Clinical Policy: Ciclesonide (Alvesco)

Reference Number: HIM.PA.65
Effective Date: 09.01.18
Last Review Date: 08.20
Line of Business: HIM

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Ciclesonide (Alvesco®) is an inhaled corticosteroid.

FDA Approved Indication(s)

Alvesco is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and adolescent patients 12 years of age and older.

Limitation(s) of use: Alvesco is not indicated for the relief of acute bronchospasm.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Alvesco is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Asthma (must meet all)**:**

1. Diagnosis of asthma;
2. Age ≥ 12 years;
3. Failure of one formulary inhaled corticosteroid (e.g., Arnuity® Ellipta®, Asmanex®, Flovent®, Pulmicort Flexhaler®, QVAR®) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 640 mcg per day (2 inhalers per 30 days).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Asthma (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;

3. If request is for a dose increase, new dose does not exceed 640 mcg per day (2 inhalers per 30 days).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Arnuity Ellipta (fluticasone furoate)	≥ 12 years: 100-200 mcg inhaled QD 5-11 years: 50 mcg inhaled QD	≥ 12 years: 200 mcg/day 5-11 years: 50 mcg/day
Asmanex HFA (mometasone)	≥ 12 years: 2 puffs (100-200 mcg/puff) inhaled BID 5-11 years: 2 puffs (50 mcg/puff) inhaled BID	≥ 12 years: 800 mcg/day 5-11 years: 200 mcg/day
Asmanex Twisthaler (mometasone)	Starting dose for patients ≥ 12 years who received bronchodilators or inhaled corticosteroids: 220 mcg inhaled QD in the evening	440 mcg/day (can be administered as 220 mcg BID or 440 mcg QD)
	Starting dose for patients ≥ 12 years who received oral corticosteroids: 440 mcg inhaled BID	880 mcg/day
	Starting dose for patients 4-11 years: 110 mcg inhaled QD in the evening	110 mcg/day
Flovent Diskus (fluticasone propionate)	≥ 12 years: 100 mcg inhaled BID 4-11 years: 50 mcg inhaled BID	≥ 12 years: 2,000 mcg/day 4-11 years: 200 mcg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Flovent HFA (fluticasone propionate)	88 mcg inhaled BID	≥ 12 years: 1,760 mcg/day 4-11 years: 176 mcg/day
Pulmicort Flexhaler (budesonide)	≥ 18 years: 360 mcg inhaled BID 6-17 years: 180 mcg inhaled BID; some patients may start with adult dosing	≥ 18 years: 1,440 mcg/day 6-17 years: 720 mcg/day
QVAR, QVAR RediHaler (beclomethasone)	≥ 12 years: 40 mcg, 80 mcg, 160 mcg, or 320 mcg inhaled BID 4-11 years: 40 mcg or 80 mcg inhaled BID	≥ 12 years: 640 mcg/day 4-11 years: 160 mcg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): status asthmaticus or other acute episodes of asthma where intensive measures are required, known hypersensitivity to ciclesonide or any of the ingredients of Alvesco
- Boxed warning(s): none reported

Appendix D: General Information

- Use in pediatric patients < 12 years of age: Two identically designed randomized, double-blind, parallel, placebo-controlled clinical trials of 12-weeks treatment duration were conducted in 1,018 patients aged 4 to 11 years with asthma but efficacy was not established. In addition, one randomized, double-blind, parallel, placebo-controlled clinical trial did not establish efficacy in 992 patients aged 2 to 6 years with asthma.
- Historical management of asthma has involved an as-needed short-acting beta agonist for reliever therapy, with stepwise approach to add on controller maintenance therapies such as inhaled corticosteroids and long-acting beta agonists. In 2019, the Global Initiative for Asthma (GINA) guidelines for asthma management and prevention began recommending that inhaled corticosteroids be initiated as soon as possible after diagnosis of asthma, including use as reliever therapy (to be administered as-needed alongside a short-acting beta agonist).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Asthma	Starting dose for patients who received bronchodilators alone: 80 mcg inhaled BID	320 mcg/day
	Starting dose for patients who received inhaled corticosteroids: 80 mcg inhaled BID	640 mcg/day
	Starting dose for patients who received oral corticosteroids: 320 mcg inhaled BID	640 mcg/day

VI. Product Availability

Inhalation aerosol: 80 mcg/actuation, 160 mcg/actuation

VII. References

1. Alvesco Prescribing Information. Marlborough, MA: Sunovion Pharmaceuticals Inc.; April 2019. Available at http://www.alvesco.us. Accessed April 13, 2020.
2. National Heart, Lung, and Blood Institute. Expert panel report 3: guidelines for the diagnosis and management of asthma. National Asthma Education and Prevention Program. Published August 28, 2007. Available from: https://www.nhlbi.nih.gov/health-topics/guidelines-for-diagnosis-management-of-asthma. Accessed April 13, 2020.
3. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2020 report). Available from: www.ginasthma.org. Accessed April 6, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policy split from HIM.PA.73 Inhaled corticosteroids to individual Alvesco policy; no significant changes; age added; quantity limit added based on maximum dose; references reviewed and updated.	04.17.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	04.22.19	08.19
3Q 2020 annual review: no significant changes; added Arnuity Ellipta and Asmanex HFA as preferred options per core Ambetter formulary; references reviewed and updated.	04.13.20	08.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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