December 2, 2015

David E. Mino, MD, MBA **Via Email**
National Medical Director - Orthopaedic Surgery and Spinal Disorders
Cigna Healthcare

Ramnik Singh, MD **Via Email**
Medical Director
Cigna Healthcare

Re: Cigna Precertification Program and Coverage Policies

Dear Dr. Mino and Dr. Singh:

On behalf of the Spine Intervention Society, a multi-specialty association of 3,000 physicians dedicated to the development and promotion of the highest standards for the practice of interventional procedures in the diagnosis and treatment of spine pain, I would like to take this opportunity to thank you for sharing information about Cigna's Precertification Program and providing an opportunity to share our thoughts and suggestions.

The Society's membership includes many of the clinicians and academicians whose published literature provides the seminal references upon which the practice of evidence-informed interventional spine care is based. Our organization has a strong record of working to eliminate fraudulent, unproven, and inappropriate procedures. At the same time, we are equally committed to assuring that appropriate, effective, and responsible treatments are preserved so that patients do not have to suffer or undergo more invasive and often unnecessary surgical procedures.

Over the past several weeks, we have worked primarily on reviewing the coverage policies proposed for implementation in January 2016. Below please find comments and suggestions targeted at improving the policies to ensure that procedures are accessible to appropriately-selected patients.

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Epidural Steroid Injections (CMM 200)

CMM-200.1 Definitions:
The definition of radiculopathy in this document is severe pain, disabling pain, dysaethesia(s) or paresthaesia(s) plus motor deficit OR sensory deficit OR reflex deficit OR advanced imaging demonstrating compression of the spinal nerve root OR EMG diagnosis. The requirement for "compression of the involved named spinal nerve root(s)" is problematic. Epidural steroid injections are not a treatment for radiculopathy; they are a treatment for radicular pain. In fact, our best evidence shows that they are helpful when there is not compression of the nerve root (Ghahreman), and are very effective in treating radicular pain in this scenario (disc herniation without nerve root compression).[1]

Reference:

1. Ghahreman A, Ferch R, Bogduk N. The efficacy of transforaminal injection of steroids for the treatment of lumbar radicular pain. Pain Med 2010; 11 (8): 1149-68.

CMM-200.2 General Guidelines:

- 2nd statement could be altered to read: "An epidural steroid injection administered for axial spinal pain without documentation of radiculopathy, myelopathy, or myeloradiculopathy should not be considered part of routine management and should be considered only after conservative treatment has been attempted."
- 6th statement could be altered to read: "No more than 3 ESIs should be performed in a 6 month span and no more than 6 epidural sessions should be performed in a 12 month span."

CMM 200.4 Therapeutic Epidural Steroid Injections:

- Change the subtitle to read: Transforaminal, Interlaminar, or Caudal Epidural Steroid Injections
- A required 4-week course of conservative treatment is inappropriate in the presence of acute radicular pain. Other treatments (e.g. physical therapy) have not been shown to be effective in the treatment of acute radicular pain.
- Precluding other spine procedures in the same region on the same day is generally a good policy; however, there should be exceptions. A common exception would be a facet joint cyst causing lateral recess stenosis with radicular pain, which would require facet joint injection with facet cyst rupture or aspiration as well as lumbar epidural steroid injection.
- While anecdotal evidence would seem to support an active rehabilitation/therapeutic exercise regimen in association with an epidural injection, this is not supported by the medical literature.
- 5th statement: Would replace "severe" spinal stenosis with "symptomatic" spinal stenosis.

Facet Joint Injections/Medial Branch Blocks (CMM 201)

CMM-201.3 Indications and Non-Indications

DRAFT POLICY:
Facet joint injections/medial branch blocks are considered medically necessary for facet mediated pain resulting from disease, injury or surgery and confirmed by provocative testing resulting in reproducible pain (i.e., hyperextension, rotation) that has not responded sufficiently to at least four (4) weeks of conservative therapy (exercise, physical methods including physical therapy, chiropractic care, NSAIDs and/or analgesics).

COMMENTS/SUGGESTIONS:
Physical exam findings poorly correlate with etiology of low back pain. Provocative tests should not be required to proceed with facet joint injections/medial branch blocks.[1-5]

Would recommend: Facet joint injections/medial branch blocks are considered medically necessary for facet mediated pain resulting from disease, injury or surgery and confirmed by history, exam, or imaging, that has not responded sufficiently to at least four (4) weeks of conservative therapy (exercise, physical methods including physical therapy, chiropractic care, NSAIDs and/or analgesics).

DRAFT POLICY:
One diagnostic facet joint injection/medial branch block is considered medically necessary to determine whether chronic neck or back pain is of facet joint origin when ALL of the following criteria are met:

- *Pain is exacerbated by extension and rotation, or is associated with lumbar rigidity*
- *Pain has persisted despite appropriate conservative treatment (e.g., nonsteroidal anti-inflammatory drugs (NSAIDs, exercise)*
- *Clinical findings and imaging studies suggest no other obvious cause of the pain (e.g., spinal stenosis, disc degeneration or herniation, infection, tumor, fracture)*

COMMENTS/SUGGESTIONS:
Once again, facet mediated pain correlates poorly with physical exam findings, including extension and rotation. Would recommend excluding physical exam findings as a requirement.

DRAFT POLICY:
When there is greater than 80% pain relief from a single diagnostic facet joint injection/medial branch block, there is sufficient evidence of facet pathology and a second confirmatory block is unnecessary.

COMMENTS/SUGGESTIONS:
We disagree with this statement. A second diagnostic medial branch block is considered medically necessary and should even be required to make the diagnosis

of facet mediated pain. There are a significant percentage of false positives with a single block.[6-14] Requiring a more rigorous diagnostic criteria for facet mediated pain will better select patients that will benefit from lumbar radiofrequency ablation. This will also result in fewer, but more appropriate, patients receiving radiofrequency neurotomy.

DRAFT POLICY:
To avoid coming to an improper diagnosis or providing unnecessary treatment, the performance of facet joint injections/medial branch blocks is considered not medically necessary on the same day of service when performing other spinal injections in the same region.

COMMENTS/SUGGESTIONS:
While as a diagnostic test, we agree with this statement. There are some exceptions that should be taken into account. When a facet joint cyst is present that is resulting in associated nerve root impingement and associated radiculopathy, it is medically necessary to inject the associated facet joint and attempt aspiration or cyst rupture. This procedure would be done in combination of with an epidural injection to also treat the radiculopathy.

References:

1. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. Clinical features of patients with pain stemming from the lumbar zygapophysial joints. Is the lumbar facet syndrome a clinical entity? Spine 1994; 19:1132-1137.
2. Schwarzer AC, Wang S, Bogduk N, McNaught PJ, Laurent R. Prevalence and clinical features of lumbar zygapophysial joint pain: a study in an Australian population with chronic low back pain. Ann Rheum Dis 1995; 54:100-106.
3. Schwarzer AC, Derby R, Aprill CN, Fortin J, Kine G, Bogduk N. Pain from the lumbar zygapophysial joints: a test of two models. J Spinal Disord 1994; 7:331-336.
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5. Cohen SP, Hurley RW, Christo PJ, Winkley J, Mohiuddin MM, Stojanovic MP. Clinical predictors of success and failure for lumbar facet radiofrequency denervation. Clin J Pain 2007; 23:45-52.
6. Bogduk N. On the rational use of diagnostic blocks for spinal pain. Neurosurgery Quarterly 2009; 19:88-100.
7. Barnsley L, Lord S, Bogduk N. Comparative local anaesthetic blocks in the diagnosis of cervical zygapophysial joint pain. Pain 1993; 55:99-106.
8. Lord SM, Barnsley L, Bogduk N. The utility of comparative local anaesthetic blocks versus placebo-controlled blocks for the diagnosis of cervical zygapophysial joint pain. Clin J Pain 1995; 11:208-213.
9. Schwarzer AC, Aprill CN, Derby R, Fortin J, Kine G, Bogduk N. The false-positive rate of uncontrolled diagnostic blocks of the lumbar zygapophysial joints. Pain 1994; 58:195-200.

10. Manchikanti L, Pampati V, Fellows B, Bakhit CE. Prevalence of lumbar facet joint pain in chronic low back pain. Pain Physician 1999; 2:59-64.
11. Manchikanti L, Pampati V, Fellows B, Bakhit CE. The diagnostic validity and therapeutic value of lumbar facet joint nerve blocks with or without adjuvant agents. Curr Rev Pain 2000; 4:337-44.
12. Manchikanti L, Boswell MV, Singh V, Pampati V, Damron KS, Beyer CD. Prevalence of facet joint pain in chronic spinal pain of cervical, thoracic, and lumbar regions. BMC Musculoskeletal Disorders 2004; 5:15.
13. Manchukonda R, Manchikanti KN, Cash KA, Pampati V, Manchikanti L. Facet joint pain in chronic spinal pain: an evaluation of prevalence and false-positive rate of diagnostic blocks. J Spinal Disord Tech 2007; 20:539-545.
14. Barnsley L, Lord S, Wallis B, Bogduk N. False-positive rates of cervical zygapophysial joint blocks. Clin J Pain 1993; 9:124-130.

Sacroiliac Joint Injections (CMM 203)
No edits suggested. The policy seems reasonable as proposed.

Prolotherapy (CMM 204)
No edits suggested. The policy seems reasonable as proposed.

Epidural Adhesiolysis (CMM 207)
No edits suggested. The policy seems reasonable as proposed.

Radiofrequency Joint Ablations/Denervations (CMM 208)

CMM-208.3 Indications and Non-Indications

- Importance of dual diagnostic blocks: When an injection or block is considered positive, a second (confirmatory) medial branch block **is medically necessary** to perform a radiofrequency joint denervation/ablation.
- Definition of positive response to a diagnostic block: should be 80% pain relief reported for the duration of the effect of the local anesthetic, not 50% pain relief reported for 80% of the duration of the effect of the local anesthetic use.
- Repeat radiofrequency joint denervation/ablation after 6 months:
    - Should require 50% relief for 6 months combined with functional improvement in terms of activities of daily living.
    - A second radiofrequency joint denervation/ablation involving a different combination of facet joints, selected after new positive dual diagnostic blocks, should be permitted.
- Radiofrequency joint denervation/ablation in a patient with a previous spinal fusion: If such a patient has a positive response to dual comparative medial branch blocks, there is no justification for restricting access to radiofrequency joint denervation/ablation at the level of a fusion.
- Sacroiliac Joint Radiofrequency Neurotomy: Several studies have demonstrated clinical effectiveness of sacroiliac joint radiofrequency neurotomy.[1-4]

- This procedure should be covered in patients who have had symptoms for at least 2-3 months and obtained more than 80% relief from dual diagnostic blocks.
- Repeat radiofrequency joint denervation/ablation should be covered if patients experience at least 50% relief for at least 3 months following an initial denervation/ablation.

References:

1. Patel N, Gross A, Brown L, Gekht G. A randomized, placebo controlled study to assess the efficacy of lateral branch denervation for chronic sacroiliac joint pain. Pain Med 2012;13:383–98.
2. Cohen SP, Hurley RW, Buckenmaier CC, et al. Randomised placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. Anesthesiology 2008;109:279–88.
3. Cohen SP, Strassels SA, Kurihara C, et al. Outcome predictors for sacroiliac joint (lateral branch) radiofrequency denervation. Reg Anesth Pain Med 2009;34:206–14.
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Regional Sympathetic Blocks (CMM 209)

The role of sympathetic blocks for treatment of complex regional pain syndrome (CRPS) is largely empirical, but has been shown to be clinically important when the procedure ameliorates pain and improves function. Allowing for a less painful "window of opportunity" for rehabilitation techniques promotes pain relief that is a therapeutically necessary adjunct to facilitate physical therapy/functional restoration.[1-3]

References:

1. Harden RN, Oaklander AL, Burton AW, Perez RS, Richardson K, Swan M, Barthel J, Costa B, Graciosa JR, Bruehl S. Complex regional pain syndrome: practical diagnostic and treatment guidelines, 4th edition. Pain Med. 2013;14:180-229.
2. Dworkin RH, O'Connor AB, Kent J, Mackey SC, Raja SN, Stacey BR, Levy RM, Backonja M, Baron R, Harke H, Loeser JD, Treede RD, Turk DC, Wells CD. Interventional management of neuropathic pain: NeuPSIG recommendations. Pain. 2013 Jun 5. doi:pii: S0304-3959(13)00297-2.
3. van Eijs F, Geurts J, van Kleef M, Faber CG, Perez RS, Kessels AG, Van Zundert J. Predictors of pain relieving response to sympathetic blockade in complex regional pain syndrome type 1. Anesthesiology. 2012;116:113-21.

Implantable Intrathecal Drug Delivery Systems (CMM 210)

No edits suggested. The policy seems reasonable as proposed.

Spinal Cord and Implantable Peripheral Nerve Stimulators (CMM 211)

CMM-211.1 Definitions:

- Suggest rewording second sentence as follows: "The technical goal of conventional stimulation therapy is to achieve stimulation of paresthesia of the dorsal horn of the spinal cord…"
- Suggest defining short-term trial as a minimum of 3 days and including a range of 3-10 days throughout all sections of the policy. (HF10 trials are more commonly 5-10 days.)

CMM-211.2 Indications and Non-Indications

- Dorsal Column Spinal Cord Stimulator:
  - Suggest increasing total contact/electrodes to 32. "A dorsal column spinal cord stimulator (SCS) with up to two leads and no more than a total of 16 contact/electrodes per lead is considered medical necessary…" The medical necessity/rationale for number of contacts should be documented in the medical record.
  - Suggest adding "Severe peripheral neuropathy" to the list of procedures for which SCS is considered medically necessary. Although less robust than for FBSS and CRPS, there is substantial literature for a variety of neuropathic pain symptoms.[1-7]

    References:

    1. Slangen R, Schaper NC, Faber CG, *et al*. Spinal cord stimulation and pain relief in painful diabetic peripheral neuropathy: a prospective two-center randomized controlled trial. Diabetes Care 2014;37:3016–3024.
    2. de Vos CC, Meier K, Zaalberg PB, *et al*. Spinal cord stimulation in patients with painful diabetic neuropathy: a multicenter randomized clinical trial. Pain 2014;155:2426–2431.
    3. Daousi C, Benbow SJ, MacFarlane IA. Electrical spinal cord stimulation in the long-term treatment of chronic painful diabetic neuropathy. Diabet Med 2005;22:393–398.
    4. Slangen R, Pluijms WA, Faber CG, Dirksen CD, Kessels AG, van Kleef M. Sustained effect of spinal cord stimulation on pain and quality of life in painful diabetic peripheral neuropathy. Br J Anaesth 2013;111:1030–1031.
    5. Tesfaye S, Watt J, Benbow SJ, Pang KA, Miles J, MacFarlane IA. Electrical spinal-cord stimulation for painful diabetic peripheral neuropathy. Lancet 1996;348:1698–1701.
    6. McGreevy K, Williams K. Contemporary insights into painful diabetic neuropathy and treatment with spinal cord stimulation. Curr Pain Headache Rep 2012;16:43-49.

7. van Beek M, Slangen R, Schaper N, Faber C, Joosten E, Dirksen C, van Dongen R, Kessels A, van Kleef M. Sustained treatment effect of spinal cord stimulation in painful diabetic peripheral neuropathy: 24-month follow-up of a prospective two-center randomized controlled trial. Diabetes Care 2015;38:e132-e134.

- Dorsal Column Spinal Cord Stimulator Replacement:
  - Suggest deleting "…and cannot be repaired". There is no role for "repairing" an already implanted dorsal column stimulator lead(s) or IPG.
  - Suggest deleting "for an individual who meets ALL of the above criteria". If a system was implanted for an off-label indication, why should the patient not have a treatment that is working replaced when the only reason for doing so is end of life of the system - not an inherent failure of the therapy.
- Dorsal Column Spinal Cord Stimulator Not Covered Services
  - Suggest removing peripheral neuropathy here and moving that to a covered indication.
  - Suggest increasing total contact/electrodes to 32. "Implantation of a dorsal column spinal cord stimulator (SCS) with more than two leads and/or more than a total of 32 contacts/electrodes is considered experimental, investigational or unproven for any indication."

- Implanted Peripheral Nerve Stimulation
  - Suggest coverage for occipital nerve stimulation (ONS). Several studies have been published that suggest effectiveness in this patient population. Regarding literature supporting the efficacy of ONS, the majority of these studies focus on occipital neuralgia and cluster or migraine headache, with promising results ranging from 40% to >80% success.[1-11] As far as other chronic forms of primary headaches are concerned, Burns et al[12] performed ONS in 6 patients with hemicrania continua (6–21 months), and reported that 4 of them had a pain reduction exceeding 80%. Nine patients with drug-resistant SUNCT and 3 with SUNA (short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing – SUNCT- or with autonomic symptoms - SUNA) had a benefit of at least 50% under ONS and 4 patients were nearly pain free after +/− 14 months follow-up.[13,14]
  - It should be noted that the literature does not support the notion that pain relief with occipital nerve block is a predictor of success with occipital nerve stimulation trial and implant.[1-4]

References:

1. Schwedt TJ, Dodick DW, Trentman TL, Zimmerman RS. Response to occipital nerve block is not useful in predicting efficacy of occipital nerve stimulation. Cephalalgia 2007; 27: 271–274.
2. Burns B, Watkins L, Goadsby PJ. Treatment of intractable chronic cluster headache by occipital nerve stimulation in 14 patients. Neurology 2009; 72: 341–345.

3. Magis D, Allena M, Bolla M, De Pasqua V, Remacle JM, Schoenen J. Occipital nerve stimulation for drug-resistant chronic cluster headache: a prospective pilot study. Lancet Neurol 2007; 6: 314–321.
4. Saper JR, Dodick DW, Silberstein SD, McCarville S, Sun M, Goadsby PJ. Occipital nerve stimulation for the treatment of intractable chronic migraine headache: ONSTIM feasibility study. Cephalalgia 2011; 31:271–85.
5. Weiner RL, Reed KL (1999) Peripheral neurostimulation for control of intractable occipital neuralgia. Neuromodulation 2:217–22.
6. Lipton R, Goadsby P, Cady R, Aurora SK, Grosberg B, Freitag F *et al.* PRISM study: occipital nerve stimulation for treatment-refractory migraine. Cephalalgia 2009;29:30.
7. Silberstein S, Dodick D, Saper J, Huh B, Slavin KV, Sharan A *et al*. Safety and efficacy of peripheral nerve stimulation of the occipital nerves for the management of chronic migraine: Results from a randomized, multicenter, double-blinded, controlled study. Cephalalgia 2012;32(16):1165–79.
8. Magis D, Schoenen J. Advances and challenges in neurostimulation for headaches. Lancet Neurol 2012;11:708–19.
9. Reed KL, Black SB, Banta CJ 2nd, Will KR. Combined occipital and supraorbital neurostimulation for the treatment of chronic migraine headaches: initial experience. Cephalalgia 2010;30:260–71.
10. Magis D, Gerardy PY, Remacle JM, Schoenen J. Sustained effectiveness of occipital nerve stimulation in drug-resistant chronic cluster headache. Headache 2011;51:1191–201.
11. Fontaine D, Christophe Sol J, Raoul S, Fabre N, Geraud G, Magne C *et al*. Treatment of refractory chronic cluster headache by chronic occipital nerve stimulation. Cephalalgia 2011;31:1101–5.
12. Burns B, Watkins L, Goadsby PJ. Treatment of hemicrania continua by occipital nerve stimulation with a bion device: long-term follow-up of a crossover study. Lancet Neurol 2008;7:1001–12.
13. Marin JC, Goadsby P. Response of SUNCT (short-lasting unilateral neuralgiform headaches with conjunctival injection and tearing), SUNA (short-lasting unilateral neuralgifom headaches with autonomic symptoms) and primary stabbing headaches to occipital nerve stimulation (ONS). Neurology 2010;74:P04.006, abstract.
14. Shanahan P, Watkins L, Matharu M. Treatment of medically intractable short-lasting unilateral neuralgiform headache attacks with conjunctival injection and tearing (SUNCT) and short-lasting unilateral neuralgiform headache attacks with autonomic symptoms (SUNA) with occipital nerve stimulation (ONS) in 6 patients. Cephalalgia 2009;29:150.
15. Reed K. Peripheral neuromodulation and headaches: history, clinical approach, and considerations on underlying mechanisms. Curr pain Headache Rep 2013;17:305.
16. Skaribas I, Calvillo O, Delikanaki-Skaribas E. Occipital peripheral nerve stimulation in the management of chronic intractable occipital neuralgia in a patient with neurofibromatosis type 1: a case report. Journal of Medical Case Reports 2011;5:174.

17. Lambru G, Matharu M. Occipital nerve stimulation in primary headache syndromes. Ther Adv Neurol Disord 2012;5(1):57-67.

Spine Imaging Guidelines

SP-2.2 MRI of the Spine:

DRAFT POLICY:
With contrast "for patients having undergone recent spinal surgery… when history and physical exam is suspicious for hematoma, post-surgical infection, or CSF leak".

COMMENTS/SUGGESTIONS:

- Should also include when the physician suspects a disc herniation or epidural fibrosis.
- Should not have to be "recent" surgery.

We are certainly interested in learning more about the precertification program and providing input to ensure the program will be useful in ensuring appropriate use of procedures, while at the same time not proving unduly onerous to participating physicians.

We hope that this information, as well as any dialogue and collaboration between Cigna and the Spine Intervention Society, will lead to the establishment of a reasonable precertification program and implementation of coverage policies that will eliminate inappropriate utilization while preserving access in appropriately selected patients. We offer our ongoing input and expertise in this matter. If we may answer any questions or provide any assistance, please feel free to contact Belinda Duszynski, Senior Director of Policy and Practice, at bduszynski@spinalinjection.org.

Sincerely,

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President
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