Clinical Policy: Indacaterol/Glycopyrrolate (Utibron Neohaler)

Reference Number: PA.CP.PMN.147
Effective Date: 10.17.18
Last Review Date: 07/17/19

Revision Log

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

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 PA Health & Wellness® 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. Failure of one of the following (a or b) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced:
   a. One formulary long-acting beta-2 agonist (e.g., Serevent®) in combination with one formulary long-acting anticholinergic (e.g., Tudorza® Pressair®, Incruse® Ellipta®);
   b. One formulary inhaled corticosteroid in combination with a formulary long-acting beta-2 agonist (e.g., Symbicort®);
3. Dose does not exceed 2 inhalations/day (2 capsules/day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Currentlyreceiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2 inhalations/day (2 capsules/day.

Approval duration: 12 months

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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 – PA.CP.PMN.53;

B. Asthma.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration

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
Incruse Ellipta (umeclidinium)	1 inhalation (62.5 mcg) QD	62.5 mcg/day
Symbicort (budesonide/ formoterol)	2 inhalations of 80/4.5 mcg BID	2 inhalations of 80/4.5 mcg BID
Serevent (salmeterol)	1 inhalation (50 mcg) BID	100 mcg/day
Tudorza Pressair (aclidinium)	1 inhalation (400 mcg) BID	800 mcg/day

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

- All long-acting beta-2 agonists are contraindicated in patients with asthma without use of a long-term asthma controller medication. Utibron Neohaler is not indicated for the treatment of asthma.

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: Capsules contain 27.5 mcg of indacaterol and 15.6 mcg glycopyrrolate inhalation powder for use with the Neohaler device

VII. References

1. Utibron Neohaler Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2018. Available at https://www.utibron.com/. Accessed April 17, 2018.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2018 report). Published January 2018. Available at: http://www.goldcopd.org/. Accessed April 9, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy Created	10/18	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	