

PREFERRED STEP THERAPY POLICY

POLICY: Pulmonary – Long-Acting Muscarinic Antagonist/Long-Acting Beta₂-Agonist Combination Inhalers Preferred Step Therapy Policy

- Anoro[®] Ellipta[®] (umeclidinium and vilanterol inhalation powder – GlaxoSmithKline)
- Bevespi Aerosphere[®] (glycopyrrolate and formoterol fumarate inhalation aerosol – AstraZeneca)
- Duaklir[®] Pressair[®] (aclidinium bromide and formoterol fumarate inhalation powder – AstraZeneca)
- Stiolto[®] Respimat[®] (tiotropium bromide and olodaterol inhalation spray – Boehringer Ingelheim)

REVIEW DATE: 10/21/2020

OVERVIEW

Anoro Ellipta, Bevespi Aerosphere, Duaklir Pressair, and Stiolto Respimat are long-acting muscarinic antagonist (LAMA)/long-acting beta₂-agonist (LABA) combination inhalers.^{1,4} Anoro Ellipta, Bevespi Aerosphere, and Duaklir are indicated for the maintenance treatment of patients with **chronic obstructive pulmonary disease** (COPD).^{1,2,4} Stiolto Respimat is similarly indicated for the long-term, once daily maintenance treatment of patients with COPD.³ Utibron[®] Neohaler[®] (indacaterol and glycopyrrolate inhalation powder) is another LAMA/LABA inhaler that is similarly indicated, but is not targeted in this policy.⁵

Anoro Ellipta and Duaklir Pressair are dry-powder inhalers (DPIs).^{1,4} In general, DPIs are convenient, portable, and provide rapid medication delivery.⁶⁻⁸ However, they require the patient to generate a certain inspiratory flow to properly deliver the drug to the lungs. Elderly patients, as well as patients with hyperinflation and flattened diaphragms may not be able to achieve the required inspiratory flow. Patients who are cognitively impaired may have difficulty using DPIs as well. Bevespi Aerosphere is a pressurized metered-dose inhaler (MDI).² MDIs are convenient and portable; however, they require training and skill to use properly.⁶⁻⁸ If used alone, the MDI actuation must be closely coordinated with the start of the patient's inhalation. This may be difficult to achieve, especially for patients with arthritis or hand deformities, or patients with muscle weakness. If used with a spacer, pMDIs are easier to use and more effective. 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.^{3,6-8} The Respimat inhaler requires less coordination between device actuation and inhalation than a traditional MDI. Current COPD guidelines note that randomized controlled trials have not identified superiority of any one device or formulation.⁶

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. NOTE: Utibron Neohaler is not targeted in this policy. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

Step 1: Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat

Step 2: Duaklir Pressair

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

REFERENCES

1. Anoro[®] Ellipta[®] inhalation powder [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; June 2019.
2. Bevespi Aerosphere[®] inhalation aerosol [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2019.
3. Stiolto[®] Respimat[®] inhalation spray [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2019.
4. Duaklir[®] Pressair[®] inhalation powder [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2019.
5. Utibron[®] Neohaler[®] inhalation powder [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019.
6. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2020 report. Global Initiative for Chronic Obstructive Lung Disease, Inc. Available from: <http://goldcopd.org/>. Accessed on September 23, 2020.
7. 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.
8. Tashkin DP. A review of nebulized drug delivery in COPD. *Int J Chron Obstruct Pulmon Dis.* 2016;11:2585-2596.