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ORIGINAL RESEARCH

Budget Impact Analysis of Single-Inhaler Fluticasone Furoate/Umeclidinium/Vilanterol in Patients with Asthma in the Dubai Academic Healthcare Corporation

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Purpose: Asthma is a common, chronic respiratory disorder associated with substantial societal and economic burden globally, despite the availability of different treatment modalities. GSK has developed a once-daily single-inhaler triple therapy (SITT), comprised of fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI); a combination of inhaled corticosteroid, long-acting muscarinic antagonist, and long-acting β_2-agonist for patients with uncontrolled asthma. A budget impact analysis was conducted to determine the financial impact of introducing FF/UMEC/VI SITT from the perspective of the Dubai Academic Healthcare Corporation (DAHC).

Methods: A budget impact model was constructed using an epidemiology-based approach and used to estimate the expected 5-year budget impact of including FF/UMEC/VI for the treatment of eligible patients within the DAHC in the United Arab Emirates (UAE). The model included both pharmacy and efficacy-related costs. The perspective of the DAHC healthcare payer was adopted, thus only direct payer costs were included in the analysis. A one-way sensitivity analysis was conducted to test the robustness of the model structure, assumptions, and input parameters.

Results: The total budget impact was estimated to save 1 million United States Dollars (USD) over 5 years, with budget impacts of 0.08 million USD in Year 1; 0.14 million USD in Year 2; 0.22 million USD in Year 3; 0.28 million USD in Year 4; and 0.33 million USD in Year 5. The overall budget impact per patient was estimated to save 12.2 USD over 5 years. In one-way sensitivity analyses, the budget impact was most sensitive to changes in the market uptake of FF/UMEC/VI.

Conclusion: Healthcare payers may consider FF/UMEC/VI in the management of uncontrolled asthma which would save costs and reduce healthcare resource use in the UAE.

Keywords: asthma, asthma maintenance therapy, budget impact analysis, triple therapy, United Arab Emirates

Introduction

Asthma is a common, chronic respiratory disease usually characterized by chronic airway inflammation.[1] It is associated with variable symptoms of wheezing, shortness of breath, chest tightness, and coughing, along with variable expiratory airflow obstruction.[1] Estimates from 2016 suggest that approximately 340 million individuals worldwide have asthma, an increase of 17% from 2006 estimates,[2] while the prevalence of childhood asthma in high-income countries has sharply increased since the mid-20th century.[3] As such, the economic burden is substantial, ranging across countries from 150 United States Dollars (USD) per patient to more than 3000 USD per patient.[4] In Dubai, the total direct cost of asthma has been estimated at 24 million USD (converted from Arab Emirates Dirham) annually.[5] The indirect costs are also far-reaching, with approximately 79,000 workdays lost per year among adult male patients with asthma.[5]

According to the Global Initiative for Asthma (GINA) 2023 report, the goals of asthma treatment are to achieve and maintain asthma control and to reduce the future risk of exacerbations.[1] Inhaled corticosteroids (ICS) are a cornerstone of

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asthma management and work by treating inflammation.[1] A combination of ICS and a long-acting β_2-agonist (LABA) is recommended by GINA as reliever therapy for treatment steps 1–2, and as maintenance and reliever therapy for treatment steps 3–4.[1] However, despite treatment with ICS/LABA per management guidelines, approximately 30–50% of patients remain symptomatic and poorly controlled,[6–9] which may substantially influence health-related quality of life.[10]

In line with the stepwise treatment approach recommended in the GINA 2023 report, multiple therapy options are available for patients with uncontrolled asthma despite treatment with medium- or high-dose ICS/LABA. One option is biologic therapy, which has transformed the treatment paradigm for patients with severe asthma.[11–13] Another option is add-on long-acting muscarinic antagonist (LAMA) to ICS/LABA as triple therapy.[1] Several different triple therapy formulations have been evaluated for the treatment of asthma, including add-on tiotropium delivered as multiple-inhaler triple therapy (MITT), as well as single-inhaler triple therapy (SITT) options, including mometasone/glycopyrronium/indacaterol and beclometasone/glycopyrronium/formoterol.[1,14–17] Additionally, the Phase IIIA CAPTAIN trial investigated the efficacy and safety of fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) SITT among patients with inadequately controlled asthma despite ICS/LABA therapy. Results from CAPTAIN demonstrated that treatment with FF/UMEC/VI led to significant improvements in lung function, as well as numerical improvements in symptom control and numerical reductions in moderate/severe exacerbation rates compared with FF/VI.[17] Estimates of comparative efficacy for MITT versus SITT across multiple endpoints have been derived from the CAPTAIN study. Here, we present the results from a budget impact analysis, which was conducted to determine the financial impact of introducing FF/UMEC/VI SITT from the perspective of the Dubai Health Authority, now referred to as the Dubai Academic Healthcare Corporation (DAHC).

Materials and Methods

Model Overview

An epidemiology-based budget impact model was developed by ICON Corporation for GSK adaptation and used to estimate the 5-year impact of listing FF/UMEC/VI on the DAHC formulary of approved treatments with the United Arab Emirates (UAE). The number of patients with asthma eligible for treatment with FF/UMEC/VI in the UAE was estimated, and the market share of FF/UMEC/VI for the 5-year time horizon was projected. Uptake, ie, which treatment classes FF/UMEC/VI took market share from, was also determined. Pharmacy- and efficacy-related costs in each market share scenario were applied. The model was then used to calculate the total costs per year and cumulative costs over the 5-year time horizon for two scenarios: "with FF/UMEC/VI" and "without FF/UMEC/VI", with the cost difference between these scenarios representing the incremental budget impact of including FF/UMEC/VI in the DAHC formulary (Figure 1). A one-way sensitivity analysis was conducted to test the robustness of the model structure, assumptions and input parameters.

The model complied with the standards of the International Society for Pharmacoeconomics and Outcomes Research budget impact analysis guidelines.[18]

Patient Population

The patient population of interest was aligned with the population in the CAPTAIN trial, ie, adult patients with asthma who are uncontrolled despite ICS/LABA treatment. Estimation of the population eligible for FF/UMEC/VI treatment in the UAE is summarized in Table 1 and described below. Firstly, estimation of the total UAE population, annual population growth rate, percentage of population of adult age, and the annual asthma prevalence/incidence rates were based on data derived from Worldometer, the World Bank, Statista, and from the SNAPSHOT program.[19–22] For the base case analysis, the percentage of patients with asthma treated with any asthma medication was 89.5%, based on the UK population from Demoly et al 2009.[23] The percentage of patients treated with asthma maintenance controllers (82.1%) was based on a recent study in the UK and on the assumption that patients with asthma of GINA steps 2–5 would require such treatment.[24] As the target population expected to be eligible for FF/UMEC/VI excludes those on a low-dose ICS regimen, the population for analysis was further refined to pool only those patients treated with medium- or high-dose ICS/LABA, assumed to include those with asthma of GINA steps 4–5 (34.2% of those with GINA steps 2–5), as noted by Suruki et al, 2017.[24] Two studies were identified with data relevant to the proportion of patients with uncontrolled asthma on at least medium-dose ICS/LABA. To inform the base case analysis, the average of the

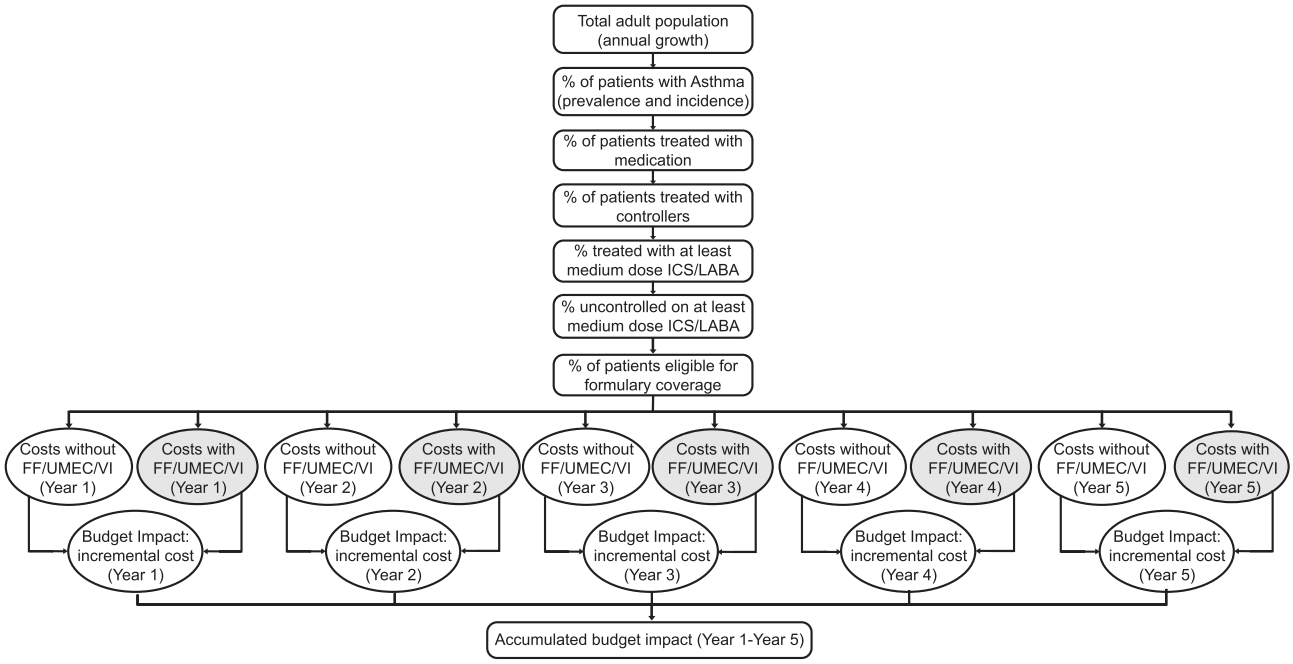

Figure 1 Schematic of budget impact model structure.
Abbreviations: ICS, inhaled corticosteroid; FF, fluticasone furoate; LABA, long-acting β_2-agonist; UMEC, umeclidinium; VI, vilanterol.

proportions of patients with not well-controlled asthma reported in Lee et al 2018[9] and Davis et al 2019[8] (52.5%) was used as the base case input. The proportion of patients eligible for formulary coverage was set to 100% for the base case analysis.

Market Share and Uptake of FF/UMEC/VI

Based on the British Guideline on the Management of Asthma 2019[25] and GINA 2019,[26] the treatments recommended for patients in the target population and therefore included in the model were SITT (ICS/LABA/LAMA), ICS/LABA, MITT (ICS/LABA/LAMA) and ICS/LABA + leukotriene receptor antagonists (Table 2). Proportions of eligible patients on different asthma treatment classes were validated by clinical experts within the DAHC between January and March 2021. These represented assumed patients' shares in the base case analysis. The projected market share of FF/UMEC/VI over the 5-year time horizon (Tables S1 and S2), along with the estimated market share taken from each

Table 1 Summary of Eligible Patients

Input Variable	Base Case Value
Total UAE population[a]	9,982,706
Annual population growth rate[b]	1.4%
Percentage of population of adult age (≥18 years)[c]	80.0%
Annual asthma prevalence rate	7.6%
Annual asthma incidence rate	0.0%
Percentage of asthma patients (adults) treated with medication	89.5%
Of those treated, percentage treated with asthma maintenance controllers	82.3%
Percentage treated with at least medium-dose ICS/LABA	34.2%
Percentage treated uncontrolled on at least medium-dose ICS/LABA	52.5%
Percentage eligible for formulary coverage	100.0%

Notes: [a]Value is based on data from 11 April 2021 (13); [b]Value is based on data from 2019 (14); [c]Value is estimated based on data from 2020 (15).
Abbreviations: ICS, inhaled corticosteroid; LABA, long-acting β_2-agonist; UAE, United Arab Emirates.

Table 2 List of Treatments Included in the Base Case Analysis

Treatment Class	Individual Treatments
SITT – ICS (medium/high dose)/LAMA/LABA	FF/UMEC/VI BDP/GLY/FOR MF/GLY/IND
ICS (medium/high dose[a])/LABA	FP/SAL FP/FOR BUD/FOR FF/VI BDP/FOR
MITT – ICS (medium/high dose)/LABA + LAMA	FP/SAL + TIO FP/FOR + TIO BUD/FOR + TIO FF/VI + TIO BDP/FOR + TIO
ICS (medium/high dose[a])/LABA + LTRA	FP/SAL + MON FP/FOR + MON BUD/FOR + MON FF/VI + MON BDP/FOR + MON

Note: [a]The definition of medium and high dose for ICS in dual therapies was based on the British Guidelines on the Management of Asthma 2019 (19).

Abbreviations: BDP, beclomethasone dipropionate; BUD, budesonide; FF, fluticasone furoate; FOR, formoterol; FP, fluticasone propionate; GLY, glycopyrronium; ICS, inhaled corticosteroid; IND, indacaterol acetate; LABA, long-acting β_2-agonist; LAMA, long-acting muscarinic antagonist; LTRA, leukotriene receptor antagonist; MF, mometasone furoate; MITT, multiple-inhaler triple therapy; MON, montelukast; SAL, salmeterol; SITT, single-inhaler triple therapy; TIO, tiotropium; UMEC, umeclidinium; VI, vilanterol.

treatment class by the uptake of FF/UMEC/VI (Table S3), was assessed based on the manufacturer's input and informed by insights from clinical practice.

Pharmacy-Related Costs

The annual pharmacy-related costs incurred in each scenario were estimated based on the number of patients using each treatment (Tables S4 and S5) multiplied by the average cost per patient per year for that treatment. The unit drug costs were drawn from the pharmacy drug costs of the published UAE drug list prices. Dose, pack size, and cost per pack for branded and generic drugs were used to calculate the treatment acquisition cost per day, and subsequently the cost per year.

Other model parameters included in the analysis were dispensing fee, pharmacy drug price adjustments (fixed at 0%), and co-pay or percent of co-insurance per prescription fill/refill. Dispensing fees and pharmacy price adjustments were added to acquisition costs to calculate the net costs per year, whereas co-pay or co-insurance were subtracted from acquisition costs to calculate the net costs per year. Dispensing fees and co-pay/co-insurance were fixed at 0% as the analysis accounted only for the payer perspective.

Efficacy-Related and Healthcare Resources Use (HCRU) Costs

Efficacy-related costs were applied based on the estimated change in HCRU due to improved symptom control with treatment, assessed using Asthma Control Questionnaire (ACQ)-7 data from CAPTAIN.[17,27] The model assumed a change from baseline in ACQ-7 score of 0.089 for FF/UMEC/VI, based on the treatment difference in ACQ-7 change from baseline with FF/UMEC/VI versus FF/VI in CAPTAIN;[17,27] all other treatment comparators were set at an ACQ-7 change from baseline of 0. The HCRU baseline rate, incidence, and unit costs were calculated based on local healthcare

cost data (Table S6), according to recommendations by Sullivan et al 2014.[18] Annual HCRU costs per patient were calculated by multiplying the annual HCRU rates by the corresponding HCRU unit costs.[18]

A universal adherence rate of 82.4% was assumed for all treatments for the base case analysis.

Sensitivity Analysis

As with all models, there are uncertainties around the parameter values incorporated in the model. Therefore, univariate sensitivity analyses were performed to test the robustness of the model (Table 3). An estimate of the likely range for each parameter was calculated based on the base case value (estimated at +/- 20%) for all variables except adherence rate and FF/UMEC/VI market share. The market share uptake rates were modified by a wider range, testing the impact of FF/UMEC/VI uptake by half or double the base case projections, while the adherence rate was varied by +/- 10% of the base case input.

Results

Base Case Analysis

Based on the parameters included in this analysis, the estimated numbers of patients to be treated with single-inhaler FF/UMEC/VI in each year between 2022 and 2026 were 1628, 2889, 4185, 5516, and 6884, respectively, in the UAE.

In the base scenario, the total incremental budget impact of adding FF/UMEC/VI, including pharmacy- and efficacy-related and HCRU costs, over 5 years was cost saving at 1.03 million USD or 12.2 USD per eligible patient (Figure 2; Table S7).

The total incremental budget impact of adding FF/UMEC/VI, including only pharmacy costs, over 5 years was 0.97 million USD or 11.6 USD per eligible patient.

After the introduction of FF/UMEC/VI, the total budget decreased, driven mainly by cost savings in drug acquisition costs, and a slight HCRU cost reduction related to symptom control benefits.

One-Way Sensitivity Analysis

In the one-way sensitivity analyses, the budget impact was most sensitive to changes in the uptake and final market share of FF/UMEC/VI, which demonstrated impact across the widest range of total incremental costs (Figure 3). Uptake of FF/UMEC/VI by double the base case projection improved cost savings from 1.03 million USD to 2.06 million USD, while halving the projected uptake of FF/UMEC/VI in the base case led to lower cost savings of 0.51 million USD (Figure 3).

Discussion

This analysis estimated the budget impact of listing FF/UMEC/VI in the DAHC formulary for treatment of adult patients with asthma in the UAE who remain uncontrolled on at least medium-dose ICS/LABA combination treatment. In the

Table 3 Univariate Sensitivity Analysis

Scenario	Current Value	Lower Bound	Upper Bound
Prevalence of asthma	7.6%	6.1%	9.1%
Annual population growth rate	1.4%	1.12%	1.68%
Percent treated with asthma controllers	82.3%	65.8%	98.8%
Percent treated with at least medium-dose ICS/LABA	34.2%	27.4%	41.0%
Percent uncontrolled on at least medium-dose ICS/LABA	52.5%	42.0%	63.0%
Price adjustment (mark-up)	0.0%	0.0%	20.0%
Co-pay[a]	0.0	0.0	20.0
Co-insurance[a]	0.0%	0.0%	20.0%
Adherence rate	Current values	−10.0%	+10.0%
FF/UMEC/VI market share	Current values	−50.0%	+100.0%

Notes: [a]The model applied either co-pay or co-insurance via the control settings. Depending on which setting the model used, only one of these rows was displayed in the one-way sensitivity analysis table.

Abbreviations: FF, fluticasone furoate; ICS, inhaled corticosteroid; LABA, long-acting β_2-agonist; UMEC, umeclidinium; VI, vilanterol.

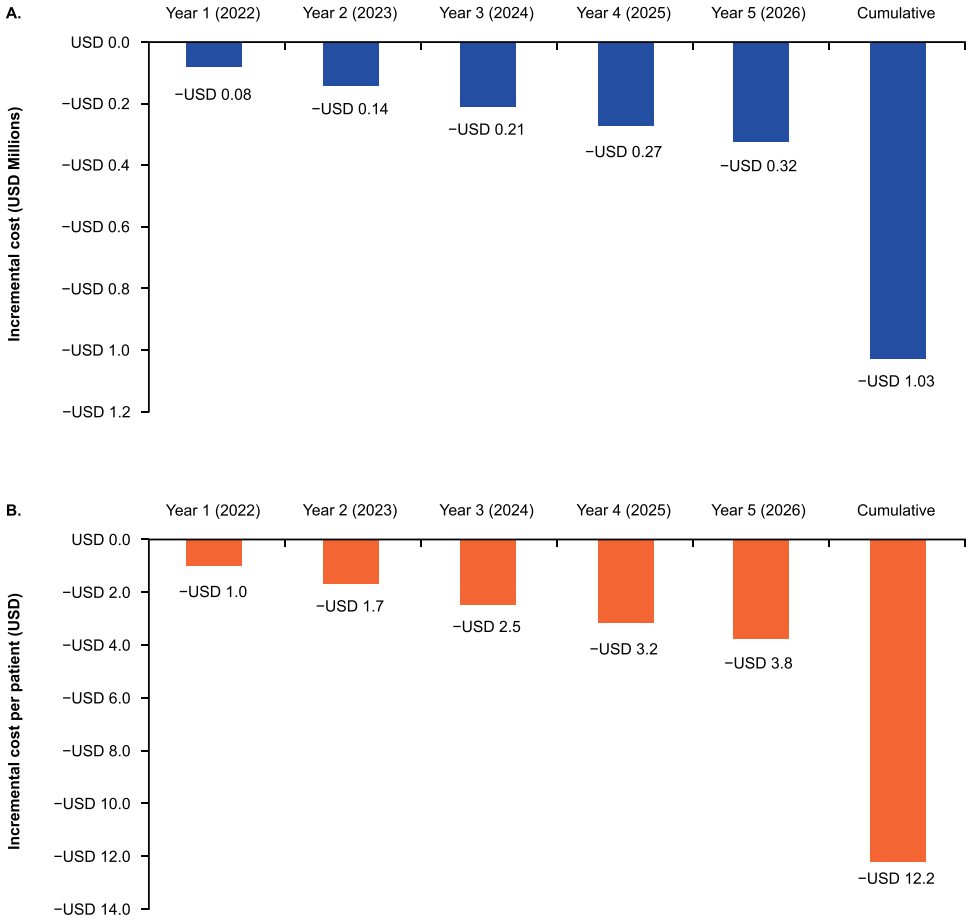

Figure 2 Incremental cost overall (**A**) and per patient (**B**), including all cost categories, over the 5-year time horizon.
Abbreviation: USD, United States Dollar.

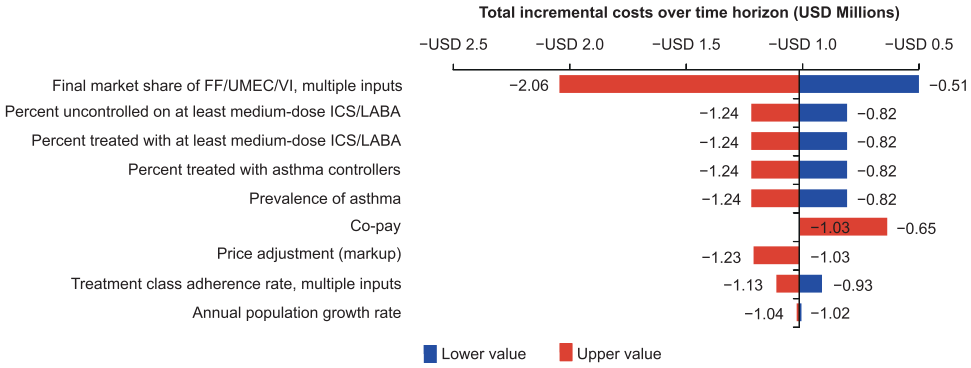

Figure 3 One-way sensitivity analysis.
Abbreviations: ICS, inhaled corticosteroid; FF, fluticasone furoate; LABA, long-acting β_2-agonist; UMEC, umeclidinium; USD, United States Dollar; VI, vilanterol.

base case analysis, introduction of FF/UMEC/VI was cost saving to the value of 1 million USD over 5 years. In the sensitivity analyses, the budget impact was most sensitive to changes in the market uptake of FF/UMEC/VI. These results provide robust evidence for the cost savings estimated to be associated with introduction of FF/UMEC/VI for the treatment of adult patients with asthma uncontrolled on at least medium-dose ICS/LABA treatment in the UAE.

A strength of this budget impact analysis was that the model accounted for efficacy-related costs. This was based on the idea that patients with uncontrolled asthma who are switched from dual therapies to SITT are likely to have reduced HCRU because of

better symptom control.[17] As such, additional therapy costs may be partially or fully offset by savings from reduced HCRU. Therefore, total HCRU costs were lower in the "with FF/UMEC/VI" scenario than in the "without FF/UMEC/VI" scenario to provide some cost offset to the payer. Including such an adjustment in the model greatly improves the accuracy of the analysis.

Given the variability in healthcare systems and decision maker perspectives, this budget impact analysis is not intended to provide a single budget implication for all decision makers, hence generalizability of this analysis to other settings should be limited. Additionally, there were some model assumptions that may not be accurate in all settings. For example, due to lack of local data, incidence was set at 0% and patient numbers were therefore based on prevalence only. The model also assumed a universal adherence rate (82.4%) across all treatment classes. If a lower adherence rate for comparators was assumed, cost savings would be reduced compared with the base case due to overall lower drug costs. In addition, it may be expected that patients have better adherence (ie, ~100%) to FF/UMEC/VI delivered via a single inhaler compared with MITT. Indeed, a study by Busse et al found that patients with asthma who initiated SITT were twice as adherent (proportion of days covered ≥0.8) and 49% more likely to persist with treatment at 12 months than MITT initiators.[28] Higher adherence to SITT versus MITT may potentially lead to higher drug costs with FF/UMEC/VI, which in turn may increase the budget impact. However, the GINA 2023 report highlights the importance of medication adherence in asthma management and symptom control,[1] and several studies have reported that low adherence is associated with worse asthma control and increased oral corticosteroid (OCS) use, HCRU and costs.[29–31] Therefore, the potential for better outcomes given better adherence to SITT should also be included when considering the budget impact of adopting FF/UMEC/VI.

Assumptions made in this model may not fully reflect all possible permutations in the study population. For example, patients' real-world treatment preferences and availability of different SITT and MITT options may affect the market share and budget impact of FF/UMEC/VI. Moreover, as the study population included patients with uncontrolled asthma receiving at least medium-dose ICS/LABA, these patients may also be receiving OCS.[1] This may impact the real-world market share of triple therapy, as clinicians may favor prescribing biologics, given the observed reductions in OCS use following biologic therapy.[13,32–34] Similarly, the model does not consider the potentially higher market share of biologics to manage comorbidities of severe asthma, such as chronic rhinosinusitis,[35–37] for which there is currently no evidence regarding the benefit of triple therapy. In addition, the budget impact from treatment-related complications was not accounted for in this model, because patients typically do not attend the clinic in the local setting to manage adverse events due to asthma treatments. Lastly, the methodology used to estimate HCRU costs, using change from baseline in ACQ-7 score, may introduce bias; however, as the budget impact was predominantly driven by treatment costs, any potential bias is expected to be minimal.

Despite the limitations of the model, this analysis provides valuable information on the positive budget impact of introducing FF/UMEC/VI in the DAHC formulary. The introduction of FF/UMEC/VI provides a once-daily single-inhaler option for patients who require triple therapy. This would significantly reduce the burden of treatment and may contribute to addressing the issue of adherence to treatment given that single-inhaler treatments have been shown to be associated with better adherence than multiple inhalers among patients with asthma.[38] In addition, there is a medical need in the UAE for a new drug that has demonstrated benefits in reducing symptom burden for patients (measured by change on ACQ-7) and reducing HCRU. The current analyses have shown that the introduction of FF/UMEC/VI could result in efficacy-related cost offsets from the UAE perspective. Therefore, FF/UMEC/VI represents a valuable option for eligible patients, with an estimated budget impact of 1 million USD (12.2 USD per eligible patient) in the first 5 budget years.

Conclusions

DAHC healthcare payers may consider FF/UMEC/VI SITT in the management of uncontrolled asthma which would save costs and reduce HCRU among eligible patients with uncontrolled asthma in the UAE.

Abbreviations

ACQ-7, 7-item Asthma Control Questionnaire; DAHC, Dubai Academic Healthcare Corporation; FF, fluticasone furoate; GINA, Global Initiative for Asthma; HCRU, healthcare resource use; ICS, inhaled corticosteroid; LABA, long-acting β_2-agonist; LAMA, long-acting muscarinic antagonist; MITT, multiple-inhaler triple therapy; OCS, oral corticosteroid; SITT, single-inhaler triple therapy; UAE, United Arab Emirates; UMEC, umeclidinium; USD, United States Dollars; VI, vilanterol.

Data Sharing Statement

Model input parameters were derived from public sources and peer-reviewed research, which have been cited in the manuscript where applicable and included in the Supplementary Material. The budget impact model adaptation is available upon written request to the corresponding author.

Ethics Approval

While the approach taken to obtain anonymized and aggregated data inputs for this budget impact analysis adaptation does not fall within GSK's definition of Human Subject Research, confirmation was still obtained from the relevant Ethics Committee of the Dubai Academic Healthcare Corporation that prior ethics approval was not required for the budget impact analysis adaptation, except a notification prior to external publication of the analysis.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

MH is an employee of GSK; SAD is President of the Emirates Health Economics Society; MF has no competing interests. The authors report no other conflicts of interest in this work.

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