Clinical Policy: Indacaterol (Arcapta Neohaler)
Reference Number: CP.PMN.203
Effective Date: 09.01.18
Last Review Date: 08.20
Line of Business: Medicaid

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

Description
Indacaterol (Arcapta® Neohaler®) is long-acting beta2 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 beta2 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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
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</thead>
<tbody>
<tr>
<td>Serevent® (salmeterol)</td>
<td>1 inhalation (50 mcg) BID</td>
<td>100 mcg/day</td>
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<tr>
<td>Stiverdi Respimat</td>
<td>2 inhalations (total 5 mcg) QD</td>
<td>5 mcg/day</td>
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*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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
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<tbody>
<tr>
<td>COPD</td>
<td>75 mcg inhaled orally QD</td>
<td>75 mcg/day</td>
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VI. Product Availability
Inhalation powder hard capsules: 75 mcg

VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
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<tbody>
<tr>
<td>3Q 2018 annual review: policy split from HIM.PA.74 Inhaled Long-</td>
<td>05.21.18</td>
<td>08.18</td>
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<td>Acting Beta\textsubscript{2} Agonists and Combination Products into</td>
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<td>individual Arcapta Neohaler policy; redirection modified from short-</td>
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<td>acting bronchodilator to LABA; age added; references reviewed and</td>
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<td>updated.</td>
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<tr>
<td>3Q 2019 annual review: no significant changes; added Medicaid line</td>
<td>04.22.19</td>
<td>08.19</td>
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<tr>
<td>of business to HIM.PA.101 and retired HIM.PA.101; references reviewed</td>
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<td>and updated.</td>
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<tr>
<td>Removed HIM line of business per SDC, prior authorization no longer</td>
<td>10.22.19</td>
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<td>required.</td>
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<tr>
<td>3Q 2020 annual review: no significant changes; added Striverdi</td>
<td>04.15.20</td>
<td>08.20</td>
</tr>
<tr>
<td>Respimat as a preferred LABA option per core Medicaid formulary status;</td>
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<td>references reviewed and updated.</td>
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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.

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**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.

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