Clinical Policy: Aclidinium/Formoterol (Duaklir Pressair)

Reference Number: IL.ERX.PMN.200
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

Revision Log

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

Description
Aclidinium/formoterol (Duaklir® Pressair®) is a combination product containing a long-acting anticholinergic and a long-acting beta-2 agonist.

FDA Approved Indication(s)
Duaklir Pressair is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

Limitation(s) of use: Duaklir Pressair is not indicated for relief of acute bronchospasm or for the treatment of asthma.

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 Envolve Pharmacy Solutions that Duaklir Pressair is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Diagnosis of COPD;
2. Age ≥ 18 years;
3. Failure of one of the following (a or b) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced:
   a. One formulary long-acting beta-2 agonist (e.g., Serevent®) in combination with Spiriva®;
   b. One formulary inhaled corticosteroid in combination with a formulary long-acting beta-2 agonist (e.g., Symbicort®, Wixela®);
4. Dose does not exceed 2 inhalations per day (1 inhaler per 30 days).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under Section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 2 inhalations per day (1 inhaler per 30 days).

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents;

B. Asthma.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration

Appendix B: Contraindications/Boxed Warnings

- Contraindications: hypersensitivity; use of a long-acting beta2-adrenergic agonist (LABA), including formoterol fumarate, one of the active ingredients in Duaklir Pressair, without an inhaled corticosteroid in patients with asthma.
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COPD	One inhalation by mouth BID	2 inhalations/day

VI. Product Availability

Inhalation powder: 30 and 60 metered dose dry powder inhaler metering 400 mcg aclidinium bromide and 12 mcg formoterol fumarate per actuation

VII. References

1. Duaklir Pressair Prescribing Information. Morrisville, NC: Circassia Pharmaceuticals Inc.; March 2019. Accessed April 2, 2019.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2018 report). Published January 2018. Available at: http://www.goldcopd.org/. Accessed April 9, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.