Clinical Policy: Inhaled Combination Long-acting Anticholinergic & Beta-2-agonist Agents
Reference Number: CP.PMN.69
Effective Date: 11/15
Last Review Date: 08/17
Line of Business: Medicaid Revision Log

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

Description
The following are inhaled combination long-acting anticholinergic & beta-2-agonist agents requiring prior authorization: umeclidinium-vilanterol (Anoro Ellipta®), tiotropium-olodaterol (Stiolto Respimat®), and indacaterol-glycopyrrolate (Utibron Neohaler®).

FDA approved indication
Inhaled combination long-acting anticholinergic & beta-2-agonist agents are indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

Limitation of use: Not indicated for relief of acute bronchospasm or for the treatment of asthma. Stiolto Respimat is not indicated to treat acute deterioration of COPD.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that inhaled combination long-acting anticholinergic & beta-2-agonist agents 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. ~~3.~~2. Failure of one of the following (a or b) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced ~~(must meet a or b)~~:
   a. ~~Adherent use of at least o~~One ~~PDL~~ long-acting beta agonist (LABA) (~~i.~~e.g., Serevent) and one ~~PDL~~ long-acting anticholinergic (LAA) (~~i.~~e.g., Tudorza)~~, each trialed for ≥ 30 days~~;
   b. ~~Adherent use of o~~One ~~PDL~~ inhaled corticosteroid (ICS) in combination with a LABA (e.g., budesonide/formoterol ~~fluticasone/salmeterol [Advair®]~~Symbicort]~~, trialed for ≥ 12 weeks~~;
4. ~~4.~~3. An inhaled LABA, ICS/LABA combination, or ~~inhaled long-acting anticholinergic~~LAA ~~(i.e. Tudorza)~~ must have been used ~~for ≥ 30 days~~ in the last 60 days, unless ~~ALL~~ all agents are contraindicated;

~~5. [Criteria relating to the BBW];~~
4. Dose does not exceed ~~(a, b, or c):~~the following:
   a. -Anoro Ellipta: 1 inhalation/day (1 inhaler/month);
   b. Stiolto Respimat: 2 inhalations/day (1 inhaler/month)
   ~~6.~~c. Utibron Neohaler: 2 inhalations/day (2 capsules/day). ~~[XX mg, tablets, injections/day, month, year].~~

Approval duration: 12 months

B. Other diagnoses/indications
1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 (a, b, or c);
   a. Anoro Ellipta: 1 inhalation/day (1 inhaler/month);
   b. Stiolto Respimat: 2 inhalations/day (1 inhaler/month);
   ~~3.~~c. Utibron Neohaler: 2 inhalations/day (2 capsules/day). ~~[XX mg, tablets, injections/day, month, year].~~

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – CP.PMN.53 or evidence of coverage documents.

~~A.~~B. Asthma

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

- COPD: chronic obstructive pulmonary disease
- FDA: Food and Drug Administration
- ICS: inhaled corticosteroid
- LAA: long-acting anticholinergic
- LABA: long-acting beta agonist

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose

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Umeclidinium-vilanterol (Anoro Ellipta)	One inhalation by mouth once daily	1 inhalation/day
Tiotropium-olodaterol (Stiolto Respimat)	Two inhalations by mouth once-daily at the same time of day	2 inhalations/day
Indacaterol-glycopyrrolate (Utibron Neohaler)	The inhalation of the powder contents of one capsule twice daily	Contents of 2 capsules/day

VI. Product Availability

Drug	Availability
Umeclidinium-vilanterol (Anoro Ellipta)	Inhalation powder: Inhaler containing 2 foil blister strips of powder formulation for oral inhalation. One strip contains umeclidinium 62.5 mcg per blister and the other contains vilanterol 25 mcg per blister.
Tiotropium-olodaterol (Stiolto Respimat)	Inhalation spray: Each actuation from the mouthpiece contains 3.124 mcg tiotropium bromide monohydrate, equivalent to 2.5 mcg tiotropium, and 2.736 mcg olodaterol hydrochloride, equivalent to 2.5 mcg olodaterol.
Indacaterol-glycopyrrolate (Utibron Neohaler)	Inhalation powder: Capsules contain 27.5 mcg of indacaterol and 15.6 mcg glycopyrrolate inhalation powder for use with the Neohaler device.

VII. Workflow Document

N/A

VIII. References

1. Tiotropium bromide-olodaterol. In: Clinical Pharmacology. Tampa, FL: Gold Standard; 2016.Available at http://www.clinicalpharmacology-ip.com. Accessed ~~June 2016~~June 2017.
2. Umeclidinium-vilanterol. In: Clinical Pharmacology. Tampa, Fl: Gold Standard; 2016.Available at http://www.clinicalpharmacology-ip.com. Accessed ~~June 2016~~June 2017.
3. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease ~~2016~~2017. http://www.goldcopd.org/. Accessed June ~~2016~~2017.
4. ~~Ferguson GT, Make B. Management of stable chronic obstructive pulmonary disease. In: UpToDate, Waltham, MA: Walters Kluwer Health; 2016. Available at www.UpToDate.com. Accessed June 2016~~Anoro Ellipta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; March 2017. Available at http://www.startwithanoro.com/ Accessed June 2017.
5. Stiolto Respimat Prescribing Information. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2016. Available at https://www.stiolto.com/. Accessed June 2017.

~~4.~~6. Utibron Neohaler Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2017. Available at https://www.utibron.com/. Accessed June 2017. ~~-~~

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
New guideline created	09/15	11/15
Changed trial of 2 PDL long-acting beta agonists to 1 PDL long-acting beta agonist and one PDL long acting anticholinergic to reflect GOLD guideline 2016 recommendation and because Foradil is no longer on the market; modified specific max quantity limit to generalized FDA max recommended dose and health plan approved QL statement; updated references;	06/16	08/16
Removed age requirement as age is not an absolute contraindication. Removed trial durations and instead required that drugs be trialed at up to maximally indicated doses based on the nature of COPD (poor disease control can be life-threatening) per GOLD 2017 recommendation of exacerbation follow-up within 1 to 4 weeks. Changed example of inhaled corticosteroid (ICS) in combination with a LABA from Advair to Symbicort. (Advair now requires a prior authorization.)	06/17	08/17

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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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.