

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Fluticasone furoate-umeclidinium-vilanterol (Trelegy Ellipta)

Notes:

- Quantity Limits: No
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ^ Adequate trial is defined as at least 30 days treatment duration

Initiation (new start) criteria: Non-formulary **fluticasone furoate-umeclidinium-vilanterol (Trelegy Ellipta)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber is an Allergist or Pulmonologist
- Patient is at least 18 years of age
- Patient has either diagnosis of chronic obstructive pulmonary disease (COPD) or uncontrolled asthma.
 - Any one of the following indicates the patient has uncontrolled asthma:
 - i. Frequent severe exacerbations: Two or more asthma exacerbations requiring systemic corticosteroids in the past 12 months
 - ii. History of serious exacerbation: at least one hospitalization, intensive care unit (ICU) stay, or mechanical ventilation in the previous year
 - iii. Poor symptom control: Asthma Control Test is consistently less than 20
- History of failure, contraindication, or intolerance* to treatment with an adequate trial^ of a triple therapy regimen containing an inhaled corticosteroid (ICS), a long acting anti-cholinergic (LAMA), and a long acting beta-agonist (LABA) from separate devices.
- Documented clinical rationale that the patient is unable to use separate inhaler products.

Examples of a triple therapy ICS+LAMA+LABA regimen using multiple inhaler devices (List is not inclusive to all possible combinations):

Inhaler #1	Inhaler #2
Fluticasone propionate/salmeterol (Wixela Inhub, Advair Diskus, Advair HFA)	Tiotropium (Spiriva Respimat, Spiriva HandiHaler)
Budesonide/formoterol (Symbicort)	Tiotropium (Spiriva Respimat, Spiriva HandiHaler)
Tiotropium/olodaterol (Stiolto Respimat)	ciclesonide (Alvesco) fluticasone propionate (Flovent)

- Patient does not have a hypersensitivity to milk proteins

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Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary fluticasone furoate-umeclidinium-vilanterol (Trelegy Ellipta) will be covered on the prescription drug benefit when the following criteria are met:

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- Patient has either diagnosis of chronic obstructive pulmonary disease (COPD) or uncontrolled asthma.
 - Any one of the following indicates the patient has uncontrolled asthma:
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 - History of serious exacerbation: at least one hospitalization, intensive care unit (ICU) stay, or mechanical ventilation in the previous year
 - Poor symptom control: Asthma Control Test is consistently less than 20
- History of failure, contraindication, or intolerance* to treatment with an adequate trial[^] of a triple therapy regimen containing an inhaled corticosteroid (ICS), a long acting anti-cholinergic (LAMA), and a long acting beta-agonist (LABA) from separate devices.

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