Clinical Policy: Mometasone/Formoterol (Dulera)
Reference Number: CP.PMN.230
Effective Date: 03.01.20
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
Mometasone/formoterol (Dulera®) is a combination product containing a corticosteroid and a long acting beta-2 agonist.

FDA Approved Indication(s)
Dulera is indicated for the treatment of asthma in patients aged 5 years and older.

Limitation(s) of use: Dulera is not indicated for relief of acute bronchospasm.

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 Dulera is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Asthma (must meet all):
      1. Diagnosis of asthma;
      2. Age ≥ 5 years;
      3. Failure of fluticasone/salmeterol (generic Advair Diskus®) or budesonide/formoterol (generic Symbicort®) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
      4. Dose does not exceed (a or b):
         a. Age 5 to 11 years: 4 inhalations of 50 mcg mometasone/5 mcg formoterol per day (1 inhaler every 30 days);
         b. Age ≥ 12 years: 4 inhalations of 200 mcg mometasone/5 mcg formoterol per day (1 inhaler every 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. Asthma (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 (a or b):
   a. Age 5 to 11 years: 4 inhalations of 50 mcg mometasone/5 mcg formoterol per day (1 inhaler every 30 days);
   b. Age ≥ 12 years: 4 inhalations of 200 mcg mometasone/5 mcg formoterol per day (1 inhaler every 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.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/ Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>fluticasone/salmeterol (Advair Diskus)</td>
<td>1 inhalation BID (starting dosage is based on asthma severity)</td>
<td>500/50 mcg BID</td>
</tr>
<tr>
<td>budesonide/formoterol (Symbicort)</td>
<td>2 inhalations BID</td>
<td>160/4.5 mcg BID</td>
</tr>
</tbody>
</table>

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): primary treatment of status asthmaticus or acute episodes of asthma requiring intensive measures, hypersensitivity to any ingredient
- Boxed warning(s): none reported
V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
</table>
| Asthma     | Age 5 to 11 years: 2 inhalations of 50/5 mcg BID  
Age ≥ 12 years: 2 inhalations of 100/5 mcg or 200/5 mcg BID (starting dosage is based on asthma severity) | 200/5 mcg/day  
800/20 mcg/day |

VI. Product Availability
Inhalation aerosol containing mometasone/formoterol: 50/5 mcg, 100/5 mcg, 200/5 mcg

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per SDC CY2020 strategy: policy split from CP.PST.01 and created with re-direction to generic Advair Diskus based on prior clinical guidance.</td>
<td>12.10.19</td>
<td>02.20</td>
</tr>
<tr>
<td>Added additional step through option of budesonide/formoterol (generic Symbicort) per February SDC and prior clinical guidance.</td>
<td>03.26.20</td>
<td></td>
</tr>
<tr>
<td>3Q 2020 annual review: no significant changes; references reviewed and updated.</td>
<td>04.15.20</td>
<td>08.20</td>
</tr>
</tbody>
</table>

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.

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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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