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September 17, 2022

MolDX Program
Palmetto GBA
17 Technology Circle
Columbia, SC 29202

Submitted electronically: MOLDX.POLICY@palmettogba.com

Re: MolDX: Molecular Biomarker Testing to Guide Targeted Therapy in Rheumatoid Arthritis (DL39424)

Dear Sir or Madam:

The Coalition of State Rheumatology Organizations (CSRO) is comprised of over 40 state and regional professional rheumatology societies whose mission is to advocate for excellence in the field of rheumatology, ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease. Our coalition serves the practicing rheumatologist.

Today, we write in response to Palmetto GBA's proposed local coverage determination (LCD) under the Molecular Diagnostic Services (MolDX) Program titled, *Molecular Biomarker Testing to Guide Targeted Therapy in Rheumatoid Arthritis (DL39424)*. As the scope of the Palmetto GBA MolDX program covers several Medicare Administrative Contractor (MAC) jurisdictions[i], LCDs established by the MolDX Program are of interest to most of the states and regions under the CSRO umbrella.

Proposed Non-Coverage Decision for Molecular Biomarker Testing to Guide Targeted Therapy in Rheumatoid Arthritis (RA)

In the proposed LCD, Palmetto GBA has concluded that *"clinical validity has not yet been established for molecular biomarker tests that guide targeted therapy selection in RA."* On that basis, Palmetto GBA proposes non-coverage for emerging technologies in this space. This is disappointing considering that Palmetto GBA's *"[Contractor Advisory Committee] subject matter expert (SME) panelists noted that physicians would welcome predictive tests to guide targeted therapy in RA patients and find them useful if they could help minimize the trial-and-error approach of current therapy."*

Even with adherence to the American College of Rheumatology (ACR) Guideline for the Treatment of Rheumatoid Arthritis, identifiying the most effective therapy involves a "try-and-fail" approach. After a patient fails conventional disease-modifying antirheumatic drugs (DMARDs), the current clinical evidence does not support initiating treatment with one biologic or targeted synthetic DMARD over another. Nevertheless, tumor necrosis factor inhibitors (TNFis) are the most frequent first-line biologic DMARD prescribed. This is despite the fact that approximately 30-40% of patients do not achieve a meaningful clinical improvement with this drug class. Unfortunately, because of insurer requirements (e.g., dose escalation, in-class cycling, etc.), moving to another mechanism of action is often challenging, meaning patients may spend an extended period of time on a therapy that will not work for them. The consequence to the patient is increased disease severity, disability, and pain, not to mention diminished quality of life and difficulty with activities of daily living.

It should be noted that sustained high level of disease activity is associated with increased costs now and in the future. Those patients with uncontrolled disease often require increasing doses of steroids leading to diabetes, infections, osteoporosis and a myriad of other well known side effects. Looking to the future, RA patients with active disease can incur more joint replacements, heart attacks and even some malignancies which will lead to long term increases in costs.

Rheumatologists and our patients are desperate for solutions to this "fail first" or "fail harder" paradigm. Molecular biomarker tests are the first tool offering an objective, science-based approach to identifying appropriate medication therapies for RA treatment and management. Recent studies support the clinical validity and utility, and most rheumatologists and patients are eager to gain access to these precision medicine tools in clinical practice to improve outcomes in RA. The proposed LCD seems to suggest that such precision tools may *never* be available for RA patients, but that, in any event, the current approach is good enough. On behalf of our patients, we reject that assertion. Our colleagues in oncology have experienced remarkable growth in the field of genetically-driven precision diagnostics and therapies, which has greatly improved not only the survival rates but also the management of certain cancers. Our patients deserve no less in terms of proactive, data-driven disease management, but we are concerned that the proposed LCD sends the message that investment in this field is simply not worth it.

Given the aforementioned, ***our coalition urges you establish a local coverage policy and associated payment for the use of molecular biomarker testing to guide targeted therapy in RA with the following caveats:***

- ***The ordering and interpretation of molecular biomarker testing in rheumatoid arthritis should be at the sole discretion of the treating rheumatologist.***

- ***Patients who are <u>stable</u> on their medication should not be switched to a different drug or denied coverage of their current medication by the Medicare program, including Medicare Advantage, based on the results of molecular biomarker testing.***

Thank you for considering the feedback of practicing rheumatologists. Should you have any questions, please contact me at mfeldman@csro.info.

Sincerely,

Madelaine A. Feldman, MD, FACR
Past President and Vice President, Advocacy & Government Affairs
CSRO

[i] See Molecular Diagnostic Program (MolDX®) Coverage, Coding, and Pricing Standards and Requirements (M00106), Chapter 1.2, Current Scope of the Palmetto GBA MolDX program.