Alliance for Patient Access

Advocacy Win for Asthma Patients

Protecting Access to Clinician-Administered Biologics

CASE STUDY

The Issue

Tezepelumab is a novel severe asthma treatment that was approved for clinician administration in late 2021. After a few months on the market, however, several Medicare Administrative Contractors made the unprecedented decision to place tezepelumab, a biologic approved for physician administration, on the Self-Administered Drug list.

This decision would have restricted access for Medicare patients and forced clinicians seeking to utilize tezepelumab to prescribe it off-label. In addition to challenging the FDA label, the move presented patient safety issues, as patient instructions for storage and administration are not available.

The Action

The Alliance for Patient Access and its Respiratory Therapy Access Working Group sprang into action, organizing clinicians and advocacy partners. The community launched a campaign aimed at Centers for Medicare & Medicaid Services and the Medicare Administrative Contractors to reverse this harmful decision. The campaign educated providers and other stakeholders on the issue, as well as encouraged Medicare to ensure that the Medicare Administrative Contractors were held responsible for this egregious overreach.

AfPA's advocacy campaign included:

- A convening webinar for clinicians and members of the advocacy community
- A blog posted to Health Policy Today
- Letters submitted to:
  - Centers for Medicare & Medicaid Services Administrator Chiquita Brooks-LaSure
  - All Medicare Administrative Contractors
  - Key members of Congress
- Social media engagement
- Creation of educational resources

The Outcome

With pressure mounting from the physician and patient community, all of the Medicare Administrative Contractors reversed their decision and publicly announced that tezepelumab would be removed from the Self-Administered Drug List. This reversal ensures that patients and providers will be able to receive their medication as FDA-approved and indicated, from the safety of a clinician's office.

While the Alliance for Patient Access is encouraged by the progress seen in such a short time period, continued engagement is important to ensure that Medicare and its Medicare Administrative Contractors allow appropriate access for our seniors. The Alliance for Patient Access stands ready for continued engagement that protects patient access.

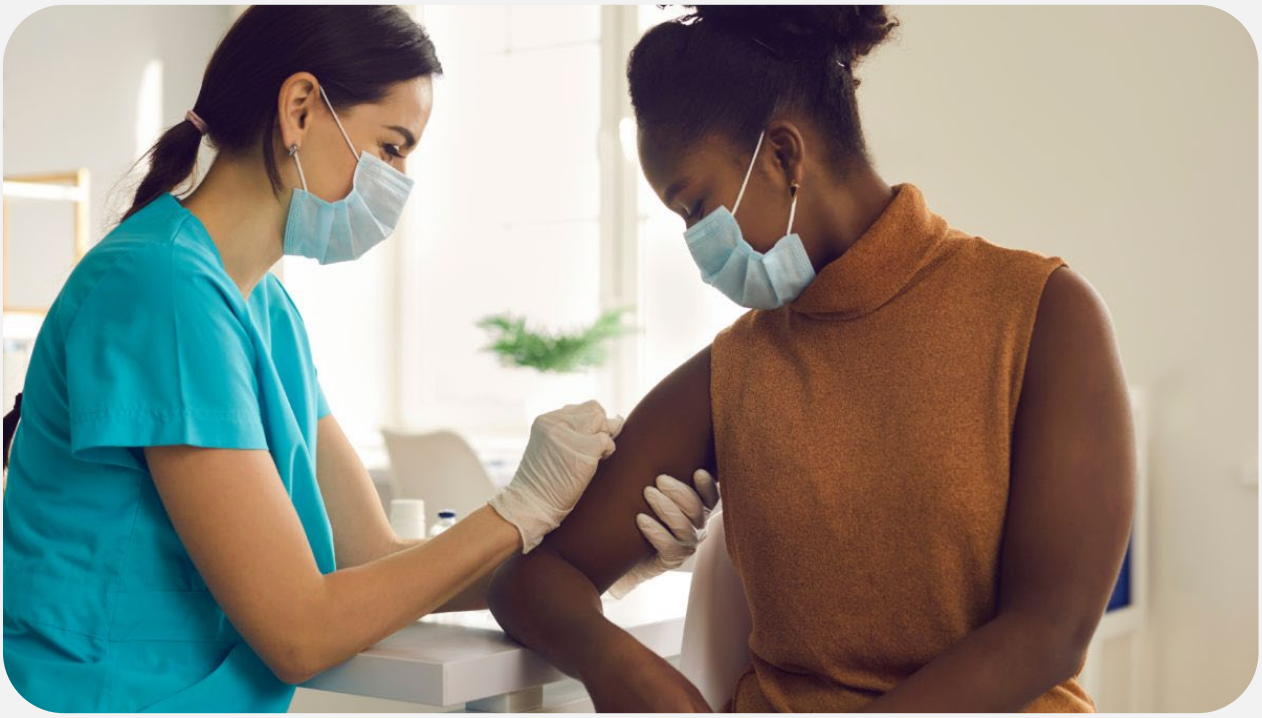
ADVOCACY CAMPAIGN **SAMPLES**

The Alliance for Patient Access launched an advocacy campaign, composed of blogs, letters, educational resources and more, to push for the reversal of tezepelumab's inclusion on the SAD List.

Health Policy TODAY

Asthma Patients Could be Forced into Unsafe Situation

June 17, 2022



Imagine being told you'll have to self-inject a medication – without instructions – that has only been FDA approved for provider-administration. Chances are, you may not use it at all, even though it means inviting dangerous symptoms.

That scenario could soon be a reality for many patients with severe asthma who are insured by Medicare.

Proposed Coverage Change Puts Patients at Risk

Many of the administrative functions of Medicare are managed regionally by private companies, Medicare Administrative Contractors. Several MACs recently proposed changing how tezepelumab is covered. They want the injectable medication moved to the "self-administered drug" list starting in July.

The medication's FDA label and instructions specify that it is "intended for administration by a health care provider." There is no patient-oriented guide explaining how tezepelumab

should be stored or injected. Asking even the savviest patient to safely do either is both inappropriate and unrealistic.

It is also important for provider-administered injectable asthma medications like this one to be administered in a clinical setting so that patients can be observed for potential side effects. Having a doctor on hand to quickly address an adverse reaction is a valuable safeguard.

Exacerbating Access Challenges for Communities of Color

Beyond safety concerns, patient advocates fear that changing the rules for tezepelumab will diminish patients' ability to manage their severe asthma using the innovative medication. This can lead to worse health outcomes for all patients and compound negative effect on patients of color.

Black Americans are nearly 1.5 times more likely to have asthma, five times more likely to visit the emergency room due to asthma and three times more likely to die from asthma compared to white Americans.

Making it harder for patients to get a treatment that controls their symptoms could further widen health inequities in the asthma community.

Calls for Action

In a letter to federal officials, the Alliance for Patient Access outlined several concerns about the policy change. Chief among them: Moving tezepelumab from being covered for physician administration under Part B to self-administration under Part D. This "is an inappropriate overstep by the Medicare Administrative Contractors," the letter warned.

The patient advocacy organization urged the Centers for Medicare and Medicaid Services to review the contractors' proposed change quickly so "our seniors have appropriate access to the treatment as FDA-approved and indicated."

In Discussion: Tezspire

Earlier this year several of the Medicare Administrative Contractors moved Tezspire, a treatment for severe asthma, to the Self-Administered Drug List. The FDA, however, has approved Tezspire only for clinician administration. As a result, there are no instructions on this medication's label or packaging for self-administration or storage.

Multiple clinicians and members of the advocacy community have spoken out and submitted comments on the harm that this potential change could have on patients. While the Medicare Administrative Contractors have postponed the decision to move Tezspire to the SAD list, many are concerned that this is only a temporary solution.

We encourage Congress and CMS to take the necessary steps to protect patient access to this critical treatment.

> We have a number of concerns with this particular policy change, including removing Part B coverage and mandating reimbursement strictly for off-label use, a heightened risk to patient safety, and the potential for this decision to widen health inequities that are already substantial in the asthma community.
>
> *Alliance for Patient Access*

> NAMAPA feels that this change raises significant concerns pertaining to patient safety, compliance, costs, patient-physician relationships, and overall healthcare outcomes.
>
> *National Association of Medication Access & Patient Advocacy*

> The FDA was clear: Tezspire is approved for clinician administration. We're glad to see the MACs have pulled back their decision to add the medication to the SAD list, but urge CMS and the MACs to ensure the medication continues to be accessible as FDA-approved.
>
> *Allen Meadows, MD, AfPA Respiratory Therapy Access Working Group Chair*

> We ask CMS to issue clear direction to the MACs that they cannot declare a medication appropriate for self-administration when the medication's label approved by the FDA states that it is intended for administration by a healthcare provider.
>
> *National Infusion Center Association*

> It is important that patients have unhindered access to all approved treatment options for severe asthma. We respectfully request that all MAC's follow the FDA recommendations for office administration of Tezspire in order to ensure patient safety.
>
> *Allergy & Asthma Network*

June 15, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Jonathan Blum
Principal Deputy Administrator & COO
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: Placement of Tezepelumab on Self-Administered Drug Lists

Dear Ms. Brooks-LaSure and Mr. Blum:

On behalf of the Alliance for Patient Access (AfPA) and provider members, we are writing to bring attention to recent proposals by several Medicare Administrative Contractors (MACs) to place tezepelumab, a treatment for severe asthma, on Self-Administered Drug (SAD) lists. We are concerned that placement of tezepelumab on these lists is not in line with its FDA label and will negatively impact access to this innovative treatment for severe asthma patients.

Founded in 2006, AfPA is a national network of policy-minded health care providers who advocate for patient-centered care. AfPA supports health policies that reinforce clinical decision-making, promote personalized care and protect the physician-patient relationship. Motivated by these principles, AfPA members participate in clinician working groups, advocacy initiatives, stakeholder coalitions and the creation of educational materials. AfPA's Respiratory Therapy Access Working Group convenes clinicians focused on ensuring policy matches the emerging state of asthma care.

Tezepelumab is a monoclonal antibody treatment indicated for treatment in those with severe asthma. FDA approved this treatment with the direction that this treatment to be administered by a health care professional. However, a majority of MACs have now indicated that they intend to place tezepelumab on the SAD list beginning in July. We have a number of concerns with this particular policy change, including removing Part B coverage and mandating reimbursement strictly for off-label use, a heightened risk to patient safety, and the potential for this decision to widen health inequities that are already substantial in the asthma community.

The FDA-approved Preparation and Administration Instructions included in the tezepelumab label clearly state that "TEZSPIRE is intended for administration by a healthcare provider." Placing tezepelumab on the SAD list, despite an explicit FDA-approval for administration by a health care provider, undermines FDA decision-making. Removing Part B coverage for physician-administered treatment, and therefore requiring off-label prescribing for reimbursement, is not only unusual, but is an inappropriate overstep of the MACs. This serves as an unnecessary and unreasonable barrier for severe asthma patients who see tezepelumab as an opportunity to finally have a treatment that can control their symptoms.

Movement of tezepelumab to the SAD list presents a number of patient safety issues as well. As mentioned above, the FDA approved tezepelumab for administration by a healthcare provider. Because of this, there are no instructions that come with the drug regarding storage or patient administration. This poses a serious threat to patient safety and again reinforces the need for Part B coverage that will allow for physician-administered treatment. Expecting even the most health literate patient to properly self-administer this treatment, without proper instructions or explanation, is unrealistic and unsafe.

As you may be aware, some previous asthma treatments had side effects that were not detected in their initial trials that clinicians began seeing in the clinic after administration. For those patients facing negative reactions, having the provider on hand was critical in controlling and properly treating a life-threatening situation. Following the FDA-approved labeling instructions is an important safeguard to keep in place as additional clinical studies and real world experience ensure that no unforeseen side effects impact patient safety.

Finally, when evaluating and considering treatments for severe asthma, it is important to acknowledge the disproportionate impact of asthma on people of color. These patient groups already deal with significant barriers to the healthcare system. Moving tezepelumab to the SAD list will only further exacerbate these disparities. Black Americans are nearly 1.5 times more likely to have asthma, five times more likely to visit the emergency room due to asthma, and three times more likely to die from asthma compared to white Americans.[1] For these patients, ease of access to a treatment that could potentially curtail their symptoms is critical to improving their quality of life and overall well-being. Moving tezepelumab to the SAD list creates an unnecessary and irresponsible barrier that has no clinical backing.

On behalf of the Alliance for Patient Access, we urge CMS to consider the decisions being made by the MACs to declare tezepelumab as SAD and ensure that our seniors have appropriate access to the treatment as FDA-approved and indicated. If you have any questions, please feel free to contact the Alliance for Patient Access at (202) 951-7097.

Sincerely,

Josie Cooper, Executive Director, AfPA

Cc: National Government Services, Inc.
Wisconsin Physicians Service Government Health Administrators
Palmetto GBA,LLC
Noridian Healthcare Solutions, LLC
CGS Administrators, LLC
Novitas Solutions, Inc.
First Coast Service Options, Inc.

[1] https://www.aafa.org/asthma-disparities-burden-on-minorities.aspx

ADVOCACY CAMPAIGN **IMPACT**

The persuasive advocacy campaign led to the MACs and CMS reversing the harmful decision, ultimately securing a win for severe asthma patients.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-15-12
Baltimore, Maryland 21244-1850

Center for Medicare

August 19, 2022

Josie Cooper
Executive Director
Alliance for Patient Access
c/o cmcpherson@allianceforpatientaccess.org

Dear Josie Cooper:

Thank you for your letter to Administrator Brooks-LaSure and Principal Deputy Administrator Blum regarding coverage and payment for tezepelumab (Tezspire) under Medicare Part B. I am responding on their behalf. Your letter expressed opposition of the addition of a severe asthma treatment, Tezspire, to the Self-Administered Drug Exclusion List (SAD list). I share your interest in supporting beneficiary access to the care they need, and I appreciate hearing from you on this important issue.

Medicare Part B includes a limited drug benefit as provided by statute. Medicare Part B covers and pays for services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished incident to a physician's professional service (see sections 1861(s)(2)(A) and (B) of the Social Security Act). The Centers for Medicare & Medicaid Services has provided guidance to Medicare Administrative Contractors (MACs) to determine whether a drug or biological is usually self-administered in Chapter 15, Section 50.2 of the Benefit Policy Manual (https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf).

We appreciate the concerns that you noted in your letter, and we have heard similar concerns from other interested parties, as have many of the MACs. In response to these concerns, the MACs have reevaluated their determination and have removed Tezspire from their SAD lists, which we understand would be the policy going forward unless the label changes.

Thank you again for your letter. I welcome your feedback and appreciate your interest in this important issue as we work towards the goal of strengthening the Medicare program for all beneficiaries.

Sincerely,

Meena Seshamani, M.D., Ph.D

Meena Seshamani, MD, PhD
Director, Center for Medicare

Alliance for Patient Access

ABOUT THE ALLIANCE FOR PATIENT ACCESS

The Alliance for Patient Access is a national network of policy-minded health care providers advocating for patient-centered care.

AllianceforPatientAccess.org