Budget impact analysis of budesonide/glycopyrronium/formoterol fumarate dihydrate for COPD in the Italian healthcare system

Danny Gibson,[1] Cecilia Saleri,[2] Enrico de Nigris,[3] Ulf Holmgren,[4] Alberto Papi[5]

AstraZeneca, Cambridge, UK[1]; AstraZeneca, Milan, Italy[2]; Formerly of AstraZeneca, Cambridge, UK[3]; AstraZeneca, Gothenburg, Sweden[4]; Respiratory Medicine, Department of Translational Medicine, University of Ferrara, Ferrara, Italy[5]

Scan QR Code for e-poster and audio narration

Acceptance code: EE602

Introduction

- Fixed-dose triple therapy with the ICS/LABA/LAMA budesonide/glycopyrronium/formoterol fumarate dihydrate (BGF) 320/14.4/10 µg is approved as maintenance treatment for patients with moderate-to-very severe COPD in the European Union.[1]
- In a network meta-analysis published in 2021,[2] BGF was reported to demonstrate comparable efficacy with other fixed-dose triple combination therapies and open triple combinations with respect to exacerbation rate reductions.
- This analysis evaluated the cost impact of BGF entry on the Italian healthcare system for managing this patient population with COPD.

Methods

Model

- A budget impact model was developed to assess the impact of BGF entry on the Italian healthcare system over 3 years (model structure – **Figure 1**; inputs – **Table 1**).
  - Scenarios including and excluding BGF were compared.
    - Inputs included the eligible Italian population, market shares of triple therapies for COPD, clinical factors and costs.
    - Outputs included costs of care and the budget impact of BGF inclusion.

Population

- A prevalence-based approach estimated the population eligible for triple therapy using the total Italian population and the proportion of people living with COPD in Italy (**Table 2**), using the following assumptions.
  - The total Italian population was 60,359,546, with 3% (1,810,786) diagnosed with COPD based on the ISTAT 2019 and the Report Health Search 2020.
  - Of those with COPD, 81.8% (1,481,222) had moderate-to-very severe COPD,[3] with 35.6% (526,655) eligible for treatment with triple therapies (unpublished analysis).
  - Patient distribution by FEV_1 severity in the ETHOS study (NCT02465567)[4] based on GOLD[5] guidance: moderate FEV_1, 28.55%; severe FEV_1, 60.59%; very severe FEV_1, 10.87%.

Market share

- BGF, fluticasone furoate/umeclidinium bromide/vilanterol trifenatate (FF/UMEC/VIL), beclometasone dipropionate/glycopyrronium bromide/formoterol fumarate dihydrate (BDP/GLY/FOR) and open triple therapies were included in the model.
  - Estimated market shares for each treatment were assessed between 2021–2023 (**Table 2**).

Clinical factors

- Clinical factors in the model included estimated exacerbation rates, based on rates from the ETHOS study[5], and additional analyses (**Table 3**).
- The mean treatment duration was assumed to be 12 months for each year.

Costs

- Disease management costs (cost per exacerbation) were included in the model (**Table 4**).
- Treatment acquisition costs were based on pricing at the time the analyses were conducted, with BGF and BDP/GLY/FOR costs based on twice-daily dosing and FF/UMEC/VIL and open triple costs based on once-daily dosing.

Outcomes

- Outcome measures included costs with and without BGF from 2021–2023, and budget impact and percent cost reductions over this period (**Figure 1**).

Figure 1. Budget impact model structure

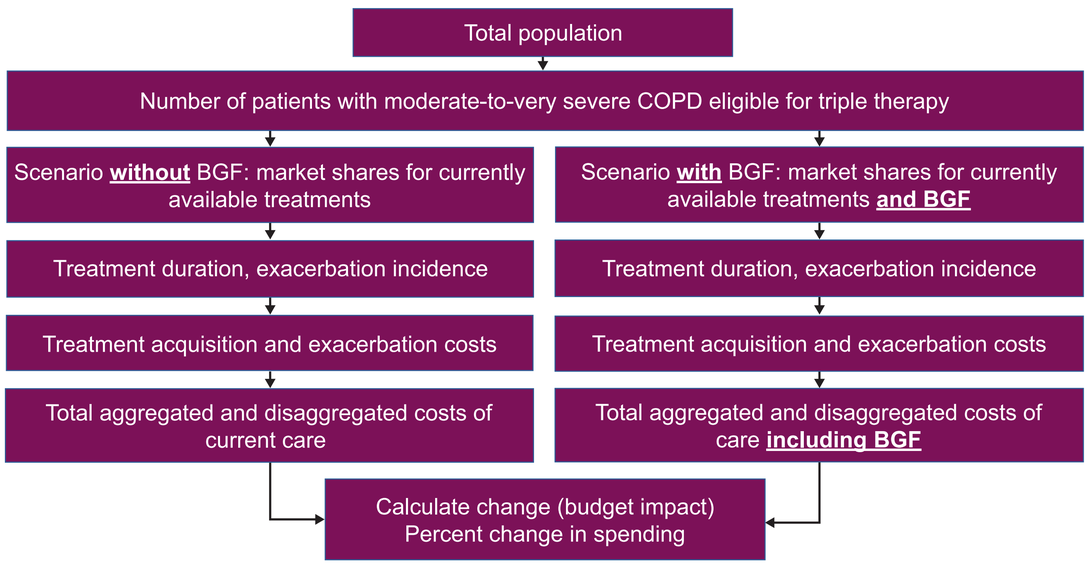


Table 1. Description of budget impact model inputs

Model aspect	Inputs
Population	Adult patients with moderate-to-very severe COPD, who are eligible for triple therapy, based on a prevalence-based approach
Time horizon	1 to 3 years
Treatments	BGF FF/UMEC/VIL BDP/GLY/FOR Open triple therapies (pooled; cost based on weighted average of ICS/LABA and LAMA treatments in the Italian market)
Cost types	Treatment acquisition costs Disease management costs • Moderate exacerbation-related • Severe exacerbation-related
Outcome measures	Total budget impact over time horizon By scenario (annual) • Disaggregated and total (aggregated) costs Incremental (annual) • Disaggregated and total (aggregated) costs • Percent change in spending

Table 2. Population and market share estimates used in the model

Characteristic	2021	2022	2023
Patients eligible for triple therapy, N	526,655	511,086	483,671
Patients on BGF, n	7321	25,350	43,385
Market share (%)			
Scenario without BGF			
BGF	0.00	0.00	0.00
FF/UMEC/VIL	19.20	27.00	31.80
BDP/GLY/FOR	17.40	24.50	28.80
Open triple therapies (pooled)	63.40	48.50	39.40
Scenario with BGF			
BGF	1.39	4.96	8.97
FF/UMEC/VIL	19.00	26.50	30.33
BDP/GLY/FOR	17.20	24.00	27.69
Open triple therapies (pooled)	62.41	44.54	33.01

Table 3. Exacerbation rates in patients with BGF and open triple therapies

	Annual exacerbation rate per patient	
Treatment	*Moderate*	*Severe*
BGF[a]	0.89	0.14
Open triple therapies (pooled)[b]	1.05	0.14

[a]Rates based on ETHOS; for modeling purposes, all fixed-dose combination triple therapies have been assumed to have equal efficacy.
[b]Rates based on post-hoc ETHOS analysis performed by AstraZeneca (unpublished data).

Table 4. Estimated disease management costs of COPD triple therapies

		Cost stratified by treatment or exacerbation severity
Disease management costs		
Cost per exacerbation (€)[a]	Moderate	53.62
	Severe	1600.00

[a]Moderate exacerbation costs estimated based on one course of levofloxacin and prednisone and one specialist visit with spirometry test; severe exacerbation costs based on hospitalization for COPD exacerbation.

Results

- Total costs per year with and without BGF decreased from 2021 to 2023 (**Figure 2**).
  - Total costs for managing moderate-to-very severe COPD from the Italian healthcare system perspective, without BGF, were estimated to be €1,400,232,133 from 2021–2023.
  - Total costs were estimated to decrease to €1,391,479,087 with BGF entry.
- The total cost saving of BGF entry into the Italian market over 2021–2023 was estimated to be €8,753,047.
  - The impact of BGF entry into the Italian healthcare system was estimated to increase annually from 2021–2023 (**Figure 3**), with cost reductions of 0.16% in 2021, 0.67% in 2022 and 1.10% in 2023.
  - Cost savings are the result of decreased treatment acquisition costs (€8,028,265) and total decreased exacerbation costs (€724,782) over 3 years.

Figure 2. Costs to the Italian healthcare system with and without BGF

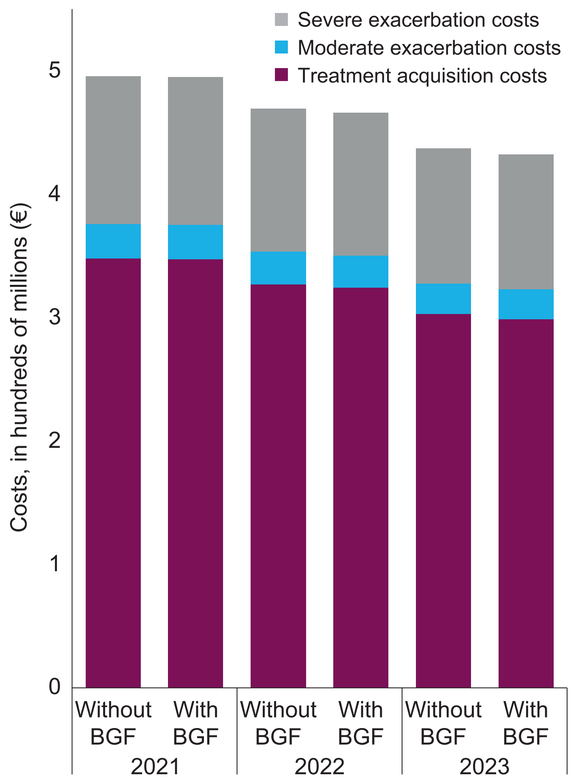
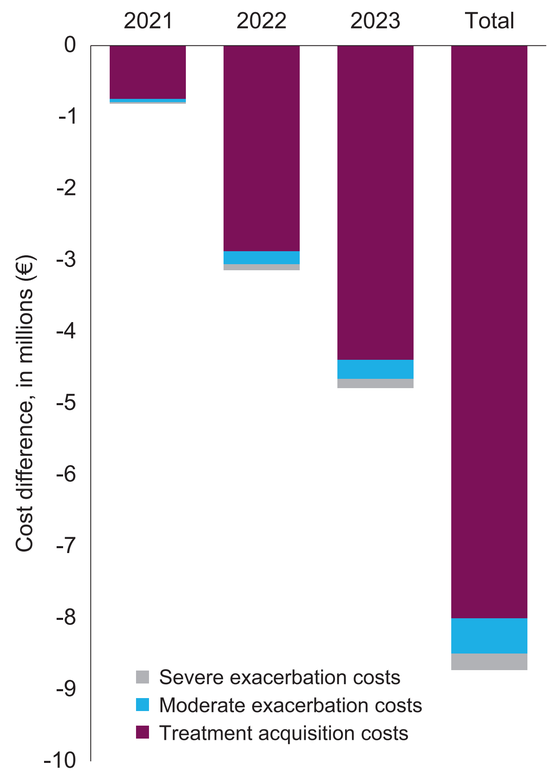


Figure 3. Budget impact of BGF entry into the Italian healthcare system



Conclusions

- In patients with moderate-to-very severe COPD, BGF decreased total costs when used in place of open triple therapies, with a total saving of €8,753,047 over 2021–2023.
- BGF offers cost savings within the Italian healthcare system, which were mainly driven by reduced treatment acquisition costs.
- Analyses were performed using price and reimbursement practices as of June 2022.

Abbreviations

BDP/GLY/FOR, beclometasone dipropionate/glycopyrronium bromide/formoterol fumarate dihydrate; BGF, budesonide/glycopyrronium/formoterol fumarate dihydrate (at a dose of 320/14.4/10 µg); COPD, chronic obstructive pulmonary disease; FEV_1, forced expiratory volume in 1 second; FF/UMEC/VIL, fluticasone furoate/umeclidinium bromide/vilanterol trifenatate; GOLD, Global Initiative for Chronic Obstructive Lung Disease; ICS, inhaled corticosteroid; ISTAT, National Statistical Institute; LABA, long-acting β_2-agonist; LAMA, long-acting muscarinic antagonist.

Acknowledgments

Medical writing support, under the direction of the authors, was provided by Eric Comeau, PhD, of CMC Connect, a division of IPG Health Medical Communications, funded by AstraZeneca in accordance with Good Publication Practice (GPP 2022) guidelines.[6]

Presented at ISPOR Europe Congress 2022
Vienna, Austria, 6–9 November

References

1. AstraZeneca UK Ltd. Trixeo Aerosphere SmPC 2021. https://www.medicines.org.uk/emc/product/12028/smpc#gref.
2. Bourdin A et al. Adv Ther 2021; 38: 3089–3112.
3. Corrado A et al Respir Med 2012; 106: 989–997.
4. Rabe KF et al. N Engl J Med 2020; 383: 35–48.
5. Global Initiative for Chronic Obstructive Lung Disease. 2022 Report. https://goldcopd.org/2022-gold-reports-2/.
6. DeTora LM et al. Ann Intern Med 2022; 175: 1298–1304.

Disclosures

DG, **CS** and **UH**: employees of AstraZeneca and hold stock and/or stock options in the company.
EdN: former employee of AstraZeneca and previously held stock and/or stock options in the company.
AP: reports funding from AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, GSK, Pfizer, Sanofi and Teva, paid to the institution; personal fees for consulting from ALS, AstraZeneca, Avillion, Chiesi Farmaceutici, Elpen Pharmaceuticals, GSK, IQVIA, Novartis and Sanofi; and personal fees for lectures and presentations from ALS, AstraZeneca, Avillion, Boehringer Ingelheim, Chiesi Farmaceutici, Edmond Pharma, Elpen Pharmaceutic, GSK, IQVIA, Menarini, MSD, Mundipharma, Novartis, Sanofi, Teva and Zambon.