Clinical Policy: Respiratory Agents: Glucocorticoid Agents – Inhaled
Reference Number: OH.PHAR.PPA.85
Effective Date: 01/01/2020
Last Review Date: 01/01/2020
Line of Business: Medicaid

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

RESPIRATORY AGENTS: GLUCOCORTICOIDS – INHALED

<table>
<thead>
<tr>
<th>NO PA REQUIRED “PREFERRED”</th>
<th>PA REQUIRED “NON-PREFERRED”</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASMANEX® Twiskhaler (mometasone)</td>
<td>AEROSPAN® HFA (flunisolide)</td>
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<tr>
<td>FLOVENT DISKUS® and HFA (fluticasone)</td>
<td>ALVESCO® (ciclesonide)</td>
</tr>
<tr>
<td>PULMICORT FLEXHALER® (budesonide)</td>
<td>ARMONAIR™ RESPICLICK® (fluticasone)</td>
</tr>
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PA REQUIRED “NON-PREFERRED”

| ASMANEX® HFA (mometasone)                        | ARNUITY ELLIPTA® (fluticasone furoate)                         |
| QVAR® (beclomethasone)                          | ASMANEX® HFA (mometasone)                                     |

RESPIRATORY AGENTS: GLUCOCORTICOIDS – NEBULIZERS

<table>
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<tr>
<th>NO PA REQUIRED “PREFERRED”</th>
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<tbody>
<tr>
<td>BUDESONIDE nebulizer solution (generic of Pulmicort®) (no PA required for age 6 or under)</td>
<td>BUDESONIDE nebulizer solution (generic of Pulmicort®) (PA required for over age 6)</td>
</tr>
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</table>

Description
The following are inhaled glucocorticoid agents requiring prior authorization: flunisolide (AEROSPAN® HFA), ciclesonide (ALVESCO®), fluticasone propionate (ARMONAIR™ RESPICLICK®), fluticasone furoate (ARNUITY ELLIPTA®), mometasone (ASMANEX® HFA), beclomethasone (QVAR®), and budesonide nebulizer solution (over age 6).

FDA Approved Indication(s)
Refer to tertiary resources such as UpToDate or Clinical Pharmacology

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 Buckeye Health Plan, an affiliate of Centene Corporation®, that flunisolide (AEROSPAN HFA), ciclesonide (ALVESCO), fluticasone propionate (ARMONAIR RESPICLICK), fluticasone furoate (ARNUITY ELLIPTA), mometasone (ASMANEX HFA), beclomethasone (QVAR), and budesonide nebulizer solution (over age 6) are medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. FDA-Approved Indications:
      1. FDA-approved indication or indication supported by standard pharmacopeias (meets a or b):
         a. Unable to switch to medication not requiring prior approval for one of the following reasons:
i. Allergy to medications not requiring prior approval

ii. Contraindication to or drug interaction with medications not requiring prior approval

iii. History of unacceptable/toxic side effects to medications not requiring prior approval

iv. Patient’s condition is clinically unstable as defined in current guidelines in terms of oral steroid use or patient’s current symptomology – changing to a medication not requiring prior approval might cause deterioration of the patient’s condition

b. Documented therapeutic failure to no less than 30 day trial of at least two preferred medications not requiring prior authorization

2. If the patient is a child under 13 years old or a patient with a significant disability, and unable to use an inhaler which does not require prior approval, or is non-compliant on an inhaler not requiring prior approval because of taste, dry mouth, infection; then may approve the requested medication.

Approval duration: 12 months

II. 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.

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PA: Prior Authorization

Appendix B: Therapeutic Alternatives
Refer to tertiary resources such as UpToDate or Clinical Pharmacology

Appendix C: Contraindications/Boxed Warnings
Refer to tertiary resources such as UpToDate or Clinical Pharmacology

IV. Dosage and Administration
Refer to tertiary resources such as UpToDate or Clinical Pharmacology

V. Product Availability
Refer to tertiary resources such as UpToDate or Clinical Pharmacology

VI. References
Refer to manufacturer prescribing information

<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>New policy</td>
<td>01.01</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.

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
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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.

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