**From:** CMD.INQUIRY
**Date:** December 13, 2021 at 6:42:57 AM CST
**To:** Laxmaiah Manchikanti, MD
**Subject: FW: L39015 – Epidural Steroid Injections for Pain Management (CGS Articles: A58731 – Billing and Coding, A58899 – Response to Comments)**

Dr. Manchikanti,

Thank you for your letter. **We have provided responses below in red.**

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December 10, 2021

CGS Medical Policy
Meredith Loveless, MD
Attn: Medical Review
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CMD.inquiry@cgsadmin.com

RE: L39015 – Epidural Steroid Injections for Pain Management (CGS Articles: A58731 – Billing and Coding, A58899 – Response to Comments)

Dear Dr. Loveless:

Thank you for the timely publication of the epidural policy. We have reviewed all 3 documents, not only for CGS covering Kentucky and Ohio, but also all other jurisdictions, except Noridian which is not available yet. We wanted to bring to your notice some of the issues we have noticed. We are hoping that these will be addressed without reconsideration:

**1. Conflicts in number of epidural sessions.**

Under Limitations #6, it reads as follows:

> *ESIs are limited to a maximum of four (4) sessions per spinal region in a rolling twelve (12) month period.*[7]

However, under Utilization Parameters, the last item reads as follows:

> *No more than 4 epidural injection sessions (CPT codes 62321, 62323, 64479, 64480, 64483, or 64484) may be reported in all anatomic regions in a rolling 12-month period regardless of the number of levels involved.*

This is probably a simple typographic error or oversight and may be corrected without any difficulty by changing in all anatomic regions to "per spinal region."

In addition, this is also present in all other policies.

Thank you this has been brought to our attention and correction is being made. Only one region may be treated per session. The need to treat more than one region with an epidural steroid injection represented <1% of cases in Medicare National data. Please see response to comment article #32. The injection of multiple regions on the same patient may trigger focused medical review.

**2. Significant changes without comment, not present in proposed policy**

Many of the changes and even original thoughts seem to have developed from AHRQ Technology Assessment reference 20 by Chou et al with revised version on July 10, 2015. This document has not included a single pain physician. Among the informants, only one, Dr. Cohen, was included. It appears that peer review may have included 3 pain physicians. The epidural portion of this technology assessment was published in the *Annals of Internal Medicine*. Both of them had multiple issues with derivation of placebo-controlled trials by converting local anesthetic into placebo, without showing any significant basis for effectiveness of steroids. As we have shown in multiple discussions, steroids have been limited in their effectiveness and in the majority of the cases, there was no significant difference between local anesthetic with steroids compared to local anesthetic alone (1-5). The issues with epidural injections published in the *Annals of Internal Medicine* has been reviewed and a comparative review was published by Manchikanti et al (6). In addition, to agree with our philosophy that local anesthetics are not placebo, Maher and Cohen (7), in a review article in 2017, stated that " …. local anesthetic epidural injections are not a truly inert placebo, or that monotherapy with ESIs are truly not sufficient to meaningfully reduce opioid use."

Even Bicket et al (8) showed in their manuscript for which Cohen was the senior author, that in performing epidural injections for spinal pain, application of a local anesthetic cannot be considered a "placebo injection".

Cohen who was also a peer reviewer for AHRQ and coauthor of Cochrane review which did the same mistake of converting active-controlled trials into placebo-controlled trials and comparing them with a conventional analysis. We have presented relevant evidence during the discussions as Chou was also on the panel, and during comment period.

The policy utilized North American Society Guidelines (NASS) extensively in the text provided in the Summary of Evidence section, which was not provided in the proposed rule (Reference 11). These are based on one society which is a surgical society. They are using these procedures as a modality for surgical management in contrast to chronic pain management, the majority of them being dealt with as not surgical candidates, not interested in surgery, or post-surgery syndrome. Those guidelines, without using any chronic pain management physicians and without appropriate references or review of the studies, may not be appropriate to meet evidence-based medicine principles.

Reference 8 by Mattie et al describes frequency of epidural steroid injections. This is somewhat of a letter to the editor or commentary without a peer review with no references. They really do not discuss much of reasons for repeat injections or what the duration of the relief is. In contrast, ASIPP guidelines quoted in the policy (1) clearly show the evidence with relief of first treatment, second treatment, and subsequent treatments over a period of 2 years in multiple studies, as procedures during comment period.

i. **Covered Indications**

We appreciate your changes in Covered Indications with addition of radicular pain; however, the language has been changed to severe enough to greatly impact quality of life or function, from severe enough to cause a significant degree of functional disability or vocational disability measured at baseline. There was not a change in language between the proposed draft and final draft for this language.. Attached is copy of the proposed and final drafts for your clarification under covered indications #1.

This may change the significance of the definition from moderate to severe pain to severe pain only. There were no references quoted to support this change.

Since it was not in the Proposed Rule, we would request that it be changed to the original definition, "to cause a significant degree of functional disability or vocational disability.

For example, moderate disability is 21% to 40% determined by Oswestry Disability Index or Neck Disability Index; however, severe disability requires 41% to 60% change in scores for severe disability.

ii. **Steroids and safety initiative related to multiple views with contrast injection and level of cervical epidural injections above C7.**

Under Covered Indications, #7 is as follows with changes:

> *An initial injection of contrast is required to confirm epidural placement, unless the patient has a contraindication to contrast. The subsequent epidural steroid injections should include corticosteroids and may be combined with anesthetics or saline.*

Now it appears that with corticosteroids, we may combine anesthetics. The option of using only local anesthetics seems to be eliminated.

On the same issue under Limitations, #12:

> *Steroid dosing should be the lowest effective amount, it is recommended not to exceed 80 mg of triamcinolone, 12 mg of betamethasone, 15 mg of dexamethasone per session.*

Under Documentation Requirements, #5:

> *Films that adequately document (minimum of 2 views) final needle position and contrast flow should be retained and made available upon request.*

There have been significant discussions and, finally, the FDA has maintained that safety initiatives were not approved by the FDA, and it is not of their opinion as below.

On April 23, 2014, the FDA issued a drug safety communication stating with the main impetus, "The Food and Drug Administration is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death." In addition, they also quoted that, "The effectiveness and safety of drugs for this use have not been established, and the FDA has not approved corticosteroids for such use." Subsequently, the FDA appointed a committee, which was represented by the American Society of Interventional Pain Physicians (ASIPP). However, when we were unable to reach consensus on safety recommendations, the group split up and went to MPW and provided safety recommendations (9,10). Discussions and subsequent publications ensued (11). Following this, ASIPP submitted a petition signed by 1,040 physicians in June 2014 (12). Subsequently, on October 5, 2015, Janet Woodcock sent a letter to ASIPP (13). The main decision was as follows:

> The working group published a list of 17 "clinical" considerations aimed at improving the safety of ESIs. The clinical considerations are intended for the medical community. They are not recommendations for the FDA, and, as such, are neither binding on FDA nor endorsed by the FDA. In a manuscript, Racoosin et al (14) discussing serious neurologic events after epidural corticosteroid injections and the FDA risk assessment, confirmed the position that epidural steroid injections are not approved by the FDA for this purpose and the warning was strengthened again.

The changes made from the proposed to final draft was in response to an abundance of comments with supporting evidence received on this topic during the comment period and is outlined in the response to comment article #9.

**Based on these issues, and also the fact that these were not included in the proposed policy, we request that these be removed with change in the language for steroids.**

The epidural steroids are off-label use, only with appropriate explanation to the patient and patient's consent. This will put CMS at significant risk because of the mandated policy. Finally, Depo-Medrol is allowed in First Coast and Novitas; whereas, it is not listed in remaining jurisdictions. We did notice that Depo-medrol was listed in previous drafts thus we wonder if this is simply an oversight. We do not know about Noridian yet. This will cause not only lack of evidence base and also confusion among the MACs. Further, FDA has not made any distinction between particulate and non-particulate steroids and specifically Depo-Medrol and triamcinolone.

While the policy is collaborative each MAC has the authority to make changes independently. The removal of methylprednisolone from the recommend steroids is addressed in the response to comment article #14.

The language in the policy requires the lowest effective dose is used and provides recommendations of agents and dose limit.

**As a result, we request this section of the LCD be *modified* to allow for the use methylprednisolone (Depo-medrol) 80 mg, equivalent to 80 mg of triamcinolone, in order to be consistent with other MACs nationally.**

As described earlier, it is also risker and unnecessary to take multiple views, specifically when we are performing cervical epidural injections, and if you were already there confirmed by appropriate contrast, it can lead to serious consequences and malpractice suits. Physicians will be using this as a defense in the future. This has already happened in the past.

If the provider elects to only perform one view the reason must be documented in the medical records to determine if medically indicated.

It is also interesting to note that the UK NICE guidelines recommend imaging for safety during epidural injections, but do not stipulate multiple views, etc. (15).

Lastly, as shown in Documentation Requirements, #4, the procedural report should clearly document the indications and medical necessity for the blocks, along with the pre- and post-percent pain relief achieved immediately post injection. Epidural steroid injections are not diagnostic injections. There are extremely rare cases were epidurals are done WITHOUT the use of steroids (which since steroids are mandated by this policy that makes this a therapeutic) for diagnostic purposes but once steroids are introduced for longer term "therapeutic" pain relief, this concept of immediate assessment for pain relief through the duration of local anesthetic activity is no longer relevant. The diagnostic nerve root blocks have very little or no evidence. Patients may not differentiate between needle pain, and their original pain with exacerbated anxiety will be an extremely difficult issue. Additionally, it will not provide any new information. Since epidural injections are for the treatment of chronic pain and there is a lead time for the steroid to actually work it is impractical to mandate a immediate post percent pain relief. In fact, it may even increase the pain if local anesthetic is not used. There will be no relevant clinically actionable information to assess immediate pain scores when it is not expected immediately.

**Thus we request that requirement for post-percent pain relief mandated assessment/documentation be eliminated from the LCD.** It may be made as a requirement for diagnostic blocks, but not all procedures, similar to facet joint diagnostic blocks.

The policy requires pain relief documented before and after every ESI. The patient must have a 50% improvement in pain and/or function using the same scale before repeat injection is considered. Without this documentation a patient would not be a candidate for repeat injection. This is outlined in coverage requirement #1 and #6. If the patient does not meet the improvement criteria outlined in the LCD than repeat injections may not be covered. This must be documented as explained in the B&C article. Pain scales are addressed in response to comment article #24 & 25, and repeat injections in #8, 12, and 15.

Thank you for your consideration of our request. If you have any questions, please feel free to contact us.

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