Sample Letter of Medical Necessity for TEZSPIRE™ (tezepelumab-ekko)

Note: This example letter is provided as a courtesy and not intended to be directive. Physicians should exercise medical judgment and discretion to appropriately diagnose and characterize the individual patient's medical condition. In addition, providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

[Physician/Practice Letterhead]
[Date]
[Payer Name]
[Payer Address]
[City, State ZIP Code]
[Payer Fax Number]

RE: Coverage of TEZSPIRE™ (tezepelumab-ekko)
[Patient Name]
[Patient DOB]
[Policy Number]
[Group Number]
[Treatment Date and Claim Number]
[Amount of Claim]

Attention: [Payer Representative], [Claims Department]

Dear Director of Claims,

I am writing this letter on behalf of my patient, [Patient Name].

TEZSPIRE is indicated to [indication].

[If a prior authorization form has been submitted previously, indicate the date of submission and the outcome].

Based on the FDA-approved indication, I strongly believe that treatment with TEZSPIRE is required. TEZSPIRE is medically necessary for [patient's name] as documented by:

• History of severe asthma: [Based on your clinical judgment, you may wish to describe the patient's history with asthma including acute events, lab values, hospitalizations, etc.]

In my clinical opinion, [patient's name] should receive TEZSPIRE for the following reasons:

[List reasons]

In summary, based on my clinical opinion, TEZSPIRE is medically necessary for [patient's name].

Please call my office at [office phone number] if I can provide you with any additional information to approve my request.

Sincerely,
[Physician's name]

[List enclosures as appropriate: Examples of enclosures may include excerpt(s) from patient's medical record, relevant treatment guidelines, and product Prescribing Information.]

This page is for reference only. Content on this page does not need to be sent to the insurance company.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Known hypersensitivity to tezepelumab-ekko or excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (eg, rash and allergic conjunctivitis) can occur following administration of TEZSPIRE. These reactions can occur within hours of administration, but in some instances have a delayed onset (ie, days). In the event of a hypersensitivity reaction, initiate appropriate treatment as clinically indicated and then consider the benefits and risks for the individual patient to determine whether to continue or discontinue treatment with TEZSPIRE.

Acute Asthma Symptoms or Deteriorating Disease

TEZSPIRE should not be used to treat acute asthma symptoms, acute exacerbations, acute bronchospasm, or status asthmaticus.

Abrupt Reduction of Corticosteroid Dosage

Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with TEZSPIRE. Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Parasitic (Helminth) Infection

It is unknown if TEZSPIRE will influence a patient's response against helminth infections. Treat patients with pre-existing helminth infections before initiating therapy with TEZSPIRE. If patients become infected while receiving TEZSPIRE and do not respond to anti-helminth treatment, discontinue TEZSPIRE until infection resolves.

Live Attenuated Vaccines

The concomitant use of TEZSPIRE and live attenuated vaccines has not been evaluated. The use of live attenuated vaccines should be avoided in patients receiving TEZSPIRE.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥3%) are pharyngitis, arthralgia, and back pain.

USE IN SPECIFIC POPULATIONS

There are no available data on TEZSPIRE use in pregnant women to evaluate for any drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Placental transfer of monoclonal antibodies such as tezepelumab-ekko is greater during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

INDICATION

TEZSPIRE is indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.

TEZSPIRE is not indicated for the relief of acute bronchospasm or status asthmaticus.

Full <u>Prescribing Information</u> including <u>Patient Information</u>.

You may report side effects related to AstraZeneca products by clicking here.