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Re: Coverage Changes to Provider-administered Stelara

The Coalition of State Rheumatology Organizations (CSRO) is a national organization composed of state and regional professional rheumatology societies. CSRO was formed to ensure excellence, and access, to the highest quality care for patients with rheumatologic, autoimmune, and musculoskeletal disease. We write to you regarding the recent decision to remove Stelara (ustekinumab) from the Medicare Part B provider-administered drug list, which will result in Stelara coverage being exclusively available through the Medicare Part D self-administered drug (SAD) list. Due the COVID-19 public health emergency, and concerns with the methodology used to remove Stelara from coverage under the Medicare Part B benefit, CSRO requests you delay implementation of the new coverage policy until the public health emergency and its ramifications have been resolved.

Delaying implementation will allow for evaluation of the data supporting this change at a time when practices and insurers are no longer under the strain of managing the COVID-19 crisis. As it stands, CSRO is concerned that the methodology used to calculate the share of Medicare beneficiaries taking the self-administered formulation as opposed to the physician-administered formulation is flawed. An informal poll of rheumatologists from various states could not identify a single patient utilizing the self-administered formulation of Stelara. This calls into question whether 50% of Medicare beneficiaries are actually utilizing Stelara's self-administered formulation, which is required for moving the product to the SAD list. A formal national survey will soon be underway to determine the extent to which these findings can be extrapolated to the greater rheumatology community. It is likely that this national survey will confirm our informal polling.

There are discrepancies in dosing and frequency that may account for this disconnect. Discrepancies in dosing size and schedule between inflammatory bowel patients, plaque psoriasis, and psoriatic arthritis patients may inflate spend and unit utilization for the self-administered formulation. For example, GI patients with inflammatory bowel disease take the drug every 8 weeks as opposed to every 12 weeks for psoriasis and psoriatic arthritis patients. In addition, GI patients often take double the dose of Stelara (90mg vs 45mg). This increase in frequency and dosing may lead to an incorrect calculation of Part D usage when units of a drug are substituted as a calculation for patients utilizing the drug. Finally, it may be the case that self-administered forms are purchased and brought to a physician's office for administration.

At this time, however, we recognize that both the MACs and physicians' offices are running on limited staff while managing patients during this unprecedented time. As such, we urge you to postpone this coverage change until the end of the Public Health Emergency, so that we can engage in an informed discussion of these discrepancies without inadvertently jeopardizing patient access to their medicine during the pandemic.

We would like the opportunity to discuss our concerns with you in further detail, and you may contact Madelainefeldman@gmail.com or Kevin.Daley@naylor.com to schedule a time that is mutually convenient.

Sincerely,

Madelaine A. Feldman, MD
President, CSRO