



# Cost-effectiveness of a 17-gene classifier to guide initial treatment choice in Crohn's disease in the UK

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## Background

PredictSURE IBD™ is a CE-marked whole blood-based biomarker test that uses a 17-gene qPCR-based classifier to stratify Crohn's Disease (CD) patients into high and low risk subgroups. High-risk patients experience significantly more aggressive disease than low-risk patients, with the need for earlier and more frequent treatment escalation over time. Early stratification could therefore enable personalised treatment strategies for CD.

The objective of this study was to examine the cost-effectiveness of PredictSURE in guiding the use of early biologic therapy in newly diagnosed CD patients in the UK.

## Methods

A cost-utility analysis was conducted from a UK NHS perspective over a 15 year time horizon. A decision tree leading into a Markov state-transition model was built, comparing (figure 1):

- 1) Standard of care 'step up' (SU) treatment: sequences of induction with corticosteroids (CS) and escalation to immunomodulator followed by biologic upon relapse
- 2) Targeted therapy guided by PredictSURE: high-risk patients receive 'top-down' (TD) treatment consisting of upfront anti-TNF followed by other biologic classes upon relapse. Low-risk patients receive standard SU treatment. Patients move from one treatment to the next in the sequence when they experience a disease flare requiring treatment escalation (figure 2). Patients on TD treatment have a reduced risk of flare and treatment escalation, a reduced risk of surgery and higher remission rates compared to when they receive step-up. Parameter values were sourced from the literature, clinical trials and previous technology appraisals of interventions for CD.

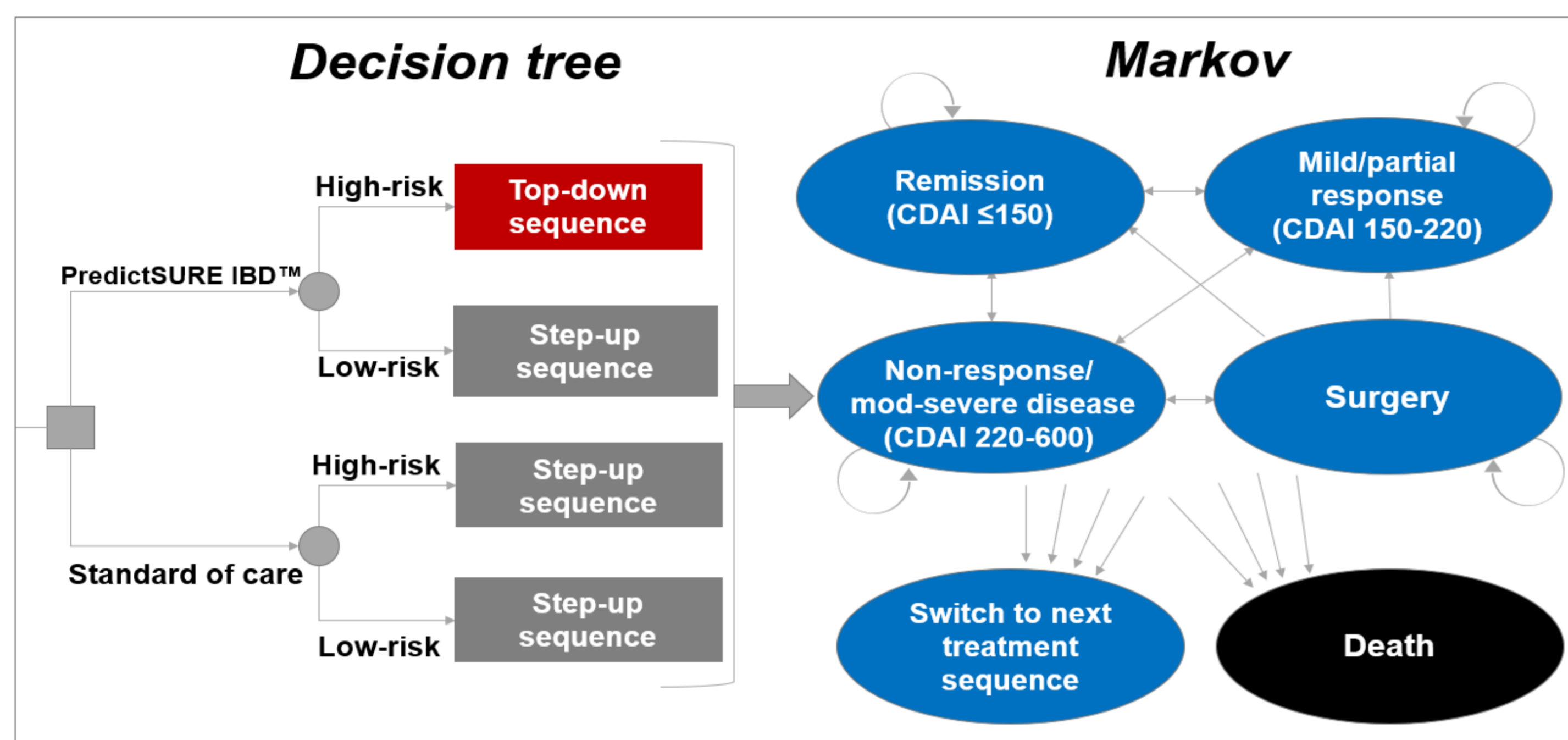


Figure 1: Model schematic

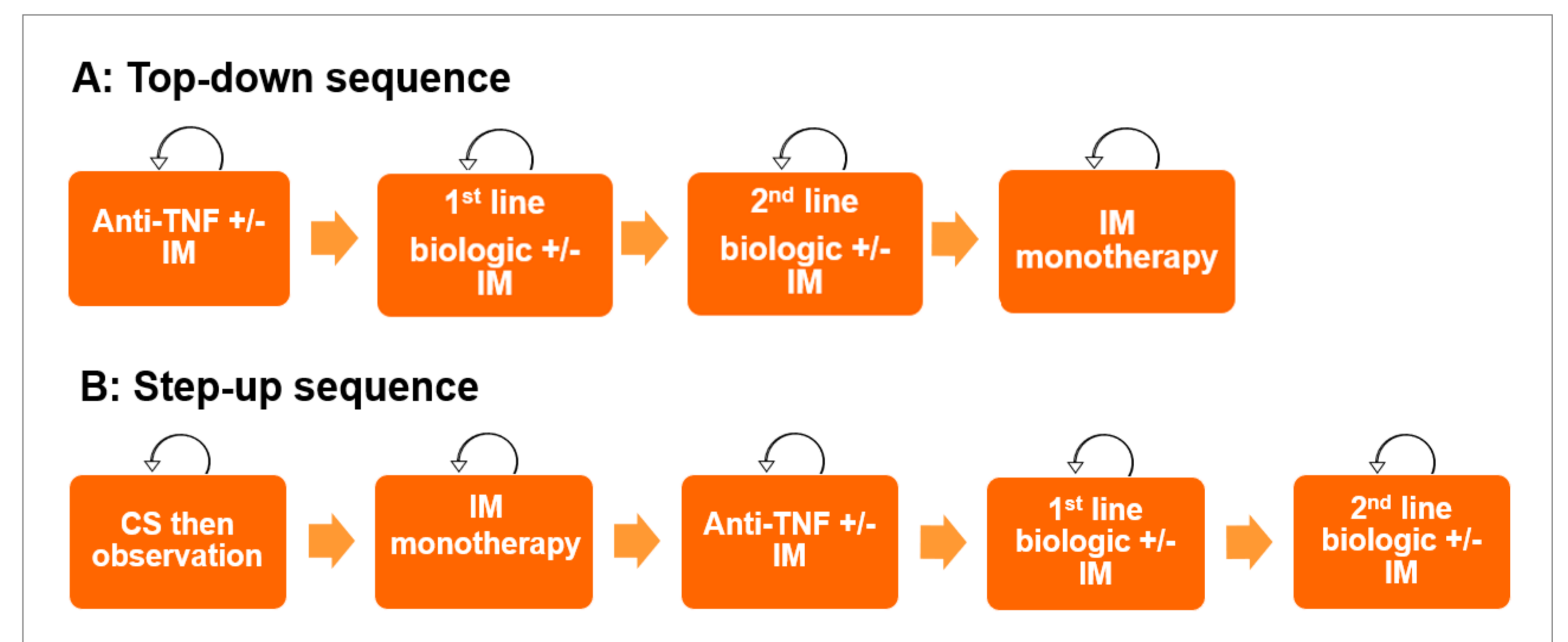


Figure 2: Treatment sequences

## Results

TD treatment guided by PredictSURE resulted in an incremental cost-effectiveness ratio (ICER) of £7,179 per quality-adjusted life year (QALY), with £1,852 incremental costs and 0.258 incremental QALYs vs. standard of care (table 1). Additional costs relating to earlier biologic use were offset by reductions in healthcare use. Incremental QALYs were driven by increased time spent in remission and improved quality of life from reduced flares and surgery. Sensitivity analyses were conducted to identify the parameters that most affected the ICER. One-way sensitivity analysis (OWSA) revealed that the model was most sensitive to the time horizon, rates of mucosal healing on top-down vs. step-up therapy, the costs of hospitalisation and the costs and quality of life in the severe disease health state (figure 3). The results of probabilistic sensitivity analysis, which involves running multiple simulations of uncertain parameters, showed that PredictSURE had a ≥95% probability of being cost-effective at NICE's threshold for cost-effectiveness, which lies between £20 - £30,000 per incremental QALY.

	PredictSURE	No test	Increment		PredictSURE	No test	Increment
<b>Discounted costs</b>				<b>Clinical outcomes</b>			
Induction	£3,627	£3,480	£147	Number of surgeries per person	0.895	1.145	-0.250
Maintenance	£27,704	£19,679	£8,024	Life years	14.806	14.803	0.003
Disease management costs	£19,748	£24,855	£-5,107	<b>Discounted QALYs</b>			
Flares	£1,210	£2,237	£-1,027	QALYs lost to surgery	-0.002	-0.003	0.001
Surgery and complications	£5,141	£6,576	£-1,435	QALYs lost to flares	-0.006	-0.008	0.002
PredictSURE	£1,250	£0	£1,250	Health state QALYs	8.816	8.561	0.255
Total costs	£58,679	£56,827	£1,852	Total QALYs	8.808	8.550	0.258

Table 1: Base-case results

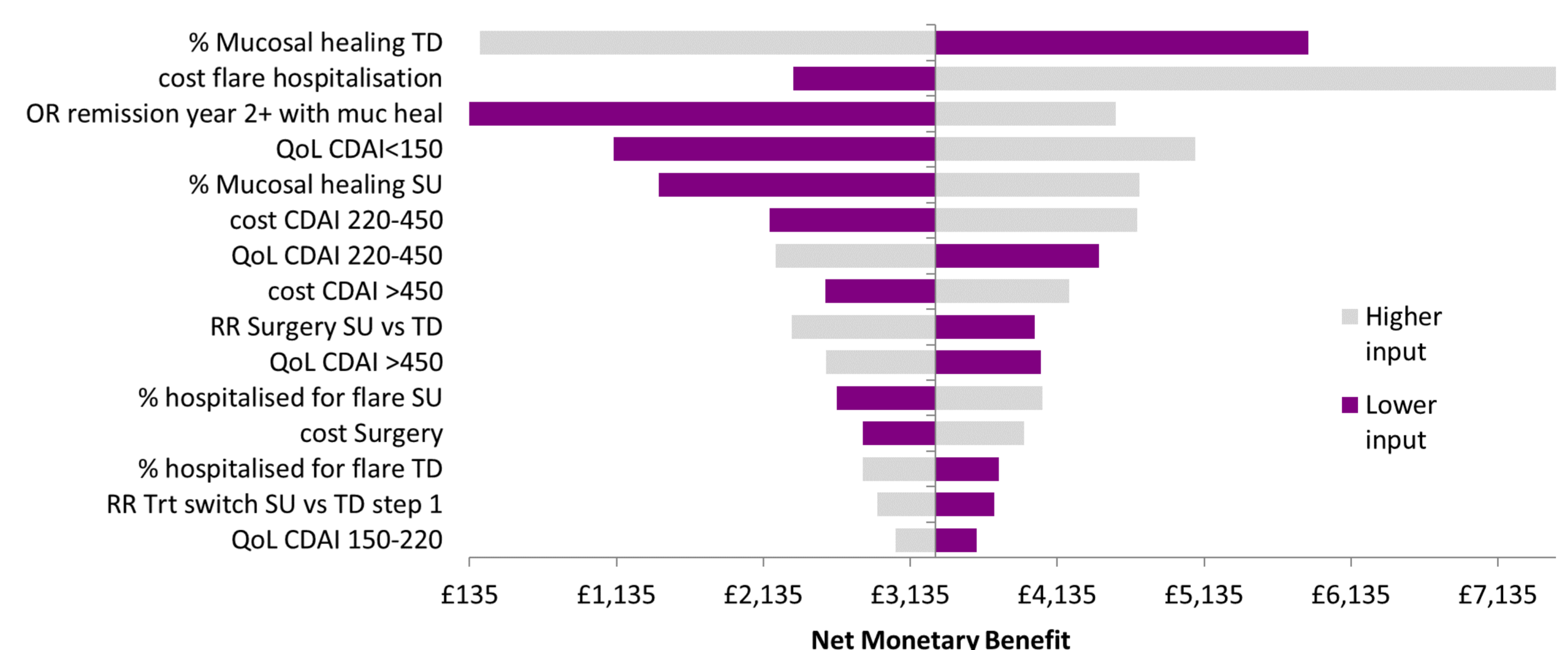


Figure 3: Tornado diagram showing OWSA results

## Conclusion

TD therapy guided by PredictSURE substantially improves clinical outcomes for high-risk patients by increasing remission rates and reducing flares, surgery and treatment escalations. The ICER for PredictSURE was well below the £20-£30k/QALY threshold used by the UK National Institute for Health and Care Excellence (NICE). TD treatment guided by PredictSURE would not only represent a treatment paradigm shift for CD patients but would also be a highly cost-effective use of resources in the UK NHS.