April 13, 2020

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

Dear Administrator Verma,

On behalf of the undersigned organizations and the thousands of physicians, health professionals, and patients we represent, we are writing regarding Medicare contractors’ decisions to terminate Part B coverage for ustekinumab (Stelara) and move this drug to the self-administered drug (SAD) list. This decision will leave vulnerable patients with limited treatment options and serious health risks. Furthermore, given the unprecedented health crisis we are facing as a result of COVID-19, we urge you to advise the MACs to delay implementation of this change and avoid causing further disruption to Medicare patients’ care and access to treatments at this critical time.

Our organizations have serious concerns over removing Part B access to this FDA approved, medically necessary biologic drug. Higher deductibles and coinsurance restrict access to many biologics through Part D, so forcing this switch will necessitate treatment abandonment for most of these patients. Medicare patients are by definition older, often with multiple health conditions, and so should be considered vulnerable. A forced switch or discontinuation of treatment such as this would be considered very high risk for these patients. Access to affordable, quality care should be everyone’s top priority especially during the current crisis when all Americans are facing health and economic challenges.

Biologic drugs are vitally important therapeutic options for patients with autoimmune diseases. The decision to choose one drug over another requires careful clinical evaluation and consideration by a physician specialized in the diagnosis and treatment of autoimmune diseases. An individual patient’s age, gender, diagnosis, medications, specific organ manifestations, antibody status, disease severity, comorbid conditions, functional status, social support, and ability to tolerate the route of administration strongly influence the specific biologic choice as well as site of care.

As noted above, many Medicare patients are unable to afford biologic treatments unless offered through Part B. Already, these Medicare patients have far fewer therapeutic options than patients on commercial insurance plans. For example, patients with psoriasis and psoriatic arthritis may be treated with injectable/intravenous biologic drugs from at least five different classes. These therapies have revolutionized treatment of these diseases in the last 20 years, dramatically improving quality of life and even survival. However, only three of these five classes are currently available through Part B, and by removing ustekinumab (the only IL12/23 antagonist), only two classes will remain (TNF antagonists, i.e. infliximab, golimumab, certolizumab), and abatacept. It is not uncommon for these patients to fail multiple agents and often respond better to drugs with different mechanisms of action. To reiterate, ustekinumab is the only FDA-
approved biological therapy that blocks the interleukin 12 and 23 (IL12/23) pathways. As a result, this decision by the MACs and CMS effectively removes an entire class of biological therapies for the Medicare B population, not just removing one drug. Many patients with contra-indications to TNF antagonists (cancer, demyelinating disease, infections, heart failure) may more safely be treated with ustekinumab. It is clinically inappropriate to force these patients to discontinue the treatment that has controlled their disease.

It is not the right of an insurance company or health care agency to choose a patient’s therapy or impose new clinical risks to a patient’s health. When compared to other immunosuppressants used for indications across inflammatory diseases (active psoriatic arthritis, moderate to severe plaque psoriasis, moderate to severely active Crohn’s disease, and moderate to severely active ulcerative colitis), IL12/23 antagonism has been demonstrated to be one of the safest biological therapies currently available. Our organizations oppose the forced discontinuation of treatment for administrative reasons, and we cannot emphasize strongly enough that patients on ustekinumab through Part B are on it because they cannot afford treatment through Part D or could/should not self-administer treatment (due to joint deformities, complex medical conditions warranting close in office monitoring, failure of other therapies, etc). As such, this is not a simple mandate to move to Part D; this is a forced discontinuation of treatment for these fragile patients.

Our organizations are not aware of any provider or patient groups that were given the opportunity to give input on these policy changes. It is unclear to us what evidence the contractors are using to justify these changes. Utilization in our provider practices indicates satisfaction of SAD exclusion requirements. We have reviewed the criteria used to determine SAD list placement by several MACs, which make specific mention that drugs administered less than monthly are usually considered NON-self-administered. For rheumatologic indications, the initial two doses of ustekinumab are 4 weeks apart after which the dosing shifts to every 12 weeks. Moreover, and especially considering the current state of emergency in our country, providers and patients did not receive sufficient notice of this change to allow time for consultation. Due to currently restricted in-person visits, many patients will not be able to have in-person discussions with their providers about alternative options if the MACs move forward as planned. Undoubtedly, this change could harm patients and add further confusion and anxiety to a health care system that is already in crisis.

We ask that CMS review the decision by these contractors to terminate Part B coverage of ustekinumab. At a minimum, we urge you to advise the MACs to delay implementation of this change, so it can be given further consideration after the current health crisis with COVID-19 subsides. If you have questions or concerns, please do not hesitate to contact Meredith Strozier, ACR Director of Practice Advocacy, at mstrozier@rheumatology.org or (404) 633-3777.

Sincerely,

American Academy of Dermatology
American College of Gastroenterology
American College of Rheumatology
American Gastroenterological Association
Arthritis Foundation
Coalition of State Rheumatology Organizations