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August 12, 2016

RE: **Proposed Local Coverage Determination (LCD) DL 33616**

LCD Comments
P.O. Box 7108
Indianapolis, IN 46207-7108

To Whom It May Concern:

I write to inform you of our opposition to the proposed Local Coverage Determination (LCD) DL 33616. Adoption of this proposed LCD will negatively impact patient care by compromising access to osteopathic manipulative treatment (OMT) and is inconsistent with existing policies of the Centers for Medicare and Medicaid Services.

The American College of Osteopathic Internists (ACOI), which represents the nation's osteopathic internists and medical subspecialists, is committed to assisting its members' efforts to provide high-quality care and to ensuring that their patients have access to this care when they need it most. This proposed LCD threatens the ability of our members to provide care consistent with the principles and practice of osteopathic medicine and would result in limiting patient access to appropriate medical treatments.

The LCD limits indication of OMT to when treatment is "likely to result in improved symptoms (e.g. less pain) or functional status." It is unclear from the proposal as to what improved symptoms or functional status are beyond this single example.

Additionally, the LCD notes that OMT procedure codes include pre-procedure, intra-procedure, and post-procedure work inherent in the procedure, and that, as a result, physicians should not report an E&M service for this work or the work associated with the decision to perform an OMT procedure, whether the patient is new or an established patient. However, current Relative Value Scale Update Committee (RUC) valuation already takes into account the potential of any overlap between OMT and evaluation and management (E&M) services with a relative value unit (RVU) adjustment, and states that physicians should report both services. The proposed LCD clearly conflicts with existing CMS policy.

The *Limitations* section states that OMT is not covered "when further clinical improvement cannot be reasonably expected." Again, this definition is unclear and necessitates further clarification. This paragraph also states that OMT used to "...maintain or prevent the deterioration of a chronic condition, are considered maintenance, and not covered by Medicare." The maintenance of

medical conditions and prevention of the resulting health deterioration due to these conditions is a fundamental part of providing cost-effective, quality patient care.

This section also states that “further scheduled visits, for the purpose of manipulative intervention only, do not necessitate separate E&M services.” However, a physician’s determination to use OMT is typically done on a visit-by-visit basis. OMT is a separate, distinct procedure from the evaluation performed at each visit, and follow-up visits are not for additional OMT, but are to evaluate the patient’s response and progress with their condition. Any decision to apply additional OMT is made after a reevaluation and reexamination of a patient during the next visit.

We also seek clarity on the *Documentation Requirements* section, as these guidelines are confusing as written. This section states in the fourth paragraph that “monitoring the effect of the interventions is an integral part of any intervention, and this is true for OMT.” The proposed LCD goes on to state, “. . . assessment of these performance metrics contributes to a distinct E&M service when appropriately documented, as does the development of a Plan of Care when these services are included in a comprehensive assessment at the initiation of treatment.” The proposal is contradictory at the most basic level. How can assessment of performance be a distinct E&M service at the initiation of treatment when there is nothing yet to compare it to, but not be a separate service at a subsequent visit?

With regard to the *Utilization Guidelines* section, the guideline in 3B proposes that “treatment courses extending beyond six months should be infrequent and the rationale for continuance clearly explained within the medical records.” While the proposed LCD provides two limited examples of such potential circumstances (ongoing spasticity post-CVA, or progressive neurodegenerative disorder), it again fails to provide clarity on what rationale should be provided, how this should be documented, and to what level of detail.

We also note that the *Sources of Information and Basis for Decision* section listed in the proposed LCD does not include any scientific evidence or any sources of information to support the changes made in this proposal. In fact, they reference only a previous LCD from 2011, and an existing definition of OMT that was itself referenced in the 2011 LCD (NHIC LCD L3206).

The ACOI is concerned with what appears to be a comingling of osteopathic manipulative treatment and chiropractic services. OMT provided by an osteopathic internist is not comparable to services provided by chiropractors, and therefore should not be treated as such. Osteopathic internists complete premedical undergraduate courses, four years of medical school, and at least three years of residency training after medical school. A considerable portion of the language in the LCD appears to have come directly from the NGS LCD on Chiropractic Services (L33613) and uses terminology that is used in chiropractic, nursing, and therapy assessments, which does not align with the approach to care used by a residency-trained, board-certified, licensed osteopathic internist.

The ACOI opposes the proposed LCD, and asks that NGS not proceed in finalizing it. We are concerned that it will result in further confusion for physicians and limit access to appropriate care for their patients. As our country seeks to address issues of prescription drug and substance use

disorders, we should be looking for ways to expand access to effective nonpharmacological interventions such as OMT, and not create, new unnecessary barriers to appropriate care. The proposed guidance fails to consider the principles and practices of osteopathic medicine and does nothing to further the delivery of cost-effective, quality care.

We thank you for your consideration and the opportunity to provide these comments on behalf of the ACOI and its members.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Bulger". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

John B. Bulger, DO, MBA, FACOI
President