

Clinical Policy: Acclidinium/Formoterol (Duaklir Pressair)

Reference Number: CP.PCH.23

Effective Date: 03.01.20

Last Review Date: 02.20

Line of Business: Commercial, HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Acclidinium/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 Centene Corporation[®] 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 \geq 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 one formulary long-acting anticholinergic (e.g., Incruse[®] Ellipta[®], Spiriva[®] Handihaler[®]/Respimat[®]);
 - b. One formulary inhaled corticosteroid in combination with a formulary long-acting beta-2 agonist (e.g., generic Advair[®] Diskus[®]/Wixela[™] Inhum[™], Advair[®] HFA, Breo[®] Ellipta[®], Symbicort[®]);
4. Dose does not exceed 2 inhalations per day (1 inhaler per 30 days).

Approval duration:

HIM – 12 months

Commercial – Length of Benefit

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): CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Chronic Obstructive Pulmonary Disease (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 2 inhalations per day (1 inhaler per 30 days).

Approval duration:

HIM – 12 months

Commercial – Length of Benefit

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): CP.CPA.09 for commercial and 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 – CP.CPA.09 for commercial and HIM.PHAR.21 for health insurance marketplace 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: 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
Incruse Ellipta® (umeclidinium)	1 inhalation (62.5 mcg) QD	62.5 mcg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Symbicort [®] (budesonide/ formoterol)	2 inhalations of 160/4.5 mcg BID	2 inhalations of 160/4.5 mcg BID
Serevent [®] (salmeterol)	1 inhalation (50 mcg) BID	100 mcg/day
Tudorza Pressair [®] (aclidinium)	1 inhalation (400 mcg) BID	800 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

- 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 per SDC and prior clinical guidance (adapted from HIM.PA.06 which is being retired); revised examples of formulary products appropriate for redirection by removing Tudorza Pressair, adding Advair [®] HFA, and clarifying generic Advair Diskus/Wixela Inhum.	01.21.20	02.20

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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