June 23, 2022

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

Tamara Syrek-Jensen, JD
Director, Coverage and Analysis Group, CCSQ
U.S. Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Local Coverage Decision to Allow Self Administration of Tezspire

Dear Administrator Brooks-LaSure and Director Syrek-Jensen,

On behalf of the American College of Allergy, Asthma and Immunology (ACAAI) and the patients we serve, I am writing to express our strong opposition to a Medicare Local Coverage Determination (LCD) that moves the severe asthma treatment Tezspire to the Self-Administration Drug (SAD) list and will require Medicare patients to self-administer Tezspire.

ACAAI represents more than 6,000 board certified allergists and health care professionals. We specialize in treating patients with severe asthma. Tezspire, a biologic that treats severe asthma, was approved by the U.S. Food and Drug Administration in December 2021.

In approving Tezspire, the FDA acknowledged that it is intended for administration by a healthcare provider and allergists have used this promising new biologic to better manage Medicare patients' severe asthma. Requiring patients to self-administer Tezspire presents many challenges that could jeopardize correct utilization and stability of the drug.

While Tezspire is available in pre-filled syringes, it was intended to be administered by healthcare professionals in the physician office setting under the direct supervision of a physician. Tezspire it is not available in a consumer-friendly delivery method and meets the statutory and Centers for Medicare & Medicaid Services (CMS) regulatory requirements for a "not usually" self-administered drug.

Patients should not be burdened with specific time, storage and administration requirements. In addition, many seniors may not have the understanding of how to properly administer the injection or have the dexterity or comfort level for self-injection. Further, there is nothing in the label for Tezspire that would indicate how a patient should self-administer this medicine, and there is no FDA approved Instructions for Use (IFU). Meeting these unique requirements is best left to a trained medical professional.

Receiving Tezspire in the office setting guarantees that the patient's physician can verify that the treatment was administered – per the prescribed protocol - once every four weeks, that it was correctly stored and prepared, and that it was administered to the patient safely and effectively. Failure to correctly administer Tezspire can result in serious patient harm through exacerbated severe asthma symptoms, unsafe injections, and other complications.

Tezspire has the potential to reduce overall Medicare spending by preventing unnecessary emergency department utilizations, and hospitalization. Tezspire that is self-administered incorrectly, may result in persistent, uncontrolled severe asthma, increased emergency room visits and sacrifices the improved asthma management savings potentials.

This LCD is not in the best interest of patients with severe asthma. The LCD does not comport with the FDA's approval that specified Tezspire is intended for administration by a healthcare professional. It also has the potential to sacrifice the cost-saving opportunities for the Medicare program through better care management. For these reasons, we strongly urge you to remove Tezspire from your SAD exclusion lists.

If you wish to discuss this issue further, please contact Susan Grupe (suegrupe@acaai.org), Director of Advocacy Administration.

Sincerely,

Mark L. Corbett, MD, FACAAI
President

CC:
NGS
WPS
Palmetto
Noridian
CGS
Novitas