Oscar Clinical Guideline: Duaklir (aclidinium/formoterol) (PG107, Ver. 7)

Duaklir (aclidinium/formoterol)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Chronic obstructive pulmonary disease (COPD) is a long-term inflammatory lung disease that causes persistent respiratory symptoms and airflow limitation due to airway abnormalities often resulting from significant exposure to noxious particles or gases. Symptoms include breathing difficulty, cough, mucus (sputum) production and wheezing. The main risk factor for COPD is tobacco smoking, but other environmental exposures such as fuel exposure and air pollution may contribute. Aside from exposures, individual factors, such as history of infections (e.g. childhood pneumonia, tuberculosis, human immunodeficiency virus [HIV]) genetic abnormalities, abnormal lung development, and sex (female sex provides a higher risk of COPD), predispose individuals to develop COPD as well.

COPD is associated with significant concomitant chronic diseases, which increase its morbidity and mortality. Emphysema and chronic bronchitis are the two most common conditions that contribute to COPD. People with COPD are at increased risk of developing heart disease, lung cancer and a variety of other conditions. Although COPD is a progressive disease that gets worse over time, it is treatable. With proper management, most people with COPD can achieve good symptom control and quality of life, as well as reduced risk of other associated conditions.

According to the 2026 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, for patients not currently on maintenance therapy, GOLD recommends the following:

- A bronchodilator for Group A (low symptom burden and low exacerbation history), or
- Dual bronchodilator therapy with a long-acting beta-2 agonist (LABA)/long-acting muscarinic antagonists (LAMA)* for Groups B (more symptomatic, low exacerbation history) and E (high risk of exacerbation)
- In Group E, initiation of LABA/LAMA/inhaled corticosteroid (ICS) may be considered when blood eosinophils are ≥300 cells/μL.

*GOLD also notes that single-inhaler therapy may be more convenient and effective than multiple inhalers and may improve adherence.

Duaklir (aclidinium/formoterol) is a combination of aclidinium, a respiratory long-acting muscarinic antagonist (LAMA) or anticholinergic, and formoterol, a long-acting beta-2 agonist (LABA) that is FDA approved for the maintenance treatment of chronic obstructive pulmonary disease (COPD) in adults. Duaklir (aclidinium/formoterol) is not approved for the treatment of asthma and should not be used to treat acute bronchospasm. Both LAMAs and LABAs reduce the risk of COPD exacerbations. LAMA/LABA combination therapy is associated with greater improvements in lung function compared to monotherapy.

Definitions

"Chronic bronchitis" is inflammation of the lining of the bronchial tubes, which carry air to and from the air sacs (alveoli) of the lungs. It is characterized by a chronic daily cough and mucus (sputum) production.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Emphysema" is a condition in which the fragile walls and elastic fibers of the alveoli at the end of the smallest air passages (bronchioles) of the lungs are destroyed. Small airways collapse during exhalation, impairing airflow out of a person's lungs.

"Eosinophil"is a type of white blood cell and is part of the immune system's response to allergens, parasites, and certain infections. Higher levels of eosinophils in COPD may contribute to inflammation and airway obstruction.

"Exacerbation" or "Flare-up" refers to a worsening or an increase in the severity of a disease or its signs and symptoms. For example, an exacerbation might occur as a result of exposure to a trigger leading to shortness of breath.

"Trigger" refers to a stimulus that may worsen or cause an increase in symptoms and/or airflow limitation.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Chronic Obstructive Pulmonary Disease (COPD)

The Plan considers Duaklir (aclidinium/formoterol) medically necessary when ALL the following criteria are met:

1. The member is 18 years of age or older*; AND*
2. The member has a documented diagnosis of COPD (including chronic bronchitis or emphysema)*; AND*
3. The requested product is being used as maintenance treatment for COPD exacerbations (i.e., NOT for relief of acute symptoms of bronchospasm)*; AND*
4. The member is unable to use, or has tried and failed (e.g., lack of symptom control, adverse effects, or intolerance) BOTH of the following alternatives[s]:
    a. Anoro Ellipta (umeclidinium/vilanterol)*; and*
    b. Bevespi (glycopyrrolate/formoterol)*; AND*

5. Duaklir (aclidinium/formoterol) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above prior authorization criteria are met, the requested product will be approved for up to 12-months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Chronic Obstructive Pulmonary Disease (COPD)

The Plan considers Duaklir (aclidinium/formoterol) medically necessary when ALL the following criteria are met:

1. The member meets the above applicable Initial Clinical Review; *AND*
2. Chart documentation (e.g., progress notes, spirometry results, or patient-reported outcomes) shows the member has experienced therapeutic response to the requested medication as evidenced by ONE (1) of the following:
    a. clinical improvement in symptoms since starting the requested medication; *or*
    b. disease stability since starting the requested medication.

If the above prior authorization criteria are met, the requested product will be approved for up to 12-months.[s]

Experimental / Investigational, unproven[s]

Duaklir (aclidinium/formoterol) for any other use is considered experimental, investigational, or unproven.

References

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Clinical Guideline Revision / History Information

Original Date: 10/14/2021

Reviewed/Revised: 12/01/2021, 06/23/2022, 06/29/2023, 12/19/2024, 01/01/2026, 01/04/2027