American Society *of* Interventional Pain Physicians®
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Re: Carelon Guidelines for Interventional Pain Management 2024-06-30

Dear Dr. Mandel:

On behalf of American Society of Interventional Pain Physicians (ASIPP), 48 state societies and membership, we are writing this letter to express our concern on several policies developed by Carelon and used by multiple Medicare Advantage carriers. These policies contradict Medicare LCDs and create numerous access issues, including double copays and major inconvenience, all of this is without accepted evidence base, causing substantial harm to Medicare Advantage recipients. It is well known that Medicare Advantage recipients are already suffering significant hardship, along with all other recipients who are supplementing Medicare Advantage. The literature shows that Medicare spends over $100 billion more a year on Medicare Advantage compared to Medicare fee-for-service. Further, Medicare fee-for-service individuals, as well as Medicare Advantage, also pay a premium to support Medicare Advantage of $198 or $13 billion over a period of one year.

Based on the Medicare policy, Medicare Advantage shall follow LCDs and use the medical necessity criteria and frequency of the procedures as described in the LCDs. When there is no LCD, Medicare Advantage shall use similar criteria based on evidence base and what Medicare is applying.

Several issues also pertain to commercial payers, particularly Anthem, which continues to use outdated, unreliable, undocumented, and non-evidence-based criteria to deny necessary care.

The Medicare Managed Care Manual reinforces this obligation, stating that any adverse medical necessity determination must be conducted by a licensed professional with expertise in Medicare criteria and that coverage policies must be no more restrictive than Original Medicare.

Medicare Advantage (MA) plans are legally required to follow the coverage guidelines established by traditional Medicare, as mandated under federal law and reinforced by the Centers for Medicare & Medicaid Services (CMS). Specifically, under 42 U.S.C. § 1395w-22(a)(1)(A), MA plans must provide coverage that is at least actuarially equivalent to the benefits offered under Original Medicare Parts A and B. Additionally, CMS Medicare Managed Care Manual, Chapter 4, Section 10.1 explicitly states that Medicare Advantage plans are obligated to "provide all Part A and Part B covered services," and must adhere to the national and local coverage determinations (NCDs and LCDs) established by CMS

and the Medicare Administrative Contractors (MACs). Furthermore, 42 C.F.R. § 422.101(b) mandates that MA plans must follow CMS's national coverage determinations and may not apply coverage rules that are more restrictive than those established under Original Medicare. Deviating from these standards can undermine health equity by creating disparities in access to medically necessary care, especially for vulnerable populations who rely on consistent, evidence-based national coverage criteria. Inconsistent application of benefits across plans can result in delays, denials, or administrative barriers that disproportionately affect individuals from underserved communities, thereby perpetuating systemic health inequities and contradicting CMS's own stated commitment to promoting equity in healthcare delivery.

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
http://www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf)

Interventional pain management techniques are defined as, "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.
https://permanent.fdlp.gov/lps21261/dec2001PainManagement.pdf)

Established in 1998, ASIPP is a non-profit professional organization that currently boasts a membership of over 4,500 interventional pain physicians and other practitioners. Its mission is to promote safe, appropriate, fiscally neutral and effective pain management services for patients nationwide who grapple with chronic and acute pain. The United States is home to approximately 8,500 proficient physicians with the requisite training and qualifications in interventional pain management. ASIPP is composed of 48 state societies of Interventional Pain Physicians, encompassing Puerto Rico, and includes the affiliated Texas Pain Society.

While there are multiple issues, we would like to call your attention to unusual policies and restricted care for epidural injections, facet joint interventions, and spinal cord stimulation.

1. **Epidural Injection Procedures and Diagnostic Selective Nerve Root Blocks**

   PROCEDURAL REQUIREMENTS AND RESTRICTIONS
   The fifth item is as follows:

   > "No more than two (2) transforaminal injections may be performed at a single setting (e.g., single level bilaterally or two levels unilaterally). Injecting one level bilaterally would be considered two injections. Injecting two levels, each unilaterally, would also be considered two injections."

   While the first part of the sentence is appropriate, the second part which states that injecting one level bilaterally or injecting 2 levels, unilaterally, would be considered 2 injections.

   In contrast, the LCDs is as follows:

> "Transforaminal epidural steroid injections (TFESIs) involving a maximum of two (2) levels in one spinal region are considered medically reasonable and necessary. It is important to recognize that most conditions would not ordinarily require ESI at two (2) levels in one spinal region."

In this policy, there is no statement regarding to one level bilaterally would be considered as 2 injections and 2 levels each unilaterally would also be considered as 2 injections.

This inappropriate language restricts and reduces the number of treatments available for a person to 2 instead of 4 in a 12-month rolling period. A significant proportion of patients are involved with bilateral or 2 levels unilaterally. In fact, Medicare LCD shows that 2 bilateral levels are acceptable, even though that is rarely performed.

In reference to the steroid injections, after 3 injections in the same region, the total cumulative dose of steroid must be documented and may not exceed 240 mg of methylprednisolone or triamcinolone, 36 mg of betamethasone or 45 mg of dexamethasone.

In contrast, the LCD reads as follows:

> d. The primary care provider must be notified regarding continuation of procedures and prolonged repeat steroid use."

There are multiple issues with this statement.

Carelon essentially is reverting to outdated discarded policies of 3 injections, they also are stating in the same region.

Instead, it is the yearly recommendation for cumulative purposes, whether it is one region or 2 regions. Steroid doses are always documented.

In contrast to the statement during preauthorization process, Carelon deviates from its own policy and requests the documentation and information to the family physician.

On the commercial side, particularly with Anthem, you are enforcing non-existent requirements—such as mandating that patients undergo diagnostic blocks within six months. Even when patients meet this criterion, care is still denied using the same justification, suggesting a predetermined intent to refuse coverage. Additionally, reimbursement rates for ambulatory surgery centers are extremely low in certain states like Kentucky, where Anthem pays only 55% of Medicare and Medicaid rates.

Repeat Therapeutic Epidural Steroid Injections
Under this section, in reference to the imaging:

> "Confirmed evidence demonstrated on advanced imaging (MRI or CT) which correlates with the clinical findings. For herniated nucleus pulposus (HNP), advanced imaging should be performed within the previous 18 months of current request. This imaging requirement is waived for repeat injection if previously satisfied for the initial injection of **EITHER** of the following:
> - Nerve root compression secondary to herniated disc
> - Spinal stenosis (central, lateral recess, foraminal, or extraforaminal)"

Advanced imaging within the previous 18 months of current treatment is unnecessary and wasteful.

Contraindications
Additional contraindications, Carelon lists uncontrolled diabetes; however, if patient is in severe pain and function is deteriorating, this will only be prolonging the agony. In these cases, with appropriate documentation, epidural injections may be performed without steroids with local anesthetic only. There is abundance of evidence showing lack of superiority of addition of steroids to local anesthetic in epidural injections.

Manchikanti L, Knezevic NN, Navani A, et al. Epidural interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) comprehensive evidence-based guidelines. *Pain Physician* 2021; 24:S27-S208.

Knezevic NN, Manchikanti L, Urits I, et al. Lack of superiority of epidural injections with lidocaine with steroids compared to without steroids in spinal pain: A systematic review and meta-analysis. *Pain Physician*. 2020; 23:S239-S270.

Shanthanna H, Busse J, Wang L, et al. Addition of corticosteroids to local anaesthetics for chronic non-cancer pain injections: A systematic review and meta-analysis of randomised controlled trials. *Br J Anaesth* 2020; 125:779-801.

Manchikanti L, Knezevic E, Knezevic NN, et al. A comparative systematic review and meta-analysis of 3 routes of administration of epidural injections in lumbar disc herniation. *Pain Physician* 2021; 24:425-440.

Manchikanti L, Knezevic E, Latchaw RE, et al. Comparative systematic review and meta-analysis of Cochrane review of epidural injections for lumbar radiculopathy or sciatica. *Pain Physician* 2022; 25:E889-E916.

Manchikanti L, Knezevic E, Knezevic NN, et al. Epidural injections for lumbar radiculopathy or sciatica: A comparative systematic review and meta-analysis of Cochrane review. *Pain Physician* 2021; 24:E539-E554.

Lee JH, Kim DH, Kim DH, et al. Comparison of clinical efficacy of epidural injection with or without steroid in lumbosacral disc herniation: A systematic review and meta-analysis. *Pain Physician* 2018; 21:449-468.

Li BZ, Tang WH, Li Y, Zhou L, Liu MG, Bao SX. Clinical efficacy of epidural injections of local anesthetic alone or combined with steroid for neck pain: A systematic review and meta-analysis. *Biomed Res Int* 2022; 2022:8952220.

Mesregah MK, Feng W, Huang WH, et al. Clinical effectiveness of interlaminar epidural injections of local anesthetic with or without steroids for managing chronic neck pain: A systematic review and meta-analysis. *Pain Physician* 2020; 23:335-348.

2. Paravertebral Facet Joint Injection/Medial Branch Nerve Block/Neurolysis

This policy has not been updated as per LCDs. Updated LCDs and subsequent performance shows therapeutic intraarticular facet joint injections and medial branch blocks are essential when radiofrequency is contraindicated such as implant; however, individual consideration may be

considered under unique circumstances and with sufficient documentation of medical necessity on appeal.

The same clinical principles that guide care for Medicare patients should also apply to those with commercial insurance. It would be far more appropriate for Carelon to revise its policies to reflect consistent, evidence-based standards rather than create disparities based on insurance type. Currently, Medicaid patients are often receiving higher quality care with broader options at a lower cost, highlighting a concerning inequity in treatment access for commercially insured individuals.

3. Spinal Cord and Dorsal Root Ganglion Stimulation

Under Clinical Indications, Spinal Cord Stimulation:

Peripheral diabetic neuropathy shows multiple criteria. Among these, following may be duplicative or inappropriate:

- Objective evidence for presence of neuropathy and severity: moderate-severe neuropathy on EMG/NCS (electromyography/nerve conduction studies).
- Confirmation of PDN diagnosed by at least one other specialist (e.g., neurologist).

  Only one of them may be appropriate to achieve. In general, patient's symptoms and questioning on PainDETECT is appropriate.

- BMI of ≤ 35

  An additional issue is related to BMI of ≤ 35. Majority of diabetics are overweight and obese, reaching morbid obesity levels.

  Essentially, BMI requirements are inappropriate. There is significant literature showing there is no relevance for BMI in any longer. It would be appropriate if we eliminate the requirement for BMI.

Gans J. American Medical Association says use of BMI metric on its own has done 'historical harm.' *The Hill,* June 16, 2023. Accessed 5/6/2025. https://thehill.com/policy/healthcare/4054274-american-medical-association-says-use-of-bmi-metric-on-its-own-has-done-historical-harm/

Mahoney MA. Controversy continues over use of body mass index to calculate obesity. *Tallahassee Democrat*, January 27, 2005. Accessed 5/6/2025. https://www.tallahassee.com/story/life/wellness/2025/01/27/questions-arise-about-best-method-to-calculate-weight-risks/77781156007/

Yu A. Why is BMI no longer used? NCESC, February 17, 2025. Accessed 5/6/2025. https://www.ncesc.com/geographic-faq/why-is-bmi-no-longer-used/

We are also contacting multiple members of the Congress in the House of Representatives and Senate, along with administration on these issues to express our concern.

Hopefully the issues will be resolved, and the previous errors will be corrected.

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

Thank you,

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To view some of Dr. Manchikanti's publications go to:
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"The most entrenched conflict of interest in medicine is a disinclination to reverse a previous opinion." *Yudkin JS et al. Lancet 2011*

"There is no limit to what a man or woman can do, or where he or she can go if he or she doesn't mind who gets the credit." *Ronald Reagan*-modified