

American Society of Interventional Pain Physicians®

"The Voice of Interventional Pain Management"

81 Lakeview Drive, Paducah, KY 42001

Phone: (270) 554-9412 - Fax: (270) 554-5394

www.asipp.org

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David E. Mino, M.D., M.B.A.
National Medical Director
Orthopaedic Surgery and Spinal Disorders
Cigna Healthcare
david.mino@cigna.com

Ramnik Singh, MD
Diplomate, American Board of Physical Medicine and Rehabilitation
Diplomate, American Board of Pain Medicine
Medical Director, Cigna Healthcare
Ramnik.Singh@Cigna.com

RE: Cigna Musculoskeletal Precertification Program

Drs. Mino and Singh:

On behalf of American Society of Interventional Pain Physicians (ASIPP) and 51 state societies including Puerto Rico Society of Interventional Pain Physicians, we would like to thank you for requesting our input for Cigna Musculoskeletal Precertification Program. As you well know, we have corresponded with your organization in the past requesting consideration of multiple coverage issues with 684 signatures of interventional pain physicians from across the nation ([see letter](#)) and we would like to ensure that these procedures are provided appropriately and that patients insured by Cigna to maintain access to care. All our comments are based on evidence-based principles and available literature derived from randomized controlled trials and systematic reviews. In cases of lack of presence of randomized controlled trials, the evidence is derived from observational literature and consensus and we will state so.

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 discectomy, 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 Cigna Musculoskeletal Precertification Program and various issues related to the coverage policies. We will focus our comments on epidural injections, facet joint interventions, radiofrequency neurotomy, sacroiliac joint injections, facet joint injections and medial branch blocks, regional sympathetic blocks, and epidural adhesiolysis.

1.0 EPIDURAL STEROID INJECTIONS

The epidural steroid injections policy defines transforaminal epidural steroid injections, selective nerve root blocks, interlaminar epidural steroid injection, and caudal epidural injections. Further, the policy also defines radiculopathy with presence of pain and one or more of other signs including loss of strength, altered sensation, diminished or asymmetric reflexes, or concordant radiologist's interpretation of an advanced diagnostic imaging study or electrodiagnostic studies.

The policy also defines spinal stenosis with pain distribution.

The changes we request based on evidence-based medical principles **is that one or more of the following should include a positive straight leg raising or cross straight leg raising test (1).**

- Loss of strength of specific muscle or myotomal distribution concordant with nerve root compression of the involved spinal nerve root may not cover straight leg raising. A positive straight leg raising may be present without evidence of loss of strength.
- Radiculopathy or radiculitis may also be caused secondary to chemical discs.

General Guidelines

The policy considers an epidural steroid injection administered for axial spinal pain without documentation of radiculopathy, myelopathy, or myeloradiculopathy is considered "not medically necessary" (2).

- Based on the available evidence, the policy should be changed to include axial or discogenic spinal pain after appropriate measures have been taken to rule out facet joint pain or sacroiliac joint pain with diagnostic blockade.

Systematic reviews and randomized controlled trials demonstrate efficacy of epidural injections in discogenic pain after elimination of facet joint pain (1-12).

- The policy states based on the fact that a caudal epidural steroid injection is not target specific, the injectate is diluted, and the injectate rarely reaches the level above L5-S1, a caudal epidural steroid injection for levels above L5-S1 without a supporting clinical rationale (why it is preferred over translaminar or transforaminal, e.g., status post fusion with anatomical limitations) for alternative approaches, is considered not medically necessary.
- This is not accurate in many cases, flow can be observed up to L4 or L3 levels. Even though post fusion with anatomical limitations permits this, this is not an accurate statement.
- The description says no more than 3 epidural steroid injections should be performed per episode of pain.

Further, this also describes a series of 3 injections.

- We support lack of evidence for series of 3 injections. There is no such benefit for any of the approaches with series of 3. We also support lack of evidence to support epidural steroid injection with ultrasound guidance for any indication.
- However, changing the number of injections will be appropriate. The average relief from an epidural injection in the early phases is approximately 3 weeks with the first procedure and for 6 weeks with the second procedure. Consequently, it will be more appropriate to divide and also improve the compliance with provision of 2 epidural injections during the diagnostic phase or initial phase within the first 3 months and restrict to 4 therapeutic injections per region per year thereafter (3-5,13).

Therapeutic Epidural Steroid Injections

An epidural steroid is considered medically necessary for presumed radiculopathy resulting from disease, injury or surgery that has not responded sufficiently to a reasonable course (four week minimum) of conservative treatment (exercise, physical methods including physical therapy and/or chiropractic care, NSAID's and/or muscle relaxants).

- Once again, we would request to add proven discogenic pain after eliminating facet joint or sacroiliac joint pain if a patient has no facet joint or sacroiliac joint pain with axial pain will continue to suffer without any options if this is not included (1-12).

References

There has been substantial new literature which has not been included in these references. We suggest to add additional randomized controlled trials and systematic reviews published recently. With addition of these references, multiple old references can be deleted.

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2.0 FACET JOINT INJECTIONS/MEDIAL BRANCH BLOCKS

Comments on facet joint injections and medial branch blocks are as follows:

1. Facet joint injections/medial branch blocks

Even though generally 2 diagnostic blocks are required, your policy of one diagnostic block with 80% pain relief is acceptable, but it will increase false-positives and also will reduce outcomes with radiofrequency neurotomy.

2. Therapeutic facet joint injections/medial branch blocks

The guideline reads that subsequent facet joint injections are considered experimental, investigation, or unproven because of lack of evidence. These statements are inappropriate or unproven. There is significant evidence with randomized controlled trials, systematic reviews, and guidelines showing the effectiveness of therapeutic medial branch blocks similar to radiofrequency neurotomy. In fact, qualitative evidence synthesis showed Level II evidence for cervical, thoracic, and lumbar medial branch blocks based on randomized controlled trials (1-15); however, we agree with your assessment of intraarticular injections. There is only Level III evidence for intraarticular injections in the lumbar spine; however, some patients may require intraarticular injections and they do extremely well. These patients also may not be suitable for radiofrequency neurotomy.

- Approval of medial branch blocks with appropriate consideration of clinical improvement of 2½ to 3 months will essentially be equal in expense or even more cost effective.
- As you are aware, radiofrequency neurotomy costs twice as much as therapeutic medial branch blocks. If you approve one radiofrequency neurotomy for each 6 months, therapeutic medial branch blocks every 3 months will be more appropriate, less risk, and less painful.
- In the cervical spine, since radiofrequency neurotomy may not be performed bilaterally at one sitting, the majority of the patients are receiving 2 procedures within the time period. This will definitely add cost savings to approve them.
- Consequently we request the following language:

If a patient experiences after initial 50% pain relief, at least 50% pain relief with improvement in functional status lasting at least 3 weeks a patient may be a candidate for therapeutic medial branch blocks. These blocks will be limited to 4 per year per region bilaterally with documentation of 2½ to 3 months of relief with improvement in functional status.

References

The references appear to be somewhat outdated. There are multiple updated and recent references as shown here. With addition of these references, multiple old references can be deleted.

1. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques of chronic spinal pain: Part II: Guidance and recommendations. *Pain Physician* 2013; 16:S49-S283.
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3.0 RADIOFREQUENCY JOINT ABLATIONS/DENERVATIONS

The majority of the guideline is appropriate except that 50% relief for 80% of the duration of the effect of the local anesthetic used appears to be contradicting the requirement in medial branch blocks. It says 80% relief for diagnostic blocks is required. Further, this relief may increase false-positive rates significantly and decrease the efficacy. If 50% pain relief is used as a diagnostic criteria, dual diagnostic blocks may be appropriate (1,2).

Based on the recent systematic review of therapeutic facet joint interventions with multiple trials included the evidence is Level II for radiofrequency neurotomy and therapeutic facet joint nerve blocks (3).

Once again we would request that therapeutic facet joint nerve blocks be added as an alternate modality to radiofrequency neurotomy. This will be a cost effective measure without increasing cost utility and at times reducing the cost utility.

References

The references appear to be somewhat outdated. There are multiple updated and recent references as shown here. With addition of these references, multiple old references can be deleted.

1. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques of chronic spinal pain: Part II: Guidance and recommendations. *Pain Physician* 2013; 16:S49-S283.
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4.0 SACROILIAC JOINT INJECTIONS

The sacroiliac joint injection section includes the definitions of intraarticular sacroiliac joint injection, periarticular injection, and sacroiliac joint pain; however, it does not describe blockade of the nerve supply to the joint as well as therapeutic modalities with radiofrequency neurotomy.

Radiofrequency Neurotomy

Lateral branch radiofrequency neurotomy as a therapeutic modality has not been described in this document. It may be appropriate to add to approve radiofrequency neurotomy with strict inclusion criteria with positive results with 2 diagnostic blocks and appropriate response for a repeat procedure.

There is emerging evidence that radiofrequency neurotomy of sacral lateral branches is effective and if the patient has failed other conservative and invasive treatments, there are really no other treatment options for these patients. Invasive surgical fusion has not been proven to be more effective.

There is emerging evidence for cooled radiofrequency neurotomy, even though it may be more expensive than traditional radiofrequency neurotomy. It is an option to be considered.

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Appropriate references may be utilized with elimination of old and outdated references as shown in this manuscript.

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5.0 REGIONAL SYMPATHETIC BLOCKS

Indications and Non-Indications

Indications and non-indications describe a maximum of 6 therapeutic blocks; however, some patients may require these on a long-term basis; consequently it may be essential to state that further blocks after initial 6 may be performed only with appropriate response of 2½ to 3 months with significant improvement with at least 50% pain relief and functional status improvement.

6.0 EPIDURAL ADHESIOLYSIS

Epidural adhesiolysis is shown as a non-covered procedure; however, there is substantial evidence even more than other procedures with multiple randomized controlled trials specifically in post lumbar surgery syndrome and spinal stenosis along with recalcitrant pain with degenerative disc disease with cost utility analysis showing appropriate cost effectiveness and clinical outcomes. It has been covered by medicare carriers ever since its inception and also it continues to be covered by medicare carriers throughout the United States.

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.

References

You may want to consider recent references and recent systematic reviews and update the references. With addition of these references, multiple old references can be deleted.

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