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April 26, 2021

Tamara Syrek-Jensen, JD
Director, Coverage and Analysis Group (CAG), CCSQ
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Existing and Emerging Issues with Medicare's Self-Administered Drug (SAD) List

Dear Ms. Syrek-Jensen:

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 and the patients they serve.

We thank your team for meeting with us earlier this year to discuss broad concerns about Medicare's SAD List, including a recent challenge with beneficiary access to a key medication used in auto-immune diseases (Ustekinumab). This letter summarizes our concerns in more detail and offers pathways toward improving the SAD list in the long- and short-term.

SAD List Concerns

With some exceptions, Medicare Part B generally does not cover drugs that can be self-administered by the patient, such as those in pill form or are used for self-injection. To determine whether a drug or biologic is usually self-administered and excluded from payment under Part B, Medicare Administrative Contractors (MACs) consider a number of factors, including, but not limited to:

- Whether the drug is produced in parenteral form
- Based on claims and other data
    - The route of administration
    - The clinical setting for administration
    - The frequency of administration
    - Clinical indication(s)

In this context, "usually self-administered" means more than 50 percent of the time for all Medicare beneficiaries who use the drug, regardless of indication and "by the patient" means Medicare beneficiaries as a collective whole.

In our experience, these factors are not consistently considered nor applied by MACs, leading some drugs to be added to the SAD list inappropriately, thus hindering beneficiary access. An recent example is discussed in the paragraphs that follow.

ustekinumab (Stelara)

At the outset of the COVID-19 public health emergency (PHE), several MACs added ustekinumab (Stelara) to the SAD list (which will take effect 45-days after the PHE ends). Ustekinumab has a number of approved clinical indications, including plaque psoriasis, psoriatic arthritis and Crohn's disease.

According to CMS' claims data, ustekinumab is usually self-administered; however, in clinical practice, we note that patients with psoriatic arthritis are unable to inject the drug themselves due to joint pain and swelling caused by the disease. These patients seek the assistance of their rheumatologist, another health care professional, or caregiver/family friend, to administer their medication. In fact, a recent survey by the Global Healthy Living Foundation (GHLF) found that, of Medicare beneficiary respondents taking a treatment that requires an injection, 35.7% are unable to self-inject and have a family member/friend/acquaintance administer or a health care provider administer the injection.

These situations do not meet the definition of self-administration; more importantly, they are not visible in claims data for consideration by MACs. Further, this situation is not limited to ustekinumab; patients with other rheumatic diseases, such as rheumatoid arthritis, have faced similar challenges accessing the needed formulation for their prescribed medication(s).

Over the past several months, CSRO has engaged in multiple positive discussions with Contractor Medical Directors (CMD) about this concern. There is broad recognition and appreciation of the problem; however, CMDs have been unable to meaningfully address the issue or find a pathway for patients to access an infused formulation of a SAD List drug, even when medically necessary.

Overhaul the "SAD List"

CMS' SAD List policies have not kept pace with real-world use of medicines that have multiple indications and formulations. Specifically, they have the unintended consequence of discriminating against patients who are unable to self-administer certain medications based on their disease. For this reason, CMS should eliminate the SAD List concept and establish a new policy that better accounts for innovation in medication therapy.

To inform a new policy, we urge CMS to issue a Request for Information (RFI), as well as host a Town Hall or Listening Session, to solicit feedback from key stakeholders, including physicians and their patients, about the challenges facing patients accessing infused formulations of medications on the SAD List. Informed by stakeholder feedback, CMS should initiate rulemaking to propose a new policy as a replacement for the SAD List, which could be accomplished through the annual Medicare Physician Fee Schedule (MPFS).

In the interim, we urge CMS to provide enhanced guidance for MACs related to SAD List determinations, allowing payment for infused formulations of SAD List drugs when the patient cannot self-administer.

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Thank you for considering our concerns and recommendations related to the SAD List. Please do not hesitate to contact us, should you require additional information.

Sincerely,

Madelaine A. Feldman, MD
President
CSRO

Michael C. Schweitz, MD
Federal Advocacy Chair
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