

CARE VALUE POLICY

- POLICY:** Pulmonary – Corticosteroid Inhalers Care Value Policy
- Alvesco® (ciclesonide inhalation aerosol – Sunovion)
 - ArmonAir® Digihaler® (fluticasone propionate inhalation powder – Teva Respiratory)
 - Arnuity™ Ellipta® (fluticasone furoate inhalation powder – GlaxoSmithKline)
 - Asmanex® HFA (mometasone inhalation aerosol – Merck)
 - Asmanex® Twisthaler® (mometasone inhalation powder – Merck)
 - Flovent® Diskus® (fluticasone inhalation powder – GlaxoSmithKline)
 - Flovent® HFA (fluticasone inhalation aerosol – GlaxoSmithKline)
 - Pulmicort Flexhaler® (budesonide inhalation powder – Astra Zeneca)
 - Qvar® RediHaler™ (beclomethasone HFA inhalation aerosol – Teva Respiratory)

REVIEW DATE: 02/03/2021

OVERVIEW

All of the corticosteroid inhalers are indicated for the **maintenance treatment of asthma**.¹⁻⁹ Flovent (Diskus and HFA), Qvar RediHaler, and Asmanex Twisthaler are approved for patients ≥ 4 years of age; Arnuity Ellipta, and Asmanex HFA are approved for patients ≥ 5 years of age; Pulmicort Flexhaler is approved for patients ≥ 6 years of age; Alvesco and ArmonAir Digihaler are approved for patients ≥ 12 years of age. None of the corticosteroid inhalers are indicated for the relief of acute bronchospasm.

Guidelines

The Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention (2020) refer to the inhaled corticosteroids as a class; one product is not preferred over any other.¹² However, some devices may be more preferable for certain patients due to individual patient preferences and device characteristics.

Eosinophilic Esophagitis

Eosinophilic esophagitis is chronic allergic/immune condition of the esophagus.¹³ Pharmacologic treatments for eosinophilic esophagitis include acid suppression to treat gastroesophageal reflux disease and topical glucocorticoids to decrease esophageal inflammation. No formulation of topical/inhaled glucocorticoids is FDA-approved for eosinophilic esophagitis. However, among the inhaled corticosteroids, fluticasone and budesonide have the most data to support their use in this condition. Fluticasone is administered using an MDI (e.g., Flovent HFA) without a spacer. The medication is sprayed into the patient's mouth and then swallowed. Ciclesonide and mometasone have also been studied for the treatment of eosinophilic esophagitis. However, additional studies are needed before these agents can be routinely recommended for this use. The American College of Gastroenterology (ACG) published guidelines on the diagnosis and management of eosinophilic esophagitis (2013) recommend fluticasone or budesonide (swallowed not inhaled) as first-line pharmacologic therapy for the treatment of eosinophilic esophagitis.¹⁴

POLICY STATEMENT

This program has been developed to encourage the use of a Preferred Product prior to the use of a Non-Preferred Product. If the Step Therapy rule is not met for the Non-Preferred Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Preferred Product within the 130-day look-back period is excluded from Step Therapy.

Basic Formulary and National Preferred Formulary:

Preferred Products: Arnuity Ellipta, Asmanex Twisthaler, Asmanex HFA, Flovent HFA, Flovent Diskus, Pulmicort Flexhaler, Qvar RediHaler

Non-Preferred Products: Alvesco, ArmonAir Digihaler

CRITERIA

1. If the patient has tried one Preferred Product, approve a Non-Preferred Product.
2. No other exceptions are recommended.

High Performance Formulary:

Preferred Products: Qvar RediHaler

Non-Preferred Products: Alvesco, ArmonAir Digihaler, Arnuity Ellipta, Asmanex Twisthaler, Asmanex HFA, Flovent HFA, Flovent Diskus, Pulmicort Flexhaler

CRITERIA

1. If the patient has tried one Preferred Product, approve a Non-Preferred Product.
2. If the patient is being treated for eosinophilic esophagitis, approve Flovent HFA.
3. No other exceptions are recommended.

REFERENCES

1. Alvesco[®] inhalation aerosol [prescribing information]. Marlborough, MA. Sunovion Pharmaceuticals Inc.; January 2013.
2. Asmanex[®] HFA inhalation aerosol [prescribing information]. Whitehouse Station, NJ. Merck & Co., Inc.; August 2019.
3. Asmanex[®] Twisthaler[®] inhalation powder [prescribing information]. Whitehouse Station, NJ. Merck & Co., Inc.; December 2019.
4. Flovent[®] Diskus[®] inhalation powder [prescribing information]. Research Triangle Park, NC. GlaxoSmithKline; January 2019.
5. Flovent[®] HFA inhalation aerosol [prescribing information]. Research Triangle Park, NC. GlaxoSmithKline; January 2019.
6. Pulmicort Flexhaler[®] inhalation powder [prescribing information]. Wilmington, DE. Astra Zeneca; September 2019.
7. Arnuity[™] Ellipta[®] inhalation powder [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.

8. ArmonAir® Digihaler® inhalation powder [prescribing information]. Frazer, PA: Teva Respiratory; September 2020.
9. Qvar® RediHaler® inhalation aerosol [prescribing information]. Frazer, PA: Teva Respiratory; January 2021.
10. Brocklebank D, Wright J, Cates C on behalf of the National Health Technology Assessment Inhaler Review Group. Systematic review of clinical effectiveness of pressurised metered dose inhalers versus other hand held inhaler devices for delivering corticosteroids in asthma. *BMJ*. 2001;323:896-900.
11. Dolovich MB, Ahrens RC, Hess DR, et al. Device selection and outcomes of aerosol therapy: evidence-based guidelines: American College of Chest Physicians/American College of Asthma, Allergy, and Immunology. *Chest*. 2005;127:335-371.
12. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2020. Accessed on January 27, 2021. Available at: <http://www.ginasthma.org>.
13. Bonis PAL, Gupta SK. Treatment of eosinophilic esophagitis. Version 57.0. ©2020 UpToDate, Inc. Last updated: Dec 8, 2020. Available at: www.uptodate.com. Accessed on: 01/27/2021.
14. Dellon ES, Gonsalves N, Hirano I, et al. ACG clinical guideline: Evidenced based approach to the diagnosis and management of esophageal eosinophilia and eosinophilic esophagitis (EoE). *Am J Gastroenterol*. 2013;108(5):679-92.