Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (including a review of TA140 and TA262): Clinical effectiveness systematic review and economic model. Addendum 2: Additional analysis of surgery costs and colectomy rates following NICE pre-meeting briefing held 21st August 2014

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Overview

Comments received during the consultation on the independent assessment report indicated that the costs of surgical procedures and the costs of stoma care may not be fully represented within the Assessment Group model. In addition, there remains uncertainty with respect to the rate at which patients undergo colectomy after the failure of medical treatments for UC. As requested by NICE during the pre-meeting briefing held on 21st August 2014, this addendum provides additional analyses using the Assessment Group model to examine the impact of increased costs of UC surgery and post-surgical care and an increased colectomy rates on the cost-effectiveness of infliximab, adalimumab and golimumab.

Additional evidence on the costs of surgery and post-surgical care

The base case Assessment Group model used NHS Reference Costs[1] to value the costs of surgery, whilst health state costs for post-surgical care were taken from Tsai *et al*.[2] Within the analyses presented within this addendum, the costs of surgery and subsequent stoma care have instead been taken from a study of the costs of long-term care of inflammatory bowel disease patients reported by Buchanan *et al*.[3] Within this study, modelled pathways and resource use estimates were based on expert input from two gastroenterologists, with additional input on patient resource use post-surgery from a stoma nurse and colorectal nurse specialist. Buchanan *et al* reported an estimated cost of surgery of £11,619.72 assuming that 40% of patients undergo proctocolectomy with ileostomy and 60% undergo subtotal proctocolectomy with pouch formation +/- loop ileostomy.[3] Costs were valued using NHS Reference Costs. The monthly cost of stoma consumables was estimated to be £66.75 per month.[3]

Amendments to the Assessment Group model

The following amendments were made to the Assessment Group model:

1. The cost of surgery within the model was amended to reflect the £11,619.72 value reported by Buchanan *et al* and uplifted to current prices (£12,917.33). The cost of 1-year of stoma consumables, uplifted to current prices, was also assumed for 60% patients undergoing

surgery. A total cost of surgery of £13,451.60 was thus applied as a once-only cost when patients undergo surgery.

2. The 6-monthly cost of stoma consumables for patients undergoing surgery was estimated to be £178.09 based on Buchanan *et al*; this was uplifted to current prices and applied to the 40% of patients who are assumed to have an ileostomy. The cost of 1.5 nurse visits per 6-month cycle was estimated to be £136.88. The combined cost of stoma consumables and nurse visits was added to the other 6-monthly costs for the post-surgery state from Tsai *et al*.[2]

Additional analyses conducted

Eight additional analyses are presented using this amended version of the Assessment Group model:

1. Base case analysis plus additional costs of surgery and stoma care, adult patients in whom colectomy is an option (medical and surgical treatments), excluding proposed PAS for golimumab
2. Base case analysis plus additional costs of surgery and stoma care, adult patients in whom colectomy is not an option (medical treatments only), excluding proposed PAS for golimumab
3. Doubled colectomy rate plus additional costs of surgery and stoma care, adult patients in whom colectomy is an option (medical and surgical treatments), excluding proposed PAS for golimumab
4. Doubled colectomy rate plus additional costs of surgery and stoma care, adult patients in whom colectomy is not an option (medical treatments only), excluding proposed PAS for golimumab
5. Base case analysis plus additional costs of surgery and stoma care, adult patients in whom colectomy is an option (medical and surgical treatments), including proposed PAS for golimumab
6. Base case analysis plus additional costs of surgery and stoma care, adult patients in whom colectomy is not an option (medical treatments only), including proposed PAS for golimumab
7. Doubled colectomy rate plus additional costs of surgery and stoma care, adult patients in whom colectomy is an option (medical and surgical treatments), including proposed PAS for golimumab
8. Doubled colectomy rate plus additional costs of surgery and stoma care, adult patients in whom colectomy is not an option (medical treatments only), including proposed PAS for golimumab

All reported analyses are based on the probabilistic version of the model.

Model results

1. **Base case analysis plus additional costs of , adult patients in whom colectomy is an option (medical and surgical treatments), excluding proposed PAS for golimumab**

Option	QALYs	Costs	Incremental QALYs	Incremental cost	ICER
Colectomy	14.72	£56,294.72	-	-	dominating
Adalimumab	10.83	£91,225.40	-	-	dominated
Infliximab	10.82	£96,598.30	-	-	dominated
Golimumab	10.65	£90,090.53	-	-	dominated
Conventional treatment	10.48	£73,623.71	-	-	dominated

2. **Base case analysis plus additional costs of surgery and stoma care, adult patients in whom colectomy is not an option (medical treatments only), excluding proposed PAS for golimumab**

Option	QALYs	Costs	Incremental QALYs	Incremental cost	ICER
Adalimumab	10.83	£91,225.40	0.35	£17,601.69	£50,353.43
Infliximab	10.82	£96,598.30	-	-	dominated
Golimumab	10.65	£90,090.53	-	-	ext dom
Conventional treatment	10.48	£73,623.71	-	-	-

3. **Doubled colectomy rate plus additional costs of surgery and stoma care, adult patients in whom colectomy is an option (medical and surgical treatments), excluding proposed PAS for golimumab**

Option	QALYs	Costs	Incremental QALYs	Incremental cost	ICER
Colectomy	14.72	£56,294.72	-	-	dominating
Adalimumab	11.34	£89,654.96	-	-	dominated
Infliximab	11.33	£95,038.55	-	-	dominated
Golimumab	11.16	£88,478.59	-	-	dominated
Conventional treatment	11.01	£71,958.08	-	-	dominated

4. **Doubled colectomy rate plus additional costs of surgery and stoma care, adult patients in whom colectomy is not an option (medical treatments only), excluding proposed PAS for golimumab**

Option	QALYs	Costs	Incremental QALYs	Incremental cost	ICER
Adalimumab	11.34	£89,654.96	0.32	£17,696.89	£54,548.07
Infliximab	11.33	£95,038.55	-	-	dominated
Golimumab	11.16	£88,478.59	-	-	ext dom
Conventional treatment	11.01	£71,958.08	-	-	-

5. **Base case analysis plus additional costs of surgery and stoma care, adult patients in whom colectomy is an option (medical and surgical treatments), including proposed PAS for golimumab**

Option	QALYs	Costs	Incremental QALYs	Incremental cost	ICER
Colectomy	14.72	£56,294.72	-	-	dominating
Adalimumab	10.83	£91,225.40	-	-	dominated
Infliximab	10.82	£96,598.30	-	-	dominated
Golimumab	10.65	£84,608.01	-	-	dominated
Conventional treatment	10.48	£73,623.71	-	-	dominated

6. **Base case analysis plus additional costs of surgery and stoma care, adult patients in whom colectomy is not an option (medical treatments only), including proposed PAS for golimumab**

Option	QALYs	Costs	Incremental QALYs	Incremental cost	ICER
Adalimumab	10.83	£91,225.40	0.35	£17,601.69	£50,353.43
Infliximab	10.82	£96,598.30	-	-	dominated
Golimumab	10.65	£84,608.01	-	-	ext dom
Conventional treatment	10.48	£73,623.71	-	-	-

7. **Doubled colectomy rate plus additional costs of surgery and stoma care, adult patients in whom colectomy is an option (medical and surgical treatments), including proposed PAS for golimumab**

Option	QALYs	Costs	Incremental QALYs	Incremental cost	ICER
Colectomy	14.72	£56,294.72	-	-	dominating
Adalimumab	11.34	£89,654.96	-	-	dominated
Infliximab	11.33	£95,038.55	-	-	dominated
Golimumab	11.16	£82,996.07	-	-	dominated
Conventional treatment	11.01	£71,958.08	-	-	dominated

8. **Doubled colectomy rate plus additional costs of surgery and stoma care, adult patients in whom colectomy is not an option (medical treatments only), including proposed PAS for golimumab**

Option	QALYs	Costs	Incremental QALYs	Incremental cost	ICER
Adalimumab	11.34	£89,654.96	0.32	£17,696.89	£54,548.07
Infliximab	11.33	£95,038.55	-	-	dominated
Golimumab	11.16	£82,996.07	-	-	ext dom
Conventional treatment	11.01	£71,958.08	-	-	-

Conclusions

The inclusion of higher costs of surgery and post-surgical care do not have a material impact upon the economic conclusions drawn from the base case Assessment Group model. Increasing the colectomy rate in combination with these additional costs also does not materially influence the economic conclusions of the Assessment Group. Neither conclusion is influenced by the proposed PAS for golimumab.

References

1. Department of Health. NHS Reference Costs 2012-2013. London: DH.
2. Tsai, H.H., Punekar, Y.S., Morris, J., Fortun, P. A model of the long-term cost effectiveness of scheduled maintenance treatment with infliximab for moderate-to-severe ulcerative colitis. *Alimentary Pharmacology & Therapeutics* 2008; 28(10):1230-1239.
3. Buchanan, J., Wordsworth, S., Ahmad, T., Perrin, A., Vermeire, S., Sans, M. et al. Managing the long term care of inflammatory bowel disease patients: The cost to European health care providers. *Journal of Crohns & Colitis* 2011; 5(4):301-316.