostic MBBs if prior treatment was within past 24 months.

Comment:

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. There are patients who go several years without interval diagnostic blocks with continued therapeutic facet joint interventions. Some of our patients have been treated for 15 years or longer with repeat therapeutic facet joint interventions, within the limits of LCDs, without interval diagnostic blocks.

Solution:

Consequently, this language must be deleted.

Proposed

8. Therapeutic intraarticular facet joint are not covered unless there is justification in the medical documentation on why RFA cannot be performed.

Solution

We discussed this in therapeutic intraarticular and facet joint nerve blocks section extensively. Consequently, this restriction may be removed or appropriately modified.

Not Reasonable and Necessary

4. Facet joint procedure performed at a fused posterior spinal motion segment.

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. Consequently, this sentence may be deleted.

Thank you again for all your dedication. We hope these comments will be helpful in revising the LCD, which will be acceptable to all involved, which will not only improve the patient care, but within the parameters of Chapter 13 of Medicare Program Integrity Manual and Medicare's promise to provide appropriate care to elderly.

REFERENCES

1. Manchikanti L, Kaye AD, Soin A, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) guidelines. *Pain Physician* 2020; 23:S1-S127. https://asipp.org/wp-content/uploads/2020/11/REF1MA1.pdf
2. Manchikanti L, Kosanovic R, Pampati V, et al. Low back pain and diagnostic lumbar facet joint nerve blocks: Assessment of prevalence, false-positive rates, and a philosophical paradigm shift from an acute to a chronic pain model. *Pain Physician* 2020;23:519-530. https://asipp.org/wp-content/uploads/2020/11/Ref-2.-Manchikanti-et-al.-Low-Back-Pain-and-Diagnostic-Lumbar-Facet-Joint-Nerve-Blocks.pdf
3. Manchikanti L, Kosanovic R, Cash KA, et al. Assessment of prevalence of cervical facet joint pain with diagnostic cervical medial branch blocks: Analysis based on chronic pain model. *Pain Physician* 2020; in press. https://asipp.org/wp-content/uploads/2020/11/Ref-3.-Assessment-of-prevalence-of-cervical-facet-joint-pain-with-diagnostic-cervical-medial-branch-blocks.pdf
4. Shanthanna H, Busse J, Wang L, et al. Addition of corticosteroids to local anaesthetics for chronic non-cancer pain injections: A systematic review and meta-analysis of randomised controlled trials. *Br J Anaesth* 2020; 125:779-801. https://asipp.org/wp-content/uploads/2020/11/Ref-4.-Shanthanna-etl-al.-Addition-of-corticosteroids-to-local-anaesthetics-for-chronic-non-cancer-pain-injections.pdf
5. Knezevic N, Manchikanti L, Urits I, et al. Lack of superiority of epidural injections with lidocaine with steroids compared to without steroids in spinal pain: A systematic review and meta-analysis. *Pain Physician* 2020; 23:S239-S270. https://asipp.org/wp-content/uploads/2020/11/Ref-5.-Knezevic-et-al.-Lack-of-superiority-of-epidural-injections-with-lidocaine-with-steroids.pdf
6. Manchikanti L, Knezevic NN, Parr A, et al. Does epidural bupivacaine with or without steroids provide long-term relief? A systematic review and meta-analysis. *Curr Pain Headache Rep* 2020; 24:26. https://asipp.org/wp-content/uploads/2020/11/Ref-6.-Manchikanti-et-al.-Does-epidural-bupivacaine-with-or-without-steroids-provide-long-term-relief.pdf
7. Lee JH, Kim DH, Kim DH, et al. Comparison of clinical efficacy of epidural injection with or without steroid in lumbosacral disc herniation: A systematic review and meta-analysis. *Pain Physician* 2018; 21:449-468. https://asipp.org/wp-content/uploads/2020/11/Ref-7.-Lee-et-al.-Comparison-of-clinical-efficacy-of-epidural-injection-with-or-without-steroid-.pdf
8. Mesregah MK, Feng W, Huang WH, et al. Clinical effectiveness of interlaminar epidural injections of local anesthetic with or without steroids for managing chronic neck pain: A systematic review and meta-analysis. *Pain Physician* 2020; 23:335-348. https://asipp.org/wp-content/uploads/2020/11/Ref-8.-Mesregah-et-al.-Clinical-effectiveness-of-interlaminar-epidural-injections-of-local-anesthetic-.pdf
9. Zhao W, Wang Y, Wu J, et al. Long-term outcomes of epidurals with lidocaine with or without steroids for lumbar disc herniation and spinal stenosis: A meta-analysis. *Pain Physician* 2020; 23:365-374. https://asipp.org/wp-content/uploads/2020/11/Ref-9.-Zhao-et-al.-Long-term-outcomes-of-epidurals-with-lidocaine-with-or-without-steroids-.pdf
10. Civelek E, Cansever T, Kabatas S, et al. Comparison of effectiveness of facet joint injection and radiofrequency denervation in chronic low back pain. *Turk Neurosurg* 2012; 22:200-206. https://asipp.org/wp-content/uploads/2020/11/Ref-10.-Civelek-et-al.-Comparison-of-effectiveness-of-facet-joint-injection-and-radiofrequency-denervation-in-chronic-LBP.pdf

11. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V. Evaluation of lumbar facet joint nerve blocks in managing chronic low back pain: A randomized, double-blind, controlled trial with a 2-year follow-up. *Int J Med Sci* 2010; 7:124-135. https://asipp.org/wp-content/uploads/2020/11/Ref-11.-Manchikanti-et-al.-Evaluation-of-lumbar-facet-joint-nerve-blocks-in-managing-chronic-low-back-pain.pdf
12. Manchikanti L, Pampati V, Bakhit C, et al. Effectiveness of lumbar facet joint nerve blocks in chronic low back pain: A randomized clinical trial. *Pain Physician* 2001; 4:101-117. https://asipp.org/wp-content/uploads/2020/11/Ref-12.-Manchikanti-et-al.-Effectiveness-of-lumbar-facet-joint-nerve-blocks-in-chronic-low-back-pain.pdf
13. Manchikanti L, Singh V, Falco FJE, Cash KA, Fellows B. Comparative outcomes of a 2-year follow-up of cervical medial branch blocks in management of chronic neck pain: A randomized, double-blind controlled trial. *Pain Physician* 2010; 13:437-450. https://asipp.org/wp-content/uploads/2020/11/Ref-13.-Manchikanti-et-al.-Comparative-outcomes-of-a-2-year-follow-up-of-cervical-medial-branch-blocks-in-management-CNP.pdf
14. Manchikanti L, Manchikanti K, Damron K, Pampati V. Effectiveness of cervical medial branch blocks in chronic neck pain: A prospective outcome study. *Pain Physician* 2004; 7:195-201. https://asipp.org/wp-content/uploads/2020/11/Ref-14.-Manchikanti-et-al.-Effectiveness-of-cervical-medial-branch-blocks-in-chronic-neck-pain.pdf
15. Hahn T, Halatsch ME, Wirtz C, Klessinger S. Response to cervical medial branch blocks in patients with cervicogenic vertigo. *Pain Physician* 2018; 21:285-294. https://asipp.org/wp-content/uploads/2020/11/Ref-15.-Hahn-et-al.-Response-to-cervical-medial-branch-blocks-in-patients-with-cervicogenic-vertigo..pdf
16. Lee DW, Huston C. Fluoroscopically guided cervical zygapophyseal therapeutic joint injections may reduce the need for radiofrequency. *Pain Physician* 2018; 21:E661-E665. https://asipp.org/wp-content/uploads/2020/11/Ref-16.-Lee-and-Huston.-Fluoroscopically-guided-cervical-zygapophyseal-therapeutic-joint-injections.pdf
17. Manchikanti L, Singh V, Falco FJE, Cash KA, Pampati V, Fellows B. The role of thoracic medial branch blocks in managing chronic mid and upper back pain: A randomized, double blind, active control trial with a 2-year follow-up. *Anesthesiol Res Pract* 2012; 2012:585806. https://asipp.org/wp-content/uploads/2020/11/Ref-17.-Manchikanti-et-al.-The-role-of-thoracic-medial-branch-blocks-in-managing-chronic-mid-and-upper-back-pain.pdf
18. Manchikanti L, Manchikanti KN, Manchukonda R, Pampati V, Cash KA. Evaluation of therapeutic thoracic medial branch block effectiveness in chronic thoracic pain: A prospective outcome study with minimum 1-year follow up. *Pain Physician* 2006; 9:97-105. https://asipp.org/wp-content/uploads/2020/11/Ref-18.-Manchikanti-et-al.-Evaluation-of-therapeutic-thoracic-medial-branch-block-effectiveness-in-chronic-thoracic-pain.pdf
19. Lee DG, Ahn SH, Cho YW, Do KH, Kwak SG, Chang MC. Comparison of intraarticular thoracic facet joint steroid injection and thoracic medial branch block for the management of thoracic facet joint pain. *Spine (Phila Pa 1976)* 2018; 43:76-80. https://asipp.org/wp-content/uploads/2020/11/Ref-19.-Lee-et-al.-Comparison-of-intraarticular-thoracic-facet-joint-steroid-injection-and-thoracic-medial-branch-block.pdf
20. Park KD, Jee H, Nam HS, et al. Effect of medial branch block in chronic facet joint pain for osteoporotic compression fracture: One year retrospective study. *Ann Rehabil Med* 2013; 37:191-201. https://asipp.org/wp-content/uploads/2020/11/Ref-20.-Park-et-al.-Effect-of-medial-branch-block-in-chronic-facet-joint-pain-for-osteoporotic-compression-fracture.pdf
21. Chang MC. Effect of pulsed radiofrequency treatment on the thoracic medial branch for managing chronic thoracic facet joint pain refractory to medial branch block with local anesthetics. *World Neurosurg* 2018; 111:e644-e648. https://asipp.org/wp-content/uploads/2020/11/Ref-21.-Chang.-Effect-of-pulsed-radiofrequency-treatment-on-the-thoracic-medial-branch-.pdf

22. North American Spine Society (NASS) Coverage Policy Recommendations: Facet Joint Interventions. *October* 2016. Accessed 10/12/2020. https://www.spine.org/Coverage
23. Manchikanti L, Pampati V, Kaye AD, Hirsch JA. Therapeutic lumbar facet joint nerve blocks in the treatment of chronic low back pain: Cost utility analysis based on a randomized controlled trial. *Korean J Pain* 2018; 31:27-38. https://asipp.org/wp-content/uploads/2020/11/Ref-23.-Manchikanti-et-al.-Therapeutic-lumbar-facet-joint-nerve-blocks-in-the-treatment-CLBP-Cost-utility-analysis.pdf
24. Manchikanti L, Pampati V, Kaye AD, Hirsch JA. Cost utility analysis of cervical therapeutic medial branch blocks in managing chronic neck pain. *Int J Med Sci* 2017; 14:1307-1316. https://asipp.org/wp-content/uploads/2020/11/Ref-24.-Manchikanti-et-al.-Cost-utility-analysis-of-cervical-therapeutic-medial-branch-blocks-in-managing-chronic-neck-pain.pdf
25. Manchikanti L, Pampati V, Soin A, Vanaparthy R, Sanapati MR, Kaye AD, Hirsch JA. Trends of expenditures and utilization of facet joint interventions in fee-for-service (FFS) Medicare population from 2009-2018. *Pain Physician* 2020; 23:S129-S147. https://asipp.org/wp-content/uploads/2020/11/Ref-25.-Manchikanti-et-al.-Trends-of-expenditures-and-utilization-of-facet-joint-interventions.pdf
26. Manchikanti L, Sanapati MR, Pampati V, Soin A, Atluri S, Kaye AD, Subramanian J, Hirsch JA. Update of utilization patterns of facet joint interventions in managing spinal pain from 2000 to 2018 in the US fee-for-service Medicare population. *Pain Physician* 2020; 23:E133-E149. https://asipp.org/wp-content/uploads/2020/11/Ref-26.-Manchikanti-et-al.-Update-of-utilization-patterns-of-facet-joint-interventions.pdf

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