Pharmacy Drug Policy

SUBJECT: Tezspire™ (tezepelumab-ekko subcutaneous injection) **POLICY NUMBER: PHARMACY-102** **EFFECTIVE DATE: 02/10/2022** **LAST REVIEW DATE:11/12/2026**
If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Asthma is a complex disease estimated to affect over 25 million Americans, including over 5 million children < 18 years of age.[1] Generally, asthma is characterized by chronic airway inflammation and respiratory symptoms such as wheezing, shortness of breath, chest tightness, and cough.[2] It is estimated that 3% to 10% of the total asthma population may have severe asthma. Severe asthma is a heterogeneous syndrome that might be better described as a constellation of phenotypes, each with distinct cellular and molecular mechanisms, rather than as a singular disease. Multiple inflammatory pathways, including thymic stromal lymphopoietin (TSLP), may play a role.

TSLP is an upstream cytokine in the asthma inflammatory cascade. Epithelial cells produce TSLP in response to environmental stimuli (e.g., allergens, viruses, bacteria, smoke).[3,4] Tezspire is a human monoclonal antibody that blocks TSLP from interacting with its receptor. Blocking TSLP inhibits downstream signaling and decreases the biomarkers and cytokines associated with inflammation including blood eosinophils, airway submucosal eosinophils, IgE, FeNO, IL-5, and IL-13.[3]

Tezspire (tezepelumab-ekko) is indicated for the add-on maintenance treatment of severe asthma in patients ≥ 12 years of age.

POLICY:

Severe Asthma

Based upon our criteria and review of the peer-reviewed literature, treatment with Tezspire administered in accordance with FDA guidelines, has been medically proven to be an effective and well tolerated treatment that reduces the risk of asthma exacerbations in patients with severe asthma. Therefore, it is considered medically appropriate if all the following criteria are met:

1. Patient must be at least 12 years of age **AND**
2. Patient must be followed by, and drug ordered by an allergist/immunologist or pulmonologist **AND**
3. Patient must have severe asthma **AND**
4. Patient must be a non-smoker. Non-smoker is defined as someone who has not smoked in the preceding 6 months **AND**

5. Patient must have well-documented use of high-dose inhaled corticosteroids (ICS) (see Tables 1-3 in policy guidelines section) for **at least 3 months**, be compliant with existing therapy, and have followed GINA guidelines for asthma treatment including an adequate trial of a high-dose inhaled steroid in combination with a long-acting beta agonist
    a. Compliance will be assessed based on pharmacy refill history. If the patient does not have pharmacy benefits through this health plan, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested.
    b. If there is a contraindication to use of a long-acting beta agonist, then an alternative controller drug may be used in combination with a high-dose inhaled steroid such as a leukotriene inhibitor or long-acting muscarinic antagonist.
    c. Patient must have documentation of inadequate control despite optimal therapy (above) for a period of at least 3 months **AND**
6. Must be used in combination with existing asthma therapy (as defined above)
    a. Monotherapy will not be authorized as this agent is only FDA-approved as an add-on maintenance treatment **AND**
7. The patient must have eosinophils <150 cells per microliter (the measurement must have been taken within the last 6 weeks) **AND** the patient must NOT be oral corticosteroid dependent (OCS; OCS-dependence is defined as reliance on daily, maintenance oral prednisone, methylprednisolone, etc. [OCS-dependence should be supported by clinical progress notes and/or pharmacy claims]) **AND**
8. If Tezspire (pen/vial/syringe) is being requested for coverage under the **medical benefit**, the patient must have documentation of the inability to self-inject. ****New starts:** applies to *all* lines of business. ****Recertifications (including new to plan):** applies to all lines of business *except* Medicare B (Medicare Advantage)
    a. For pediatric patients < 18 years of age, documentation must also include the inability of a caregiver to administer the medication
9. Patient must have experienced **2 or more** asthma exacerbations within the **preceding 12 months** that required medical intervention (defined as non-routine doctor visits, urgent care visits, emergency room visits, hospital admissions, or documented need for acute systemic steroids) despite existing therapy as outlined in criterion #5.
10. Initial approval will be for 6 months. Subsequent recertifications will be for 2 years and will require an objective assessment of response from the provider (reductions in hospitalizations, ER visits, and rescue medication use) as well as compliance history with the inhaled corticosteroid and controller medication. Recertification will not be granted if the patient starts or re-starts smoking. See recertification statement and additional approval time-period table for medical benefit in policy guidelines section of this policy.
11. Dosing: 210mg subcutaneously once every 4 weeks

Chronic Rhinosinusitis with Nasal Polyps

Based upon our criteria and review of the peer-reviewed literature, treatment with **Tezspire** administered in accordance with FDA guidelines, has been medically proven to be an effective and well tolerated treatment for chronic rhinosinusitis with nasal polyps. Therefore, it is considered medically appropriate if all the following criteria are met:

1. Must be prescribed by or in consultation by an Allergist/Immunologist, or Otolaryngologist **AND**
2. Must have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)
    a. Chronic is defined as having lasted for at least 12 weeks **AND**
    b. Must currently have nasal polyposis, confirmed by evidence (such as direct examination, nasal endoscopy, imaging studies such as a sinus CT scan)

3. Must be ≥ 12 years of age **AND**
4. Must have had either:
   a. Prior nasal surgery **OR**
   b. Prior treatment with a course of systemic corticosteroids
5. Step therapy applies – Step therapy (a **AND** b) applies to New Starts for all lines of business, **including** Medicare Part B:
   a. Must have documented inadequate response despite at least 3 months of compliant use of mometasone nasal spray at a dose of 2 sprays in each nostril twice daily (compliance will be verified through pharmacy claims history. Note: each inhaler =17g = 120 sprays, therefore claims should reflect **34g/30 days** for the required dosing) **AND**
   b. Must have documented inadequate response despite at least 3 months of compliant use of Xhance nasal spray at a dose of 2 sprays in each nostril twice daily (compliance will be verified through pharmacy claims history. Note: each inhaler =16ml = 120 sprays, therefore claims should reflect **32ml/30 days** for the required dosing) **AND**
6. Must have had serious side effects or drug failure of Dupixent unless there is a medical reason why Dupixent cannot be used
7. Must be used in combination with an intranasal corticosteroid
   a. Tezspire as monotherapy for this indication will not be authorized as both agents are only FDA approved as an add-on maintenance treatment
8. Requests for Tezspire vial/pen/syringe for office-administration as medical benefit will require documentation of an inability to self-inject. ****This applies to New Start AND Recertification requests (including new to plan) for all lines of business, except Medicare. Does NOT apply to Medicare B (Medicare Advantage) ****
9. Approved dosing: Tezspire 210mg once every 4 weeks
10. Initial approval will be granted for **6** months. All recertifications will be for 2 years and will require documentation of continued use of an intranasal corticosteroid and clinical benefit from Tezspire use (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell)
11. Tezspire will not be approved for use in combination with Dupixent, Nucala or Xolair for Chronic Rhinosinusitis with Nasal Polyps

POLICY GUIDELINES:

1. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
2. Tezspire is available as a 210 mg/1.91 mL (110 mg/mL) solution in a single-dose glass vial, a single-dose prefilled syringe, and a single-dose pre-filled pen:
   a. According to the Tezspire prescribing information, the vial and prefilled syringe (PFS) are intended for administration by a healthcare provider and are covered under the medical benefit. The pre-filled pen can be administered by patients/caregivers or healthcare providers and is covered under the pharmacy or medical benefit.
3. Tezspire will not be authorized in the following circumstances:
   a. Concurrent use with omalizumab (Xolair)
   b. Concurrent use with interleukin inhibitors (Adbry, Dupixent, Fasenra, Cinqair, Nucala)
   c. Tezspire is only approved for subcutaneous administration. Administration in any other manner will not be authorized.
   d. Relief of acute bronchospasm or status asthmaticus
   e. Any non-FDA approved dosing regimen

4. For any diagnosis, if Tezspire therapy is initiated with samples and the member does not meet our criteria for coverage (as outlined above) before the start of Tezspire therapy, upon completion of the samples, coverage of Tezspire will not be granted.
5. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and the requesting prescriber provides rationale and documentation for one of the following circumstances, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
6. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
7. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to criteria being added to the policy.
8. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent if the preferred drug is not found in claims history.
9. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
10. Unless otherwise stated within the individual drug criteria, approval time frames are as follows:

Line of Business	Initial approval	Continued approval
Commercial, Exchange, and SafetyNet (Medicaid, HARP, CHP, Essential Plan)	6 months	2 years
Medicare	2 years	2 years

    a. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e.,

generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

11. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
12. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
13. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
14. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
15. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.htm
16. The requested site of care may impact approval timeframe and subject to review.
17. Approval timeframes may be extended to align authorization periods for drugs administered as part of a multidrug regimen, including when regimen components are administered across different benefits. This provision does not apply when the approval timeframe reflects a drug-specific limitation on duration of therapy.

Table 1:

Estimated comparative daily doses for inhaled glucocorticoids in adolescents ≥12 years and adults

Drug	Low dose (total daily dose)	Medium dose (total daily dose)	High dose (total daily dose)*
Beclomethasone HFA (Qvar RediHaler product available in United States) Administer as 2 divided doses	80 to 160 mcg	>160 to 320 mcg	>320 to 640 mcg
40 mcg per actuation	2 or 4 inhalations	¶	¶
80 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Beclomethasone HFAΔ (Qvar product available in Canada, Europe, and elsewhere) Administer as 2 divided doses	100 to 200 mcg	>200 to 400 mcg	>400 to 800 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
100 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Budesonide DPI (Pulmicort Flexhaler product available in United States) Administer as 2 divided doses	180 to 360 mcg	>360 to 720 mcg	>720 to 1440 mcg
90 mcg per actuation	2 or 4 inhalations	¶	¶
180 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Budesonide DPIΔ (Pulmicort Turbuhaler or Turbohaler product available in Canada, Europe, and elsewhere) Administer low doses (ie, ≤400 mcg/day) once daily; administer higher doses (ie, >400 mcg/day) as 2 to 4 divided doses	200 to 400 mcg	>400 to 800 mcg	>800 to 2400 mcg
100 mcg per actuation	2 to 4 inhalations	¶	¶
200 mcg per actuation	1 to 2 inhalations	3 to 4 inhalations	¶
400 mcg per actuation	1 inhalation	2 inhalations	3 to 6 inhalations
Ciclesonide HFA (Alvesco product available in United States, Europe, and elsewhere) United States: Administer as 2 divided doses Australia, Europe, and elsewhere: Administer lower doses (ie, 160 to 320 mcg/day) once daily; administer 640 mcg dose as 2 divided doses	160 mcg	320 mcg	640 mcg
80 mcg per actuation	2 inhalations	4 inhalations	¶
160 mcg per actuation	◇	2 inhalations	4 inhalations
Ciclesonide HFAΔ (Alvesco product available in Canada) Administer lower doses (eg, 100 to 400 mcg) once daily; administer 800 mcg dose as 2 divided doses	100 to 200 mcg	>200 to 400 mcg	>400 to 800 mcg
100 mcg per actuation	1 to 2 inhalations	3 to 4 inhalations	¶
200 mcg per acutation	1 inhalation	2 inhalations	3 to 4 inhalations

Fluticasone propionate HFA (Flovent HFA product available in United States) Administer as 2 divided doses	176 to 220 mcg	>220 to 440 mcg	>440 to 1760 mcg
44 mcg per actuation	4 inhalations	¶	¶
110 mcg per actuation	2 inhalations	4 inhalations	¶
220 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
Fluticasone propionate HFAΔ (Flovent HFA product available in Canada; Flixotide Evohaler product available in Europe and elsewhere) Administer as 2 divided doses	100 to 250 mcg	>250 to 500 mcg	>500 to 2000 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
125 mcg per actuation	2 inhalations	4 inhalations	¶
250 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
Fluticasone propionate DPI (Flovent Diskus product available in United States and Canada; Flixotide Accuhaler product available in Europe and elsewhere) Administer as 2 divided doses	100 to 250 mcg	>250 to 500 mcg	>500 to 2000 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
100 mcg per actuation	2 inhalations	4 inhalations	¶
250 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
500 mcg per actuation (strength not available in United States)	◇	◇	2 or 4 inhalations
Fluticasone propionate DPI (Armonair Digihaler product available in United States; Aermony Respiclick product available in Canada) Administer as 2 divided doses	110 mcg	226 mcg	464 mcg
55 mcg per actuation	2 inhalations	¶	¶
113 mcg per actuation	◇	2 inhalations	¶
232 mcg per actuation	◇	◇	2 inhalations
Fluticasone furoate DPI (Arnuity Ellipta product available in United States, Canada, Australia, and elsewhere, but not available in Europe or UK) Administer once daily **NOTE:** Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only once daily.	50 mcg (by use of pediatric DPI, which is off-label in adolescents and adults)	100 mcg	200 mcg
50 mcg per actuation	1 inhalation	¶	¶
100 mcg per actuation	◇	1 inhalation	2 inhalations
200 mcg per actuation	◇	◇	1 inhalation
Mometasone DPI (Asmanex Twisthaler product available in United States) May administer lower doses (ie, 220 to 440 mcg/day) once daily; administer 880 mcg dose as 2 divided doses	220 mcg	>220 to 440 mcg	>440 to 880 mcg
110 mcg per actuation	2 inhalations	¶	¶
220 mcg per actuation	1 inhalation	2 inhalations	4 inhalations

Mometasone DPI (Asmanex Twisthaler product available in United States) May administer lower doses (ie, 220 to 440 mcg/day) once daily; administer 880 mcg dose as 2 divided doses	220 mcg	>220 to 440 mcg	>440 to 880 mcg
110 mcg per actuation	2 inhalations	¶	¶
220 mcg per actuation	1 inhalation	2 inhalations	4 inhalations
Mometasone HFA (Asmanex HFA product available in United States) Administer as 2 divided doses	200 mcg	>200 to 400 mcg	>400 to 800 mcg
100 mcg per actuation	2 inhalations	4 inhalations	¶
200 mcg per actuation	◇	2 inhalations	4 inhalations
Mometasone DPIΔ (Asmanex Twisthaler product available in Canada, Europe, and elsewhere) May administer lower doses (ie, 200 to 400 mcg/day) once daily; administer 800 mcg dose as 2 divided doses	200 mcg	>200 to 400 mcg	>400 to 800 mcg
200 mcg per actuation	1 inhalation	2 inhalations	¶
400 mcg per actuation	◇	1 inhalation	2 inhalations

- **The most important determinant of appropriate dosing is the clinician's judgment of the patient's response to therapy.** The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effects.
- Suggested total daily doses for low, medium, and high dose inhaled glucocorticoid regimens are based on daily doses recommended by Global Initiative for Asthma (GINA), National Asthma Education and Prevention Program (NAEPP), and/or product labeling[1-5]. This is not a table of equivalence.
- Depending on the specific product, total daily doses are administered once or divided and given twice daily. Refer to local product information or a clinical drug reference (eg Lexicomp).
- Some doses are outside the approved product information recommendations.

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant metered dose inhaler.

* Evidence for additional improvement with dose increases >1000 mcg/day is limited.

¶ Select alternate preparation with higher mcg/actuation to improve convenience.

Δ Products shaded in light gray color are not available in the United States but are available widely elsewhere.

◇ Select preparation with fewer mcg/actuation.

Table 2

Usual doses of combined inhaled glucocorticoids and bronchodilators

Medication	Low dose	Medium dose	High dose
ICS-SABA combination			
Budesonide-albuterol HFA (Brand name: Airsupra)*			
NOTE: Not used for maintenance therapy.			
Acute symptom relief: Budesonide-albuterol (80 mcg/90 mcg) 2 inhalations as needed (usual maximum: 12 inhalations/day).			
ICS-LABA combinations			
Beclomethasone [beclometasone]-formoterol DPI or HFA (Not available in United States or Canada, but available elsewhere [sample brand names: Formodual, Fostair, Foster])¶Δ			
100 mcg/6 mcg	1 inhalation twice a day	2 inhalations twice a day	
200 mcg/6 mcg			2 inhalations twice a day
Budesonide-formoterol HFA (Brand name: Symbicort)¶			
80 mcg/4.5 mcg	2 inhalations twice a day		
160 mcg/4.5 mcg		2 inhalations twice a day	
Fluticasone furoate-vilanterol DPI (Brand name: Breo Ellipta)Δ			
NOTE: Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only **once** daily.			
50 mcg/25 mcg◇	1 inhalation once daily		
100 mcg/25 mcg		1 inhalation once daily	
200 mcg/25 mcg			1 inhalation once daily
Fluticasone propionate-formoterol MDI (Not available in United States or Canada, but available elsewhere [sample brand name: Flutiform])			
50 mcg/5 mcg	2 inhalations twice daily		
125 mcg/5 mcg		2 inhalations twice daily	
250 mcg/10 mcg			2 inhalations twice daily
Fluticasone propionate-salmeterol DPI (Brand names: Advair Diskus, Wixela Inhub)Δ			
100 mcg/50 mcg	1 inhalation twice a day		
250 mcg/50 mcg		1 inhalation twice a day	
500 mcg/50 mcg			1 inhalation twice a day
Fluticasone propionate-salmeterol HFA (Brand name: Advair HFA)			
45 mcg/21 mcg	2 inhalations twice a day		
115 mcg/21 mcg		2 inhalations twice a day	
230 mcg/21 mcg			2 inhalations twice a day
Fluticasone propionate-salmeterol DPI (Brand names: AirDuo RespiClick, AirDuo Digihaler)Δ§			
55 mcg/14 mcg	1 inhalation twice a day		
113 mcg/14 mcg	1 inhalation twice a day	1 inhalation twice a day	
232 mcg/14 mcg			1 inhalation twice a day
Mometasone-formoterol HFA (Brand name: Dulera)			
100 mcg/5 mcg		2 inhalations twice a day	
200 mcg/5 mcg			2 inhalations twice a day
Mometasone-indacaterol DPI (Brand name: Atectura Breezhaler; available in Canada)Δ			
80 mcg/150 mcg	1 inhalation (capsule) once a day		
160 mcg/150 mcg		1 inhalation (capsule) once a day	
320 mcg/150 mcg			1 inhalation (capsule) once a day
ICS-LAMA-LABA combinations¥			
Fluticasone furoate-umeclidinium-vilanterol DPI (Brand name: Trelegy Ellipta)Δ			
100 mcg/62.5 mcg/25 mcg		1 inhalation once daily	
200 mcg/62.5 mcg/25 mcg			1 inhalation once daily
Mometasone-glycopyrrolate (glycopyrronium)-indacaterol DPI (Brand name: Enerzair Breezhaler; available in Canada)*Δ			
160 mcg/50 mcg/150 mcg			1 inhalation (capsule) once a day

Do not exceed the maximum number of inhalations/puffs per day listed in the table due to the risk of toxicity from an excess dose of long-acting beta-agonist (ie, salmeterol, formoterol, or vilanterol). Brand names and dose per puff or per inhalation of commercially available fixed dose combinations are according to United States prescribing information, unless otherwise noted. Consult local product information before use.

ICS: inhaled glucocorticoid (inhaled corticosteroid); SABA: short-acting beta-agonist; LABA: long-acting beta-agonist; LAMA: long-acting muscarinic antagonist; HFA: metered dose inhaler with hydrofluoroalkane propellant; DPI: dry powder inhaler; SMI: soft mist inhaler.

* Not approved for use in patients <18 years old.

¶ When using ICS-formoterol as reliever, use one to two inhalations as needed. Maximum daily dose of maintenance and rescue is 12 inhalations.

Δ DPI contains lactose which may have small amounts of milk protein.

◇ Fluticasone furoate-vilanterol 50 mcg/25 mcg DPI is approved for use in patients 5 to 11 years old; use in adolescents and adults is off-label.

§ In AirDuo inhalers, the daily dose of salmeterol is approximately one-fourth of the dose in Advair, and the daily dose of fluticasone is approximately one-half that of the comparable low-, medium-, and high-dose strengths of Advair.

¥ Alternatively, tiotropium SMI (Brand name: Spiriva Respimat) can be used with an ICS or ICS-LABA inhaler. The dose in asthma is two inhalations (1.25 mcg/inhalation) once daily.

Reference: Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/wp-content/uploads/2023/05/GINA-2023-Full-Report-2023-WMS.pdf. Updated 2023 (Accessed on June 13, 2023).

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Table 3

Estimated comparative daily doses for inhaled glucocorticoids in children

Drug	Low daily dose		Medium daily dose		High daily dose	
	Child 0 to 4	Child 5 to 11	Child 0 to 4	Child 5 to 11	Child 0 to 4	Child 5 to 11
Beclomethasone HFA 40 or 80 mcg/puff	NA	40 mcg/puff - 1 to 2 puffs twice per day	NA	40 mcg/puff - 2 to 4 puffs twice per day 80 mcg/puff - 1 to 2 puffs twice per day	NA	80 mcg/puff - 3 to 4 puffs twice per day
Budesonide DPI* (breath activated) 90 or 180 mcg/inhalation	NA	90 mcg/inhalation - 1 to 2 inhalations twice per day	NA	180 mcg/inhalation - 1 to 2 inhalations twice per day	NA	180 mcg/inhalation - 3 to 4 inhalations twice per day
Budesonide nebulization suspension¶ 0.25 mg/2 mL, 0.5 mg/2 mL, or 1 mg/2 mL	0.25 to 0.5 mg once daily or as 2 divided doses	0.5 mg once daily or as 2 divided doses	0.75 to 1 mg once daily or as 2 or 3 divided doses	1 mg once daily or as 2 divided doses	1.25 to 2 mg once daily or as 2 divided doses	2 mg once daily or as 2 divided doses
Ciclesonide HFAΔ 80 or 160 mcg/puff	NA	80 mcg/puff - 1 to 2 puffs once daily	NA	80 mcg/puff - 3 to 4 puffs once daily	NA	80 mcg/puff - 5 to 6 puffs once daily or as 2 divided doses 160 mcg/puff - 3 puffs once daily or as 2 divided doses
Fluticasone HFA◇ 44, 110, or 220 mcg/puff	44 mcg/puff - 2 puffs twice per day◇	44 mcg/puff - 1 to 2 puffs twice per day	44 mcg/puff - 2 to 4 puffs twice per day 110 mcg/puff - 1 puff in AM and 2 puffs in PM	44 mcg/puff - 2 to 4 puffs twice per day 110 mcg/puff - 1 puff in AM and 2 puffs in PM	110 mcg/puff - 2 puffs twice per day 220 mcg/puff - 1 puff twice per day	110 mcg/puff - 2 puffs twice per day 220 mcg/puff - 1 puff twice per day
Fluticasone DPI (breath activated)§ 50, 100, or 250 mcg/inhalation	NA	50 mcg/inhalation - 1 to 2 inhalations twice per day	NA	50 mcg/inhalation - 3 to 4 inhalations twice per day 100 mcg/inhalation - 1 inhalation in AM and 2 inhalations in PM to 2 inhalations twice per day	NA	100 mcg/inhalation - 2 inhalations in AM and 3 inhalations in PM 250 mcg/inhalation - 1 inhalation twice per day
Mometasone aerosol DPI (breath activated)* 110 or 220 mcg/inhalation	NA	110 mcg/inhalation - 1 inhalation once daily	NA	110 mcg/inhalation - 2 to 3 inhalations once daily	NA	110 mcg/inhalation - 4 inhalations once daily or 2 inhalations twice per day 220 mcg/inhalation - 2 inhalations once daily or 1 inhalation twice per day
Mometasone HFA MDI 50, 100, or 200 mcg/puff	NA	50 mcg/puff - 1 puff once or twice per day	NA	50 mcg/puff - 2 to 3 puffs twice per day 100 mcg/puff - 1 puff twice per day	NA	100 mcg/puff - 2 puffs twice per day 200 mcg/puff - 1 inhalation twice per day

Some doses may be outside approved package labeling, especially in the high-dose range. Doses shown and strengths (ie, mcg per puff or inhalation) are based upon product descriptions approved in the United States, which may differ from how strengths are described for products available in other countries. Consult local product information before use.

HFA: hydrofluoroalkane; NA: not approved and no data available for this age group; DPI: dry-powder inhaler; AM: in morning; PM: in evening; US FDA: US Food and Drug Administration; MDI: metered-dose inhaler.

* Contains milk protein.

¶ Budesonide suspension is compatible with albuterol, ipratropium, and levalbuterol nebulizer solutions in the same nebulizer. Use only jet nebulizers as ultrasonic nebulizers are ineffective for suspensions.

Δ Ciclesonide is not approved by the US FDA for use in children under 12. It is approved for use in children 6 years of age and older in Canada, some European countries, and elsewhere.

◇ For fluticasone HFA, the low dose for children <4 years is higher than for children 5 to 11 years of age due to lower dose delivered with facemask and data on efficacy in young children.

§ Contains lactose.

Data from:

1. National Heart, Blood, and Lung Institute Expert Panel Report 3 (EPR 3): Guidelines for the Diagnosis and Management of Asthma. NIH Publication no. 08-4051, 2007.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. Updated 2012. Available at www.ginasthma.org.

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CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. Codes may not be covered under all circumstances. Please read the policy and guideline statements carefully. Codes may not all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I). Not medically necessary/appropriate = (NMN).
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HCPCS:

UPDATES:

Date	Revision
11/12/2026	Reviewed / P&T Committee Approval
09/14/2026	Revised
08/13/2026	P&T Committee Review & Approval
06/01/2026	Revised
02/12/2026	P&T Committee Review & Approval
12/22/2025	Revised
11/19/2025	Revised
11/06/2025	Revised
03/06/2025	Revised
02/06/2025	P&T Committee Review & Approval
01/01/2025	Revised
06/24/2024	Revised
02/08/2024	Reviewed / P&T Committee Approval
12/06/2023	Revised
07/13/2023	Revised
05/01/2023	Revised
03/20/2023	Revised
02/27/2023	Revised
02/09/2023	P&T Committee Approval
08/2022	Revised
06/2022	Revised
02/2022	Created & Effective
02/2022	P&T Committee Approval

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1. Asthma data, statistics, and surveillance. Centers for Disease Control and Prevention (CDC) Web site. Available at: https://www.cdc.gov/asthma/asthmadata.htm. Last reviewed September 2021. **Accessed on 02/08/2024**.
2. Global Initiative for Asthma (GINA); Global Strategy for Asthma Management and Prevention; 2022. Available at http://www.ginasthma.org. **Accessed: 02/08/2024**
3. Tezspire™ subcutaneous injection [prescribing information]. Thousand Oaks, CA: Amgen; February 2023.

4. Corren J, Parnes JR, Wang L, et al. Tezepelumab in adults with uncontrolled asthma. *N Engl J Med*. 2017;377:936-946.
5. Estimated comparative daily doses for inhaled glucocorticoids in adolescents ≥ 12 years and adults. In: Post TW, ed. *UpToDate.* UpToDate; 2023. **Accessed July 13, 2023**.
6. Usual doses of combined inhaled glucocorticoids and bronchodilators. In: Post TW, ed. *UpToDate.* UpToDate; 2023. **Accessed July 13, 2023**.
7. Estimated comparative daily doses for inhaled glucocorticoids in children. In: Post TW, ed. *UpToDate.* UpToDate; 2023. **Accessed July 13, 2023**.
8. Tezspire™ subcutaneous injection [prescribing information]. Revised 10/2025. Manufacturer website.