January 26, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Oz,

On behalf of the undersigned organizations, ***we respectfully urge the Centers for Medicare and Medicaid Services (CMS) to propose a policy in the CY 2027 Medicare Physician Fee Schedule (PFS) rulemaking to address barriers to treatment created by Medicare's Self-Administered Drug (SAD) Exclusion List.*** Specifically, CMS should propose a policy that ensures Part B coverage of physician-administered drug formulations when self-administration is not clinically appropriate or feasible, while ensuring consistent nationwide application and appropriate program integrity safeguards. Background information and specific policy recommendations are provided below to explain the need for CMS action through the CY 2027 PFS rulemaking.

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, CMS established criteria – based on its interpretation of the statute – that 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.

Drugs placed on the SAD Exclusion List are excluded from Part B coverage, leaving beneficiaries who require the physician-administered formulation to pay out-of-pocket. We are concerned that CMS' interpretation of the statute and its implementation through subregulatory guidance create barriers to clinically appropriate care for certain beneficiaries and, in some cases, increase Medicare spending rather than reducing it.

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*." The Manual defines "*usually*" to mean that a drug is self-administered more than 50 percent 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*

[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".

afflicted with paraplegia or advanced dementia." CMS' interpretation of self-administration is also literal in that determinations must account for beneficiaries who receive assistance administering their medication from another individual, including a family member, caregiver, or health professional.

CMS' interpretation of the statute and its implementation through subregulatory guidance are concerning. The 50 percent threshold and weighted-average methodology appear arbitrary and result in 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 even when the physician-administered formulation is medically necessary. We believe that all beneficiaries in traditional Medicare who use the drug should be included in the denominator to ensure determinations are truly based on "*Medicare beneficiaries as a collective whole*," consistent with the Manual.

Even if the criteria were reasonable, it is unclear how MACs apply them. CMS has not provided transparency regarding the data sources or methodologies MACs use to make SAD Exclusion List determinations, including whether and how "white-bagging" is considered, or how beneficiaries who require assistance with drug administration are accounted for, despite repeated stakeholder requests for this information.

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.

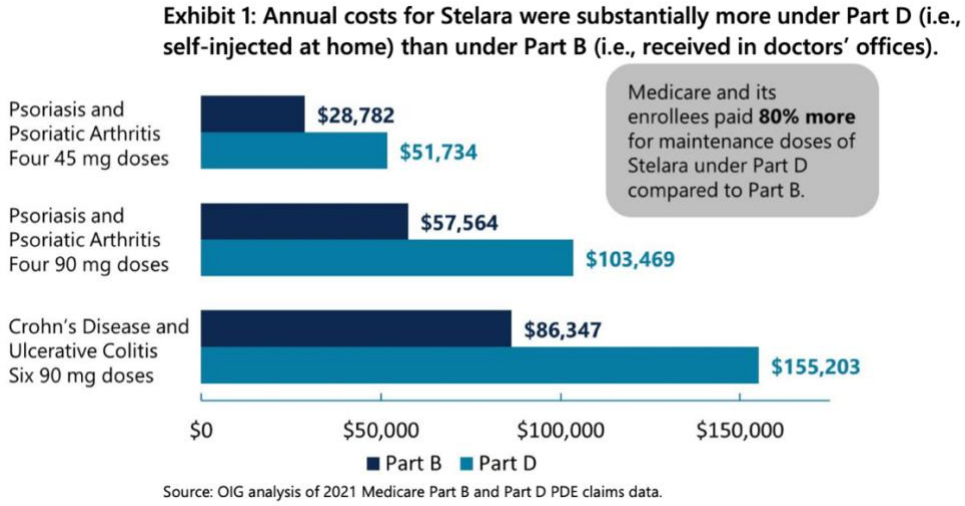
In these circumstances, the physician-administered formulation is medically necessary and should be available. However, under the current methodology, these medications are excluded from Part B coverage, meaning a beneficiary would need to pay out-of-pocket for the full cost of the drug.

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).



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.*" Further, OIG emphasized that these data limitations and cost impacts are not unique to Stelara and affect coverage determinations for other drugs with both self-administered and physician-administered formulations.

These same access and affordability concerns are also reflected in ongoing litigation, including *Beitzel v. Kennedy*, which highlights the substantial out-of-pocket costs and coverage disruptions beneficiaries can face when clinically necessary, physician-administered therapies lose Part B coverage as a result of SAD Exclusion List determinations.

Policy Options

CMS acknowledged stakeholder concerns regarding the SAD Exclusion List in the CY 2024 PFS final rule and indicated that it would consider these issues in future rulemaking and guidance. ***We respectfully urge CMS to use the CY 2027 Medicare Physician Fee Schedule rulemaking to propose and implement the following policies:***

- ***Reinterpret "not usually self-administered by the patient" and revise the Manual to:***
  - ***Include all Medicare beneficiaries in the denominator for SAD Exclusion List determinations;***

    - ***Transparently and appropriately account for real-world administration and distribution practices, including white-bagging, as well as beneficiaries who receive assistance with medication administration; and***
    - ***Establish an exception allowing Part B coverage of the physician-administered formulation when physical or cognitive limitations are present and documented.***
- ***Direct the MACs to:***
    - ***Remove drugs with both physician- and self-administered formulations from the SAD Exclusion List pending updated CMS criteria;***
    - ***Defer adding new dual-formulation drugs to the SAD Exclusion List until CMS finalizes revised criteria and instructions consistent with the above; and***
    - ***Publish the data sources and analytic methodologies used to make SAD Exclusion List determinations to improve transparency and consistency.***

To support program integrity, CMS could establish a billing modifier that practices would append to the applicable drug code to indicate that physician administration is medically necessary due to documented beneficiary limitations. Existing medical-necessity requirements and enforcement authorities, including the False Claims Act, would provide strong safeguards against inappropriate use. Our organizations would welcome the opportunity to work with the Agency to help develop appropriate documentation guidelines to support accurate and consistent use of such a modifier.

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

Sincerely,

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