



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3071-13
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, 11/2021, 11/2022, 11/2023, 11/2024
Effective Date	2/1/2025

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 beta₂-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^a:

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*),
fluticasone/salmeterol (generic Advair Diskus*), Advair HFA]

-OR-

2) Breo Ellipta*

Authorization will be issued for 12 months.

^a 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.



* budesonide/formoterol [Breyne (generic Symbicort)], brand AirDuo RespiClick, brand Advair Diskus, Dulera, Fluticasone/Salmeterol HFA (authorized brand alternative for Advair HFA) and Fluticasone/Vilanterol Ellipta (authorized brand alternative for Breo Ellipta) 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]. Durham, NC: GlaxoSmithKline; June 2023.
2. Advair HFA [package insert]. Durham, NC: GlaxoSmithKline; May 2024.
3. AirDuo RespiClick [package insert]. Parsippany, NJ: Teva Respiratory LLC.; February 2024.
4. Breo Ellipta [package insert]. Durham, NC: GlaxoSmithKline; May 2023.
5. Dulera [package insert]. Jersey City, NJ: Organon & Co; June 2021.
6. Symbicort [package insert]. Wilmington, DE: AstraZeneca; July 2019

Program	Step Therapy – Dulera (mometasone furoate/formoterol fumarate)
Change Control	
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.
11/2021	Annual Review. Updated references.
11/2022	Annual review. Updated references.
11/2023	Annual review. Updated list of excluded products. Updated references.
11/2024	Annual review. Updated covered fluticasone/salmeterol products. Updated references.