Clinical Policy: Indacaterol/Glycopyrrolate (Utibron Neohaler)

Reference Number: HIM.PA.102
Effective Date: 09.01.18
Last Review Date: 08.20
Line of Business: HIM

Revision Log

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

Description

Indacaterol/glycopyrrolate (Utibron™ Neohaler®) is a combination product containing a long-acting beta-2 agonist (LABA) and a long-acting anticholinergic (LAMA).

FDA Approved Indication(s)

Utibron Neohaler is indicated for the long-term, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).

Limitation(s) of use: Utibron Neohaler is not indicated for the relief of acute bronchospasm or for the treatment of asthma.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Utibron Neohaler is **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. Failure of Anoro® Ellipta® and Bevespi Aerosphere®, at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
4. Dose does not exceed 2 inhalations per day (2 capsules per day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

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 2 inhalations per day (2 capsules per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

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 policies – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents;

B. Asthma.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration
GOLD: Global Initiative for Chronic Obstructive Lung Disease
ICS: inhaled corticosteroid
LABA: long-acting beta$_2$ adrenergic agonist
LAMA: long-acting anticholinergic

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Anoro Ellipta (umeclidinium/vilanterol)	1 inhalation (62.5/25 mcg) QD	62.5/25 mcg/day
Bevespi Aerosphere (glycopyrrolate/formoterol fumarate)	2 inhalations (9/4.8 mcg) BID	2 inhalations of 9/4.8 mcg BID

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Use of a LABA, including Utibron Neohaler, without an ICS in patients with asthma
  - History of known hypersensitivity to indacaterol, glycopyrrolate, or to any of the ingredients

- Boxed warning(s): none reported

Appendix D: General Information

- Per the 2020 GOLD COPD guidelines, combination therapy (LAMA + LABA, ICS + LABA, or ICS + LAMA + LABA) is recommended for Group D patients (i.e., those who are very symptomatic and are at high risk of exacerbation). Selection of which combination to use depends on the individual patient:
  - For those with more severe symptoms, LAMA + LABA may be used.
  - For those with a history of asthma or blood eosinophil counts at least 300 cells/uL, LABA + ICS may be used.
  - For those who are inadequately controlled by dual therapy, triple therapy with ICS + LAMA + LABA may be used.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COPD	Inhalation of the contents of one capsule BID	2 capsules/day

VI. Product Availability

Inhalation powder in capsule, for use with the Neohaler device: 27.5 mcg of indacaterol and 15.6 mcg glycopyrrolate

VII. References

1. Utibron Neohaler Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019. Available at https://www.utibron.com. Accessed April 15, 2020.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2020 report). Published January 2020. Available at: http://www.goldcopd.org. Accessed April 13, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.21.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	04.23.19	08.19
Removed Tudorza Pressair from list of preferred LAMA as this will be non-formulary per SDC.	10.22.19	
3Q 2020 annual review: no significant changes; added Arcapta Neohaler and Striverdi Respimat as preferred LABAs and specified that generic (as opposed to brand) Advair Diskus and Symbicort are preferred per core Ambetter formulary status; updated Appendix C to reflect revised CI language and that the asthma-related death boxed warning was removed; references reviewed and updated.	04.13.20	08.20
Revised redirections to require Anoro Ellipta and Bevespi Aerosphere (removed redirection to either one formulary LABA in	08.19.20	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
combination with LAMA, or one formulary ICS in combination with LABA) per August SDC and prior clinical guidance.		

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.