PDL NEW DRUG REVIEW

Proprietary Name: Incruse Ellipta®
Common Name: umeclidinium bromide
PDL Category: Antiasthmatics- Anti-Cholinergics

Comparable Products	Preferred Drug List Status
Atrovent HFA	Preferred
Spiriva	Preferred
Tudorza	Non-Preferred

Summary

Indications and Usage: For the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. This is a pregnancy category C medication. The safety and efficacy of use in children have not been established.

Dosage Forms: Inhalation powder, with 30 blisters per strip, each containing powder for oral inhalation. Each blister contains 62.5mcg umeclidinium.

Recommended Dosage: Administer one inhalation orally once daily. Dose adjustments are not required for those with renal impairment or with mild or moderate hepatic impairment. Use in severe hepatic impairment has not been studied.

The concomitant use of Incruse Ellipta® with other anticholinergic-containing medications should be avoided.

Common Adverse Drug Reactions: *Listed % incidence for adverse drug reactions= reported % incidence for drug (Incruse Ellipta®) minus reported % incidence for placebo. Please note that an incidence of 0% means the incidence was the same or that the active drug was less than placebo.* The most frequently reported adverse events included nasopharyngitis (1%), upper respiratory tract infection (1%), pharyngitis (<1%), viral upper respiratory tract infection (<1%), cough (1%), arthralgia (1%), myalgia (<1%), upper abdominal pain (<1%), toothache (<1%), contusion (<1%), and tachycardia (<1%).

Incruse Ellipta® should be used with caution in those with narrow-angle glaucoma and with urinary retention.

Contraindications: Severe hypersensitivity to milk proteins and hypersensitivity to umeclidinium or any of the components of the product

Manufacturer: GlaxoSmithKline

Analysis: Umeclidinium, the active ingredient of Incruse Ellipta®, is a long-acting antimuscarinic agent, also known as an anticholinergic. While it has affinity for muscarinic receptors M1 through M5, it works in the airways via inhibition of the M3 receptor at the smooth muscle, causing bronchodilation. A warning with Incruse Ellipta® indicates that it should not be used for the relief of acute symptoms, such as rescue therapy for the treatment of

acute episodes of bronchospasm, and it should not be started in patients during rapidly deteriorating or potentially life-threatening episodes of COPD.

The safety and efficacy was established in 3 dose-ranging studies, 2 placebo-controlled studies (one 12-week study and one 24-week study), and a 12 month long-term safety study. The two randomized, placebo-controlled confirmatory studies included adults diagnosed with COPD with a smoking history and a post-albuterol FEV1 ≤70% of predicted normal values. Study 1 was 24 weeks in duration, with a primary endpoint of the change from baseline in trough (predose) FEV1 at day 169 as compared with placebo. Results suggested a larger increase in mean change from baseline in trough FEV1 vs placebo (115ml difference from placebo). Comparable results were seen in study 2, which was a 12 week study. In study 1, an improvement in health-related quality of life was seen with umeclidinium vs placebo, as assessed per the St. Georges Respiratory Questionnaire (SGRQ; treatment difference of -4.69). The proportion with a clinically meaningful decrease at week 24, defined as a decrease of ≥4 units from baseline, was greater with umeclidinium vs placebo (42% vs 31%).

Place in Therapy: Incruse Ellipta® is for the once-daily maintenance treatment of COPD. It should not be used for the relief of acute symptoms or acute episodes of bronchospasm.

Based on a review of the package insert information and noted clinical resources, there is no data found to suggest that Incruse Ellipta® is safer or more effective than the currently available, more cost-effective medications. It is therefore recommended that Incruse Ellipta® remain non-preferred and require prior authorization and be available to the few who are unable to tolerate or who have failed on any preferred medications.

PDL Placement:

- ☐ **Preferred**
- ☒ **Non-Preferred**
- ☐ **Preferred with Conditions**

References

[1] Incruse Ellipta [package insert]. Research Triangle Park, NC: GlaxoSmithKline; 2014.

[2] UpToDate Desktop version 14.0. Role of anticholinergic therapy in COPD. Accessed February 2015.