

## 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.

**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
Mild persistent	Symptoms more than twice a week, but no more than once in a single day

Moderate persistent	Symptoms once a day and more than one night a week
Severe persistent	Symptoms throughout the day on most days and frequently at night

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 patients. Since flare-ups may occur even in people taking asthma treatment, all patients should have an asthma action plan. Asthma treatment should be customized to the individual patient.

Treatment with inhaled corticosteroid (ICS)-containing medications markedly reduces the frequency and severity of asthma symptoms as well as the risk of flare-ups or dying of asthma. Inhaled corticosteroids (ICSs) are the preferred pharmacologic treatment in the long-term management of persistent asthma for most patients. Alvesco [ciclesonide] inhalation is beneficial in treating asthma and is FDA approved for use in adult and pediatric patients 12 years of age and older.

**Table 2: Alvesco Dosage Information**

Previous Therapy	Recommended Starting Dose	Highest Recommended Dose
Patients ≥12 years who received bronchodilators alone	80 mcg twice daily	160 mcg twice daily
Patients ≥12 years who received inhaled corticosteroids	80 mcg twice daily	320 mcg twice daily
Patients ≥12 years who received oral corticosteroids	320 mcg twice daily	320 mcg twice daily

### 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. For example, an exacerbation of asthma might occur as a result of exposure to a trigger leading to shortness of breath or an acute asthma attack.

“**Trigger**” refers to a stimulus that may worsen or cause an increase in asthma symptoms and/or airflow limitation.

### Medical Necessity Criteria for Initial Authorization

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 **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 12-months.**

### Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **ALL** of the following are met:

1. the member still meets the applicable initial criteria; **AND**
2. chart documentation shows the member has experienced therapeutic response to the requested medication as evidenced by **ONE** 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.

### 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.
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4. Global Initiative for Asthma (GINA). GINA report, Global Strategy for Asthma Management and Prevention. <https://ginasthma.org>. Updated 2018.
5. 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.
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### Clinical Guideline Revision / History Information

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