

July 15, 2022

Mr. Jonathan Blum
Deputy Principal Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Deputy Administrator Blum:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing to bring your attention to an issue of immediate concern to a number of physician specialties. The AMA has been made aware of an issue within some Medicare jurisdictions regarding coverage and payment for the administration of a number of complex biological drugs that could ultimately result in patients losing access to these critical treatments. Due to the ongoing concerns about the lack of opportunity to provide input to Medicare Administrative Contractors (MACs) and about the process used in making coding, coverage, and payment determinations for administration of the impacted drugs, **the AMA urges the Centers for Medicare & Medicaid Services (CMS) to continue to delay implementation of coding policies seeking to change coding guidance for the administration of non-chemotherapy complex biological drugs and to work with interested stakeholders towards an appropriate resolution of this issue.**

It has recently been brought to our attention that certain MACs are engaging in practices that use local coverage articles (LCAs) to unilaterally issue policy changes that ultimately restrict coverage or access to physician services. Most recently, this has happened with LCAs from both First Coast Service Options, Inc. (A59074) and Novitas Solutions, Inc. (A59073) that seek to disallow the use of CPT 96401-96549 when coding for the administration of biological drugs used to treat conditions such as rheumatic diseases. The AMA is concerned this downcoding is medically inappropriate and will ultimately severely impact physicians' ability to administer these therapeutics to patients in office-based settings. The therapeutics at issue require multiple staff members with specialized training to administer, along with specialized equipment and systems. The proposed downcoding would result in a situation where a number of practices would no longer be able to employ the staff needed to administer these treatments.

Should it become no longer financially feasible for physicians to administer these therapeutics to patients directly, patients will need to receive treatment in a hospital-affiliated infusion center setting. This will not only significantly increase costs for both patients and the Medicare program, but will add unnecessary burden to patients with additional travel and appointments. Additionally, not every hospital is well-equipped to provide these therapeutics, meaning patients could face additional burdens in seeking treatment.

Especially troublesome is the process by which these changes have been proposed. By utilizing the LCA process to communicate this new coding paradigm, MACs are leaving no opportunity for impacted

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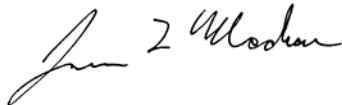
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stakeholders to provide input into what appropriate coding for these services should be and are likewise unable to appropriately communicate the severity of the impacts of these changes on their practices and patients. It also does not require any demonstration of evidence by the MAC in question that would support the policy changes. When a policy change ultimately results in significant changes to coverage and payment for physician services, an appropriate process for stakeholder review and input should be guaranteed. The intent of the changes to the local coverage determination process included in the 21st Century Cures Act was to ensure this very situation would be avoided. **We strongly urge CMS and its MACs to ensure that any policy changes resulting in significant changes to coverage and reimbursement for physician services be provided appropriate opportunity for public review and input.**

The AMA and impacted specialties are available for continued discussion on this issue and strongly urge CMS to extend the delay on implementation of these policy changes to allow impacted specialties time to provide additional evidence and information about appropriate coding for the administration of these therapeutics. We also welcome any opportunity to further discuss how to better utilize the local coverage determination processes to avoid situations like this in the future. For any questions or to further discuss, please contact Shannon Curtis, Assistant Director of Federal Affairs at Shannon.Curtis@ama-assn.org. We look forward to working with you on this important issue.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD