Effective Date: 04/27/2022
Last P&T Approval/Version: 04/27/2022
Next Review Due By: 04/2023
Policy Number: C23042-A

Tezspire (tezepelumab-ekko)

PRODUCTS AFFECTED

Tezspire (tezepelumab-ekko)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.
This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:
Severe asthma

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

A. SEVERE ASTHMA:
1. Documented diagnosis of severe asthma and prescriber has ruled out acute bronchospasm, status asthmaticus or chronic obstructive pulmonary disease (COPD)
   AND
2. Documentation member has a history of 2 or more asthma exacerbation requiring systemic corticosteroid treatment or 1 asthma exacerbation resulting in hospitalization within the past 12 months
   AND
3. Documentation of symptoms inadequately controlled (as documented in criteria above) after an

adherent regimen of at least 3 months of the following COMBINATION THERAPY or labeled contraindication or clinical intolerance to the agent(s): 1)High-dose inhaled corticosteroid(or maximally tolerated dose) AND ONE (1) ADDITIONAL ASTHMA CONTROLLER MEDICATION (Long-acting beta- agonists, Leukotriene Receptor Antagonists, inhaled long- acting muscarinic antagonist, Theophylline)
AND

4. Prescriber attests that Tezspire (tezepelumab-ekko)) will not be used as monotherapy for asthma or concurrently with other monoclonal antibodies typically used to treat asthma: Xolair (omalizumab), Cinqair (reslizumab), Nucala (mepolizumab), Dupixent (dupilumab or Fasenra (benralizumab)
AND
5. Prescriber attests to (or the clinical reviewer has found that) the member not having any FDA labeled contraindications that haven't been addressed by the prescriber within the documentation submitted for review [Contraindications to Tezspire (tezepelumab-ekko) include: Known hypersensitivity to tezepelumab-ekko or excipients
AND
6. IF THIS IS A FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or intolerance to a majority (not more than 3) of the preferred formulary alternatives for the given diagnosis. Documentation of medication(s) tried, dates of trial(s) and reason for treatment failure(s) is required.

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required)
AND
2. Documentation of no intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by significant reduction in corticosteroid dosage or asthma exacerbations

DURATION OF APPROVAL:

Initial authorization: 6 months, Continuation of Therapy: 12 months

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an allergist, immunologist, or pulmonologist.
[If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:

12 years of age and older

QUANTITY: 1 prefilled syringe or 1 single-dose vial per 28 days.

PLACE OF ADMINISTRATION:

The recommendation is that injectable medications in this policy will be for pharmacy or medical benefit coverage and the subcutaneous injectable products administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Tezspire (tezepelumab-ekko). For information on site of care, see "place holder for hyperlink for Specialty Medication Administration Site of Care coverage criteria policy"

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral, Subcutaneous, Intravenous, Intraarticular, etc.

DRUG CLASS:
Thymic Stromal Lymphopoietin (TSLP) Antagonists

FDA-APPROVED USES:
indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma.
Limitations of Use:
- *Not for relief of acute bronchospasm or status asthmaticus.*

COMPENDIAL APPROVED OFF-LABELED USES:

APPENDIX

APPENDIX:
https://ginasthma.org/severeasthma/

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Tezspire is a first-in-class monoclonal antibody that blocks the action of thymic stromal lymphopoietin (TSLP), an epithelial cytokine that acts at the top of the inflammatory cascade implicated in the pathogenesis of asthma

In the NAVIGATOR trial, 1061 patients 12 years of age and older were randomly assigned 1:1 to receive tezepelumab 210mg subcutaneously every 4 weeks or placebo, in addition to standard of care. The primary endpoint was the annualized asthma exacerbation rate during the 52-week treatment period.

Results from NAVIGATOR showed that treatment with tezepelumab was associated with a statistically significant and clinically meaningful 56% reduction in annualized asthma exacerbation rate in the overall patient population compared with placebo (0.93 vs 2.10; rate ratio, 0.44 [95% CI, 0.37-0.53]; P <.001). Moreover, tezepelumab was associated with a significantly lower rate of annualized asthma exacerbations requiring an emergency room visit or hospitalization (0.06 vs 0.28 for placebo; rate ratio, 0.21 [95% CI, 0.12-0.37]).

Compared with placebo, tezepelumab provided clinically meaningful improvements in the mean change from baseline in FEV1 (LS mean change vs placebo 0.13 L; 95% CI, 0.08-0.18), as well as in patient reported outcomes, as measured by the Asthma Control Questionnaire 6 and Standardized Asthma Quality of Life Questionnaire for ages 12 and older.

Similar findings were observed in the 52-week PATHWAY trial, which enrolled 550 adult patients with severe asthma. Tezepelumab significantly reduced the annualized rate of asthma exacerbations compared with placebo (0.20 vs 0.72; rate ratio, 0.29 [95% CI, 0.16-0.51]).

A total of 82 pediatric patients aged 12 to 17 years were enrolled in the NAVIGATOR trial. Compared with placebo, improvements in annualized asthma exacerbation (rate ratio 0.70; 95% CI, 0.34-1.46) and FEV1

(LS mean change vs placebo 0.17 L; 95% CI, -0.01, 0.35) were observed in patients treated with tezepelumab.

The most common adverse reactions reported with tezepelumab included pharyngitis, arthralgia, and back pain.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Tezspire (tezepelumab-ekko) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to Tezspire (tezepelumab-ekko) include: Known hypersensitivity to tezepelumab-ekko or excipients.

OTHER SPECIAL CONSIDERATIONS:
Avoid use of live attenuated vaccines. TEZSPIRE is intended for administration by a healthcare provider

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:
Tezspire 210 mg/1.91 mL (110 mg/mL) solution in a single-dose glass vial. , 210 mg/1.91 mL (110 mg/mL) solution in a single-dose pre-filled syringe.

REFERENCES

1. Tezspire (tezepelumab) [prescribing information]. Thousand Oaks, CA: Amgen, Inc; December 2021.
2. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf. Updated 2021
3. Menzies-Gow A, Colice G, Griffiths JM, et al. NAVIGATOR: a phase 3 multicenter, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy and safety of tezepelumab in adults and adolescents with severe, uncontrolled asthma. Respir Res. 2020;21(1):266. doi:10.1186/s12931-020-01526-6
4. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in adults and adolescents with severe, uncontrolled asthma. N Engl J Med. 2021;384(19):1800-1809. doi:10.1056/NEJMoa2034975

SUMMARY OF REVIEW/REVISIONS	DATE
New Development	Q2 2022