Example 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 judgement 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, when applicable.

[Insert Office Letterhead here]

[Date]
[Payer Name]
[Payer Address]
[Payer City, State, Zip Code]
[Payer Fax Number]

Re: Coverage of TEZSPIRE® (tezepelumab-ekko)
[Patient Name]
[Patient Date of Birth]
[Policy Number or Member ID Number]
[Group Number]
[Treatment Date and Claim Number (if applicable)]
[Amount of Claim (if applicable)]

Attention: [Payer Representative], [Claims Department]

Dear [Contact Name]:

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

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
- the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP)

[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 judgement, you may wish to describe the patient's history with asthma including prebronchodilator forced expiratory volume in 1 second (FEV1) and last test date, number of exacerbations in the past 12 months (e.g., oral prednisone utilization, hospital, and ER visits), level of asthma control (e.g., frequent short-acting beta agonist utilization, nighttime awakenings, limited activity due to asthma), previous therapies and responses, any relevant comorbidities, history prior to your care, if applicable, supporting literature, chart notes and patient factors such as; ability to self-administer medication or ability of care giver to assist, ability to attend office visits every 4 weeks for administration.]

- History of chronic rhinosinusitis with nasal polyps:
  [Based on your clinical judgment, you may wish to describe the patient's history with CRSwNP including level of nasal congestion, nasal polyp size, details on patient's previous therapies including duration and responses (e.g. intranasal corticosteroid sprays, fluticasone (brand name XHANCE), intranasal saline irrigations in conjunction with intranasal corticosteroids, oral nonsedating antihistamines, oral antileukotriene agents, oral corticosteroids, oral antibiotics), history of prior surgery including # of surgeries and dates of surgeries, history prior to your care, if applicable, supporting literature, chart notes and patient factors such as; ability to self-administer medication or ability of care giver to assist, ability to attend office visits every 4 weeks for administration.]

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.]

Please see Indication and Important Safety Information on the next page

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

IMPORTANT SAFETY INFORMATION for TEZSPIRE® (tezepelumab-ekko)

CONTRAINDICATIONS
Known hypersensitivity to tezepelumab-ekko or excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions
Hypersensitivity reactions were observed in the clinical trials (eg, rash and allergic conjunctivitis) following the administration of TEZSPIRE. Postmarketing cases of anaphylaxis have been reported. These reactions can occur within hours of administration, but in some instances have a delayed onset (i.e., days). In the event of a hypersensitivity reaction, 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:
- **Asthma:** pharyngitis, arthralgia, and back pain.
- **Chronic rhinosinusitis with nasal polyps:** nasopharyngitis, upper respiratory tract infection, epistaxis, pharyngitis, back pain, influenza, injection site reaction and arthralgia

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
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*Full **Prescribing Information** including **Patient Information** and **Instructions for Use.***

*You may **report side effects related to AstraZeneca products (Opens new window).***