AMERICAN OSTEOPATHIC ASSOCIATION

142 E. Ontario St., Chicago, IL 60611-2864 ph (312) 202-8000 | (800) 621-1773 | www.osteopathic.org

August 12, 2016

Virginia Muir
LCD Comments
P.O. Box 7108
Indianapolis, IN 46207

Re: Proposed Draft LCD ID DL33616

Dear Ms. Muir:

The American Osteopathic Association (AOA), representing over 123,000 osteopathic physicians (DOs) and osteopathic medical students, appreciates this opportunity to provide comment to the National Government Services (NGS) proposed draft Local Coverage Determination (LCD) on Osteopathic Manipulative Treatment (OMT) (DL33616) (hereafter 'draft LCD').[1] We have reviewed the draft LCD and oppose its implementation as written. The proposed changes are not supported by clinical evidence. Additionally, the draft LCD as proposed is inconsistent with the principles and practices of osteopathic medicine. If adopted, unnecessary barriers would hinder the delivery of OMT services for Medicare beneficiaries. The AOA has provided the attached red-lined version of the draft LCD, which reflects our proposed changes discussed below that we strongly recommend NGS adopt as the final LCD.

General Comments

Access to Care

OMT has proven to be effective in reducing pain, and increasing mobility and function.[2,3,4] It can be an effective substitute for opioid prescriptions for chronic pain, especially back pain.[5,6,7] More than half of regular opioid users report back pain.[8] A sharp increase of deaths from our nation's rapidly growing opioid epidemic have recently amplified scrutiny on routine prescribing of opioids for pain. As a result, the Administration is devoting significant resources to its multipronged approach to address the opioid epidemic.

---

[1] National Government Services. *Local Coverage Determination: Osteopathic Manipulative Treatment (L33616)*. June 30, 2016.
[2] *Journal of Obstetrics & Gynecology*. 2010; 43.e1–43.e8. doi:10.1016/j.ajog.2009.07.057
[3] *Journal of Manual and Manipulative Medicine*. 2013; 5-15. http://dx.doi.org/10.1179/2042618611Y.0000000016
[4] *The Journal of the American Osteopathic Association*, March 2016, Vol. 116, 144-155. doi:10.7556/jaoa.2016.031
[5] BMC Musculoskeletal Disorders. 2005; 6:43. 10.1186/1471-2474-6-43
[6] BMC Musculoskeletal Disorders 2014; 15:286. 10.1186/1471-2474-15-286
[7] *New England Journal of Medicine* http://www.nejm.org/doi/10.1056/NEJM199911043411903
[8] BMJ 2015; 350:g6380

Earlier this year, the Centers for Disease Control and Prevention (CDC) released its Guideline on Prescribing Opioids for Chronic Pain[9]. One of its top-line recommendations in the guideline is that nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain and should be used instead of opioids; as well, if opioids must be used, they should be combined with these therapies rather than being given alone. The draft LCD is therefore strikingly discordant to the Administration's position on this issue, since if finalized it will limit access to OMT, one such nonpharmacologic therapy.

The Administration is also greatly expanding efforts to educate prescribers on safer prescribing practices around opioids, including consideration of non-opioid alternatives. The AOA was invited by the Administration as an early partner to these efforts, joining with the American Dental Association and the American Medical Association to set goals for provider groups to commit to expand education around opioid prescribing practices. As well, the AOA worked with the Administration to secure commitments from medical schools to require such prescriber education in their curricula for all students beginning this fall; 28 of the 61 medical schools who committed to the effort are colleges of osteopathic medicine.

Most recently, the United States Surgeon General, Vivek H. Murthy, MD, announced his "Turn The Tide RX" campaign, which is seeking pledges from health care professionals that includes a commitment to educating themselves to treat pain safely and effectively. All of these efforts signal a new national focus on how to effectively treat pain and ways to reduce the use of opioids when appropriate. We are therefore disappointed that the draft LCD is seemingly seeking to limit access to OMT in Medicare by creating barriers and disincentives for physicians to provide the service to their patients, rather than expanding access to this valuable treatment option for beneficiaries.

Medicare Policy
The draft LCD is not consistent with longstanding Medicare policy on reporting Evaluation & Management (E/M) services on the same date that other services are also furnished to the same beneficiary. As discussed in more detail below, current Medicare policy clearly allows reporting an E/M service on the same date as OMT (and other) services so long as the E/M is separately identifiable and the line item on the claim for the E/M appends the modifier -25 to the E/M reported. The draft LCD essentially changes what constitutes "separately identifiable" thus making it nearly impossible for OMT to qualify as such.

RUC
Furthermore, the draft LCD is not consistent with the current valuation of OMT services. Specifically, the value of OMT services is limited to the pre-, intra-, and post- service work required to perform OMT and was valued by CMS specifically to exclude any overlap with the work required to perform E/M services. In April 2010, the American Medical Association (AMA) Relative Value Scale Update Committee (RUC) requested that the AOA survey the OMT codes (CPT® Codes 98925-98929) to develop accurate and unbiased information for the relative value of the physician work involved in performing OMT as part of the Centers for Medicaid and Medicare Services (CMS) fourth five-year review of Resource-Based Relative Value Scale (RBRVS).

[9] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. dx.doi.org/10.15585/mmwr.rr6501e1

The survey process required the creation of vignettes to describe the typical patient for CPT® Codes 98925-98929. Additionally, a description of the pre-service, intra-service, and post-service work for OMT was included. The vignettes for the typical patient and the pre-service, intra-service and post-service descriptors for CPT® Codes 98925-98929 are contained within the RUC database and detail the typical work to perform OMT services associate with CPT® Codes 98925-98929.[10] These services include pre- and post-service activities that require physician time beyond the time allocated within CPT® Codes 98925-98929. For example, CPT® Code 98927 provides two minutes of pre-service time for: the physician to 1) determine which osteopathic technique would be the most appropriate for the patient, in what order the affected body regions need to be treated and whether those body regions should be treated with specific segmental or general technique approaches; 2) explain the intended procedure to the patient, answer any preliminary questions, and obtain verbal consent for the OMT; and 3) place the patient in the appropriate position on the treatment table for the initial technique and region(s) to be treated.[11] Two minutes of time is insufficient to complete this work. As such, the OMT codes were developed to dovetail with existing E/M codes which supplement these times and values. RUC recommended physician times for OMT codes are:

CPT® Code	Pre-service	Intra-service	Post-service	Total
98925	2 minutes	10 minutes	2 minutes	14 minutes
98926	2 minutes	15 minutes	2 minutes	19 minutes
98927	2 minutes	20 minutes	2 minutes	24 minutes
98928	2 minutes	25 minutes	2 minutes	29 minutes
98929	2 minutes	30 minutes	2 minutes	34 minutes

CMS

Following the RUC survey of the OMT codes during the fourth five-year review of the RBRVS, CMS acknowledged in the 2011 Physician Fee Schedule Final Rule the differences between E/M services and OMT, and the possible overlap in the work of E/M and OMT services. After reviewing the RUC recommendations for physician work and time, CMS reduced the pre- and post- service times to reflect only the time required to perform the work associated with the OMT service and to exclude any time that could be associated with an E/M service. This adjustment clearly recognizes the payment for OMT only consists of the work required to perform the OMT service:

> *"Based on the comments we received, we referred CPT codes 98925, 98926, 98927, 98928, and 98929 to the CY 2011 multi-specialty refinement panel for further review. The refinement panel median work RVUs were 0.49, 0.74, 0.99, 1.24, 1.49 for CPT codes 98925, 98926, 98927, 98928, and 98929, respectively. While the AMA RUC asserts that it reduced physician times to account for the E/M service on the same day, we do not believe the recommended physician times adequately account for the overlap in services with an E/M visit on the same day. We continue to believe that some of the activities in the pre- and post-service times of the osteopathic manipulative treatment codes and the E/M visit overlap, and that our proposal to remove 1 minute of pre- and 1 minute of post-service time appropriately accounts for this overlap. As detailed earlier in section III.A. of this final rule with comment period, we do not believe the overlap in activities should be counted in developing these procedures' work values. In order to ensure consistent and appropriate valuation of physician work, we are continuing with the*

[10] American Medical Association. RBRVS Database. CPT® Code 98927. Accessed August 11, 2016.
[11] American Medical Association. RBRVS Database. CPT® Code 98927. Accessed August 11, 2016.

> *application of our methodology, explained in the Fourth Five-Year Review (76 FR 32422), to address the overlapping activities when a service is typically billed on the same day as an E/M service. After consideration of the public comments, refinement panel results, survey responses, and our clinical review, we are finalizing the proposed work RVUs and refined times associated with these codes. CMS time refinements can be found in Table 16. We are finalizing work RVUs of 0.46 for CPT code 98925, 0.71 for CPT code 98926, 0.96 for CPT code 98927, 1.21 for CPT code 98928, 1.46 for CPT code 98929."*[12]

Therefore, after thorough review of the draft LCD, the AOA strongly urges that NGS not finalize its draft LCD as written and that it adopt the attached red-line revisions to the draft LCD.

Section-by-Section Comments

The AOA proposes the following edits to the draft LCD, which we believe are both consistent with CMS policy as well as with current medical practice. The attached red-line version follows these comments and includes language to better reflect how OMT is delivered and to appropriately guide coverage decisions. All line numbers referenced refer to the red-line draft.

Abstract

The language in the draft LCD in this section lacks clarity regarding both OMT and somatic dysfunction. Our proposed language included in the attached red-line is derived from the *Indications* section of the current First Coast Service Options, Inc. LCD for OMT (L29246). Specifically, the language we propose inserting from L29246 draws from definitions in the Glossary of Osteopathic Terminology:

> "*OMT is defined in the Glossary of Osteopathic Terminology as the therapeutic application of manually guided forces by an osteopathic physician to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction. OMT encompasses a wide variety of techniques, including but not limited to muscle energy, high velocity-low amplitude, counterstrain, myofascial release, visceral, articulatory, and cranial. The chosen treatment will vary depending on patient's age, clinical condition and the effectiveness of prior methods of treatment. (Note: OMT can be performed by a D.O. or by an M.D. who has been trained in OMT.)*
>
> *Somatic dysfunction is defined in the Glossary of Osteopathic Terminology as impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial, and myofascial structures, and related vascular, lymphatic, and neural elements. The definition of somatic dysfunction implies reversibility, and it is treatable using OMT."*

Indications

The draft LCD's added language to paragraph 1: "when such treatment is likely to result in improved symptoms (e.g. less pain) or functional status" in the draft LCD is unclear and the rest of the section in the draft LCD only provides a single example of a "result in improved symptoms." We urge greater clarity in terms to minimize confusion and streamline interpretation. Our proposed language in the attached red-line provides additional clarity by incorporating language from the First Coast Service Options LCD.

[12] Federal Register, Vol. 76, No. 228, 42 CFR Parts 410, 414, 415, et. al., November 28, 2011.

Additionally, paragraph 2 language is inconsistent with CMS policy as the OMT codes have already been adjusted to account for any overlap that might occur between OMT and E/M. As noted in the "General Comments" section of this letter, CMS policy clearly states this:

> *"We continue to believe that some of the activities in the pre- and post-service times of the osteopathic manipulative treatment codes and the E/M visit overlap, and that our proposal to remove 1 minute of pre- and 1 minute of post-service time appropriately accounts for this overlap. As detailed earlier in section III.A. of this final rule with comment period, we do not believe the overlap in activities should be counted in developing these procedures' work values. In order to ensure consistent and appropriate valuation of physician work, we are continuing with the application of our methodology, explained in the Fourth Five-Year Review (76 FR 32422), to address the overlapping activities when a service is typically billed on the same day as an E/M service. After consideration of the public comments, refinement panel results, survey responses, and our clinical review, we are finalizing the proposed work RVUs and refined times associated with these codes. CMS time refinements can be found in Table 16. We are finalizing work RVUs of 0.46 for CPT code 98925, 0.71 for CPT code 98926, 0.96 for CPT code 98927, 1.21 for CPT code 98928, 1.46 for CPT code 98929."*[13]

In 2010, the AOA surveyed the OMT codes and recommended relative value units based on vignettes for the typical patient. CMS accepted the recommendations of the RUC with an adjustment to the values of the pre- and post-service work to account for any overlap in work between the E/M and OMT. Therefore, based on the CMS discussion cited above, it is very clear that the pre-service work of the OMT codes does not include the history, physical exam, or medical decision-making elements of the E/M service. We oppose any language that intimates anything different and believe the language in the draft LCD on this topic should not be included in any final NGS LCD. The new language we have provided in the attached red-line on lines 56-70 adds clarity that is consistent with CMS policy.

Further, we believe the language (lines 81-82 of our attached red-line draft) of the draft LCD "note" should be deleted and the following language (lines 75-77 of our attached red-line draft) in the existing LCD should be maintained: "Osteopathic Manipulative Treatment specifically encompasses only the procedure itself. E&M services are covered as a separate and distinct service when medically necessary and appropriately documented."[14] This will maintain consistency with National Correct Coding Initiative (NCCI) Policy Manual Guidance which states that coding policies are overruled when there are active specific procedure-to-procedure (P2P) edits in place. Per the NCCI edits on procedure-to-procedure (P2P) for OMT and E/M service, these coding combinations have been assigned a modifier indictor of 1, allowing for the reporting and payment for each service when reported with modifier -25. These P2P edits were implemented on January 1, 2005. For clarification, the language in the existing NGS LCD should be maintained over the proposed language in the draft LCD. However, the language should be changed slightly as revised in the attached red-line to reflect that the modifier -25 does not need to be used should it be the case that the OMT and E/M services are delivered on different dates.

---

[13] Federal Register, Vol. 76, No. 228, 42 CFR Parts 410, 414, 415, et al, November 28, 2011

[14] National Government Services. *Local Coverage Determination (LCD): Osteopathic Manipulative Treatment (L33616).* April 2, 2014.

The examples in paragraph 4 of the draft LCD of "a significant and separately identifiable service" are inconsistent with CPT guidelines and the above referenced NCCI policy. In addition, they are confusing and contradictory. The second sentence which starts on line 85 of our attached red-line draft, "An E&M service may be caused or prompted by the same symptoms or condition for which the OMT service was provided and correct coding does not require different diagnoses for the reporting of the OMT and E&M service on the same date." is inconsistent with the third and fourth sentences of that paragraph that "…if, for example, a beneficiary has neck pain and OMT is used as the treatment for the neck pain, an E&M service for the neck pain would generally not be considered a significant and separately identified service. Other than for the initial visit, which requires a comprehensive assessment, an E&M service for the same condition as that being treated with OMT, is included in the OMT service." This also contradicts NCCI policy and other CMS policies on modifier -25 (e.g., with chemotherapy services where assessment of a complication of chemotherapy is considered grounds for reporting an E/M with modifier -25 when chemotherapy is given).

Limitations

The draft LCD's language in paragraph 2 that OMT is not covered when "further clinical improvement cannot be reasonably expected…[OMT] that seek to prevent disease, promote health, prolong and enhance the quality of life, or maintain or prevent the deterioration of a chronic condition, are considered maintenance, and not covered by Medicare" is verbatim from the Local Coverage Determination (LCD): Chiropractic Services (L33613) and is not consistent with OMT and the delivery of physician services. Osteopathic physicians complete four years of osteopathic medical school. DOs acquire advanced skills in providing preventive, comprehensive care. They also receive in depth training in the musculoskeletal system, which is the body's interconnected system of nerves, muscles, and bones. DOs use this knowledge to perform OMT, a series of hands-on techniques used to help diagnose illness or injury and facilitate the body's natural tendency toward self-healing. Upon graduating from osteopathic medical school, DOs complete internships, residencies and fellowships, which prepare them to become licensed and board-certified. Chiropractic philosophy and science is a system of adjusting the segments of the spinal column by hand only; whereas, Osteopathic Manipulative Medicine is much more comprehensive, seeking to restore arterial, venous, and lymphatic circulation; restore balance between the parasympathetic and sympathetic nervous systems; and increase or restore flexibility, mobility, and appropriate range of motion.

Treatment of existing medical conditions and prevention of deterioration is much of what medicine does; medicine is not simply "maintenance." The draft LCD as worded in paragraph 2 of the *Limitations* section could be used to argue that physical and occupational therapy for the purpose of maintaining function should also not be covered. Any such policy would be inconsistent with the standard of medical care, as it is here with respect to OMT. Therefore, we believe the language should be removed from the draft LCD.

As well, the language in paragraph 3 of the *Limitations* section in the draft LCD, "Further scheduled visits, for the purpose of manipulative intervention only, do not necessitate separate E&M services." lacks clarity and could lead to confusion as written. To clarify, the decision to utilize OMT is typically on a visit-by-visit basis. At each visit, the physician needs to obtain the patient's medical history needs, perform a physical examination, and decide on appropriate treatment on that date of service (which may or may not include OMT). The OMT provided is separate and distinct from the evaluation that needs to be performed. In clinical practice, the follow up visit is not typically for pre-

determined OMT, but to evaluate the patient's response and or improvement over time. The decision to apply more OMT is made after a re-evaluation and re-exam of the patient at the next visit. This approach differs from that used with the chiropractic manipulative treatment (CMT) codes, which include a pre-manipulation patient assessment. The AOA's proposed language in the attached red-lined draft in lines 102-109 includes examples of those rare instances when E/M may not be necessary, and speaks to the point with greater specificity.

Documentation Requirements

Overall within this section of the draft LCD, the AOA believes there needs to be greater clarity added in order to mitigate confusion that currently exists. The language we propose to be incorporated (see attached red-lined document lines 117-131) draws from the First Coast Service Options LCD. With the addition of this new language, paragraphs 4-6 of the draft LCD are no longer necessary, and we therefore propose to delete them (see red-lined document, lines 131-144).

In paragraph 6 of the draft LCD, we propose adding "or related" after "identifiable" (see line 145 of attached red-line document). Otherwise, this language as drafted is inconsistent with CMS policy according to a 1994 memo issued by the Department of Health and Human Services (HHS) to all Medicare Administrative Contractors on "Policy Issues Related to Osteopathic Manipulative Treatment." The memo stated:

> *"On June 23, 1992 we issued a memorandum to our regional offices on the issue of the -25 modifier. It had come to our attention that some carriers were not paying for E/M codes with a -25 modifier unless they were "unrelated" to the OMT. We indicated in the memo that was not correct and stated: "A documented, separately identifiable related service is to be paid for. We would define related as being caused or prompted by the same symptoms or conditions." Thus, carriers should not deny claims for OMT and an E/M service with a -25 modifier simply because they both are reported with the same diagnosis code. This policy applies whether or not it is a first or subsequent encounter with the patient."*[15]

The final language we propose adding to this paragraph in lines 146-149 of the attached red-lined document also provides the important distinction between OMT utilized at a follow-up visit, and follow-up OMT.

Finally, the term "Plan of Care" has been added in the draft LCD. Both historically and presently, this term is not associated with OMT. Furthermore, the draft LCD attempts to apply it to OMT in a manner very similar to its use for chiropractic services, which we have already noted is significantly different from OMT. We therefore recommend deleting the term "plan of care" from the draft LCD because OMT is furnished based on a patient's condition at the time of a visit and is rarely "planned" over time. In those instances where a physician determines that two or more OMT sessions are required, the medical record should document this determination and support the use of OMT on multiple occasions.

Utilization Guidelines

The AOA's proposed language (lines 155 and 158-179 of the attached red-line) is primarily taken from the First Coast Service Options LCD. We believe the additional specificity regarding the acute, subacute, and chronic phases serves to strengthen the LCD. The language we propose to delete is

---

[15] U.S. Department of Health and Human Services. *Memorandum: Policy Issues Related to Osteopathic Manipulative Treatment.* July 6, 1994.

no longer necessary with the language we propose to add. Additionally, the language regarding "Plan of Care" should be deleted for reasons we previously noted in this letter.

Sources of Information and Basis for Decision

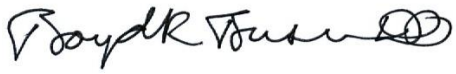
There is no new scientific evidence provided to support the changes being proposed by NGS in the draft LCD as demonstrated by only one reference in this section to a previous LCD from 2011 and a definition from the American Osteopathic Association Glossary of Osteopathic Terminology from 1998. However, we believe our proposed additions in lines 193-195 of the reference to the 2011 Federal Register and First Coast Services LCD do support the red-lined draft we propose.

Conclusion

The American Osteopathic Association strongly believes the proposed changes in the NGS draft LCD, if adopted, would severely impose barriers to access to OMT services for the patients our 123,000 osteopathic physicians and osteopathic medical students serve. We believe the edits we have provided to the proposed draft LCD will align with current CMS policy and appropriately reflect the delivery of OMT.

Please contact Ray Quintero, AOA Senior Vice President of Public Policy at 202-349-8753 or rquintero@osteopathic.org should you have any questions.

Sincerely,



Boyd R. Buser, DO
President