Clinical Policy: LAMA/LABA Combination Inhalers

Reference Number: AZ.CP.PMN.1021
Effective Date: 01.27.2020
Last Review Date: 07.20
Line of Business: Arizona Medicaid (AzCH-CCP and Care1st) Revision Log

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

Description

The following drugs are combination product containing a long-acting anticholinergic (LAMA) and a long-acting beta-2 agonist (LABA):

- Aclidinium and formoterol (Duaklir Pressair®),
- Glycopyrrolate and formoterol (Bevespi Aerosphere®)
- Glycopyrrolate and indacaterol/ (Utibron™ Neohaler®)
- Tiotropium and olodaterol (Stiolto® Respimat®)
- Umeclidinium and vilanterol (Anoro Ellipta®)

AHCCCS preferred drugs in this class include: glycopyrrolate and formoterol (Bevespi Aerosphere®), tiotropium and olodaterol (Stiolto Respimat®).

AHCCCS non-preferred drugs in this class include: umeclidinium and vilanterol (Anoro Ellipta®), aclidinium and formoterol (Duaklir Pressair®), glycopyrrolate and indacaterol (Utibron®).

FDA Approved Indication(s)

Refer to Prescribing Information of each product.

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 Arizona Complete Health-Complete Care Plan and Care1st that Anoro Ellipta, Bevespi Aerosphere, Duaklir Pressair, Stiolto Respimat, and Utibron Neohaler are **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 LABA (e.g., Serevent®) in combination with one formulary LAMA (e.g., Tudorza® Pressair®, Spiriva Handihaler®);
   b. One formulary inhaled corticosteroid (ICS) in combination with a formulary LABA (e.g., Symbicort®);

4. For Anoro Ellipta, Duaklir Pressair, and Utibron Neohaler, failure of both of the following at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (a and b):
   a. Bevespi Aerosphere;
   b. Stiolto Respimat;
5. Dose does not exceed maximum dose indicated in Section V.

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): AZ.CP.PMN.53 for Arizona Medicaid.

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 does not exceed maximum dose indicated in Section V.

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): AZ.CP.PMN.53 for Arizona Medicaid.

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 – AZ.CP.PMN.53 for Arizona Medicaid;

B. Asthma.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration
GOLD: Global Initiative for Chronic Obstructive Lung Disease
ICS: inhaled corticosteroid
LABA: long-acting beta$_2$ adrenergic agonist

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LAMA: long-acting anticholinergic

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
Bevespi Aerosphere (glycopyrrolate and formoterol)	2 inhalations of 9/4.8 mcg BID	2 inhalations of 9/4.8 mcg BID
Symbicort (budesonide/ formoterol)	2 inhalations of 80/4.5 mcg BID	2 inhalations of 80/4.5 mcg BID
Serevent (salmeterol)	1 inhalation (50 mcg) BID	100 mcg/day
Spiriva Handihaler (tiotropium)	2 inhalations of 1 capsule (18 mcg) QD	1 capsule (18 mcg) in 24 hours
Stiolto Respimat (tiotropium and olodaterol)	2 inhalations of 2.5/2.5 mcg QD	2 inhalations of 2.5/2.5 mcg in 24 hours
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
- Contraindication(s):
  - Refer to Prescribing Information of each product
- Boxed warning(s):
  - Refer to Prescribing Information of each product

Appendix D: General Information
- Per the 2019 GOLD COPD guidelines, combination therapy (LAMA + LABA, ICS + LABA, or ICS + LAMA + LABA) is recommended for Group D patients (i.e., those who are very symptomatic and are at high risk of exacerbation). Selection of which combination to use depends on the individual patient:
  - For those with more severe symptoms, LAMA + LABA may be used.
  - For those with a history of asthma or blood eosinophil counts at least 300 cells/uL, LABA + ICS may be used.
  - For those who are inadequately controlled by dual therapy, triple therapy with ICS + LAMA + LABA may be used.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Umeclidinium and vilanterol (Anoro Ellipta®)	COPD	One inhalation by mouth QD	1 inhalation/day
Glycopyrrolate and formoterol (Bevespi Aerosphere®)		Two inhalation by mouth BID	4 inhalations/day
Aclidinium and formoterol (Duaklir Pressair®)		One inhalation by mouth BID	2 inhalations/day
Tiotropium and olodaterol (Stiolto® Respimat®)		Two inhalations by mouth QD at the same time of day	2 inhalations/day
Glycopyrrolate and indacaterol/ (Utibron™ Neohaler®)		Inhalation of the contents of one capsule BID	2 capsules/day

VI. Product Availability

Refer to Prescribing Information of each product.

VII. References

1. Anoro Ellipta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; July 2019. Available at http://www.anoro.com/. Accessed April 13, 2020.
2. Bevespi Aerosphere Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2019. Available at https://www.bevespi.com/. Accessed January 18, 2020.
3. Duaklir Pressair Prescribing Information. Morrisville, NC: Circassia Pharmaceuticals Inc.; March 2019. Accessed April 15, 2020.
4. Stiolto Respimat Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2019. Available at https://www.stiolto.com/. Accessed April 15, 2020.
5. Utibron Neohaler Prescribing Information East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019. Available at https://www.utibron.com/. Accessed April 15, 2020.
6. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2020 report). Published January 20120. Available at: http://www.goldcopd.org/. Accessed April 13, 2020.

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	01.18.2020	01.20
3Q 2020 annual review: no significant changes; references reviewed and updated.	07.10.20	07.20
Added Care1st logo. Added verbiage to specify that criteria also applies to Care1st.	5.10.21	04.21

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. 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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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.