April XX, 2025

The Honorable Robert F. Kennedy Jr.
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Kennedy,

We, the undersigned organizations, **are writing to formally request the U.D. Department of Health and Human Services (HHS) remove barriers to physician-administered medications included on Medicare's Self-Administered Drug (SAD) Exclusion List.**

Background on the SAD Exclusion List

The Benefits Improvement & Protection Act of 2000 (BIPA) amended sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Social Security Act (SSA) such that Medicare Part B coverage is limited to "drugs and biologicals which are not usually self-administered by the patient." To implement this provision, the Centers for Medicare and Medicaid Services (CMS) established criteria based on its broad interpretation of the statute, which are used by Medicare Administrative Contractors (MACs) to determine whether a drug, available in both self-administered and physician-administered forms, should be included on the SAD Exclusion List. Consequently, drugs on the SAD Exclusion List are excluded from Part B coverage, leaving beneficiaries who require the physician-administered form to pay out-of-pocket.

We are concerned that CMS' interpretation of the statute and implementation of associated policies creates a barrier to physician-administered drugs for certain beneficiaries, and directly conflicts with this Administration's efforts to reduce waste and make drugs more affordable.

Criteria for the SAD Exclusion List

At the crux of the issue is the SAD Exclusion List criteria (Medicare Benefit Policy Manual, Chapter 15, Section 50.2) and CMS' interpretation of "*not usually self-administered by the patient*." CMS' Manual defines "*usually*" to mean that a drug is self-administered more than 50% of the time by all Medicare beneficiaries who use the drug, with some consideration given to the drug's indication through a weighted-average approach[1].

The Manual also defines "*by the patient*" to mean "*Medicare beneficiaries as a collective whole*," excluding "*individual beneficiaries who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question*," such as "*an individual afflicted with paraplegia or advanced dementia*."
It should also be noted that CMS' definition of self-administration "*by the patient*" is quite literal; that is, to meet the 50% threshold, determinations need to consider beneficiaries that receive assistance

[1] The weighted-average approach considers the relative contribution of each indication or route of administration to the total use of that drug. If a drug is used for two primary indications, one of which requires a patient to self-administer (e.g., injections) and the other requires physician administration (e.g., intravenous), the weighted average would take into account the relative frequency of use for each indication to determine whether the drug is generally considered "self-administered".

administering their medication from another individual, such as a family member, caregiver, or a health professional.

CMS' interpretation of the statute and its implementation through subregulatory guidance are concerning. The 50% threshold and weighted-average approach appear arbitrary, leading to the exclusion of beneficiaries who, by definition, cannot self-administer drugs. As a result, an excessive number of drugs are placed on the SAD Exclusion List, restricting access for many beneficiaries—even when the physician-administered version is medically necessary. We assert that all beneficiaries in traditional Medicare who use the drug should be included in the denominator for the determination to be based on "*Medicare beneficiaries as a collective whole*" per the Manual.

Even if the criteria were reasonable, it is unclear how Medicare Administrative Contractors (MACs) are making SAD Exclusion List determinations, including how the MACs consider beneficiaries that receive assistance administering their medication from another individual in their analysis. Despite our requests, details about the data sources and methodology used by MAC to make these determinations are not transparent.

Beneficiary Administration Challenges

The SAD Exclusion List criteria have not kept pace with the real-world use of medications who have multiple indications and formulations, thus hindering access for beneficiaries that are unable to self-administer certain medications due to clinical factors. For example, several rheumatologic medications with a self-administered formulation are highly viscous and must be administered with a syringe, making it nearly impossible for a beneficiary with physical or cognitive limitations to self-administer. Even if the medication uses an auto-injector, some beneficiaries may still face difficulty with self-administration due to physical and cognitive limitations.

In these circumstances, the physician-administered formulation is medically necessary and should be available. However, under the current methodology, these medications are excluded from Part B coverage, meaning a beneficiary would need to pay out-of-pocket for the full cost of the drug.

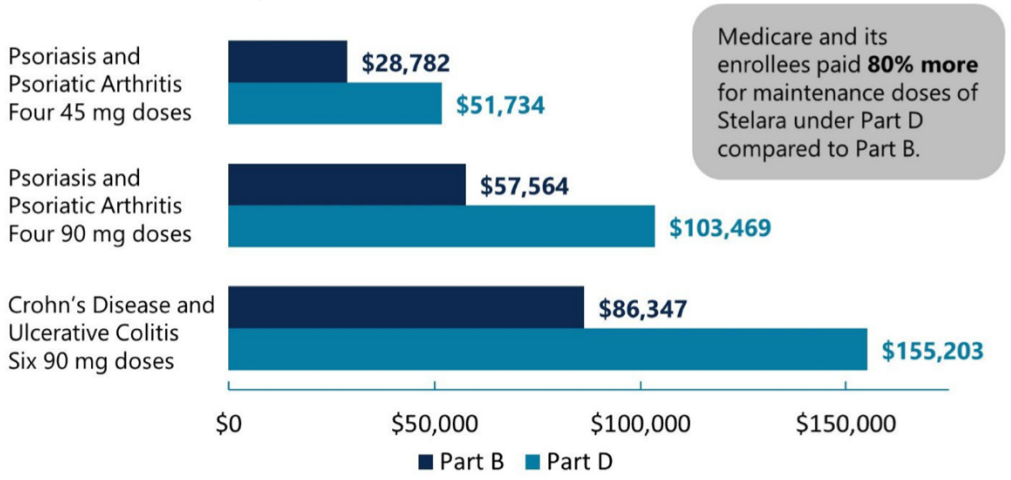
Impact of SAD Exclusion List Policies on ustekinumab (Stelara)

Ustekinumab (Stelara) is a biologic medication used to treat various conditions such as plaque psoriasis, psoriatic arthritis, and Crohn's disease, and is available in self-administered and physician-administered forms. Using CMS' aforementioned criteria, MACs determined that ustekinumab is "*usually*" self-administered "*by the patient*" and moved it to the SAD Exclusion List. As a result, this drug is no longer covered under Part B, compromising many beneficiaries' access to this medication.

In its February 2025 report, *Medicare Contractors Did Not Use Complete and Timely Utilization Data When Making Part B Coverage Determinations for Stelara*, the Office of Inspector General (OIG) confirmed our concerns that, "*MACs face challenges with utilization data when following Centers for Medicare & Medicaid Services' (CMS's) coverage guidance for drugs such as Stelara*." It also highlighted suspected data limitations, including that "*Medicare data do not allow MACs to conclusively determine how many enrollees received assistance in administering Part D drugs (i.e., administered by caregivers rather than by the enrollees themselves)*" and the omission of "*certain Medicare Advantage enrollees.*" OIG concluded that "*Missing data led MACs to overestimate self-administered Stelara use by up to 16 percentage points.*"

In its August 2024 report, *Medicare and Some Enrollees Paid Substantially More When Stelara Was Covered Under Part D Versus Part B,* OIG found that "*Medicare and some enrollees paid substantially more when Stelara injections were covered under Part D (i.e., self-administered) versus under Part B (i.e., administered by a physician),*" as a result of Stelara's inclusion on the SAD Exclusion List. Importantly, the report explains that "*Medicare expenditures for Stelara have increased almost tenfold, from $300 million in 2016 to almost $3 billion in 2023*." A graph from the report shows that the Medicare program and enrollees paid 80% more for Stelara under Part D compared to Part B (see below).

Exhibit 1: Annual costs for Stelara were substantially more under Part D (i.e., self-injected at home) than under Part B (i.e., received in doctors' offices).



Source: OIG analysis of 2021 Medicare Part B and Part D PDE claims data.

Ensuring beneficiaries are able to access the medication they need at an affordable cost, while also avoiding wasteful spending in the Medicare program, is critical to achieving this Administration's goals. OIG has recommended that CMS "*assist MACs in obtaining more complete and timely utilization data*" and "*provide guidance on how MACs should account for enrollees who receive injections in both home and professional settings*" to help address its concerns, which it explains "*are not unique to Stelara and affect coverage determinations for similar drugs.*"

Policy Options

In the CY 2024 Medicare physician fee schedule final rule, CMS acknowledged our collective requests that it update and clarify the SAD Exclusion List guidance to address beneficiary access challenges that have been raised since the policy was established. CMS agreed to consider the comments received on this topic for future rulemaking and guidance.

Our coalition remains committed to being a meaningful partner in addressing these challenges and recommends that CMS take the following steps:

1. Reinterpret "*not usually self-administered by the patient*" and revise the Manual to:
    i. Include all Medicare beneficiaries in the denominator for making SAD Exclusion List determinations,
    ii. Appropriately and transparently account for beneficiaries who receive assistance administering their medication from another individual, such as a family member, caregiver, or a health professional, and

iii. For medications included on the SAD Exclusion List, establish exclusion criteria that allow coverage and payment of the Part B formulation of medications where physical or cognitive limitations are present and documented.

2. Direct the MACs to:
   i. Temporarily remove drugs from the SAD Exclusion List that have a physician- and self-administered formulation and postpone the addition of new dual formulation drugs to the SAD Exclusion List until CMS provides updated criteria and instructions consistent with the above, and
   ii. Publish all data sources and all analysis used to make SAD Exclusion List determinations to improve transparency.

To prevent potential program integrity challenges, CMS could establish a new billing modifier that physicians would append to the medication code (i.e., J code) on their Medicare claims to indicate that the physician-administered formulation is medically necessary due to the beneficiary's physical or cognitive limitations and have been documented in the medical record as part of the beneficiary's treatment plan. The False Claims Act would serve as a strong safeguard against inappropriate use of the modifier by physicians.

We believe the requested revisions may not require notice-and-comment rulemaking, as the Medicare statute already directs CMS to make payment for items and services that are "*reasonable and necessary*." If CMS determines that rulemaking is necessary, we recommend that they Agency use its authority to issue a "CMS Ruling," given the importance of expediting this policy.

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Thank you for considering our feedback on this important issue to our patients. Please do not hesitate to contact us at info@csro.info should you require additional information.

Sincerely,

Coalition of State Rheumatology Organizations
American Academy of Allergy, Asthma and Immunology
American College of Rheumatology
American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
Association of Women in Rheumatology
Infusion Providers Alliance
National Infusion Center Association
National Organization of Rheumatology Management
Crohn's & Colitis Foundation
Infusion Access Foundation
Lupus and Allied Diseases Association, Inc.
Spondylitis Association of America

Alabama Society for the Rheumatic Diseases
Alaska Rheumatology Alliance
Arizona United Rheumatology Alliance
Arkansas Rheumatology Association

California Rheumatology Alliance
Southern California Rheumatology Society
Chicago Rheumatism Society
Colorado Rheumatism Society
Connecticut Rheumatology Association
Florida Society of Rheumatology
Georgia Society of Rheumatology
Kentuckiana Rheumatology Alliance
Rheumatology Alliance of Louisiana
Maryland Society for the Rheumatic Diseases
Massachusetts, Maine and NH Rheumatology Association
Michigan Rheumatism Society
Midwest Rheumatology Association
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Society of New Mexico
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Tennessee Rheumatology Society
State of Texas Association of Rheumatologists
Virginia Society of Rheumatology
Washington State Rheumatology Alliance
State of West Virginia Rheumatology Society
Wisconsin Rheumatology Association