Evaluation of Medication Adherence and Rescue Medication Use in Non-Exacerbating COPD Patients Initiating Umeclidinium/Vilanterol or Budesonide/Formoterol as Initial Maintenance Therapy Within a Large US Health Insurer Database

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Background

- Adherence to inhaled maintenance chronic obstructive pulmonary disease (COPD) therapy is critical to managing disease symptoms, while increasing rescue medication usage is thought to signify worsening disease progression.[1,2]
- This study evaluated adherence and use of rescue medication among patients with COPD, without a history of exacerbation, who initiated either of the following maintenance therapies:
  - Umeclidinium/vilanterol (UMEC/VI), a fixed-dose combination long-acting beta-agonist/long-acting muscarinic-antagonist (LABA/LAMA)
  - Budesonide/formoterol (B/F), a fixed-dose combination inhaled corticosteroid (ICS)/LABA

Methods

- A **retrospective cohort study** was conducted identifying subjects from the Optum's de-identified Clinformatics Data Mart Database initiating UMEC/VI or B/F from January 1, 2014 to December 31, 2017, with the earliest fill defined as the index date.

Key inclusion criteria	Key exclusion criteria
• ≥40 years of age as of index • 12 months continuous enrollment pre- and post-index • ≥1 medical claim with diagnosis of COPD in any position during 1-year pre-index	• Any pharmacy/medical claim for ICS-, LABA-, or LAMA-containing controller prior in the year prior to (and inclusive of) the index date • Moderate or severe COPD exacerbation or asthma diagnosis in the year prior to (and inclusive of) the index date • ≥1 medical claim with diagnosis of asthma in any position in year prior to (and inclusive of) the index date

Outcome Measures

PDC ≥ 0.80

Adherence

Rescue Medication

- **Adherence was defined as the proportion of days covered** (PDC) by UMEC/VI or B/F in the treatment period divided by the days until treatment switch or end of 12-month follow-up.
- **Rescue medication use was standardized to canister-equivalents** for short-acting β2-agonist (SABA), short-acting muscarinic antagonist (SAMA)-containing, and SABA/SAMA combination medication.

Statistical Analysis

Inverse Probability of Treatment Weighting (IPTW)

All observed covariates were balanced using IPTW

Results

Table 1. Post-IPTW Demographic and Clinical Comparison

Baseline Characteristics	Post-IPTW UMEC/VI N = 4,082	Post-IPTW B/F N = 9,529	ASD (%)*
Age, mean (SD)	70.5 (9.9)	70.7 (9.8)	1.5
Female, %	49.1	49.2	0.3
Payer			
Commercial, %	15.8	15.8	0.0
Medicare Advantage, %	84.2	84.2	0.0
Medicare Part D Low-Income Subsidy, %	27.2	27.3	0.2
Quan-Charlson Comorbidity Index, mean (SD)	3.2 (2.7)	3.2 (2.7)	0.1
COPD Severity Score, mean (SD)	23.4 (4.7)	23.4 (4.6)	0.6
Any Rescue Medication Fill, %	41.2	41.1	0.1
COPD-related Outpatient Visits, %	47.6	48.1	0.9
COPD-related Pulmonologist Visits, %	27.3	27.2	0.1

*Inverse Probability of Treatment Weighting (IPTW) was used to control for confounding. IPTW method cannot control for unmeasured covariates. *ASD < 10% indicates treatment groups were similar on measured confounders.

Figure 1. Adherence over the 12-Month Follow-Up Period

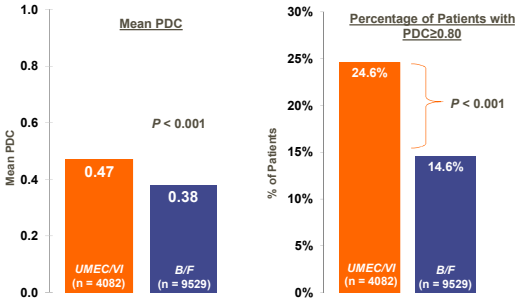
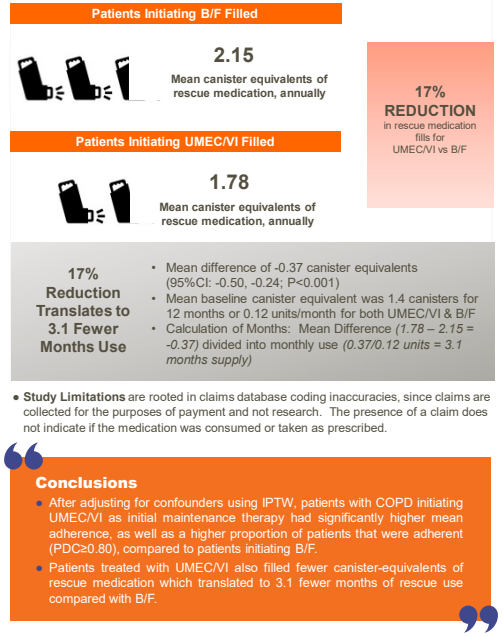


Table 2. Rescue Medication Use in the 12-Months following Treatment Initiation

Outcome	UMEC/VI N=4082	B/F N=9529	p-value
Any fill for rescue medications (%)	51.1	58.2	<0.001
SABA	46.2	50.8	
SAMA	1.9	2.9	
SABA/SAMA	10.7	14.7	
Rescue medication units			
Mean (SD)	1.8 (3.5)	2.2 (3.8)	
Median	0.1	1.0	
<6 units (%)	90.5	88.4	<0.001
6+ units (%)	9.5	11.6	

Abbreviations: B/F: Budesonide/Formoterol; SABA: short-acting beta-agonist; SAMA: short-acting muscarinic antagonist; SD: Standard deviation; UMEC/VI: Umeclidinium/Vilanterol

Figure 2. Rescue Medication Use over 12-Month Follow-Up Period



- **Study Limitations** are rooted in claims database coding inaccuracies, since claims are collected for the purposes of payment and not research. The presence of a claim does not indicate if the medication was consumed or taken as prescribed.

Conclusions

- After adjusting for confounders using IPTW, patients with COPD initiating UMEC/VI as initial maintenance therapy had significantly higher mean adherence, as well as a higher proportion of patients that were adherent (PDC≥0.80), compared to patients initiating B/F.
- Patients treated with UMEC/VI also filled fewer canister-equivalents of rescue medication which translated to 3.1 fewer months of rescue use compared with B/F.

References

1. Fan et al. *Respir Med*. 2016;116:100-106.
2. Makela et al. *Respir Med*. 2013;107(10):1481-1490.

Acknowledgements

- Clinformatics DataMart Database is owned/licensed by OptumInsight, Eden Prairie, MN.

Disclosures

- This study was funded by GlaxoSmithKline (GSK ID HO-20-19948/212922).
- AC, GM, and YL are GSK employees and hold stocks/shares in GSK. BW and AG are GSK/UNC fellows. CM and LB are former GSK employees.

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