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Robert Mandel, MD, MBA, Senior Vice President, Chief Medical Officer
AIM Specialty Health
8600 West Bryn Mawr Avenue
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RE: AIM Clinical Appropriate Guidelines: Musculoskeletal Program - Interventional Pain Management

Dear Mr. Cady and Dr. Mandel:

On behalf of the American Society of Interventional Pain Physicians (ASIPP) and 51 state societies (including the Puerto Rico Society of Interventional Pain Physicians), we would like to thank you for publishing AIM Musculoskeletal Program Interventional Pain Management guidelines to achieve the multiple functions of establishing criteria, standardizing medical practice patterns, advocating patient safety concerns, enhancing quality of care, and promoting the most efficient and cost effective use of services.

We also appreciate the guideline development process you have described in the document with applicable accreditation standards. These include the requirement that the guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the guidelines under the review and be based on the most up to date clinical principles and best practices. However, we would respectfully disagree with some of the assumptions related to evidence-based medicine, current clinical expertise, and involvement of appropriate providers. We believe that there was no involvement of stakeholder providers, and further, the available evidence may not have been utilized appropriately. Consequently, we would like to make comments and request revisions for these guidelines as these will be widely applied by multiple carriers, affecting not only the quality of care, but access to care with increasing practice expenses.

We would like to specifically comment on epidural injection procedures, diagnostic selective nerve root blocks, and paravertebral facet joint injection/nerve block/neurolysis. In addition, we are also writing about percutaneous adhesiolysis (also known as neuroplasty), a procedure which has not been included in the AIM Guideline. The majority of the insurers who are following your guidance have not approved this procedure. All our comments are based on evidence-based principles and available literature derived predominantly from randomized controlled trials and systematic reviews. In cases where there is a lack of randomized controlled trials, the evidence is derived from observational literature or consensus. We will so state when this level of evidence of applied.

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.

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 (1).

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 (2).

Interventional pain management (09) also has been provided a mandatory membership to Carrier Advisory Committees (CACs) in each state in the United States (3).

1. The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management- 09. http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf
2. Medicare Payment Advisory Commission. 2001. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December. 2001. http://www.medpac.gov/publications/congressional_reports/dec2001PainManagement.pdf
3. 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

The following are our concerns about the AIM Musculoskeletal Program – Interventional Pain Management guidelines, with its associated precertification process and various other issues. We will focus our comments on epidural injection procedures; diagnostic selective nerve root blocks; paravertebral facet injection/nerve block/neurolysis procedures; and percutaneous adhesiolysis, which has not been analyzed by AIM in their guideline development process for musculoskeletal program of interventional pain management.

EPIDURAL INJECTION PROCEDURES AND DIAGNOSTIC SELECTIVE NERVE ROOT BLOCKS

Epidural injection procedures and diagnostic selective nerve root blocks are described under this heading.

In 2014, the US Food and Drug Administration (FDA) issued a drug safety communication about epidural injection of glucocorticoids, citing the risk of rare but serious adverse effects. However, this was related to transforaminal epidural injections, mainly in the cervical spine (1-5). The guidelines describe indications for epidural steroids only for radicular pain either for workup or for therapeutic modality when noninvasive treatment strategies have failed. However, the literature also is replete with multiple other indications for this therapy, including: central spinal stenosis with or without claudication; foraminal stenosis with or without radicular pain; discogenic pain (after an appropriate diagnostic workup eliminating facet joint pain, sacroiliac joint pain and other conditions); and, finally, post surgery syndrome (6-46). The majority of the studies showed positive evidence for fluoroscopic epidural injections when performed appropriately with repeated procedures in patients who were responsive to the initial 2 procedures. Further, the misunderstanding of placebo and flawed methodology has been discussed extensively (11,13,45,47). The comprehensive evidence provided by Kaye et al (7) utilizing best evidence synthesis from Level I to V showed the following, after reviewing 52 trials that met inclusion criteria:

- The evidence in managing lumbar disc herniation or radiculitis is Level II for long-term improvement, either with caudal, interlaminar, or transforaminal epidural injections with no significant difference among the approaches.
- The evidence is Level II for long-term management of cervical disc herniation with interlaminar epidural injections.
- The evidence is Level II to III in managing thoracic disc herniation with an interlaminar approach.
- The evidence is Level II for caudal and lumbar interlaminar epidural injections with Level III evidence for lumbar transforaminal epidural injections for lumbar spinal stenosis.
- The evidence is Level II for cervical spinal stenosis management with an interlaminar approach.
- The evidence is Level II for axial or discogenic pain without facet arthropathy or disc herniation treated with caudal or lumbar interlaminar injections in the lumbar region; whereas it is Level II in the cervical region treated with cervical interlaminar epidural injections.
- The evidence for post lumbar surgery syndrome is Level II with caudal epidural injections and for post cervical surgery syndrome it is Level II with cervical interlaminar epidural injections.

Further, not only clinical efficacy evidence, but also significant evidence of cost utility has been provided thus far for caudal and lumbar interlaminar epidural injections for disc herniation, discogenic pain, and spinal stenosis, and caudal epidural injections for post surgery syndrome (48,49). The cost utility analysis was performed using highly regarded surgical literature from an analysis of Spine Patient Outcomes Research Trial (SPORT) data (50,51). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall the cost effectiveness of disc herniation surgery (50) at $69,403 per quality-adjusted life year (QALY), whereas for spinal stenosis surgery, it was $77,600 per QALY, and $115,600 per QALY for degenerative spondylolisthesis (51). More importantly, these studies showed direct costs without medication to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis, with total costs of $26,222 to $27,341 and $42,081 respectively. Based on these studies, considering the direct procedural cost, lowest indirect costs at 60% and highest indirect cost of 40%, the cost utility of caudal epidural injections is estimated to be $3,628 with multiplication of the procedural cost by 1.67. This procedure can be used to treat disc herniation, discogenic pain, spinal stenosis, and post surgery syndrome with some variations (48). Further, cost utility analysis of lumbar interlaminar epidural injections in the treatment of lumbar disc herniation, central spinal stenosis, and axial or discogenic low back pain, utilizing the extrapolation method of surgical interventions of direct cost, showed an average cost of $3,301 per QALY (49).

Thus, the guidance and evidence assessment provide not only the clinical effectiveness, but also value with lower expenses than surgical interventions per one year of QALY and well below $20,000 or $50,000 threshold utilized by many authorities.

EXCLUSIONS

The policy describes thoracic epidural injections as an exclusion for thoracic pathology. There is significant and emerging evidence of effectiveness of thoracic epidural injections (6,7,18). Consequently, we request that thoracic epidural injections should be a covered procedure. Denial of coverage for this may lead to access issues denying appropriate care in patients who require thoracic epidural injection procedures.

REQUESTED CHANGE:

We request that the policy be revised to specify the following:

- Based on the available evidence, epidural injections are considered appropriate in axial or discogenic spinal pain and post surgery syndrome after elimination of facet joint and sacroiliac joint pain in addition to disc herniation and spinal stenosis in lumbosacral, cervical and thoracic spine (6-9,31-34).

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FACET JOINT INJECTIONS/MEDIAL BRANCH BLOCKS

1. Paravertebral Facet Injection/Nerve Block/Neurolysis

Overall, this is a well written policy in reference to diagnostic facet joint nerve blocks and radiofrequency thermoneurolysis. However, even though intraarticular injections are covered, therapeutic medial branch blocks seem to be non-covered procedures. The policy excludes therapeutic medial branch blocks. Further, the policy also excludes thoracic diagnostic injections and radiofrequency thermoneurolysis in the thoracic region.

2. Thoracic Diagnostic Facet Joint Nerve Blocks

Thoracic diagnostic facet joint nerve blocks have been evaluated in 2 appropriately performed prevalence studies with dual diagnostic blocks. Systematic reviews have shown moderate or Level II evidence based on best evidence synthesis (1-5). Consequently, we request that diagnostic facet joint nerve blocks be allowed.

3. Thoracic Radiofrequency

Evidence of effectiveness of thoracic radiofrequency neurotomy, is emerging, with sources showing Level IV evidence (6,7). Consequently, this should be considered for coverage to avoid unnecessary denials, appeals, and access issues.

4. Therapeutic Medial Branch or Dorsal Ramus Blocks

Therapeutic medial branch blocks or L5 dorsal ramus blocks have been performed with increasing frequency. Essentially, based on CPT coding, therapeutic medial branch blocks are interchangeable with intraarticular injections. However, there is a wide variation in their effectiveness with medial branch or dorsal ramus blocks showing superior effectiveness. In fact, the evidence for therapeutic medial branch blocks or L5 dorsal ramus blocks is equivalent or often even better than radiofrequency neurotomy as illustrated in multiple systematic reviews, derived from multiple randomized controlled trials (1,6,8-16).

Based on the comprehensive best evidence synthesis (classified at 5 levels from Level I to Level V) assessment of effectiveness of therapeutic facet joint interventions in managing chronic spinal pain (6), with inclusion of 21 randomized controlled trials and 5 observational studies, the following evidence was presented:

- In the lumbar spine, there is Level II evidence for radiofrequency neurotomy and lumbar facet joint nerve blocks, whereas the evidence is Level III for lumbosacral intraarticular injections.
- In the cervical spine, there is Level II evidence for cervical radiofrequency neurotomy and cervical facet joint nerve blocks, and Level IV evidence for cervical intraarticular injections.
- In the thoracic spine, there is Level II evidence for thoracic facet joint nerve blocks and Level IV evidence for radiofrequency neurotomy.

Further, cost utility analysis has been assessed for lumbar and cervical facet joint nerve blocks showing favorable evidence. Based on the similar assessment, the results of cost utility analysis in the cervical spine showed with procedural costs of $2,552 and overall costs of $4,261 per one year improvement in QALY (17).

For the lumbar spine, the results of cost utility analysis showed procedural costs of $2,654.08 and overall costs of $4,432 per one year of QALY (18).

The cost utility analysis was performed from highly regarded surgical literature from analysis of Spine Patient Outcomes Research Trial (SPORT) data (19,20). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall cost effectiveness of disc herniation surgery (19) at $69,403 per quality-adjusted life year (QALY), whereas for spinal stenosis surgery, it was $77,600 per QALY, and $115,600 per QALY for degenerative spondylolisthesis (20). More importantly, these studies showed direct costs without medication costs to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis with total costs of $26,222 to $27,341 and $42,081 respectively. Based on these studies, considering the direct procedural cost lowest at 60% and highest indirect cost of 40%, the cost utility of facet joint injections is estimated to be $4,261 per one year improvement in QALY in cervical spine with facet joint nerve blocks, and $4,432 per one year of QALY in lumbar spine with facet joint nerve blocks with multiplication of the procedural cost by 1.67.

In addition to proven clinical and cost effectiveness:

- Therapeutic facet joint nerve blocks are covered by all Medicare carriers, an overwhelming majority of Medicaid carriers, and multiple commercial insurers.

- Facet joint nerve blocks elicit higher acceptance rate from patients with less fear compared to radiofrequency neurotomy, which seems to elicit more fear and the false notion of burning the nerves as promoted by many.

- It is crucial to consider the role of facet joint pain in lumbar and cervical postsurgery syndrome. Studies have shown significant prevalence of pain of facet joint origin in postsurgery patients (21-24). Further, a significant proportion of patients after post-surgery syndrome with hardware or bone fusion are not candidates for radiofrequency neurotomy; however, they can be treated with facet joint nerve blocks.

- Effectiveness of radiofrequency is not observed in all patients. Consequently, if 80% to 85% of the patients respond to radiofrequency neurotomy after appropriate diagnostic blockade, a 15% to 20% population is without response. Thus, without further treatment, after failure of radiofrequency neurotomy which is approximately 15% to 20% of the patients, these patients will be left without any further options. However, an overwhelming majority of these patients (after failure of radiofrequency neurotomy), seem to respond to facet joint nerve blocks.

- A significant proportion of obese patients also suffer with facet joint related pain. In these patients, radiofrequency neurotomy may be difficult. In these patients, facet joint nerve blocks can be performed with somewhat of an easier technical challenge providing significant improvement with lower risk (4,5,25).

- In patients with a pacemaker, radiofrequency neurotomy is difficult or associated with some risk, despite development of bipolar radiofrequency which is considered to be safe

but not foolproof. In these patients, facet joint nerve blocks will be much safer and easier to perform with patient comfort.

These are multiple and additional benefits of medial branch blocks and it will reduce the access to patient care once medial branch blocks are removed from armamentarium of treatment modalities.

We believe that your exclusion of therapeutic medial branch blocks is based on inappropriate interpretation of the evidence, with overall diminution in access and finally contributing to increased disability and health care costs rather than reducing these as you seem to believe it would (26-31).

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PERCUTANEOUS EPIDURAL ADHESIOLYSIS

Epidural adhesiolysis is not listed as a covered procedure, despite substantial evidence available by way of multiple randomized controlled trials specifically in post lumbar surgery syndrome and spinal stenosis (1-3), along with recalcitrant pain with degenerative disc disease (1-8). Overall, significant improvement has been shown in a greater proportion of patients with spinal stenosis, post surgery syndrome, and disc herniation at one and 2-year follow-ups based on pragmatic protocols and administration of the procedures. It should also be considered that these patients have already failed a multitude of interventions including interventional techniques with epidural injection and surgical interventions in many cases.

In addition, cost utility analysis also has been performed, which showed favorable cost utility (9). The cost utility analysis was performed from highly regarded surgical literature from analysis of Spine Patient Outcomes Research Trial (SPORT) data (10,11). These analyses provided a basis for estimation of indirect cost including drug therapy. They showed overall cost effectiveness of disc herniation surgery (10) at $69,403 per quality-adjusted life year (QALY), whereas for spinal stenosis surgery, it was $77,600 per QALY, and $115,600 per QALY for degenerative spondylolisthesis (11). More importantly, these studies showed direct costs without medication costs to be 60% for spinal stenosis, 68% for disc herniation, and 71% for degenerative spondylolisthesis with spinal stenosis with total costs of $26,222 to $27,341 and $42,081 respectively. Based on these studies, considering the direct procedural cost lowest at 60% and highest indirect cost of 40%, the cost utility of percutaneous adhesiolysis is estimated to be $4,425 with multiplication of the procedural cost by 1.67, with significant cost savings overall.

The evidence synthesis utilizing strict criteria of methodologic quality assessment and clinically relevant outcomes shows Level II evidence for percutaneous adhesiolysis after failure of other modalities of treatments.

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Thank you for consideration of our comments. Hopefully, you will consider these comments and revise the guidelines which will improve access and care patterns and value for the purchased insurance.

If you have any further questions, please feel free to contact us.

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