Appendix A

In order to give an overview over the available published literature on the cost-effectiveness of Remicade® in Europe, we have conducted a non-systematic literature review. The results are briefly summarized.

Rheumatoid arthritis

The cost-effectiveness of infliximab has been evaluated in a number of analyses. Table 1 gives an overview of available infliximab cost-effectiveness studies and their results. The estimates of cost-effectiveness vary widely, from being close to the cost-effectiveness threshold in one UK (1) and one Italian (2) study, whereas other studies conclude that Remicade is not cost-effective, with ICERs ranging from £36,200 to £116,000, costs per responder of up to €433,000.

Table 1: Analyses of the cost-effectiveness of infliximab (Remicade) in RA

Country	Reference	Analysis design	Result
UK	Kobelt, 2003 (1)	Cost/QALY gained with INX plus MTX compared with MTX alone, direct and indirect cost	Cost/QALY gained: 1 year of treatment: £21,600 (€34,800) 2 years of treatment: £29,900 (€48,200) Savings due to Remicade treatment did not offset treatment costs
	Jobanputra, 2002 (3)	Simulation model of introducing anti-TNF (INX) into the treatment algorithm (vs not introducing it)	For Remicade, base case ICERs were between £89,973 (discounted to start of program) and £115,937 (discounted to point of divergence)
	Malottki et al., 2011 (4)	Cost-effectiveness analysis from the UK NHS perspective, INX vs newly initiated DMARD	ICER for Remicade vs DMARD: £36,200
Germany	Gissel, 2013 (5)	Cost per responder analysis (direct cost only), vs conventional therapy	Cost per responder: €216,392 for ACR50 and €432,784 for ACR70 responses (40% overestimate due to taxes and mandatory rebate)
Italy	Cecchi, 2003 (2)	Economic appropriateness index (6).	Using this simple approach, the authors find that Remicade is not cost-effective at a WTP threshold of €10,000, but becomes cost-effective above a WTP threshold of about €24,000†
The Netherlands	Nuijten, 2001 (7)	Cost-cost analysis comparing Remicade with etanercept; direct and indirect costs.	Direct drug costs comparable (US\$ 12,610 and US\$ 12,534), but Remicade more expensive due to administration costs of US\$ 5,048 (vs US\$ 107 with etanercept)

[†]Calculated from data given in Cecchi, 2003. Abbreviations: DMARD, disease-modifying anti-rheumatic agent; ICER, incremental cost-effectiveness ratio; MTX, methotrexate; QALY, quality-adjusted life-year; RA, rheumatoid arthritis; TNF, tumor necrosis factor; WTP, willingness to pay.

In addition to the analyses detailed in Table 1, there are three Swedish (8-10) and a Finnish (11) analysis, which (with the exception of Eriksson et al, 2014), concluded that Remicade is cost-effective (compared with standard treatment). Furthermore, infliximab has been the topic of economic reviews: Jobanaputra et al, 2002 (3) and Malottki¹ et al., 2011 (4) both identified a single manufacturer model for a NICE submission, where the ICER of Remicade vs placebo was £33,618. Chen et al, 2006 (12) identified some of the studies described in Table 1.

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 $^{^{\}mathrm{1}}$ In Malottki et al, 2011, no publications focusing on Remicade fulfilled the inclusion criteria.

Ankylosing spondylitis

Examples of publications on the cost-effectiveness of infliximab in AS are detailed in Table 2. The available data indicates that Remicade is costly, but could be cost-effective when compared with placebo (supported by one UK model) (13). It appears unlikely that Remicade could be cost-effective compared with other anti-TNF therapies, due to the more costly IV (compared with oral for other TNF inhibitors) administration: A UK, a Dutch and a French study support the view that, even though the drug costs of Remicade are comparable with those of adalimumab or etanercept, the additional administration costs make Remicade less cost-effective.

Table 2: Analyses of the cost-effectiveness of infliximab (Remicade) in AS

Country	Reference	Analysis design	Result	
UK	McLeod et al, 2007 (14)	Economic evaluation of INX, adalimumab and etanercept	Due to extensive data gaps no definitive assessment could be made. The authors conclude that INX will be economically less favorable compared with adalimumab or etanercept, due to the method of administration	
	Kobelt et al, 2004 (13)	Cost-effectiveness model based on cross-sectional retrospective observational study of resource consumption and utility. Societal perspective, INX vs placebo	Cost per QALY, vs placebo: £30,000 to £40,000 for up to two years, but could be below £10,000 long-term	
The Netherlands	Boonen et al, 2006 (15)	Markov model, INX vs usual care	ICER of €67,207 to €237,010 for INX vs usual care	
France Fautrel et al, 2010 (16)		INX every 6 weeks (Q6) vs INX on demand (DEM) Based on dedicated RCT	INX Q6 is cost effective compared with INX DEM, but ICER~€50,760/QALY, i.e. close to the WTP threshold of €50,000	

Abbreviations: ICER, incremental cost-effectiveness ratio; INX, Remicade/infliximab; QALY, quality-adjusted life-year; RCT, randomized controlled trial; WTP, willingness to pay.

Crohn's disease

Examples of publications on the cost-effectiveness of infliximab in Crohn's disease are detailed in Table 3. Evidence from UK studies supports the view that Remicade may be cost-effective for some treatment modalities (i.e. induction phase) and/or patient groups (e.g. luminal or fistulising Crohn's disease). Data from Germany favors adalimumab over infliximab, based on the cost per remitter, and a French analysis found the ICER for infliximab to be above €63,000.

Resource use data from Italy highlights the increase in costs when switching from cDMARDs to infliximab.

Table 3: Analyses of the cost-effectiveness of infliximab (Remicade) in Crohn's disease

Country Reference		Analysis design	Result		
UK	Dretzke et al, 2011 (17)	Review and independent assessment: De novo Markov state transition model to calculate the ICER for infliximab compared with standard care.	Severe disease: Infliximab is dominant for induction ICER of £5 million for maintenance Moderate disease: ICER of £94,321 for induction ICER of £13.9 million for maintenance		
	Sprakes et al, 2010 (18)	Crohn's disease-related costs of care and resource use in a single center cohort 12 months pre- and post infliximab therapy	Infliximab use led to mean total savings of £2,750 per patient after 12 months, which was insufficient to offset drug costs (mean £9,037, range: £874–£36,708).		
	Lindsay et al, 2008 (19)	Cost-effectiveness analysis, Markov model, based on published trials.	ICER for infliximab vs standard care was £26,128 in luminal Crohn's disease and £29,752 in fistulising Crohn's disease at 5 years		
Germany	Yang et al, 2012 (20)	Cost-effectiveness analysis of adalimumab vs standard care and cost per remitter of adalimumab vs infliximab.	Cost effectiveness for adalimumab in Germany shows lower costs per remitter than infliximab (€54,823 vs €88,506).		
France	Jaisson-Hot et al, 2004 (21)	Life-time cost-utility analysis with an analytic Markov decision model from the perspective of the third-party payer system	ICER varied from €63,700.82 (episodic re-infusions) to >€762,245.09 (maintenance therapy).		
Italy	Favalli et al, 2008 (22)	Retrospective, observational study on resource use	Annual costs per patient treated: Infliximab: from €6,593.50 to €8,655.82 DMARDs: €227.96. Infliximab plus DMARDs: from €6,821.46 to €8,893.78		

Abbreviations: DMARD, disease-modifying anti-rheumatic agent; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; RA, rheumatoid arthritis; TNF, tumor necrosis factor; WTP, willingness to pay.

Ulcerative colitis

Examples of publications on the cost-effectiveness of infliximab in UC are detailed in Table 4.

Only evidence from the UK, as well as a single analysis from the Netherlands, could be identified.

Data on the cost-effectiveness in UC is limited and varies depending on the patient subgroup and comparator chosen. However, in all five of the identified publications (from Europe), the ICERs are well within the WTP threshold of £20,000 to £30,000 (€22,000 to €34,000) set by NICE. A US model, however, found an ICER of US \$1.5 million for medical therapy (including Remicade) compared with early colectomy.

Table 4: Analyses of the cost-effectiveness of infliximab (Remicade) in Ulcerative Colitis

Country Reference		Analysis design	Result		
UK	Bryan et al, 2010 (23) [NICE TA163 (24)]	ERG report summary; INX vs cyclosporine; NHS perspective	Manufacturer: ICER of £20,000 for INX vs cyclosporine ERG: ICER of £48,000 for INX vs cyclosporine (more appropriate evidence mix used)		
	Punekar et al, 2010 (25)	Decision analysis model; INX vs standard care, cyclosporine and surgery; hospitalized patients with acute exacerbation; NHS perspective	ICER for INX was £19,545 per QALY vs cyclosporine. Cyclosporine dominated standard care.		
	Hyde et al, 2009 (26) [NICE TA140 (27)]	ERG report summary; Markov model; INX vs standard care; NHS perspective	ICER for INX vs standard care between £25,044 and £33,866 (manufacturer, different scenarios)		
	Tsai et al, 2008 (28)	Markov model. INX vs standard care. NHS perspective. Two strategies: Responders Patients in remission	ICER for INX vs standard care at 10 years: • £27,424 in the responder strategy • £19,696 in the remission strategy		
The Netherlands	Chaudhary et al, 2013 (29)	Markov model. Cost- effectiveness of INX vs cyclosporine and surgery. Payer perspective	ICER per QALY for INX: • €24,277 vs cyclosporine • €14,639 vs surgery		
US	Park et al, 2012 (30)	Lifteime Markov model, comparing early colectomy with IPAA strategy to the standard medical therapy strategy (including INX); societal perspective.	ICER for medical therapy (including INX) compared with early colectomy with IPAA was \$1.5 million		

Abbreviations: ERG, evidence review group; ICER, incremental cost-effectiveness ratio; INX, infliximab; IPAA, ileal pouch anal anastomosis; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life-year; TA, technology appraisal.

Psoriasis

Examples of publications on the cost-effectiveness of infliximab in psoriasis are detailed in Table 5. In the available studies from the UK, Germany and Italy, infliximab was considered cost-effective for the treatment of severe psoriasis compared with etanercept. However, Italian data suggests that infliximab is not cost-effective compared with all dosing regimens of etanercept or compared with adalimumab.

Table 5: Analyses of the cost-effectiveness of infliximab (Remicade) in Psoriasis

Country	Reference	Analysis design	Result	
UK	Loveman et al, 2009 (31)	Cost-effectiveness of INX vs continuous etanercept in severe psoriasis; NHS perspective	Base-case ICER for INX vs continuous etanercept was £26,095/QALY	
Germany	Schmitt-Rau et al, 2010 (32)	Cost-effectiveness of biologics; German payer perspective; outcome: cost/patient achieving PASI-75 compared with placebo.	INX (3 mg/kg) most cost-effective, followed by adalimumab, INX (5 mg/kg) and ustekinumab. Etanercept (2 x 50 mg/week) was least cost-effective. Differences were small.	
Italy	de Portu 2010 (33)	Cost-effectiveness of INX vs other anti-TNF agents; ICER for 75% PASI improvement, payer perspective.	INX dominates etanercept 50 mg twice weekly, but not other doses and not adalimumab.	

Abbreviations: ICER, incremental cost-effectiveness ratio; INX, Remicade/infliximab; NHS, National Health Service; PASI, Psoriasis Area and Severity Index; QALY, quality-adjusted life-year; TNF, tumor necrosis factor.

Psoriatic arthritis

Examples of publications on the cost-effectiveness of infliximab in psoriatic arthritis are detailed in Table 6. Results from UK models are inconclusive, with two studies suggesting that Remicade is cost-effective vs palliative care and vs etanercept for moderate to severe disease, respectively, whereas two other studies found Remicade to be associated with ICERs above £165,000 vs etanercept and to be dominated by etanercept, respectively. In Germany, the cost per responder was found to be lower for adalimumab than for Remicade. Data from Italy suggests an ICER of €41,000 for the introduction of TNF-inhibitors, assumes however that only a small percentage of patients will use infliximab, the majority using etanercept.

Table 6: Analyses of the cost-effectiveness of infliximab (Remicade) in psoriatic arthritis

Country	Reference	Analysis design	Result	
UK	Cummins et al, 2011 (34)	Decision analytic model, NHS perspective, comparing infliximab, etanercept, adalimumab and cDMARDs.	ICER of infliximab vs palliative care with cDMARDs: £16,942–£23,022.	
	Rodgers et al, 2011 (35)	Infliximab vs etanercept, different degrees of skin involvement.	The ICER for infliximab vs etanercept becomes more favorable with increasing skin involvement: Negligible skin involvement £65,000 Mild to moderate skin involvement £44,000 Moderate to severe skin involvement £26,000	
Bravo Vergel et al, 20 (36)		NHS perspective, probabilistic decision analytical model, comparing etanercept vs infliximab vs palliative care.	ICER for infliximab vs etanercept ranges from £165,363 to £205,345	
	Woolacott et al, 2006 (37)	NHS perspective, decision tree cohort model, comparing etanercept vs infliximab vs palliative care.	With regard to the ICER, infliximab is dominated by etanercept.	
Germany	Kirson et al, 2013 (38)	Cost-per-responder analysis for adalimumab vs etanercept and infliximab. Clinical data from a trial were used.	The cost per responder was significantly lower (p<0.05) for adalimumab vs infliximab for all outcomes tested (except PASI-90 at Week 14).	
Italy	Olivieri et al, 2008 (39)	Cost-of-care analysis, societal perspective, comparing treatment with or without TNF-inhibitors (mostly etanercept, but some patients received infliximab or adalimumab)	Introduction of TNF-inhibitors (with most patients using etanercept and only some using infliximab or adalimumab) would be associated with costs/QALY of €40,877 for the NHS and of €37,591 for society.	

Abbreviations: cDMARD, conventional disease-modifying anti-rheumatic agent; ICER, incremental cost-effectiveness ratio; NHS, National Health Service; QALY, quality-adjusted life-year; TNF, tumor necrosis factor.

Appendix B

Table 12: Projected drug cost savings due to the introduction of Remsima in the first year after launch; number of additional patients that could be treated if the savings made were used; combined for switch and naïve patient populations

	RA	AS	CD	UC	PsA	Psoriasis	Total
Budget impact with list price, million ۠							
Total	3.98	4.11	19.34	8.96	5.53	3.21	45.13
Number of additional patients							
Total	580	314	1,537	741	454	276	3,900

[†] UK costs were converted to € using a conversion rate of 1.127278 (http://stats.oecd.org/Index.aspx?datasetcode=SNA_TABLE4#)

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