Alvesco (ciclesonide)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Asthma is a common chronic inflammatory disease that causes respiratory symptoms, limitation of activity, and flare-ups (attacks) that sometimes require urgent health care and may be fatal. Asthma causes symptoms such as wheezing, shortness of breath, chest tightness and cough that vary over time

in their occurrence, frequency and intensity. These symptoms are associated with variable expiratory airflow (difficulty breathing air out of the lungs) due to airway narrowing (bronchoconstriction), airway wall thickening, and increased mucus. There are different types of asthma with different underlying disease processes.

Factors that may trigger or worsen asthma symptoms include viral infections, allergens at home or work (e.g. house dust mite, pollens, cockroach), tobacco smoke, exercise and stress. Asthma can also be induced or symptoms triggered by some drugs. Asthma flare-ups (also called exacerbations or attacks) can be fatal, but they tend to be more common and more severe when asthma is uncontrolled, and in some high-risk individuals. Since exacerbations may occur even in people taking asthma treatment, everyone with asthma should have an asthma action plan. Asthma treatment should be customized to the individual.

Treatment with inhaled corticosteroid (ICS)-containing medications markedly reduces the frequency and severity of asthma symptoms as well as the risk of exacerbations or dying of asthma. Per the Global Initiative for Asthma (GINA) guidelines, inhaled corticosteroids (ICSs) are the preferred pharmacologic treatment in the long-term management for all steps of therapy - typically combined with a long-acting beta-agonist (LABA). Alvesco (ciclesonide) inhalation is beneficial in treating asthma and is FDA approved for use in those12 years of age and older. Alvesco (ciclesonide) is not indicated for the relief of acute bronchospasms or in those less than 12 years of age. The recommended starting dose is based on prior asthma treatments (see Appendix, Table 2)

Definitions

"Allergy" refers to having both allergen-specific IgE and developing symptoms upon exposure to substances containing that allergen.

"Anaphylaxis" is a severe, systemic immune response (e.g., affecting more than 1 organ system) which may be characterized by flushing, trouble breathing, vomiting/diarrhea, swelling in the mouth/throat, rash, etc. It can be rapidly fatal without immediate treatment.

"Antigen" (or Allergen) refers to an offending substance that causes the allergic reaction through the immune system hypersensitivity. An antigen can be anything including molds, dust mites, cockroaches, certain types of pollen, or the venom of a bee sting.

"Exacerbation" or "Flare-up" refers to a worsening or an increase in the severity of a disease or its signs and symptoms. In asthma, an exacerbation refers to a period of worsening symptoms, such as increased shortness of breath, wheezing, or coughing, often requiring additional medication or healthcare intervention. Exacerbations are commonly triggered by allergens, infections, or other environmental factors.

"Trigger" refers to a stimulus that may worsen or cause an increase in asthma symptoms and/or airflow limitation. Triggers vary between individuals and may include allergens, respiratory infections, exercise, stress, air pollution, or exposure to irritants like tobacco smoke.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Asthma

The Plan considers Alvesco (ciclesonide) medically necessary when ALL the following criteria are met:

1. The member is 12 years of age or older*; AND*
2. The member has a documented diagnosis of asthma*; AND*
3. The requested product is being used as preventative therapy for asthma maintenance control*; AND*
4. The member is unable to use, or has adequately tried and failed (e.g., lack of symptom control, adverse effects, or intolerance) ALL the following formulary alternatives for at least a 30-day duration:
    a. Arnuity Ellipta (fluticasone furoate)*; and*
    b. Flovent (fluticasone propionate)*; and*
    c. QVAR (beclomethasone dipropionate)*; AND*
5. Chart documentation is provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Alvesco (ciclesonide) will be approved for up to 12-months.

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Asthma

The Plan considers Alvesco (ciclesonide) medically necessary when ALL the following criteria are met:

1. The member still meets the applicable initial criteria*; AND*
2. Chart documentation (e.g., progress notes, spirometry results, or patient-reported outcomes) shows the member has experienced therapeutic response to the requested medication as evidenced by ONE (1) of the following:
    a. clinical improvement in symptoms since starting the requested medication; *or*
    b. disease stability since starting the requested medication*; AND*

3. The member maintains adherence to the prescribed dosing regimen as evidenced by pharmacy claims record.

If the above prior authorization criteria are met, Alvesco (ciclesonide) will be approved for up to 12-months.

Experimental or Investigational / Not Medically Necessary

Alvesco (ciclesonide) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. 2020 Focused Updates to the Asthma Management Guidelines. A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group.
2. Alvesco (ciclesonide) [prescribing information]. Zug, Switzerland: Covis Pharmaceuticals; February 2023.
3. Clinical Pharmacology [Internet]. Elsevier. 2020. Available at: http://www.clinicalpharmacology.com. Accessed Sept 2021.
4. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEPPCC); Cloutier MM, Baptist AP, Blake KV, Brooks EG, Bryant-Stephens T, DiMango E, Dixon AE, Elward KS, Hartert T, Krishnan JA, Lemanske RF Jr, Ouellette DR, Pace WD, Schatz M, Skolnik NS, Stout JW, Teach SJ, Umscheid CA, Walsh CG. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. J Allergy Clin Immunol. 2020 Dec;146(6):1217-1270. doi: 10.1016/j.jaci.2020.10.003. Erratum in: J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530. doi: 10.1016/j.jaci.2021.02.010. PMID: 33280709; PMCID: PMC7924476.
5. Global Initiative for Asthma. Global strategy for asthma management and prevention, 2024. Updated May 2024. Available at: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf
6. Global Initiative for Asthma (GINA). GINA report, Global Strategy for Asthma Management and Prevention. https://ginasthma.org. Updated 2018.
7. Global Initiative for Asthma (GINA). GINA report, Global Strategy for Asthma Management and Prevention. https://ginasthma.org/wp-content/uploads/2019/06/GINA-2019-main-report-June-2019-wms.pdf. Updated 2019.
8. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/gina-reports/. Updated 2022.
9. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/gina-reports/. Updated 2025.
10. MayoClinic.org - Asthma. Available at: https://www.mayoclinic.org/diseases-conditions/asthma. Updated Aug 2020. Accessed Sept 2021.
11. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, CO.
12. U.S. Department of Veterans Affairs and the Department of Defense (VA/DoD). (2019). VA/DoD Clinical Practice Guideline: The Primary Care Management of Asthma. Available at: https://www.healthquality.va.gov/guidelines/CD/asthma/VADoDAsthmaCPGFinal121019.pdf.

Appendix A

Table 1: Classification Of Asthma Severity

Asthma Classification	Signs and Symptoms
Mild intermittent	Mild symptoms up to two days a week and up to two nights a month, typically without symptoms between exacerbations.
Mild persistent	Symptoms more than twice a week, but no more than once in a single day, exacerbations may impact activity.
Moderate persistent	Symptoms dailyonce a day and more than one night a week, exacerbations occurring two or more times a week.
Severe persistent	Symptoms throughout the day on most days and frequently at night, symptoms limit physical activity.

Table 2: Alvesco (ciclesonide) Dosage Information

Previous Therapy	Recommended Starting Dose	Highest Recommended Dose
Those who previously received bronchodilators alone	80 mcg twice daily	160 mcg twice daily
Those who previously received inhaled corticosteroids	80 mcg twice daily	320 mcg twice daily
Those who previously received oral corticosteroids	320 mcg twice daily	320 mcg twice daily

Clinical Guideline Revision / History Information

Original Date: 10/14/2021

Reviewed/Revised: 12/01/2021, 06/23/2022, 06/29/2023, 12/19/2024, 01/01/2026