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Coverage Policy Number **IP0020**

Long-Acting Muscarinic Antagonist (LAMA)/Long-Acting Beta$_2$-Agonist (LABA) Combination Inhalers

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for formulary exceptions to the following long-acting muscarinic antagonist (LAMA)/long-acting beta$_2$-agonist (LABA) combination non-covered inhalers:

- **Bevespi Aerosphere™** (glycopyrrolate/ formoterol)
- **Duaklir® Pressair®** (aclidinium bromide and formoterol fumarate)

Coverage for long-acting muscarinic antagonist (LAMA)/long-acting beta$_2$-agonist (LABA) combination products varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products **in below table:**

Non-Covered Product	Criteria:
Bevespi Aerosphere (glycopyrrolate/ formoterol)	**<u>Standard/Performance/Legacy/Value/Advantage/Cigna Total Savings:</u>** **Bevespi Aerosphere is considered medically necessary for the treatment of chronic obstructive pulmonary disease (COPD) when the individual meets ONE of the following criteria:** 1. Failure, contraindication, or intolerance to **BOTH** of the following: a. Anoro Ellipta (umeclidinium/vilanterol) b. Stiolto Respimat (tiotropium/olodaterol) 2. For an individual with low inspiratory flow rate and unable to use a dry powder inhaler (DPI), failure, contraindication, or intolerance to Stiolto Respimat (tiotropium/olodaterol)
Duaklir Pressair (aclidinium bromide and formoterol fumarate)	**<u>Standard/Performance/Legacy/Value/Advantage/Cigna Total Savings:</u>** **Duaklir Pressair is considered medically necessary for the treatment of chronic obstructive pulmonary disease (COPD) when the individual meets the following criteria:** Documented failure, contraindication, or intolerance to **BOTH** of the following: 1. Anoro Ellipta (umeclidinium/vilanterol) 2. Stiolto Respimat (tiotropium/olodaterol)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy

Continuation of long-acting muscarinic antagonist (LAMA)/long-acting beta$_2$-agonist (LABA) combination inhalers are considered medically necessary for chronic obstructive pulmonary disease when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven.

Background

OVERVIEW
Anoro Ellipta, Bevespi Aerosphere, Duaklir Pressair, and Stiolto Respimat are long-acting muscarinic antagonist (LAMA)/long-acting beta$_2$-agonist (LABA) combination inhalers.[1-4] Anoro Ellipta, Bevespi Aerosphere, and Duaklir Pressair are indicated for the maintenance treatment of individuals with chronic obstructive pulmonary disease (COPD).[1,2,4] Stiolto Respimat is similarly indicated for the long-term, once daily maintenance treatment of individuals with COPD.[3]

Anoro Ellipta and Duaklir Pressair are dry-powder inhalers (DPIs).[1,4] Bevespi Aerosphere is a pressurized metered-dose inhaler (MDI).[2] Stiolto Respimat is a soft-mist inhalation spray that is propellant-free and utilizes mechanical energy to generate a slow-moving, very-fine liquid aerosol cloud.[3,5-7] Current COPD guidelines from the Global Initiative for Chronic Obstructive Lung Disease (2023) states that individual patient characteristics should be considered when choosing an appropriate inhalation device. DPIs should only be used if the patient can make a forceful and deep inhalation. MDIs, and to a lesser extent, soft mist inhalers, require coordination between device actuation and inhalation. Therefore, patients must be able to perform a slow and deep inhalation. If this is an issue, a spacer or valved holding chamber should be used, or the patient should chose an alternative device.

References

1. Anoro Ellipta inhalation powder [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; October 2022.
2. Bevespi Aerosphere inhalation aerosol [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; November 2020.
3. Stiolto Respimat inhalation spray [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; May 2019.
4. Duaklir Pressair inhalation powder [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2019.
5. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2021 report. Global Initiative for Chronic Obstructive Lung Disease, Inc. Available from: http://goldcopd.org/. Accessed on November 17, 2022.
6. Yawn BP, Colice GL, Hodder R. Practical aspects of inhaler use in the management of chronic obstructive pulmonary disease in the primary care setting. Int J Chron Obstruct Pulmon Dis. 2012;7:495-502.
7. Tashkin DP. A review of nebulized drug delivery in COPD. Int J Chron Obstruct Pulmon Dis. 2016;11:2585-2596.