



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/17
LAST REVIEW DATE: 5/17/18
LAST CRITERIA REVISION DATE: 5/17/18
ARCHIVE DATE:

TRELEGY ELLIPTA (fluticasone-umeclidinium-vilanterol) aerosol powder

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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TRELEGY ELLIPTA (fluticasone-umeclidinium-vilanterol) aerosol powder (cont.)

Criteria:

- **Criteria for initial therapy:** Trelegy Ellipta is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:

1. Individual is 12 years of age or older
2. A confirmed diagnosis of chronic obstructive pulmonary disease (COPD)
3. Individual has failure, contraindication, or intolerance to **at least two** of the following:
 - Advair Diskus or Advair HFA
 - Breo Ellipta
 - Symbicort
 - Fluticasone-Salmeterol (generic for Airduo Resplick)
4. There are **NO** contraindications.
 - Contraindications include:
 - Severe hypersensitivity to milk proteins
 - hypersensitivity to fluticasone furoate, umeclidinium, vilanterol, or any of the excipients

Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Trelegy Ellipta is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:

1. Individual has been adherent with the medication
2. The condition has not progressed or worsened while on therapy noted by in-frequent use of Albuterol or oral corticosteroids
3. Individual has not developed any contraindications or other exclusions to its continued use

Renewal duration: 12 months

Description:

Trelegy Ellipta is a combination of fluticasone furoate, an inhaled corticosteroid (ICS); umeclidinium, an anticholinergic; and vilanterol, a long-acting beta -adrenergic agonist (LABA), indicated for the long-term, once-daily, maintenance treatment of patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema, who are on a fixed-dose combination of fluticasone furoate and vilanterol for airflow obstruction and reducing exacerbations in whom additional treatment of airflow obstruction is desired or for patients who are already receiving umeclidinium and a fixed-dose combination of fluticasone furoate and vilanterol.

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The majority of inhaled medications for COPD and asthma are available as brand only products. There are a few generic nebulized options; all options that are administered via handheld device such as metered-dose inhalers (MDIs), dry powder inhalers (DPIs), and inhaled mist delivery systems (such as Respimat) are brand only. There are many generic oral medications available for the treatment of COPD and asthma.

Definitions:

Classes of medications used in COPD and/or asthma (inhaled, non-nebulizer)

Bronchodilators	
Short-acting beta-agonists (SABA)†	albuterol (ProAir HFA, ProAir RespiClick, Proventil HFA, Ventolin HFA) levalbuterol (Xopenex HFA)
Long-acting beta-agonists (LABA)†	formoterol (Foradil aerolizer) indacaterol (Arcapta Neohaler) olodaterol (Striverdi Respimat) salmeterol (Serevent Diskus)
Short-acting antimuscarinics (SAMA)†	ipratropium (Atrovent HFA)
Long-acting antimuscarinics (LAMA)†	aclidinium (Tudorza Pressair) glycopyrrolate (Seebri Neohaler) tiotropium (Spiriva, HandiHaler, Spiriva Respimat) umeclidinium (Incruse Ellipta)
Inhaled corticosteroids (ICS)†	beclomethasone (Qvar) budesonide (Pulmicort Flexhaler) ciclesonide (Alvesco) flunisolide (Aerospan) fluticasone (Arnuity Ellipta, Flovent Diskus, Flovent HFA) mometasone (Asmanex, Asmanex HFA)
Combination products	
Antimuscarinics/beta agonist†	ipratropium/albuterol (Combivent Respimat) glycopyrrolate/formoterol (Bevespi Aerosphere) glycopyrrolate/indacaterol (Utibron) tiotropium/olodaterol (Stiolto Respimat) umeclidinium/vilanterol (Anoro Ellipta)
ICS/LABA	budesonide/formoterol (Symbicort), fluticasone/salmeterol (Advair HFA, Advair Diskus) fluticasone/vilanterol (Breo Ellipta) mometasone/formoterol (Dulera)
† available as nebulized product: albuterol, levalbuterol, Brovana (arformoterol), Perforomist (formoterol), ipratropium, ipratropium/albuterol, Pulmicort Respules (budesonide)	

Resources:

Trelegy Ellipta. Package Insert. Revised by manufacturer 9/2017. Accessed 10/13/17.

Trelegy Ellipta. Package Insert. Revised by manufacturer 4/2018. Accessed 5/04/18.



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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
 Call 866-325-1794 to check the status of a request.
 All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
 Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.

REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information			
Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:
Prescribing Provider Information			
Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	
Dispensing Pharmacy Information			
Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:	
Requested Medication Information			
Medication Name:	Strength:	Dosage Form:	
Directions for Use:	Quantity:	Refills:	Duration of Therapy/Use:
<input type="checkbox"/> Check if requesting brand only <input type="checkbox"/> Check if requesting generic			
<input type="checkbox"/> Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)			
Turn-Around Time For Review			
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____ <input type="checkbox"/> Exigent (requires prescriber to include a written statement)			
Clinical Information			
1. What is the diagnosis? Please specify below. ICD-10 Code: _____ Diagnosis Description: _____			
2. <input type="checkbox"/> Yes <input type="checkbox"/> No Was this medication started on a recent hospital discharge or emergency room visit?			
3. <input type="checkbox"/> Yes <input type="checkbox"/> No There is absence of ALL contraindications.			
4. What medication(s) has the individual tried and failed for this diagnosis? Please specify below. Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.			
Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy	
5. Are there any supporting labs or test results? Please specify below.			
Date	Test	Value	

Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: _____ Date: _____

Please note: Some medications may require completion of a drug-specific request form.

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Office notes, labs, and medical testing relevant to the request that show medical justification are required.