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 patient factors, such as genetic abnormalities, abnormal lung development and accelerated aging, 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 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for COPD, long-acting beta-2 agonists (LABAs) may be used as initial monotherapy in patients in Groups A and B. In Group C patients, long-acting muscarinic antagonists (LAMAs) are preferred as initial therapy over LABAs due to effectiveness in preventing exacerbations. In Group D patients, LABAs are used as initial therapy in combination with inhaled corticosteroids (ICS) or LAMAs. If the patient has exacerbations, triple therapy with a LAMA, a LABA, and ICS can be considered.

Duaklir [aclidinium/formoterol] is a combination of aclidinium, a respiratory long-acting muscarinic antagonist (LAMA), 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. According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, Duaklir [aclidinium/formoterol] may be used as initial therapy for patients in group D (those with a high risk of exacerbation). 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.

"**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.

"**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.

Medical Necessity Criteria for Initial Authorization

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 adequately tried and failed (e.g., lack of symptom control, adverse effects, or intolerance) **BOTH** of the following for at least a 30 day duration:
    a. Anoro Ellipta (umeclidinium/vilanterol)***; and***
    b. Bevespi (glycopyrrolate/formoterol)***; AND***
5. Chart documentation is provided for review to validate the above-listed requirements.

If the above prior authorization criteria are met, Duaklir (aclidinium/formoterol) will be approved for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if **ALL** of the following are met:

1. the member still meets the applicable initial criteria***; 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** of the following:
    a. clinical improvement in symptoms since starting the requested medication; ***or***
    b. disease stability since starting the requested medication***; AND***
3. the member maintains adherence to the prescribed dosing regimen as evidenced by pharmacy claims record.

Experimental or Investigational / Not Medically Necessary

Duaklir (aclidinium/formoterol) for any other indication is considered not medically necessary by the Plan, as it is deemed to be 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