



LOCAL COVERAGE DETERMINATIONS NEGATIVELY AFFECTING BENEFICIARIES

There are disturbing trends in the process used to develop Local Coverage Determinations (LCDs), resulting in policies that limit beneficiary access to important, medically necessary services and technologies. Despite concerns raised by stakeholders, several Medicare Administrative Contractors (MACs) continue to ignore requirements outlined in the Medicare Program Integrity Manual, hindering public engagement and that of its Contractor Advisory Committees (CACs), as well as circumventing the National Coverage Determination (NCD) process through “carbon copying” of LCDs. Worse yet, MACs “pick and choose” evidence to support a predetermined conclusion, disregarding peer-reviewed literature and clinical studies supplied by constituent clinicians and national medical societies to render unfavorable coverage policies.

The following are examples of LCDs that impede access to key services for Medicare beneficiaries.

Cancer Genetic Testing: With the “Genetic Testing for Oncology” LCD, two MACs ignored requirements for LCD development and included inappropriate coverage criteria that impeded timely access to essential, well-established tests—such as those for bladder cancer and melanoma skin cancer. The LCDs inappropriately pointed to outside sources and applied default non-coverage to any genetic test not listed in at least one of three identified publications, thereby disregarding a MACs obligation to make its own review of available evidence to determine coverage. In addition to ignoring requirements, this approach also functioned as a barrier to services that were clearly medically necessary and otherwise covered under Medicare. Additionally, the final LCDs differed so substantially from the proposed versions that they could not have been deemed a logical outgrowth of the proposed policies, thereby denying the public a fair opportunity to comment on the new, final version. After intense pressure from stakeholders, CMS instructed the MACs to withdraw the LCD and reissue a new draft, with a public comment period to address the criticisms. The process took two years to complete, during which access to diagnostics that inform treatment decisions for cancer patients was impeded.

Mohs Micrographic Surgery (Skin Cancer): Several MACs have largely ignored existing requirements from the Medicare Program Integrity Manual in the development of LCDs for Mohs Micrographic Surgery (MMS) procedures. In fact, one MAC issued a policy that excluded MMS procedures from being performed in the hospital outpatient department, even though it never specifically stated this in the draft or final LCD. It was only after the policy was finalized and claims were denied that the site of service restriction became known. No rationale for the decision was provided, and stakeholders never had a meaningful opportunity to comment on the issue. Months later, the MAC revealed it was unaware that Mohs surgeons perform *all components* of MMS, even in the HOPD. Eventually, the MAC reversed its policy.

Pattern Electoretinography (Vision Disorders): Beneficiary access to Pattern Electoretinography (PERG), a diagnostic test proven to detect early signs of blinding vision disorders such as glaucoma, is being hindered due to poorly developed Medicare LCDs. For those at high risk, including minority populations where glaucoma strikes earlier and progresses faster, early diagnosis and treatment is critical to minimize vision loss and reduce unnecessary treatment. Medicare covers items and services that are reasonable and necessary for the



diagnosis or treatment of an illness or injury. However, it seems that MACs limited their evaluation of scientific evidence in support of PERG's decades-old application in early glaucoma detection to maintain a non-coverage position, leaving countless beneficiaries without access.

Prosthetic Limbs: A draft LCD was proposed to change the way Medicare patients are covered, how they qualify for, and what types of components are provided with prosthetic devices. These changes would have significantly altered the mobility of those needing prosthetic devices by ignoring the functional potential of the patient, limiting feet and ankle options, and limiting socket and liner options, among other changes. After a "We the People" petition with over 100,000 signatures was submitted to the White House in 2015, the draft Lower Limb Prostheses LCD was put on hold and eventually retired.

Special Stains (Cancer Diagnosis): In 2015, several MACs finalized an LCD establishing an arbitrary utilization threshold for stains used to diagnose cancer, impeding the physician's medical judgment. The LCD used highly selective literature citations, misrepresented the opinions of national organizations, and was contrary to generally accepted guidelines. Senior officials with the Centers for Medicare & Medicaid Services (CMS) falsely asserted during a meeting that the agency did not have the authority to intervene with the MAC in this LCD. In 2021, the College of American Pathologists requested revisions to the Special Stains LCDs based on new evidence. However, the revision process took 3.5 years for the MACs to complete, extending the barrier to diagnostic testing for Medicare beneficiaries under this LCD to over ten years.

Testing for Diagnosing Melanoma: This widespread MoIDX LCD—applicable in over 28 states—uses selective evidence to restrict physicians other than dermatopathologists from ordering certain molecular tests for diagnosing melanoma skin cancer. The restriction assumes there will always be timely and direct access to a dermatopathologist, which is not always the case—particularly in rural areas where access to subspecialty care is often limited. By denying coverage to other physicians who routinely diagnose and treat patients with melanoma, such as oncologists, otolaryngologists, MOHS surgeons, and surgical pathologists, this restriction will lead to delayed treatment, interrupted continuity of care, and avoidable disease progression, as well as added financial burden on patients.