

September 11, 2023

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1784-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via www.regulations.gov

RE: Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program

Dear Administrator Brooks-LaSure:

The undersigned organizations provide in-office drug administration services to Medicare beneficiaries and write in response to your *Request for Information: Drugs and Biologicals which are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding*, included as part of the aforementioned proposed rule. We appreciate that the Agency is taking these matters seriously and engaging the public in a meaningful dialogue on how to address the concerns our groups have raised, including the impact on beneficiary access to treatment.

Request for Action

Below are specific actions we are asking the Agency to take, in the short- and long-term, toward addressing the challenges associated with the Self-Administered Drug (SAD) Exclusion List and the “down coding” of complex drug administration services. The paragraphs that follow our requests provide additional detail and rationale.

SAD Exclusion List

- **Short-term**
 - ***CMS should direct its Medicare Administrative Contractors (MACs) to remove certain drugs from the SAD Exclusion List and postpone the addition of other medications, until a long-term solution is in place.***
- **Long-term**
 - ***CMS should work with its Office of General Counsel (OGC) to reinterpret the statute to allow coverage of the physician-administered formulation of a drug that is “not usually self-administered by the patient” when a beneficiary presents with certain clinical and/or social and economic circumstances that prevent self-administration, making it “reasonable and necessary” for them to access the physician-administered formulation of a medication on the SAD Exclusion list.***
 - ***Based on a revised statutory interpretation, CMS should amend its Program Manual to include additional criteria that account for the aforementioned clinical and/or social and economic circumstances.***

- **Based on amended Program Manual instructions, CMS should establish:**
 - **Documentation requirements that allow physicians to demonstrate in the medical record that the beneficiary’s clinical and/or social and economic circumstances prevent them from self-administering a drug on the SAD Exclusion List; and,**
 - **A new billing modifier that physicians could append to their drug administration service codes to indicate that the beneficiary’s clinical and/or social/economic circumstances warrant use of the physician-administered formulation of a drug on the SAD Exclusion List and is supported by the medical record documentation.**

Complex Drug Administration Coding

- **Short-term**
 - **CMS should immediately direct its MACs to permanently rescind and remove all articles titled: “Billing and Coding: Complex Drug Administration,” or that have the same intended effect.**
 - **CMS should make the substance of the August 12, 2022 Technical Direction Letter (TDL) public through program transmittal or a Medicare Learning Network (MLN) article, easing physician practice concerns about submitting complex drug administration service codes on Medicare claims, in contrast to guidance from the MACs.**
- **Long-term**
 - **CMS should establish, and include in its Program Manual:**
 - **New criteria for determining whether a physician-administered medication warrants use of the complex drug administration service code(s) that is (1) based on a revised definition of complexity and (2) considers the following:**
 - **AMA CPT requirements,**
 - **Medicare valuation, and**
 - **Additional clinical factors that demonstrate complexity of a given medication and its administration, and**
 - **Input provided by organizations representing providers of infusion services.**
 - **Documentation requirements that allow physicians to demonstrate in the medical record that the complex drug administration service code reported on their claim(s) meets the criteria.**
 - **To ensure consistency across the Medicare program, CMS should:**
 - **Issue a MLN article to educate practices on the new criteria and documentation requirements, and require MACs to refer to this MLN resource.**
 - **Revise its Program Manual to remove the language that allows MACs to “provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare” and prohibit MACs from establishing their own “lists” of drugs that meet complex drug administration code criteria.**

SAD Exclusion List

Our organizations have met and corresponded with CMS leadership and staff, as well as multiple Contractor Medical Directors (CMDs) at various MACs, about broad concerns with Medicare’s SAD Exclusion List policies. We remain deeply concerned that access to physician-administered medications – particularly in certain beneficiary populations – is inappropriately hindered as a result of the SAD

Exclusion List criteria, and the way these policies are applied by the Medicare Administrative Contractors (MACs).

The crux of the issue is that CMS and its MACs have interpreted “*not usually self-administered by the patient*” as generally meaning the following: medications with a self- and physician-administered formulation are excluded from Part B coverage when, collectively, more than 50% of beneficiaries are using the self-administered formulation. These drugs are relegated to the SAD Exclusion List and may only be covered through Part D.

Not all beneficiaries have a Part D plan, and even if they do – if they have a physical or other disability – they wouldn’t be able to self-administer the medication. More concerning, patients that can’t afford their Part D co-insurance or the full cost of the physician-administered formulation are likely to forego their treatment altogether, leading to an increase in disease progression and surge in additional healthcare services, but with worse health outcomes.

This Administration has made drug affordability and health equity their top priorities. There is a plethora of evidence that speaks to this, including policies in this CY 2024 PFS proposed rule. Yet, the SAD Exclusion List policies run counter to both. More frustrating, in attempting to work with several MACs, the Contractor Medical Directors (CMDs) have been unwilling to work with the physician community to address these challenges or even consider the data we have provided that demonstrates many patients are not truly self-administering medications, and have outright refused to share how they are determining a medication is *actually* self-administered by the patient *themselves* more than 50% of the time.

We have contemplated a number of ways in which the Agency could address our concerns and improve access to life-changing medications for some of the most chronically ill patients. We conclude that CMS’ underlying interpretation of the statutory language – “*not usually self-administered by the patient*” – is the problem. Our organizations believe that beneficiaries who face a physical or other disability and/or social and economic challenges, should be able to by-pass the current criteria because these patients would not “usually” self-administer a medication themselves. Indeed, it is “*reasonable and necessary*” for the physician-administered formulation to be covered for beneficiaries facing the aforementioned circumstances.

Our organizations ask you to take the following steps short- and long-term actions toward addressing the SAD Exclusion List, and will make ourselves available for any clarifying questions or assistance in taking the below steps.

- **Short-term**
 - ***CMS should direct its Medicare Administrative Contractors (MACs) to remove certain drugs from the SAD Exclusion List and postpone the addition of other medications, until a long-term solution is in place.***
- **Long-term**
 - ***CMS should work with its Office of General Counsel (OGC) to reinterpret the statute to allow coverage of the physician-administered formulation of a drug that is “not usually self-administered by the patient” when a beneficiary presents with certain clinical and/or social and economic circumstances that prevent self-administration, making it “reasonable and necessary” for them to access the physician-administered formulation of a medication on the SAD Exclusion list.***

- ***Based on a revised statutory interpretation, CMS should amend its Program Manual to include additional criteria that account for the aforementioned clinical and/or social and economic circumstances.***
- ***Based on amended Program Manual instructions, CMS should establish:***
 - ***Documentation requirements that allow physicians to demonstrate in the medical record that the beneficiary's clinical and/or social and economic circumstances prevent them from self-administering a drug on the SAD Exclusion List; and,***
 - ***A new billing modifier that physicians could append to their drug administration service codes to indicate that the beneficiary's clinical and/or social/economic circumstances warrant use of the physician-administered formulation of a drug on the SAD Exclusion List and is supported by the medical record documentation.***

We ask that you employ the most expeditious and appropriate regulatory or sub-regulatory pathway for effectuating these changes, and to provide ample opportunities for our organizations to provide feedback to ensure any revision in CMS' policy will meet the needs of our Medicare patients.

Complex Drug Administration Coding

Our organizations are deeply frustrated that MACs have established local coverage articles, commonly with the title "*Billing and Coding: Complex Drug Administration,*" that erroneously direct physicians to code the administration of highly complex medications in their offices using "therapeutic" drug administration service codes (CPT codes 96360-96379), rather than the "complex" administration service codes (CPT code series 96401-96549).

While CMS authorized MACs to "*provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare,*" defined as including "*treatment of noncancer diagnoses...*,"¹ the local coverage articles represent a significant dearth of understanding by the MACs about the complexity of non-oncologic medications; what is involved in delivering these medications to beneficiaries in the office-setting, including the associated practice costs; the acuity of the patients that require these medications; and, a flawed interpretation of the AMA CPT code descriptors and coding guidelines for these codes. Here again, when our groups have approached the MACs to seek a resolution, the CMDs were unwilling to make any modifications or meaningfully consider our concerns, despite superfluous evidence that supports use of the complex drug administration codes for infusing and injecting non-oncologic medications beyond the "examples" provided in CMS' program manual (e.g., infliximab, rituximab, alemtuzumb, gemtuzumab, and trastuzumab).

When Congress included language in the *Medicare Modernization Act (MMA)* to allow non-oncology physicians to use the complex drug administration service codes when delivering non-oncologic medications in their offices, they did not intend for it to be limited to the "older" medications listed above. Over the past 20 years, many more non-oncologic medications have become available that require the same level of supervision and specialized staff training, cost the same to administer, and have no meaningful difference from the "older" drugs considered to be "complex".

We are very appreciative of CMS leadership for attempting to mitigate the negative impact of these articles by issuing a Technical Direction Letter (TDL) on August 12, 2022 that temporarily "paused" the "down coding" of our drug administration services. Unfortunately, the *intended* effect seems to have

¹ Medicare Claims Processing Manual (MCPM) (Ch. 12, Sec. 30.5.D)

been lost; MACs continue to educate practices based on the flawed articles, with some MACs seemingly suggesting the TDL does not exist. Some MACs have continued to add more drugs to their policies. Given the TDL is not publicly accessible, practices are being advised to continue to follow the guidance by their MACs to avoid unwanted program integrity audits and the possibility of future recoupments. The result is undue financial strain on the lowest cost care settings for these medications.

Collectively and independently, our groups have provided resources (see Appendices) that address the question of complexity so that CMS could devise a more appropriate mechanism for assessing whether a medication warrants use of the complex drug administration service code. These resources rely on the factors discussed above, as well as other factor that demonstrate complexity.

Considering the information our groups have provided, we believe it is appropriate for CMS to take the following steps toward addressing our concerns.

- **Short-term**
 - ***CMS should immediately direct its MACs to permanently rescind and remove all articles titled: “Billing and Coding: Complex Drug Administration,” or that have the same intended effect.***
 - ***CMS should make the substance of the August 12, 2022 TDL public through program transmittal or a Medicare Learning Network (MLN) article, easing physician practice concerns about submitting complex drug administration service codes on Medicare claims, in contrast to guidance from the MACs.***
- **Long-term**
 - ***CMS should establish, and include in its Program Manual:***
 - ***New criteria for determining whether a physician-administered medication warrants use of the complex drug administration service code(s) that is (1) based on a revised definition of complexity and (2) considers the following:***
 - ***AMA CPT requirements,***
 - ***Medicare valuation,***
 - ***Additional clinical factors that demonstrate complexity of a given medication and its administration, and***
 - ***Input provided by organizations representing providers of infusion services.***
 - ***Documentation requirements that allow physicians to demonstrate in the medical record that the complex drug administration service code reported on their claim(s) meets the criteria.***
 - ***To ensure consistency across the Medicare program, CMS should***
 - ***Issue a MLN article to educate practices on the new criteria and documentation requirements, and require MACs to refer to this MLN resource.***
 - ***Revise its Program Manual to remove the language that allows MACs to “provide additional guidance as to which drugs may be considered to be chemotherapy drugs under Medicare” and prohibit MACs from establishing their own “lists” of drugs that meet complex drug administration code criteria.***

As above, we ask that you employ the most expeditious and appropriate regulatory or sub-regulatory pathway for effectuating these changes, and to provide ample opportunities for our organizations to

provide feedback to ensure our practices can continue to deliver in-office administrations to our Medicare patients.

Thank you for hearing our concerns and for working with us up until this point on ways to ensure Medicare beneficiaries have access to the medications they need, in the lowest cost, highest quality, and safest setting – the physician’s office.

Sincerely,

American Academy of Allergy, Asthma and Immunology
American Academy of Dermatology Association
Coalition of State Rheumatology Organizations
Digestive Physicians Health Association
Infusion Providers Alliance
National Infusion Center Association