

| Market Applicability |    |          |        |        |    |    |    |    |    |    |    |    |    |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|
| Market               | DC | FL & FHK | FL MMA | FL LTC | GA | KY | MD | NJ | NV | NY | TN | TX | WA |
| Applicable           | X  | X        | NA     | NA     | X  | X  | X  | X  | X  | X  | NA | NA | NA |

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## Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)

| Override(s)                           | Approval Duration |
|---------------------------------------|-------------------|
| Prior Authorization<br>Quantity Limit | 1 year            |

| Medications  | Quantity Limit                   |
|--|----------------------------------|
| Trelegy Ellipta<br>(fluticasone furoate/umeclidinium/vilanterol) | May be subject to quantity limit |

### **APPROVAL CRITERIA**

Requests for Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol) may be approved if the following criteria are met:

- I. Individual is using for the treatment of chronic obstructive pulmonary disease (COPD);  
**AND**
- II. Individual is currently utilizing an inhaled corticosteroid (ICS)/long-acting beta-2 agonist (LABA) agent but requires additional treatment for COPD symptoms or exacerbations ;  
**OR**
- III. Individual is currently utilizing a long-acting muscarinic antagonist (LAMA)/long-acting beta-2 agonist (LABA) agent but requires additional treatment for COPD symptoms or exacerbations (GOLD 2019).

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol) may not be approved for the following:

- I. Individual with a hypersensitivity to milk proteins.

**Note:** The safety and efficacy of Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol) in the treatment of asthma has not been established. Trelegy Ellipta is not indicated for asthma or relief of acute bronchospasm

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.  
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| Market Applicability |    |          |        |        |    |    |    |    |    |    |    |    |    |
|----------------------|----|----------|--------|--------|----|----|----|----|----|----|----|----|----|
| Market               | DC | FL & FHK | FL MMA | FL LTC | GA | KY | MD | NJ | NV | NY | TN | TX | WA |
| Applicable           | X  | X        | NA     | NA     | X  | X  | X  | X  | X  | X  | NA | NA | NA |

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| State Specific Mandates |                |   |
|-------------------------|----------------|---|
| State name              | Date effective | Mandate details (including specific bill if applicable) |
| N/A                     | N/A            | N/A   |

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 7, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2019. Available from: Available from: <http://goldcopd.org>. Accessed on: January 5, 2019.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.

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