Drug Monograph

Drug/Drug Class:	**Incruse™ Ellipta® (umeclidinium) inhalation/ COPD**
Prepared for:	MO HealthNet
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☒ **New Criteria** ☐ **Revision of Existing Criteria**

Executive Summary

Purpose:	The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be made available on an open access basis to prescribers, require a clinical edit or require prior authorization for use.
Dosage Forms & Manufacturer:	Incruse™ Ellipta® is available as an inhaler that contains 7 or 30 blister packs containing 62.5 mcg of umeclidinium. GlaxoSmithKline Research Triangle Park, NC 27709
Summary of Findings:	The effect of Incruse™ Ellipta® on lung function in the treatment of COPD was studied in two randomized, double-blind, placebo-controlled clinical trials. Incruse™ Ellipta® improved the change from baseline in trough FEV1 and health-related quality of life at 6 months compared with placebo (n=418). Results were similar in a 12-week randomized, placebo-controlled trial.
Status Recommendation:	☐ Prior Authorization (PA) Required ☐ Open Access ☐ Clinical Edit ☒ PDL
Type of PA Criteria:	☐ Increased Risk of ADE ☐ Preferred Agent ☐ Appropriate Indications ☒ Non-Preferred Agent

Purpose

The purpose of this monograph is to provide a review of new therapy to determine whether the reviewed drug should be considered a prior authorization drug, a clinical edit drug or an open access drug. While prescription expenditures are increasing at double-digit rates, payors are evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. This review will assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class.

Introduction[2]

COPD, or chronic obstructive pulmonary disease, is a progressive disease that makes it hard to breathe. COPD can cause coughing that produces large amounts of mucus, wheezing, shortness of breath, chest tightness, and other symptoms. COPD is a major cause of disability, and it's the third leading cause of death in the United States.

Dosage Form(s) [1]

Incruse™ Ellipta® is available as an inhaler that contains 7 or 30 blister packs containing 62.5 mcg of umeclidinium.

Manufacturer [1]

GlaxoSmithKline, Research Triangle Park, NC 27709

Indication(s) [1]

Incruse™ Ellipta® is indicated for long-term, maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema.

Clinical Efficacy [1,2] (mechanism of action/pharmacology, comparative efficacy)

Incruse™ Ellipta® is a long-acting anticholinergic agent that reversibly inhibits the M3 receptor at the smooth muscle, leading to bronchodilation.

Pharmacokinetics

	Incruse Ellipta
Protein binding	89%
Volume of distribution	86 L
Metabolism	Hepatic, via CYP2D6
Excretion	Feces, 58% Urine, 22%
Half-life	11 hours

Trough FEV1 at 6 months was improved significantly more in COPD patients treated with Incruse™ Ellipta® compared with placebo.

STUDY DESIGN	Randomized, double-blind, placebo-controlled, 24-week clinical trial (n=418).
INCLUSION CRITERIA	Patients 40 years or older with COPD, a smoking history of at least 10 pack-years, and a post-albuterol FEV1 of no more than 70% of predicted values.
EXCLUSION CRITERIA	Not specified.
TREATMENT REGIMEN	Patients were randomized to receive Incruse™ Ellipta® 62.5 mcg or placebo inhaled once daily.
RESULTS	The mean age of patients was 63 years, and the mean baseline percent predicted FEV1 was 47%. At day 169, Incruse™ Ellipta® significantly increased trough FEV1 from baseline (between-group difference, 115 mL) and significantly improved health-related quality of life when compared with placebo.
SAFETY	Not specified.

Contraindications [(1)]

- Severe hypersensitivity to milk proteins
- Hypersensitivity to umeclidinium or any product component

Warnings and Precautions [(1)]

- Acute symptom relief (ie, rescue therapy for acute bronchospasm); use not recommended; not studied.
- Concomitant use of anticholinergic-containing drugs; avoid use.
- Deteriorating COPD, acute, or potentially life-threatening; use not recommended; not studied.
- Hypersensitivity reactions, including anaphylaxis, may occur.
- Narrow-angle glaucoma may get worse; monitoring recommended.
- Paradoxical bronchospasm, potentially life-threatening, may occur; discontinue use immediately if occurs.
- Urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction, may be exacerbated; monitoring recommended.

Adverse Effects [1]

Most common, > 1%	Incruse™ Ellipta® (n=487)	Placebo (n=348)
Nasopharyngitis	8%	7%
Upper respiratory tract infection	5%	4%
Cough	3%	2%
Arthralgia	2%	1%

Drug Interactions [1]

- Anticholinergic agents

Dosage and Administration [1]

The recommended dose is one oral inhalation (62.5 mcg) once daily at the same time each day.

Cost

GENERIC NAME	BRAND NAME	MANUFACTURER	STRENGTH	DOSE	COST*/ PACKAGE
Umeclidinium	Incruse Ellipta	GlaxoSmithKline	62.5 mcg/inhalation blister, 30 doses/inhaler	62.5 mcg/day	$224.70
Tiotropium bromide	Spiriva	Boehringer Ingelheim	18 mcg/inhalation capsule, 30 doses/carton	18 mcg/day	$297.60

*WholesaleAcquisitionCost

Conclusion

Incruse™ Ellipta® is a once daily anticholinergic inhaled bronchodilator approved for the long-term maintenance treatment of COPD. Incruse™ Ellipta® has demonstrated efficacy in improving lung function when compared with placebo over 12 weeks and 24 weeks, but its comparative efficacy has not been evaluated with other long-acting anticholinergic agents. The most common adverse effects reported were nasopharyngitis, upper respiratory track infections, cough, and arthralgia.

Recommendation

This drug is being considered for inclusion in the state specific Preferred Drug List and is a non-preferred agent.

References

1. Product Information: Incruse™ Ellipta®, umeclidinium inhalation powder.GlaxoSmithKline, Research Triangle Park, NC, 5/2014.
2. What is COPD? Retrieved March 12 from http://www.nhlbi.nih.gov

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