Original Effective Date: 04/27/2022
Current Effective Date: 11/29/2024
Last P&T Approval/Version: 10/30/2024
Next Review Due By: 10/2025
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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. SEVERE ASTHMA:
   1. Documented diagnosis of severe asthma
      and
   2. Prescriber attests acute bronchospasm, status asthmaticus or chronic obstructive pulmonary disease (COPD) have been ruled out

AND

3. 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
4. Documentation of symptoms inadequately controlled (as documented in criteria above) after an adherent regimen of at least 3 months of the following COMBINATION THERAPY: Medium or High-dose inhaled corticosteroid (or maximally tolerated dose) AND ONE additional asthma controller medication (LABA, LAMA, LTRA)
   AND
5. Prescriber attests or clinical reviewer has found that Tezspire (tezepelumab-ekko) is NOT being used as monotherapy for asthma (must be prescribed as add-on maintenance to be used in combination with other medications for long-term control of asthma)
   AND
6. 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, use of live attenuated vaccines]
   AND
7. Prescriber attests or clinical reviewer has found that Tezspire (tezepelumab-ekko) is not prescribed for concurrent use with any of the following: Xolair (omalizumab) OR IL-5 inhibitors [benralizumab (Fasenra), mepolizumab (Nucala). reslizumab (Cinqair)] OR IL-4 antagonist Dupixent (dupilumab)
   AND
8. IF THIS IS A FOR A NON-FORMULARY/NON-PREFERRED PRODUCT/DOSAGE FORM: Documentation of trial/failure of or serious side effects 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. SEVERE ASTHMA:

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
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation of positive clinical response as demonstrated by significant reduction in corticosteroid dosage or asthma exacerbations
   AND
4. Documentation member is currently treated and is compliant with standard therapy (e.g., inhaled corticosteroids (ICS), long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA),,)

DURATION OF APPROVAL:

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

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with, a board-certified asthma specialist (allergist, immunologist, pulmonologist) or physician experienced in the management of asthma. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
12 years of age and older

QUANTITY:
210 mg once every 4 weeks

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 Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

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:
None

APPENDIX

APPENDIX 1:
Controller medications: suppress the inflammatory causes of asthma to provide clinical control over the long term, whereas reliever medications relieve bronchoconstriction quickly. Controller medications include inhaled glucocorticoids, long-acting beta-agonists (LABAs) andLeukotriene receptor antagonists (LTRA). Theophylline (Theo-24, Uniphyl, TheoChron ER, generics) is also a controller agent, however, it is not as efficacious as LABAs and not recommended for treatment.

Anticholinergic (LAMA)
Tiotropium bromide monohydrate (Spiriva Respimat)

Inhaled Corticosteroids (ICS) (list not all inclusive):
Beclometasone dipropionate (QVAR)
Budesonide DPI (Pulmicort Flexhaler)
Budesonide nebules (Pulmicort Respules)
Ciclesonide (Alvesco)
Fluticasone propionate (ArmonAir Digihaler)
Flunisolide (Aerospan)
Mometasone furoate (Asmanex Twisthaler)
Mometasone furoate (Asmanex HFA)*
Fluticasone furoate (Arnuity Ellipta)
Fluticasone propionate (Flovent Diskus)
Fluticasone propionate (Flovent HFA)

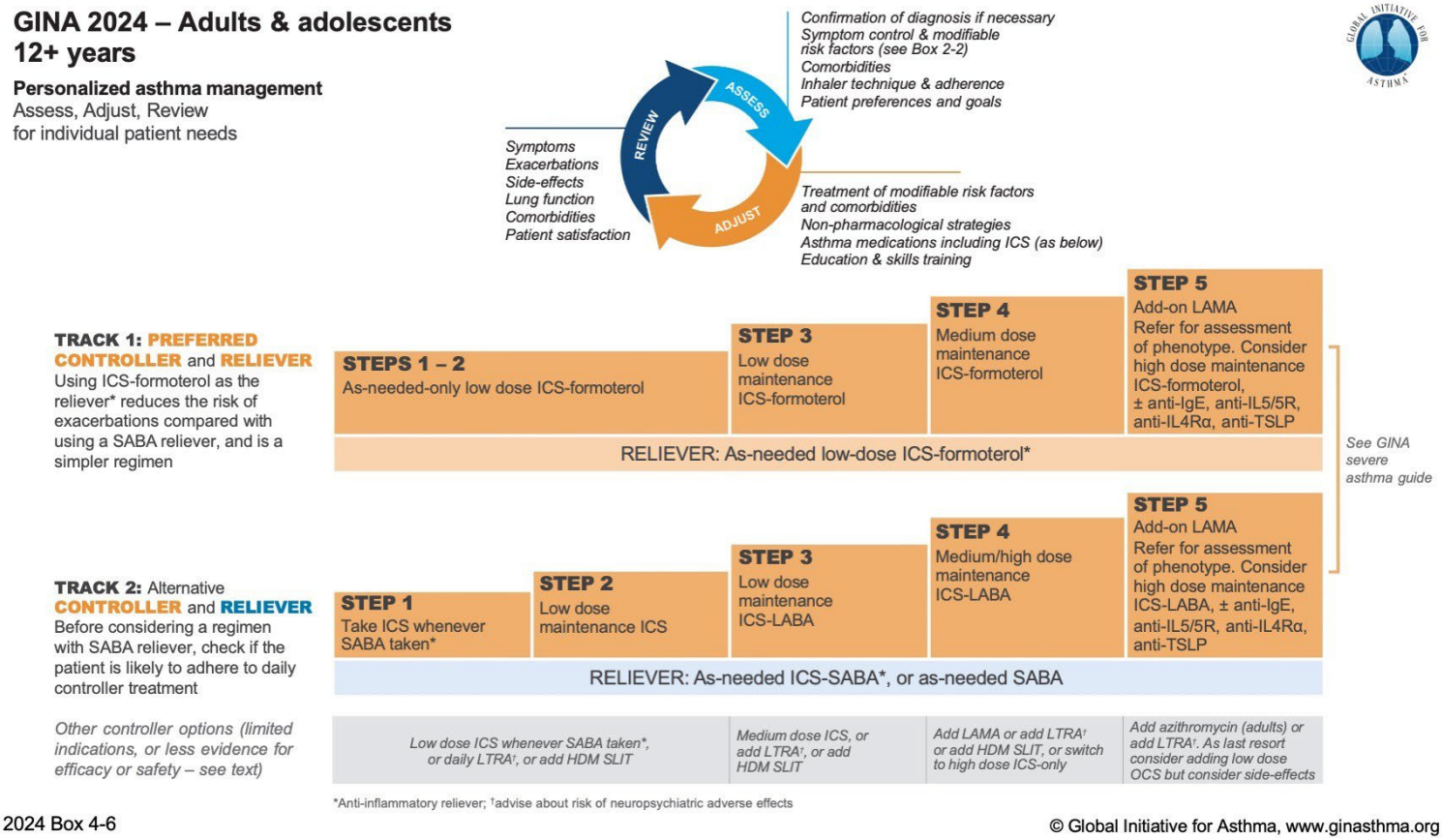
**HFA: hydrofluoroalkane propellant metered dose inhaler*
**DPI: dry powder inhaler*

Combination Long-Acting Bronchodilator and Corticosteroid (ICS+ LABA) (list not all inclusive):
Budesonide/formoterol fumarate dihydrate (Symbicort)
Fluticasone propionate/salmeterol (Advair Diskus/ Adair HFA/ AirDuo/ AirDuo RespiClick/Wixela Inhub)
Fluticasone furoate/vilanterol(Breo Ellipta)
Mometasone furoate/formoterol fumarate dihydrate (Dulera)

Combination Anticholinergic and Corticosteroid and long-acting bronchodilator (ICS+ LAMA+ LABA)
Fluticasone/umeclidnium/vilanterol (Trelegy Elipta)
Budesonide/glycopyrrolate/formoterol (Breztri Aerosphere)

Leukotriene receptor antagonist (LTRA) (list not all inclusive):
Montelukast (Singulair), Zafirlukast (Accolate), Zileuton (Zyflo)

APPENDIX 2: Managing Asthma in Adults and Adolescents 12+ Years



GINA 2024 Box 4-6

ABBREVIATIONS: HDM: house dust mite; ICS: inhaled corticosteroid; LABA: long-acting beta2-agonist; LAMA: long-acting muscarinic antagonist; LTRA: Leukotriene Receptor Antagonist; OCS: oral corticosteroids; SABA: short-acting beta2-agonist; SLIT: sublingual immunotherapy
REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from: www.ginasthma.org

APPENDIX 3: SUGGESTED TOTAL DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) IN ADULTS AND ADOLESCENTS (12 years and older):

Inhaled Corticosteroid	Low Dose ICS (mcg)	Medium Dose ICS (mcg)	High Dose ICS (mcg)
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	>500-1000	>1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200	>200-400	>400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	>400-800	>800
Ciclesonide (pMDI, extrafine particle, HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	100	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	>250-500	>500
Mometasone furoate (DPI)	Depends on DPI device – see product information		
Mometasone furoate (pMDI, standard particle, HFA)	200-400	200-400	>400

Reference: Box 4-2. Low, medium and high daily metered doses of inhaled corticosteroids (alone or with LABA) Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from: www.ginasthma.org

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.

Global Initiative for Asthma (GINA, 2024)
Add-on biologic therapy: options recommended by GINA for patients with uncontrolled severe asthma despite optimized maximal therapy include:

- Add-on anti-immunoglobulin E treatment (omalizumab [Xolair]) for patients age ≥ 6 years with **severe allergic asthma** (Evidence A)
- Add-on anti-interleukin- 5/5R treatment (SC mepolizumab [Nucala] for patients age ≥ 6 years; IV reslizumab [Cinqair] for ages ≥18 years or SC benralizumab[Fasenra] for ages ≥12 years), with **severe eosinophilic asthma** (Evidence A)
- Add-on anti-interleukin-4Rα treatment (SC dupilumab [Dupixent]) for patients aged ≥ 6 years with **severe eosinophilic/type 2 asthma** or for **patients requiring treatment with maintenance OCS** (Evidence A)
- Add-On anti-thymic stromal lymphopoietin (anti TSLP) treatment (subcutaneous tezepelumab [Tezspire]) for patients aged ≥12 years with **severe asthma** (Evidence A)
- Suggested initial trial of add-on anti-IL5 for severe eosinophilic asthma is at least 4 months. At that point, response to initial trial of add-on therapy should be reviewed. There are no well-defined criteria for good response, but exacerbations, symptom control, lung function, side effects, treatment intensity, and patient satisfaction should be considered. If the response is unclear, consider extending the trial to 6-12 months. If there is no response, stop the biologic therapy and consider switching to a different targeted therapy, if available.

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, use of live attenuated vaccines.

OTHER SPECIAL CONSIDERATIONS:
Tezspire vial and pre-filled syringe are intended for administration by a healthcare provider. Tezspire pre-filled pen can be administered by patients/caregivers or healthcare providers. Patients/caregivers may administer Tezspire pre-filled pen after proper training in subcutaneous injection technique and after the healthcare provider determines it is appropriate.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J2356	Injection, tezepelumab-ekko, 1 mg

AVAILABLE DOSAGE FORMS:
Tezspire SOAJ 210MG/1.91ML auto-injector
Tezspire SOSY 210MG/1.91ML prefilled syringe

REFERENCES

1. Tezspire (tezepelumab) [prescribing information]. Thousand Oaks, CA: Amgen, Inc; May 2023.
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
5. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from: www.ginasthma.org
6. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from: www.ginasthma.org

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Continuation of Therapy Appendix References	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Quantity Route of Administration Appendix Background Contraindications/Exclusions/Discontinuation Other Special Considerations Coding/Billing Information Available Dosage Forms References	Q4 2023
NEW CRITERIA CREATION	Q2 2022