



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2020 P 3071-9
Program	Step Therapy
Medication	Dulera (mometasone furoate/formoterol fumarate)*
P&T Approval Date	2/2016, 2/2017, 11/2017, 11/2018, 11/2019, 10/2020
Effective Date	2/1/2021; Oxford only: 2/1/2021

**1. Background:**

Dulera\* (mometasone furoate/formoterol fumarate) is indicated for the treatment of asthma in patients aged 5 years of age and older. Dulera should be used in patients not adequately controlled on a long-term asthma-control medication such as an inhaled corticosteroid (ICS) or whose disease warrants initiation of treatment with both an ICS and long-acting beta<sub>2</sub>-adrenergic agonist.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Symbicort and either fluticasone/salmeterol [fluticasone/salmeterol (AirDuo RespiClick\*) or Advair (HFA or Diskus)] or Breo Ellipta before providing coverage for Dulera for the treatment of asthma.

**2. Coverage Criteria<sup>a</sup>:**

**A. Dulera\*** will be approved based on the following criteria:

1. History of failure, contraindication, or intolerance to **both** of the following:
  - a. Symbicort

**-AND-**

- b. **One** of the following:

- 1) fluticasone/salmeterol [fluticasone/salmeterol (AirDuo RespiClick\*), Advair (HFA or Diskus\*)]

**-OR-**

- 2) Breo Ellipta

**Authorization will be issued for 12 months.**



<sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

\* Brand AirDuo RespiClick, Dulera and fluticasone/salmeterol Diskus (generic Advair Diskus) are typically excluded from coverage.

**3. Additional Clinical Programs:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

**4. References:**

1. Advair Diskus [package insert]. Research Triangle Park, NC: GlaxoSmithKline; January 2019.
2. Advair HFA [package insert]. Research Triangle Park, NC: GlaxoSmithKline; February 2019.
3. AirDuo RespiClick [package insert]. Parsippany, NJ: Teva Respiratory LLC.; February 2020.
4. Breo Ellipta [package insert]. Research Angle Park, NC: GlaxoSmithKline; January 2019.
5. Dulera [package insert]. Whitehouse Station, NJ: Merck & Co, Inc.; August 2020.
6. Symbicort [package insert]. Wilmington, DE: AstraZeneca; July 2019

Program	Step Therapy – Dulera (mometasone furoate/formoterol fumarate)
<b>Change Control</b>	
2/2016	New Program
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
2/2017	Annual Review. References updated.
11/2017	Annual Review. Added brand and generic AirDuo RespiClick and noted Dulera typically excluded from coverage. Updated mandate language and references.
11/2018	Annual Review. Updated background section and references.
11/2019	Annual Review. Updated background section and references.
10/2020	Annual Review. Updated references.