

June 19, 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 the Medicare Administrative Contractors' decisions to terminate Part B coverage for ustekinumab (Stelara) and move this drug to the self-administered drug (SAD) list. While we applaud the MACs' decision to delay this change until 45 days after the end of the public health emergency, we remain concerned that its eventual implementation will leave vulnerable patients with limited treatment options and serious health risks. We urge CMS to review the language in chapter 15 section 50.2 of the Medicare Benefit Policy Manual to ensure that patients who are unable to self-administer are protected from loss of access as a result of this change.

Removing Part B access to ustekinumab will have a significant negative impact on Medicare patients' ability to access this FDA approved, medically necessary biologic drug. Patients receiving physician-administered ustekinumab either 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). Higher deductibles and coinsurance restrict access to many Part D drugs; thus, moving ustekinumab to the SAD list will necessitate treatment abandonment for many patients. Medicare patients are, by definition, older, often with multiple health conditions. Forcing these patients to switch or discontinue treatment will jeopardize access to this therapy and pose a dangerous risk to the patient's health.

Medicare patients already have far fewer therapeutic options than patients on commercial insurance plans. Removing Part B access to ustekinumab would further limit these patients' access to safe and effective treatments. Patients with psoriasis and psoriatic arthritis are currently 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. Therefore, the decision to place ustekinumab on the SAD list not only limits access to one drug, but also effectively removes an entire class of biological therapies for the Medicare Part B population. Many patients with contraindications to TNF antagonists (cancer, demyelinating disease, infections, heart failure) may more safely be treated with ustekinumab. 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 pathways currently available. It is clinically

inappropriate to force these patients to discontinue the treatment that has been shown to effectively control their disease.

We understand that Medicare claims data indicates that the majority of ustekinumab use, across all indications, falls under part D. However, investigating the real-world use of this medication reveals two impactful observations. First, due to joint swelling, stiffness and pain, patients with psoriatic arthritis may be less able to self-administer than those prescribed ustekinumab for other indications. These patients should not be discriminated against for symptoms of their disease. Secondly, many patients do not administer their drug at home, but instead rely on a health care provider, spouse, family member or acquaintance to administer the drug. This is not captured by claims data, and these instances do not meet the definition of self-administration. We encourage CMS to determine what percentage of patients are actually self-administering a drug before a SAD list determination is made. We also ask that you revisit the language in chapter 15 section 50.2 of the Medicare Benefit Policy Manual to ensure that vulnerable patients who do not have the ability to self-administer are protected from loss of access resulting from SAD list determinations.

In addition to our concerns about patient access, we would like to point out that total Medicare spending on drugs could increase if Part B access is curtailed and instead forced to Part D. A recent study showed a 45% average price increase for specialty drugs in Medicare part D between 2012 and 2016. By contrast, the increase under Medicare part B during this same period was much lower at 21%<sup>1</sup>.

We greatly appreciate your consideration of these concerns and we request the opportunity to speak with you further about this matter. Please contact Meredith Strozier, ACR Director of Practice Advocacy, at [mstrozier@rheumatology.org](mailto:mstrozier@rheumatology.org) or (404) 633-3777 to schedule a virtual meeting at a mutually convenient time.

Sincerely,

American College of Rheumatology  
Arthritis Foundation  
Coalition of State Rheumatology Organizations

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<sup>1</sup> McCormick, N., Wallace, Z.S., Sacks, C.A., Hsu, J. and Choi, H.K. (2020), Decomposition Analysis of Spending and Price Trends for Biologic Antirheumatic Drugs in Medicare and Medicaid. *Arthritis Rheumatol*, 72: 234-241. doi:10.1002/art.41138