



Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

April 8, 2020

Administrator Verma:

The National Organization of Rheumatology Managers, the National Infusion Center Association, and the Coalition of State Rheumatology Organizations urge you to issue direction, via waiver or other appropriate regulatory mechanism, to all Medicare administrative contractors (MACs) to freeze their Self-Administered Drug (SAD) lists as of March 15, 2020 and for the remainder of the duration of the COVID-19 pandemic.

MACs often make determinations about which drugs are covered under Part B and under what circumstances. For example, some contractors have developed Self-Administered Drugs (SAD) lists that detail which drugs are excluded from coverage under Part B, because the contractor has determined that the drug is usually self-administered, and, therefore, more appropriately covered and paid under Part D. Drugs that appear on the SAD list can be covered as a Part B drug only if medical necessity is met and documented.

Showing medical necessity to the satisfaction of the contractor can be burdensome and requires significant time and effort from physician office staff. Contractors have made clear in the past that beneficiary or provider convenience, including a patient's financial liability, does not justify medical necessity. The fact that patient compliance may suffer if the drug must be self-administered also does not amount to medical necessity for the contractors.

Like small businesses across our country, many rheumatologists' offices are running on reduced office staff due to COVID-19. We are doing our part, as much as possible, to limit the spread of this devastating disease, while still meeting our responsibility as an essential business that provides medical care to patients who need it. However, at this moment, we do not have the

resources we need to engage the MACs on medical necessity determinations on behalf of patients. This means that patient care will suffer. Moving drugs to the SAD list without the safeguard of physicians obtaining appropriate exceptions for medical necessity will have detrimental impacts on continuity of care for patients, at a time when they desperately need it.

Additionally, due to COVID-19, CMS is currently not conducting audits of any kind: these are suspended for the duration of the Public Health Emergency declaration. As such, it is not a good time to impose new requirements that may require an audit, such as changes to the SAD list. While we fully support CMS' need to streamline resources and enable the carriers to act quickly during this unprecedented time, this also has the implication that the MACs are currently subject to very little oversight.

On behalf of the patients we serve, we ask you to direct the MACs to cease any additions to the SAD list as of March 15, 2020 and until such time that the COVID-19 pandemic is over and physician offices are fully staffed and have the resources again to fully engage in administrative matters with insurers.

Thank you for your consideration.

Sincerely,



James (Jay) Salliotte Jr.
President
NORM



Brian Nyquist, MPH
Executive Director
NICA



Dr. Michael Schweitz
Chairman
CSRO Federal Advocacy