From:	Laxmaiah Manchikanti, MD
To:	Dirk_McMahon@uhc.com; Anne_Docimo@uhc.com
Subject:	Recently implemented epidural steroid injections for spinal pain policy for commercial, Medicare Advantage, and Medicaid Managed Care Plans. Policy Number: 2020T000411. Kentucky Policy Number: CS308KY.01
Date:	Friday, January 29, 2021 9:04:51 AM
Attachments:	TABLES AND FIGURES.pdf

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RE: Recently implemented epidural steroid injections for spinal pain policy for commercial, Medicare Advantage, and Medicaid Managed Care Plans
Policy Number: 2020T000411
Kentucky Policy Number: CS308KY.01

Dear Mr. McMahon and Dr. Docimo:

On behalf of the American Society of Interventional Pain Physicians (ASIPP), 50 state societies, and the Puerto Rico Society of Interventional Pain Physicians, as well as the entire membership of ASIPP, we thank you for your constant updates. However, we would like to discuss our concerns about recently implemented policy effective October 1, 2020, Policy Number: 2020T000411, and Kentucky Policy Number: CS308KY.01, effective October 1, 2020.

This policy comes without appropriate medical policy making without involvement of stakeholders and principles of evidence-based medicine. It also is inconsistent with local coverage policies in multiple jurisdictions across the nation, multiple Medicare Administrative Contractors (MACs) across the nation, and evidence derived from appropriate analysis of the literature. Consequently, we would like to request for you to, without delay and retroactively apply changes to the policy:

Please follow the nationwide and evidence-based policy with 2 epidural injections in the diagnostic phase with 6 week intervals between each injection per region, followed by 4 therapeutic epidural procedures per year, per region, at minimum of 3 month intervals with documentation of 2½-3 months of significant improvement (≥ 50%). In addition, based on the current literature and coverage policies, indications should be expanded to not only lumbar radicular pain with disc herniation or spinal stenosis, to post-surgery syndrome and discogenic pain after exclusion of facet joint pain or

sacroiliac joint pain.

BACKGROUND:
As you know, chronic spinal pain is the most prevalent chronic disease with employment of multiple modalities of interventional techniques including epidural interventions. The recent studies also have shown not only the declining utilization of epidural procedures in Medicare population (1,2), and decline in inflation-adjusted costs of these procedures, not only for procedure, but also overall costs per patient and nationwide utilization based on 100,000 Medicare population. Multiple randomized controlled trials, observational studies, systematic reviews, and guidelines have been published as recently as 2021. In fact, the ASIPP published guidelines for interventional techniques in 2013, with guidelines for facet joint interventions in 2020, and for epidural interventions in the management of chronic spinal pain in 2021.

They utilized extensive and rigorous methodologic quality assessment and evidence synthesis with recommendations delivered based on not only the evidence, but considering what other modalities are available in managing these patients' pain and improving their functional status. It is imperative that utilize appropriate guidance in today's atmosphere of escalating opioid usage and illicit drug epidemic (3). The most recent studies have shown opioid usage has substantially increased since onset of COVID. Illicit drug deaths have increased substantially since onset of COVID. Section 4.3 in epidural guidelines (https://pubmed.ncbi.nlm.nih.gov/33492918/) (3) extensively discusses the opioid epidemic within the realm of COVID-19 pandemic, along with increases of opioid deaths. Recent reports show that there have been increases of opioid drug overdoses with an increase of 18.2% death rate in year ending from June 2019 to May 2020, due to COVID-19 pandemic. This is in spite of severe restrictions, declining use of opioid dosages, and prescription opioids due to decreasing access not only for opioid therapy, but for non-opioid treatments, as shown in Figures 1-4 (3,4) and Table 1 (**TABLE AND FIGURES ATTACHED**). As you can note, it is not only the dosage and number of prescriptions, morphine milligram equivalent (MME), and prescriptions which have been declining, but also the deaths related to prescription opioids have significantly been reduced even during this epidemic where illicit drug epidemic continues to explode. This is partially attributed to sending patients to the street without appropriate therapy with increased requirements for opioid therapy with lack of access to non-opioid management.

Consequently, the new policy is making it more difficult to provide non-opioid techniques, namely epidurals and facet joint interventions, beyond the national local coverage determinations (LCDs) and evidence appears to be limited.

In reference to epidurals, with appropriate methodology with utilization of trustworthy standards, ASIPP with 60 authors involved, performed extensive literature review and identified 47 systematic reviews meeting inclusion criteria from a total of 85, and 43 randomized controlled trials from a total of 116, and 64 observational studies (3). Methodologic quality assessment of the studies based on Cochrane review criteria and Interventional Pain Management techniques - Quality Appraisal of Reliability and Risk of Bias Assessment (IPM-QRB), and Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment for Nonrandomized Studies (IPM-QRBNR), was performed (3). In this analysis, only fluoroscopic randomized trials were utilized except for cervical epidural injections where 2 observational studies were used. Table 2 illustrates the characteristics of fluoroscopic randomized trials of caudal epidural injections, whereas, Table 3 shows lumbar interlaminar epidural injections, Table 4 shows characteristics of fluoroscopic randomized controlled trials of lumbar transforaminal epidural injections, Table 5, shows effectiveness of percutaneous adhesiolysis by randomized trials and observational studies, and finally, Table 6 shows cervical and thoracic interlaminar epidural injections (3). (**TABLES 2-5 ATTACHED**)

SUMMARY OF EVIDENCE

Summary of evidence as shown in Section 8.10 in epidural guidelines (3) is as follows:

8.10 Summary of Evidence

Analysis of summary of evidence for disc herniation, spinal stenosis, discogenic pain, and post-surgery syndrome is presented based on the present review of the evidence in conjunction with appropriately performed systematic reviews published in the literature.

8.10.1 Disc Herniation

8.10.1.1 Caudal

For caudal epidural injections in managing disc herniation with multiple relevant, moderate to high-quality fluoroscopically guided epidural injections with or without steroids trials, and results of previous systematic reviews, the evidence is Level I with strong recommendation for long-term effectiveness.

8.10.1.2 Lumbar Interlaminar

For lumbar interlaminar epidural injections with multiple relevant moderate to high-quality fluoroscopically guided epidural injections with or without steroids trials, and relevant previous systematic reviews, the evidence is Level I with strong recommendation for long-term effectiveness.

8.10.1.3 Lumbar Transforaminal

For lumbar transforaminal epidural injections with inclusion of multiple moderate to high-quality RCTs of fluoroscopic transforaminal epidural injections with or without steroids, and inclusion of findings of relevant previous systematic reviews, the evidence is Level I with strong recommendation for long-term effectiveness. The evidence shows no significant difference between caudal and interlaminar epidural injections, whereas, the evidence also shows some superiority of transforaminal epidural injections over caudal and interlaminar epidural injections in achieving long-term improvement with epidural injections.

8.10.1.4 Percutaneous Adhesiolysis

Based on the present assessment with one relevant high-quality, placebo-controlled, RCT, the evidence is Level II with moderate to strong recommendation for long-term effectiveness for percutaneous adhesiolysis in patients nonresponsive to conservative management and fluoroscopically guided epidural injections.

8.10.1.5 Cervical Interlaminar

In the cervical spine, for managing cervical disc herniation, based on relevant moderate to high-quality RCTs and published systematic reviews, fluoroscopically guided cervical interlaminar epidural injections, show evidence is Level I with strong recommendation for long-term effectiveness.

8.10.1.6 Thoracic Interlaminar

In the thoracic spine, for thoracic disc herniation, based on one relevant high-quality RCT using fluoroscopic guidance with or without steroids and previously published systematic reviews, the evidence is Level II with moderate to strong recommendation for long-term effectiveness.

8.10.2 Spinal Stenosis

8.10.2.1 Caudal

For lumbar central spinal stenosis, the evidence based on present assessment and previously available systematic reviews, based on one high-quality RCT, the evidence is Level

III to II with moderate to strong recommendation for long-term improvement with fluoroscopically guided caudal epidural injections.

8.10.2.2 Lumbar Interlaminar

For lumbar central spinal stenosis, with evidence synthesis with inclusion of relevant moderate to high RCTs and previously published systematic reviews, the evidence is Level II with moderate to strong recommendation with fluoroscopically guided lumbar interlaminar epidural injections for long-term improvement.

8.10.2.3 Lumbar Transforaminal

For lumbar spinal stenosis, based on the present analysis of moderate to high-quality RCTs and previously available systematic reviews, the evidence is Level IV to III with moderate recommendation with fluoroscopically guided lumbar transforaminal epidural injections for long-term improvement.

8.10.2.4 Percutaneous Adhesiolysis

The evidence of percutaneous adhesiolysis in lumbar spinal stenosis with present evidence synthesis with relevant, moderate to high-quality RCTs, observational studies and systematic reviews, is Level II with moderate to strong recommendation for long-term improvement after failure of conservative management and fluoroscopically guided epidural injections.

8.10.2.5 Cervical Interlaminar

For cervical spinal stenosis, based on present evidence synthesis with one high-quality RCT and previously published systematic reviews, the evidence is Level II with moderate to strong recommendation for fluoroscopically guided cervical interlaminar epidural injections with long-term improvement.

8.10.3 Axial Discogenic Pain

8.10.3.1 Caudal

The evidence for lumbar axial discogenic pain without facet joint pain or sacroiliac joint pain is Level II with moderate to strong recommendation for caudal epidural injections based on one fluoroscopically guided high-quality RCT for long-term effectiveness.

8.10.3.2 Lumbar Interlaminar

Based on one high-quality RCT with long-term follow-up and previous systematic reviews, the evidence is Level II for discogenic pain after exclusion of facet joint pain and sacroiliac joint pain with moderate to strong recommendation for fluoroscopically guided lumbar interlaminar epidural injections with or without steroids for long-term effectiveness.

8.10.3.3 Cervical Interlaminar

Based on the present evidence synthesis with one relevant high-quality RCT with long-term follow-up, with fluoroscopically guided cervical interlaminar epidural injection with or without steroids, the evidence is Level II with moderate to strong recommendation for long-term effectiveness.

8.10.4 Post-surgery Syndrome

8.10.4.1 Caudal

The present evidence synthesis based on one relevant high-quality RCT with long-term improvement and previously performed systematic reviews, the evidence is Level II with moderate to strong recommendation with fluoroscopically guided caudal epidural injections with

or without steroids for long-term effectiveness.

8.10.4.2 Cervical Interlaminar

The present evidence synthesis based on one relevant high-quality RCT with long-term improvement and previously performed systematic reviews, the evidence is Level II to I with moderate to strong recommendation with fluoroscopically guided cervical interlaminar epidural injections with or without steroids for long-term effectiveness.

8.10.4.3 Percutaneous Adhesiolysis

Based on present evidence synthesis with multiple moderate to high-quality RCTs in conjunction with previously published systematic reviews, the evidence for percutaneous adhesiolysis in managing post-lumbar surgery syndrome is Level I with strong recommendation for long-term improvement after failure of conservative management and fluoroscopically guided epidural injections.

COST UTILITY ANALYSIS FOR EPIDURAL INTERVENTIONS

Cost utility analysis for epidural interventions was also evaluated in the guidelines. Epidural interventions, including percutaneous adhesiolysis, have shown very favorable evidence assessment as shown in Fig. 22 of the epidural guidelines (3). All of the epidural interventions were below $5,000 quality adjusted life year (QALY).

In reference to percutaneous adhesiolysis, Cho et al (6) also showed that percutaneous adhesiolysis has better evidence than spinal cord stimulation.

INDICATIONS, MEDICAL NECESSITY AND FREQUENCY OF INTERVENTIONS

ASIPP in recent guidelines described the following criteria for indications, medical necessity, and frequency of interventions based on appropriate literature and requirement from LCDs and other payers.

Lumbar Epidural Injections

Lumbar epidural injections include caudal, interlaminar, and transforaminal. Common indications are as follows:

- Chronic low back and/or lower extremity pain of at least 3 months duration which has failed to respond or poorly responded to non-interventional and nonsurgical conservative management resulting from:
  - Disc herniation/lumbar radiculitis: (evidence – Level I with strong recommendation for caudal, interlaminar, and transforaminal)
  - Lumbar spinal stenosis: (evidence – Level II for caudal with moderate to strong recommendation, Level II for lumbar interlaminar with moderate to strong recommendation and Level IV to III with moderate recommendation for lumbar transforaminal)
  - Post-lumbar surgery syndrome: (evidence – Level II for caudal with moderate to strong recommendation)
  - Axial or discogenic low back pain without facet joint or sacroiliac joint pain or disc herniation: (evidence – Level II for caudal and lumbar interlaminar with moderate to strong recommendation)
- Moderate to severe pain causing functional disability.
- Lumbar interlaminar may be performed in post-surgery syndrome only if the access to the epidural space is obtained outside the scar (caudal and transforaminal are preferred modalities).
- Acute proven disc herniation with radiculitis with disabling pain or to avoid surgical intervention, herpes zoster, post herpetic neuralgia, CRPS I and II, epidural injections

may be performed at physician discretion without above requirements.

Cervical Epidural

While cervical epidural injections may be administered either by the interlaminar or transforaminal approach, only the interlaminar approach has been studied with appropriate indications and effectiveness. Further, cervical transforaminal epidural injections are associated with high risk. Common indications for cervical interlaminar epidurals are as follows:|

- Chronic neck and/or upper extremity pain of at least 3 months duration which has failed to respond or poorly responded to non-interventional and nonsurgical conservative management resulting from:
  - Disc herniation/cervical radiculitis (evidence – Level I with strong recommendation)
  - Cervical spinal stenosis (evidence – Level II with moderate to strong recommendation)
  - Post cervical surgery syndrome (evidence – Level II to I with moderate to strong recommendation)
  - Axial or discogenic pain without facet joint pathology or disc herniation (evidence – Level II with moderate to strong recommendation)
- Intermittent or continuous pain causing functional disability.
- Acute proven disc herniation with radiculitis with disabling pain or to avoid surgical intervention, herpes zoster, post herpetic neuralgia, CRPS I and II, epidural injections may be performed at physician discretion without above requirements.

Thoracic Epidural

Thoracic epidural injections may be performed either with an interlaminar approach or a transforaminal approach. The literature is scant in reference to thoracic epidural injections, with Level II evidence. Consequently, only interlaminar epidural injections are described herewith. Common indications are as follows:

- Chronic mid back or upper back pain of at least 3 months duration which has failed to respond or poorly responded to non-interventional and nonsurgical conservative management resulting from:
  - Thoracic disc herniation/radiculitis
  - Thoracic spinal stenosis
  - Thoracic post-surgery syndrome
  - Axial or discogenic pain without facet joint pathology or disc herniation
  - Moderate to severe pain causing functional disability.
- Acute proven disc herniation with radiculitis with disabling pain or to avoid surgical intervention, herpes zoster, post herpetic neuralgia, CRPS I and II, epidural injections may be performed at physician discretion without above requirements.

Frequency of Epidural Procedures

- Guidelines of frequency of interventions apply to epidural injections caudal, interlaminar, and transforaminal.
- In the diagnostic phase, a patient may receive 2 procedures at intervals of no sooner than 2 weeks, preferably 4-6 weeks based on the type and dosage of steroid used.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency of interventional techniques should be 2½ to 3 months or longer between each injection, provided that > 50% relief is obtained for 2½ to 3 months, not exceeding 4 per year, per region.
- If neural blockade is applied for different regions, they may be performed at intervals of no sooner than one week and preferably 2 weeks for most types of procedures. The therapeutic

frequency may remain at intervals of at least 2 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures can be performed safely.

- In the treatment or therapeutic phase, the epidural injections should be repeated only as necessary according to medical necessity criteria, and it is suggested that these be limited to a maximum of 4 times per year.
- Cervical and thoracic regions are considered as one region and lumbar and sacral are considered as one region.

Percutaneous Adhesiolysis

At the present time, the evidence is available for percutaneous adhesiolysis in the lumbar region only utilizing a caudal approach. Evidence for the cervical and thoracic regions and transforaminal approach in the lumbar region is only emerging. Common indications for percutaneous adhesiolysis with a caudal approach in lumbar region are as follows:

- Chronic low back and/or lower extremity pain of at least 6 months duration which failed to respond to or poorly responded to non-interventional and nonsurgical conservative management and fluoroscopically directed epidural injections secondary to:
  - Post-surgery syndrome (evidence – Level I with strong recommendation).
  - Central spinal stenosis (evidence – Level II with moderate to strong recommendation)
  - Disc herniation/radiculitis/severe degenerative disc disease (evidence – Level II with moderate to strong recommendation)
- Intermittent or continuous pain causing functional disability.

Frequency of Percutaneous Adhesiolysis Interventions

- The number of procedures is preferably limited to:
  - 2 interventions per year, with a 3-day protocol
  - 4 interventions per year, with a one-day protocol.

In addition, oftentimes pathology is multilevel. This is well demonstrated for degenerative disc disease and spinal stenosis. In addition, obvious or subtle injury-related patients in industries with vibration or stress related to occupations and other stresses in life may have multiple regions involved.

In addition, post lumbar surgery syndrome is becoming very frequent, along with spinal stenosis, developing after surgical intervention other than due to the degenerative processes. It is crucial that appropriate treatment is provided to these patients in the form of caudal epidural injections or percutaneous adhesiolysis.

Further, once the patient is shown to be negative for facet joint or sacroiliac joint pain in the lumbar spine and facet joint pain in the cervical spine, all the treatments are exhausted. The patient is nonresponsive to conservative modalities. In these cases, epidural injections should be allowed to improve their physical and functional status. As it is shown in the guidelines, there is Level II evidence for discogenic pain without facet joint or sacroiliac joint pain.

It is also important to note that epidural injections along with physical therapy allow for restorative therapy. In some ways, they do treat the pain, but in other ways, it can actually help the patient complete physical therapy and rehabilitate for the longer term as opposed to pharmacologic agents that simply mask symptoms. That is why it is within the best interest of the patient to obtain access to therapies like epidural injections to help facilitate restoration of function.

From an economic standpoint, epidural injections do not represent a significant cost center for UHC

compared to other modalities. In fact, most branded drugs are significantly more expensive per month than a single epidural steroid injection in office costs. Thus, trying to ration care for the sake of cost savings does not seem like a logical expense and may have the opposite effect to increase costs to the system. Patients would continue to suffer from pain when they do not have access to the therapy which may cause them to use more expensive and costlier health care services such as other prescription drugs, emergency room visits, more frequent visits to their primary care physician, and additional rounds of physical therapy or potentially very expensive surgical options. Not only could it be more expensive for the patient, it could also negatively impact their care, harm, and quality of life by restricting this therapy.

As described above, another larger concern is regarding the opioid crisis. Oftentimes when patients are suffering from severe debilitating pain that epidural steroid injections can treat, if we are not granted access to these, the patients may be prescribed opioids or may purchase them from illicit sources. This could further worsen the already worsening opioid crisis and lead to significant harm and damage to our patients. It would be unfortunate if a policy and procedure established by United Health Care pushes to the street when there are viable non-opioid and opioid alternatives available that are cost effective.

ABOUT ASIPP

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.

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 subacute, 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. www.medpac.gov).

CONCLUSION

In conclusion, once again we appreciate your concern and we would like you to consider our input seriously, which is not based on emotions or advocacy, but based on evidence using trustworthy standards with extensive methodologic considerations and best evidence synthesis available in the literature. Consequently, once again, we emphasize to adopt the following:

> Please follow the nationwide and evidence-based policy with 2 epidural injections in the diagnostic phase with 6 week intervals between each injection per region, followed by 4 therapeutic epidural procedures per year, per region, at minimum of 3 month intervals with documentation of 2½-3 months of significant improvement (≥ 50%). In addition, based on the current literature and coverage policies, indications should be expanded to not only lumbar radicular pain with disc herniation or spinal stenosis, to post-surgery syndrome and discogenic pain after exclusion of facet joint pain or sacroiliac joint pain.

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

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