ISPOR Europe 2024

EE135

17-20 November 2024, Barcelona, Spain

Cost-Effectiveness Analysis of Filgotinib as a First-Line Treatment for Biologic-Naive Patients With Ulcerative Colitis in Greece

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Background & Objective

Ulcerative colitis (UC) is a chronic, systemic, immunological disease characterized by diffuse inflammation confined to the colonic mucosa. UC is associated with decreased synthesis and altered sulphation of various mucin subtypes, compromising the epithelial barrier. The disease can be classified based on severity (mild, moderate, severe) and the extent of inflammation, which may affect only the rectum (proctitis), the rectum and sigmoid colon (proctosigmoiditis), or extend further, involving the colon distal to the splenic flexure (left-sided colitis) or the entire colon (pan-colitis). Symptoms range from mild to severe, including rectal bleeding, diarrhea, urgency, tenesmus, abdominal pain, and fever. Filgotinib (GLPG0634/GS-6034), an orally administered, preferential JAK1 inhibitor, has shown efficacy in treating moderate to severe UC. In the SELECTION Phase IIb/III trial (NCT02914522) [1], filgotinib achieved all primary endpoints at a 200 mg dose, with ongoing evaluation of long-term safety outcomes in the SELECTION-LTE extension study (NCT02914535). The objective of this study is to assess the cost-effectiveness of introducing filgotinib as a first-line treatment for biologic-naïve patients with moderate to severe ulcerative colitis in Greece. This analysis compares filgotinib to adalimumab, golimumab, and vedolizumab, focusing on the costs and health outcomes from a third-party payer perspective. The findings aim to provide valuable insights into the economic viability of filgotinib and its potential role in the treatment landscape for ulcerative colitis in Greece.

Methods

The analysis is grounded on an adaptation of a pharmacoeconomic model evaluating the cost-effectiveness of filgotinib as a first-line treatment option for biologic-naïve patients with moderate to severe UC. The model compares filgotinib with adalimumab, golimumab, and vedolizumab, assessing both the health outcomes and associated costs of each treatment. The population characteristics and main features of the economic evaluation are summarized in Table 1. The cost-effectiveness analysis employs a Markov model with multiple health states, which represent transitions between disease activity and remission, as well as potential surgical interventions. These states reflect the natural progression of UC, including responses based on the Mayo score and post-surgical outcomes.

Key clinical inputs for efficacy and safety are derived from the NCT02914522 clinical trial [1], while comparator efficacy was incorporated from a network meta-analysis of available biologics and JAK inhibitors. Health resource utilization and cost data, including drug prices, administration, and monitoring, were sourced from official Greek health system data [2-3], with drug prices adjusted to reflect a 5% hospital rebate.[4]. Additional resource utilization inputs were provided by expert opinion and clinical guidelines, particularly in areas where country-specific data were lacking. Health-related quality of life utilities, essential for calculating QALYs, were based on EQ-5D data from the SELECTION trial and the network meta-analysis.

Table 1: Main Features of Economic Evaluation

Population	**Adult biologic-naïve patients with moderate or severe ulcerative colitis**
Intervention	**Filgotinib 200mg**
Comparators	**Adalimumab 160/80/40 mg** **Golimumab 200/100 mg** **Vedolizumab 300 mg**
Perspective of the analysis	**Third-party payer: only third-party payer benefits and costs are included**
Economic evaluation	**Cost effectiveness analysis**
Time horizon	**80 years with a maximum age of 100 years**
Inputs	**Pharmaceutical cost** **Administration cost** **Monitoring cost** **Surgery cost** **Hospitalization cost** **Adverse event cost**
Outputs	**Quality adjusted life years (QALYs)** **Life years** **Costs** **Incremental cost** **Net monetary benefit** **ICER**
Discount rate	**3,5% (Costs, life years and QALYs)**

Results

The analysis demonstrated that filgotinib, when used as a first-line treatment for biologic-naïve patients with moderate to severe UC, is a cost-effective option compared to adalimumab, golimumab, and vedolizumab. While there were no significant differences in life years gained between the treatments, small differences were observed in QALYs, with variations of less than 0.04, indicating minimal clinical difference between the options. The incremental cost-effectiveness ratio (ICER) for filgotinib compared to adalimumab, and golimumab was €11,032 and €15,360 per QALY, respectively, both below the willingness-to-pay threshold of €30,000 per QALY, confirming filgotinib's cost-effectiveness in these comparisons. Against vedolizumab, filgotinib was found to dominate, offering a better clinical outcome at a lower overall cost.

The deterministic sensitivity analysis (DSA) identified drug acquisition cost and biologic exposure as key drivers influencing cost-effectiveness, reinforcing the robustness of filgotinib's economic advantage. The probabilistic sensitivity analysis (PSA) confirmed the stability of the results, with filgotinib maintaining its economic viability across a range of parameter variations. The ICER values observed in the PSA were consistent with the base case, with minimal changes in life years and QALYs across all treatment options. In particular, the ICER for filgotinib versus adalimumab in the PSA was €12,972 per QALY, while against golimumab, it was €18,302 per QALY, both remaining well within the acceptable threshold. Additionally, filgotinib dominated vedolizumab in the PSA, as it did in the base case, further solidifying its cost-effectiveness.

The cost-effectiveness acceptability curve (CEAC) highlighted that filgotinib had a 100% probability of being the most cost-effective treatment option at a willingness-to-pay threshold of €30,000 per QALY. These results underscore Filgotinib's strong positioning as a cost-saving and effective intervention in the management of UC, with a high degree of confidence in its value under uncertainty.

Table 2. Summary results of the cost effectiveness analysis

	Life years	QALYs	Incremental QALYs	Total cost (€)	Incremental cost (€)	NMB (€)	Incremental NMB (€)	ICER (€/QALY)
Filgotinib	21.437	14.057		104,371		317,327		
Adalimumab	21.437	14.021	0.04	103,978	393	316,651	676	11,032
Golimumab	21.437	14.020	0.04	103,815	556	316,797	530	15,360
Vedolizumab	21.437	14.028	0.03	109,190	-4,819	311,653	5,674	Dominates

Figure 1. Incremental cost-effectiveness plane

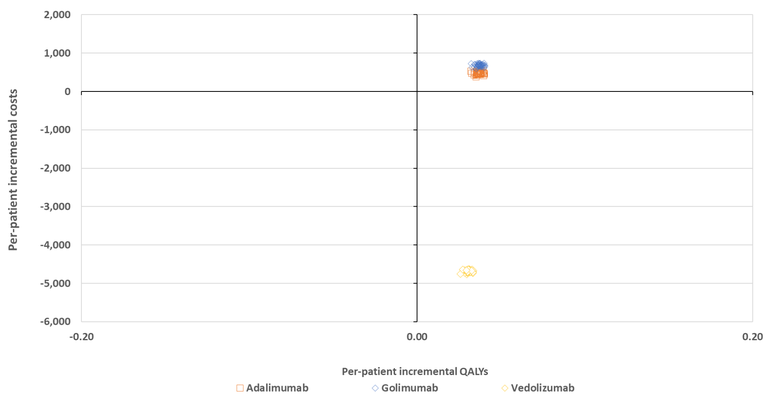
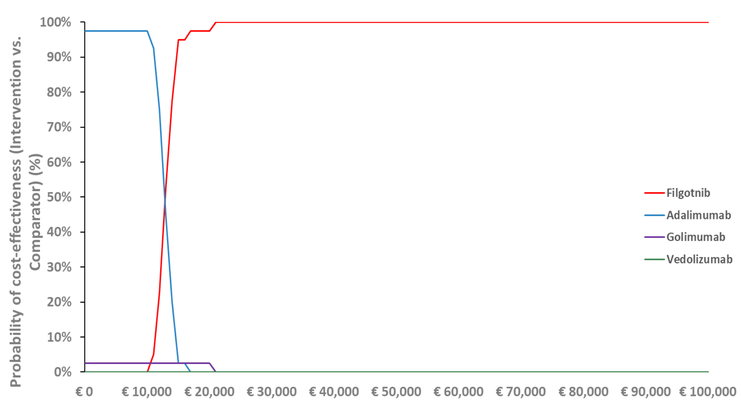


Figure 2. Cost-Effectiveness Acceptability Curve



Conclusions

Filgotinib as a first-line treatment for biologic-naïve patients with moderate to severe ulcerative colitis offers a cost-saving and effective option for the Greek healthcare system. While incremental health benefits compared to other biologics were marginal, the significant cost savings associated with Filgotinib, particularly in comparison to Vedolizumab, make it an economically favorable choice. These savings could be redirected towards other high-cost areas, such as oncology treatments, supporting the sustainability of healthcare budgets. Based on the analysis, Filgotinib presents a valuable option for managing ulcerative colitis from both a clinical and economic perspective.

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Funding: This study was financially supported Swedish Orphan Biovitrum Ltd. (Sobi).

Disclosure statement: No authors have any conflicts of interest to disclose