

Estimating the budget impact of the introduction of filgotinib for the treatment of ulcerative colitis in Spain

Poster no. POSA163



Audio available

Xiaoyan Lu,¹ Ignacio Cuervo-Arango,² Ginita Jutla,³ Gavin Jones,³ Susannah Sadler³

¹Galapagos, Paris, France; ²Galapagos, Madrid, Spain; ³Health Economics and Outcomes Research (HEOR) Ltd, Cardiff, UK

Introduction

Ulcerative colitis (UC) is a systemic chronic inflammatory disease causing diffuse inflammation that starts in the rectum and tends to progress proximally in a continuous manner through the entire colon.¹

UC predominantly presents in young adulthood, with a peak onset between 15 and 30 years of age.²

Symptoms range from mild to severe and include rectal bleeding, diarrhoea, urgency, tenesmus, abdominal pain and fever.³

With an annual incidence of approximately 7.1–9.6 per 100 000 people in Spain, UC represents the most common type of inflammatory bowel disease.⁴

Filgotinib is an oral Janus kinase 1 preferential inhibitor that has been shown to be effective in treating UC.⁵

– In the phase 2b/3 SELECTION trial, filgotinib 200 mg was efficacious in inducing and maintaining clinical remission compared with placebo in patients with moderately to severely active UC.⁵

Objective



The objective of this study was to estimate the budget impact of introducing filgotinib as a new oral targeted synthetic UC treatment in the Spanish healthcare system, from a Spanish healthcare payer's perspective.

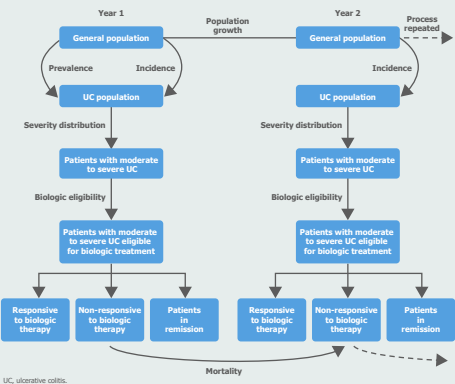
Methods

Model parameters

All model inputs were taken from published sources and verified by a Spanish clinician (Iago Rodríguez Lago, MD, PhD; Hospital de Galdakao, Bilbao, Spain) (Tables 1–3).

The patient population was aligned to the eligibility criteria of the SELECTION trial (i.e. patients with moderately to severely active UC eligible for biologics and targeted treatments).⁵

Figure 1. Summary of the budget impact model structure



Model structure and platform

A filgotinib budget impact model (BIM) was developed to capture health effects and direct healthcare costs from the perspective of the Spanish healthcare payer. The model structure is summarized in Figure 1.

For a given population, the filgotinib BIM evaluated the direct medical costs under two scenarios:

- **world without filgotinib**, reflecting the management of adults with UC in the absence of filgotinib (i.e. current standard of care)
- **world with filgotinib**, reflecting the management of adults with UC following the introduction of filgotinib.

The model used a time horizon of 5 years.

The BIM was developed in Microsoft Excel 2016.

Table 1. Spanish market share inputs used in the budget impact model

World without filgotinib					
Treatment	Year 1 (2022)	Year 2 (2023)	Year 3 (2024)	Year 4 (2025)	Year 5 (2026)
Adalimumab, %	30.32	29.39	28.74	27.83	27.06
Golimumab, %	6.20	6.19	6.18	6.17	6.16
Infliximab, %	38.27	37.09	36.27	35.12	34.14
Tofacitinib, %	3.89	4.13	4.56	4.81	5.26
Ustekinumab, %	1.73	2.29	2.86	3.42	3.99
Vedolizumab, %	19.61	20.91	21.40	22.65	23.40
World with filgotinib					
Treatment	Year 1	Year 2	Year 3	Year 4	Year 5
Filgotinib, %	0.00	1.86	3.80	5.82	7.92
Adalimumab, %	30.32	29.39	28.74	27.83	27.06
Golimumab, %	6.20	5.71	5.23	4.75	4.27
Infliximab, %	38.27	37.09	36.27	35.12	34.14
Tofacitinib, %	3.89	3.56	2.86	2.40	1.87
Ustekinumab, %	1.73	2.35	2.99	3.65	4.32
Vedolizumab, %	19.61	20.04	20.11	20.44	20.43

Table 2. Summary of treatment-specific annual costs used in the budget impact model

Treatment	Brand	Posology	Route of administration	Dose (pack size)	Pack cost	Dose escalation, %	Units required (dose escalation)		Doses required (dose escalation)		Annual cost (including conventional, excluding administration)
							Per induction 10 weeks	Per maintenance 10 weeks	Per induction 10 weeks	Per maintenance 10 weeks	
Filgotinib ¹	Jyseleca ²	200 mg o.d.	Oral	TBC	€1008.00	NA	2.33	2.33	70.00	70.00	€12 803
Adalimumab	Humira ³ Huma ⁴	160 mg wk 0, 80 mg wk 2, then 40 mg Q2W or 40 mg QW	SC	40 mg (2)	€627.00	36.1	4.56	2.50 (5.00)	6.00	5.00 (10)	€11 909
Golimumab	Simponi ⁵	(1) 200 mg wk 0 and 100 mg wk 2 (M) 50 mg wk 0, then pts < 80 kg: 50 mg Q4W or pts > 80 kg: 100 mg Q4W	SC	50 mg (1) 100 mg (1)	€1117	20.8	3.49 ⁶	2.50 (5.00)	3.49 ⁶	2.50	€21 082
Infliximab	Inflixtra ⁷	5 mg/kg wk 0, 2 and 6, then Q8W or Q4W	IV	100 mg (1)	€402.21	39.1	3.00	1.25 (2.50)	3.00	1.25 (2.50)	€13 801
Tofacitinib	Xeljanz ⁸	(1) 10 mg b.i.d. for 8 weeks (M) 5 mg or 10 mg b.i.d.	Oral	5 mg (56)	€824.00	36	5.00	2.50 (5.00)	252.00	140.00 (280)	€15 522
Ustekinumab	Stelara ⁹	Pts < 55 kg: 260 mg IV loading, then 90 mg wk 8 and 90 mg Q12W or Q8W SC Pts 55–85 kg: 390 mg IV loading, then 90 mg wk 8 and 90 mg Q12W or Q8W SC Pts > 85 kg: 520 mg IV loading, then 90 mg wk 8 and 90 mg Q12W or Q8W SC	IV/SC	130 mg IV (1) 90 mg SC (1)	€3100.00	80	3.00	0.83 (1.25)	1.00	0.83 (1.25)	€21 953
Vedolizumab	Entyvio ¹⁰	300 mg IV at wk 0, 2 and 6, then Q8W or Q4W	IV	300 mg (1)	€3466.00	29.4	3.00	1.25 (2.50)	3.00	1.25 (2.50)	€31 154

Data are based on publicly available information (list prices and summaries of product characteristics).

Not yet approved for treatment of ulcerative colitis. ¹First dose for responders only, based on predicted probability of response based on network meta-analysis performed by HEOR Ltd.

b.i.d., twice daily; i.d., induction; IV, intravenous; NA, not applicable; pts, patients; o.d., once daily; QW, every week; Q2W, every 2 weeks; Q4W, every 4 weeks; Q8W, every 8 weeks; Q12W, every 12 weeks; SC, subcutaneous; TBC, to be confirmed; wk, week.

The following inputs for a Spanish setting were included in the model:

- general population, based on the initial population size in year 1, annual percentage growth in subsequent years and annual mortality
- the eligible UC population, including UC prevalence and incidence in Spain based on two studies^{6,7}
- demographics, of which the key input was mean body weight (kg) in the overall UC population.

Following its introduction, in the base case, filgotinib's market share was estimated to grow from 1.86% in year 2 to 7.92% in year 5, based on assumptions made using the list price for filgotinib for rheumatoid arthritis and growth of tofacitinib's market share (Table 1).

Treatment efficacy, expressed as the estimated probability of patients achieving a response or remission with each modelled therapy, was derived from a network meta-analysis performed by HEOR Ltd.

Costs from 2021 incorporated into the model were related to UC treatment and disease management, and included drug acquisition (using list prices, Table 2) and costs of administration, conventional therapy, adverse events and surgery in addition to disease-state-specific costs (Table 3).

Treatment cost calculations used standard Spanish dosing regimens, and biosimilar prices were used for treatments with loss of exclusivity. The price of filgotinib used was €1008 per pack (Table 2).

Deterministic sensitivity analysis

A deterministic sensitivity analysis was carried out, with results presented as a tornado plot.

Table 3. Summary of additional healthcare costs used in the budget impact model

Drug administration costs					
IV drugs					€160 ^{1,2}
SC drugs					€0
Oral drugs					€0
Conventional therapy costs					
Treatment	Dosage	Cost per dose	Per annum cost	Personal usage	Usage as concomitant therapy
Azathioprine	One to four 50 mg tablets; q.d.	€0.24	€119.57	46%	37.2%/0% ³
Mesalazine	1.2–2.4 g; o.d.	€1.33	€1217.00	50%	46%
Prednisolone	Three injections per year	€13.20	€39.60	44%	20%
Disease-state-specific costs					
Hospital care costs for moderate to severe UC					
Non-response					€7434 ⁴
Response					€2770 ⁴
Remission					€1297 ⁴
Unit costs of treatment for adverse events					
Serious infection					€5294 ⁴
Herpes zoster					€4450 ⁴
Annual adverse event probability for moderate to severe UC					
Treatment	Serious infection, %		Herpes zoster, %		
Filgotinib ^{1,2}	2.5		0.6		
Adalimumab ^{3,4}	1.9		0.0		
Golimumab ⁵	2.6		0.0		
Infliximab ^{7,8}	1.5		0.4		
Tofacitinib ^{9,10}	4.1		3.0		
Ustekinumab ¹¹	0.2		0.0		
Vedolizumab ^{12,13}	1.4		0.3		
Cost of surgery					
Annual probability: 1.44% ²			Cost per event: €26 919 ¹⁰		

¹Azathioprine is not used as a concomitant therapy with Janus kinase inhibitors (i.e. tofacitinib); therefore, usage is 0% for tofacitinib and 37.2% for other biologics. Based on network meta-analysis performed by HEOR Ltd. Annual probability of herpes zoster assumed (not reported in trial).

²IV, intravenous; q.d., once daily; o.d., every day; SC, subcutaneous; UC, ulcerative colitis.

Results

Overall budget impact

In the 'world with filgotinib' scenario, total cumulative cost savings of €27 860 783 were seen over 5 years (total costs without filgotinib: €1 252 347 022; total costs with filgotinib: €1 224 486 239) (Figure 2a).

The estimated annual budget impact after the introduction of filgotinib was –€2 411 873, –€4 575 225, –€8 377 589 and –€12 496 096 in years 2, 3, 4 and 5, respectively (Figure 2b). Drug acquisition costs following the introduction of filgotinib accounted for cumulative savings of €25 815 413 over 5 years, equivalent to 92.7% of the total cumulative savings for this time horizon (Figure 3).

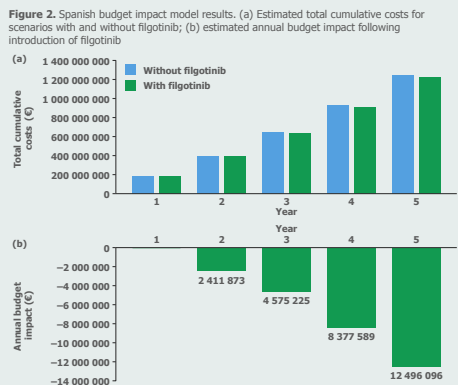
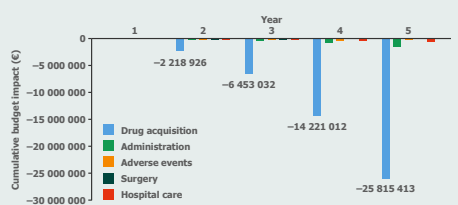


Figure 3. Cost breakdown for estimated budget impact of introducing filgotinib in Spain



References

1. Abraham C, Cho JH. *N Engl J Med* 2009;361:2086–78.
2. Hanauer SB. *Inflamm Bowel Dis* 2006;12 Suppl 1:S3–9.
3. Cotté J et al. *J Clin Gastroenterol* 2013;7:322–37.
4. Regan BG et al. *Lancet* 2013;381:2077–84.
5. Puig J et al. *Rev Esp Salud Publica* 2019;93:e1–11.
6. Chapman W et al. *Thromb Haemostas* 2019;119:1211–11.
7. Spanish General Council of Official Colleges of Pharmacists. Healthcare knowledge database – Bot PLUS 2.0; 2019. Available from: <http://botplusweb.org/pt/pt/pt/pt/pt/>
8. Chikuma Consulting. *Global healthcare costs database*; 2019. Available from: <http://esahd.dohku.com>
9. Thomson C et al. *Expert Rev Pharmacoecon Outcomes Res* 2011;11–11.
10. Caldera F et al. *Inflamm Bowel Dis* 2019;25:955–7.

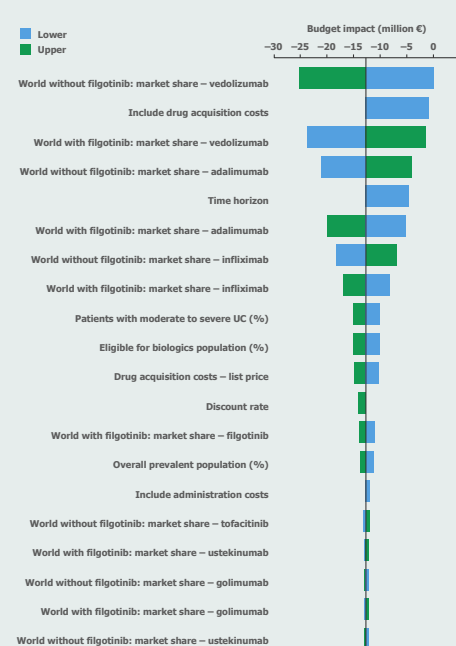
Acknowledgements

This study was funded by Galapagos Sciences Inc. and Galapagos MN, and was conducted by HEOR Ltd. Medical writing support was provided by PharmacoEconomics London, London, UK, and funded by Galapagos NV (Mechelen, Belgium).

Deterministic sensitivity analysis

Figure 4 illustrates the impact of each parameter variation in each scenario, relative to base case results. The market share of vedolizumab had the largest impact on the budget, owing to the high cost of vedolizumab.

Figure 4. Tornado plot of deterministic sensitivity analysis relative to the Spanish base case



Disclosures

XL and ICA are employees and shareholders of Galapagos. GJA was an employee of HEOR Ltd when the research was conducted. GJA and SS are employees of HEOR Ltd.

Conclusions

Introducing filgotinib as a new treatment for UC could potentially lead to substantial cost savings for the Spanish healthcare system. The estimated budget impact could increase over 5 years as filgotinib gains market share.

