September 17, 2024

The Honorable Xavier Becerra
Secretary, U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Becerra,

On behalf of the undersigned organizations, **we are writing to formally request the Department remove barriers to physician-administered medications included on the 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 & 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 added to 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.

Our organizations 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 the Administration's non-discrimination regulations, and efforts to promote health equity 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. 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 self-administration "by the patient" is quite literal; that is, to meet the 50% threshold, determinations need to consider beneficiaries that receive assistance administering their medication from another individual, such as a family member, caregiver, or a health professional.

We disagree with CMS' interpretation of the statute and the accompanying subregulatory guidance used to implement the law. The 50% threshold and weighted-average approach is arbitrary; all Medicare beneficiaries 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. CMS' current approach excludes beneficiaries who by definition cannot self-administer drugs, resulting in an inappropriately large number of drugs on the SAD Exclusion List, putting these drugs out of reach for many beneficiaries for both clinical and financial reasons. Even if the criteria were reasonable, it is unclear how Medicare Administrative Contractors (MACs) are making SAD Exclusion List determinations as the calculations used as the basis for such determinations, including how they consider beneficiaries that receive assistance administering their medication from another individual, in the analysis.

Example: 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 Ustekinumab.

Non-Discrimination

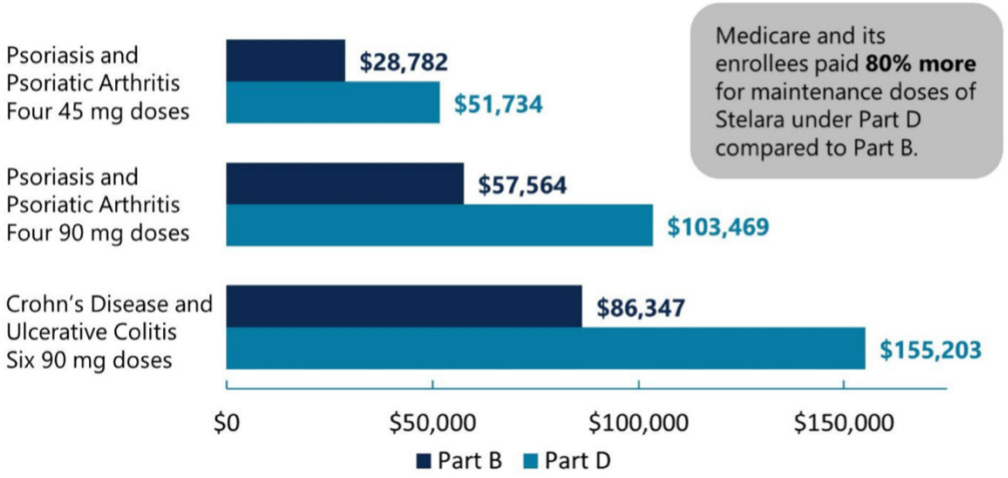
Discrimination based on disability. The SAD Exclusion List criteria have not kept pace with the real-world use of medications that have multiple indications and formulations, and unintentionally discriminate against patients who are unable to self-administer certain medications due to clinical factors. For example, several rheumatologic medications with a self-administered formulation are highly viscous and must be administered with a syringe (versus an auto-injector), making it nearly impossible for a beneficiary with a disabling condition the medication aims to treat (e.g., arthritis) or an unrelated condition (e.g., Parkinson's Disease) to self-administer. Even if an auto-injector is available, some beneficiaries may still face difficulty with self-administration based on the condition being treated or another diagnosis.

Accounting for social and economic factors. CMS' aforementioned criteria fail to consider social and economic factors that may prevent patients from self-administering their medications, even though these individuals are often the most at risk of losing access to their treatments. For example, beneficiaries facing homelessness could encounter challenges receiving the medication from a mail-order specialty pharmacy, including adequate refrigeration to store the medication prior to self-administration.

It is worth noting that the Office of Inspector General (OIG) recently 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.[1] A graph from the report explains that the Medicare program and enrollees paid 80% more for Stelara under Part D compared to Part B (see below).

[1] U.S. Department of Health and Human Services, Office of Inspector General. Medicare and Some Enrollees Paid Substantially More When Stelara Was Covered Under Part D Versus Part B. OEI-BL-19-00500, August 2024. https://oig.hhs.gov/documents/evaluation/9955/OEI-BL-19-00500.pdf

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.

Through annual Medicare Physician Fee Schedule rulemaking, CMS has proposed and finalized coding and payment for services that address health-related social needs, and has encouraged physicians to account for social determinants of health in their care plans. The SAD Exclusion List runs counter to these policies; physicians are not able to meaningfully account for social and economic factors in developing a treatment plan for certain beneficiaries because CMS has blocked access to certain physician-administered drugs through the aforementioned criteria.

We believe the SAD Exclusion List criteria inappropriately limit access to physician-administered drugs for beneficiaries with disabilities, which conflict with the Administration's non-discrimination regulations under Section 1557 of the Affordable Care Act at § 92.207(b)(2) that the Department must abide as a covered entity. Specifically, the SAD Exclusion List criteria function as a health plan "benefit design" that discriminate on the basis of disability. Further, we are concerned that health-related social needs are not a component of the SAD Exclusion List criteria, in contrast to this Administration's priority of improving access and drug affordability for those facing social and economic hardships.

Policy Options

We are committed to being a partner in addressing these challenges and recommends the Agency take the following steps:

1. Direct the MACs to:
    i. Remove dual formulation drugs from the SAD Exclusion List, and
    ii. Postpone adding dual formulation drugs to the SAD Exclusion List.
2. Reinterpret "not usually self-administered by the patient" and revise the Manual to:
    i. Include all Medicare beneficiaries (original Medicare and Medicare Advantage) in the denominator for making SAD Exclusion List determinations,
    ii. Appropriately account for beneficiaries that 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 based on clinical, social and economic factors that allow physicians, based on their clinical expertise and judgement, to provide the Part B formulation of those drugs.

3. Publish data sources and all analysis used to make SAD Exclusion List determinations to improve transparency.

To address 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, indicating that the beneficiary's clinical, social or economic circumstances warrant coverage for the physician-administered version and has been documented in the beneficiary's medical record as part of their treatment plan.

We believe the requested revisions may not require notice-and-comment rulemaking, as the Medicare statute already directs the Agency 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