Clinical Policy: Indacaterol (Arcapta Neohaler)

Reference Number: CP.PMN.203
Effective Date: 09.01.18
Last Review Date: 08.20
Line of Business: Medicaid

Revision Log

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

Description

Indacaterol (Arcapta® Neohaler®) is long-acting beta$_2$ agonist (LABA).

FDA Approved Indication(s)

Arcapta Neohaler is indicated for the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

Limitation(s) of use: Arcapta Neohaler is not indicated to treat asthma or acute deteriorations (e.g., acute bronchospasms) of COPD.

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 Arcapta 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 one formulary LABA (e.g., Serevent®, Striverdi Respimat®) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 75 mcg per day (1 inhaler per 30 days).

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): CP.PMN.53 for Medicaid.

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 75 mcg per day (1 inhaler per 30 days).

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): CP.PMN.53 for Medicaid.

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 – CP.PMN.53 for Medicaid 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
LABA: long-acting beta$_2$ adrenergic agonist

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
Serevent® (salmeterol)	1 inhalation (50 mcg) BID	100 mcg/day
Stiverdi Respimat (olodaterol)	2 inhalations (total 5 mcg) QD	5 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/Boxed Warnings

- Contraindication(s):
  - History of hypersensitivity to indacaterol or to any of the ingredients
  - Use of a LABA, including Arcapta Neohaler, without an inhaled corticosteroid in patients with asthma
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COPD	75 mcg inhaled orally QD	75 mcg/day

VI. Product Availability

Inhalation powder hard capsules: 75 mcg

VII. References

1. Arcapta Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019. Available at https://www.arcapta.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). Available from: http://www.goldcopd.org/. Accessed April 6, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2018 annual review: policy split from HIM.PA.74 Inhaled Long-Acting Beta$_2$ Agonists and Combination Products into individual Arcapta Neohaler policy; redirection modified from short-acting bronchodilator to LABA; age added; references reviewed and updated.	05.21.18	08.18
3Q 2019 annual review: no significant changes; added Medicaid line of business to HIM.PA.101 and retired HIM.PA.101; references reviewed and updated.	04.22.19	08.19
Removed HIM line of business per SDC, prior authorization no longer required.	10.22.19	
3Q 2020 annual review: no significant changes; added Striverdi Respimat as a preferred LABA option per core Medicaid formulary status; references reviewed and updated.	04.15.20	08.20

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.