June 14, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Brooks-LaSure,

On behalf of the undersigned organizations and the thousands of physicians, health professionals, and patients we represent, we are writing regarding the Medicare Administrative Contractors' (MACs) inappropriate use of Local Coverage Articles (LCAs) to issue policy changes. These actions subvert the processes for transparency and stakeholder engagement in policymaking through Local Coverage Determinations (LCDs) as intended by the 21st Century Cures Act.

The 21st Century Cures Act and related regulations demonstrate the intent of Congress and CMS to ensure processes for meaningful stakeholder review and input for substantive policy changes. These requirements include publication of the LCD in its entirety 45 days in advance of the effective date, a summary of the evidence considered and explanation of the rationale supporting the determination. MACs are further required to hold an open meeting to discuss all proposed LCDs and must allow at least 45 calendar days for public comment.

Instead of abiding by the guidelines of the 21st Century Cures Act, some MACs have used LCAs to unilaterally issue policy changes that restrict coverage or access. The MACs argue that they are merely providing billing instructions. In reality, they are using LCAs to enact policy and circumvent the standards of transparency, evidence and stakeholder input established by the LCD process. LCAs are intended to be coupled with an LCD or National Coverage Determination (NCD), with the LCA providing only additional coding/billing or other information as may be needed to implement the policy determined in the LCD or NCD. Issuing a standalone LCA to unilaterally enact policy harms Medicare beneficiaries and undermines the transparent LCD process intended by Congress and CMS.

The following examples demonstrate the MAC's use of LCAs to enact policies that restrict coverage or access for Medicare beneficiaries.

Rheumatology
Over the last several years, the MACs have issued LCAs on Complex Drug Administration Coding that prohibit use complex chemotherapy codes (CPT 96401-96549) when coding for the administration of complex biologic drugs used to treat rheumatic diseases, instead requiring a therapeutic or diagnostic code (CPT 96360-96379). This downcoding is medically inappropriate and inconsistent with the definition of the CPT codes in question. Inappropriate reimbursement

for these critical therapies threatens beneficiaries' access which may lead to disease progression and higher overall healthcare costs.

By virtue of their interactions with cells and chemicals in the body, biologic agents used in the treatment of rheumatic diseases carry a high risk for serious adverse reactions – a fact that is reflected in their FDA labeling. The immunologic risks associated with these drugs, related to anti-drug antibodies, infusion reactions, opportunistic infections (i.e., mycobacterial, fungal, or other) and allergic reactions are significant regardless of the route of administration and these risks actually increase over time. The elevated level of monitoring required prior to, during, and following the administration of these drugs defines their coding as complex.

The Medicare claims processing manual, 30.5 section D states, "Chemotherapy administration codes apply to parenteral administration of non-radionuclide anti-neoplastic drugs; and also to … *substances such as monoclonal antibody agents, and other biologic response modifiers*" (emphasis added). Furthermore, the definition of CPT 96365 specifically excludes "other highly complex drugs and highly complex biologic agents", and the definition of the complex administration code CPT 96413 specifically includes these same classes of drugs. Despite multiple requests, the MACs have repeatedly declined to provide background on the evidence reviewed or any discussion of the rationale to support this determination.

It should also be noted that, as recently as May 2021, First Coast Service Options, Inc. (FCSO) LCA (A56203) stated that administration of all biologic response modifiers in the following categories was reimbursable with the complex chemotherapy codes: monoclonal antibodies, interleukins, tumor necrosis factors and certain fusion proteins. A new FCSO LCA (A59074), effective June 6, 2022, reverses this policy and lists numerous biologic drugs that may no longer be billed with the complex administration codes. Because these policies were issued as LCAs, the MAC was not required to provide evidence for their rationale nor was there any formal opportunity for stakeholder input.

Ophthalmology

In May 2021, Novitas made an update to A57618 (Blepharoplasty, Blepharoptosis Repair and Surgical Procedures of the Brow) which included several procedure codes that are never cosmetic. The American Academy of Ophthalmology (AAO) promptly alerted Novitas to the error, but the policy was not updated until October 2021.

There are also examples of MACs delayed response to updates of CMS guidance. For example, when CMS removed CPT 67911 (*Correction of lid retraction*) from their policy on Prior Authorization for Certain Hospital Outpatient Department (OPD) Services in December 2021. AAO sent letters to all the MACs notifying them of this change, yet months later some MACs have yet to update their policies, which results in unnecessary prior authorization requests. In both of these examples, errors by MACs have placed a significant burden on providers performing those procedures and have been corrected only after a significant time and effort was spent communicating with the MAC. If stakeholders had been involved in the process of developing these policies, errors like these would have been easily avoided.

Radiology
The MACs currently use the LCAs as the vehicle to publish the lists of ICD-10 codes that meet the requirements of medical necessity for the CPT codes covered in any particular LCD. A published list of covered ICD-10 codes by definition restricts coverage to those signs and symptoms covered by the ICD-10 codes on the list. Previously, these lists of codes that met medical necessity were published in the LCD, and there was input on those lists through the notice and comment period. Frequently, the lists are incomplete and inaccurate, and having the opportunity to review those as part of the LCD process was beneficial to patients and providers. By moving ICD-10 lists to LCAs, coverage is now restricted to only those ICD-10 codes that the MAC chose to include in the LCA, which is a de facto restriction of coverage and is lacking the notice and comment period. When brought to the attention of CMS they suggest having codes within an article allows the MAC to make routine coding changes that do not affect the reasonable and necessary criteria of a policy without going through the entire LCD development process, allowing for the most up to date coding to be available to the public in a more tenable time frame. The physician community disagrees and finds these claims disingenuous as coverage additions to an existing LCD before the 21st Century Cures Act mandate were never difficult. The difficulty comes with trying to restrict coverage. The LCA process allows MACs to revise LCDs into more restrictive policies without any input from stakeholders. We would like to reiterate MACs should be encouraged by CMS to review and consider stakeholder comments related to articles that are associated with an explicit LCD policy.

An example of this issue can be found across MAC jurisdictions that have an LCD on Computed Tomography Cerebral Perfusion Analysis (CTP). The list of covered ICD-10 codes in the associated LCAs is completely inadequate for patient care. Instead of including critical signs and symptoms that would substantiate the use of this procedure (that may have significant impact on patient morbidity and mortality), the LCAs instead only list those ICD-10 codes for a known large vessel occlusion. It is important to list the signs and symptoms of large vessel occlusion, rather than the occlusion itself, as that is how patients present to the Emergency Department. An ER physician doesn't know a-priori if there is a large vessel occlusion, but he or she knows if the patient is exhibiting the signs and symptoms of one, and he or she needs to be able to get a CT Perfusion exam for the patient in those circumstances. This scenario is currently denied for Medicare patients.

We greatly appreciate your consideration of these concerns and ask that you compel the MACs to discontinue the inappropriate use of LCAs and ensure that all current LCAs restricting coverage or access are invalidated and subject to future review through the LCD process. Please contact Meredith Strozier, ACR Director of Practice Advocacy, at mstrozier@rheumatology.org or (404) 633-3777 to schedule a virtual meeting at a mutually convenient time.

Sincerely,

American Academy of Allergy, Asthma & Immunology
American Academy of Dermatology Association

American Academy of Ophthalmology
American Association of Orthopaedic Surgeons
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Orthopaedic Foot & Ankle Society
Coalition of State Rheumatology Organizations