

**NATIONAL INSTITUTE FOR HEALTH AND
CLINICAL EXCELLENCE**

Technology appraisals

**Patient access scheme submission
template**

October 2009

1 Introduction

The 2009 Pharmaceutical Price Regulation Scheme (PPRS)

(www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalalpriceregulationscheme/2009PPRS) is a non-contractual scheme between the Department of Health and the Association of the British Pharmaceutical Industry. The purpose of the 2009 PPRS is to ensure that safe and cost-effective medicines are available on reasonable terms to the NHS in England and Wales. One of the features of the 2009 PPRS is to improve patients' access to medicines at prices that better reflect their value through patient access schemes.

Patient access schemes are arrangements which may be used on an exceptional basis for the acquisition of medicines for the NHS in England and Wales. Patient access schemes propose either a discount or rebate that may be linked to the number, type or response of patients, or a change in the list price of a medicine linked to the collection of new evidence (outcomes). These schemes help to improve the cost effectiveness of a medicine and therefore allow the National Institute for Health and Clinical Excellence (NICE) to recommend treatments which it would otherwise not have found to be cost effective. More information on the framework for patient access schemes is provided in the 2009 PPRS

(www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalalpriceregulationscheme/2009PPRS).

Patient access schemes are proposed by a pharmaceutical company and agreed with the Department of Health, with input from the Patient Access Schemes Liaison Unit (PASLU) within the Centre for Health Technology Evaluation at NICE.

2 Instructions for manufacturers and sponsors

This document is the patient access scheme submission template for technology appraisals. If manufacturers and sponsors want the National Institute for Health and Clinical Excellence (NICE) to consider a patient access scheme as part of a technology appraisal, they should use this template. NICE can only consider a patient access scheme after formal referral from the Department of Health.

The template contains the information NICE requires to assess the impact of a patient access scheme on the clinical and cost effectiveness of a technology, in the context of a technology appraisal, and explains the way in which background information (evidence) should be presented. If you are unable to follow this format, you must state your reasons clearly. You should insert 'N/A' against sections that you do not consider relevant, and give a reason for this response.

Please refer to the following documents when completing the template:

- 'Guide to the methods of technology appraisal'
(www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/guidetothemethodsoftechnologyappraisal.jsp)
- 'Specification for manufacturer/sponsor submission of evidence'
(<http://www.nice.org.uk/aboutnice/howwework/devnicetech/singletechnologyappraisalsubmissiontemplates.jsp>) and
- Pharmaceutical Price Regulation Scheme 2009
(www.dh.gov.uk/en/Healthcare/Medicinespharmacyandindustry/Pharmaceuticalpriceregulationscheme/2009PPRS).

For further details on the technology appraisal process, please see NICE's 'Guide to the single technology appraisal (STA) process' and 'Guide to the multiple technology appraisal (MTA) process' (http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp). The

'Specification for manufacturer/sponsor submission of evidence' provides details on disclosure of information and equality issues.

Make the submission as brief and informative as possible. Only mark information as confidential when absolutely necessary. Sufficient information must be publicly available for stakeholders to comment on the full content of the technology appraisal, including details of the proposed patient access scheme. Send submissions electronically to NICE in Word or a compatible format, not as a PDF file.

Appendices may be used to include additional information that is considered relevant to the submission. Do not include information in the appendices that has been requested in the template. Appendices should be clearly referenced in the main submission.

When making a patient access scheme submission, include:

- an updated version of the checklist of confidential information, if necessary
- an economic model with the patient access scheme incorporated, in accordance with the 'Guide to the methods of technology appraisal' (www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/guidetothemethodsoftechnologyappraisal.jsp).

If you are submitting the patient access scheme at the end of the appraisal process, you should update the economic model to reflect the assumptions that the Appraisal Committee considered to be most plausible. No other changes should be made to the model.

3 Details of the patient access scheme

3.1 Please give the name of the technology and the disease area to which the patient access scheme applies.

Name of the technology:*	Tocilizumab (RoActemra™)
Disease area for which the proposed patient access scheme applies:	<p>Moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, RoActemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.</p> <p>Active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. RoActemra can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.</p>
*Please detail all names which apply and include all trading names.	

3.2 Please outline the rationale for developing the patient access scheme.

Current NICE guidance for tocilizumab (TA 198) does not permit its use in biologic naive DMARD-IR patients; the Final Appraisal Determination (FAD) considered that tocilizumab does not represent a cost-effective use of NHS resources in this population.

Currently, only TNF- α inhibitors are recommended by NICE for use in the DMARD-IR population.

The rationale for the tocilizumab patient access scheme (PAS) is to allow DMARD-IR patients and rheumatologists the option to access a pharmacologically distinct alternative to the currently available TNF- α inhibiting biologics, where considered clinically appropriate. A range of medicines is required to effectively treat a heterogeneous condition and the IL-6 inhibiting action of tocilizumab represents a potential further choice in this range for NHS patients.

In the FAD for TA198, etanercept was used as the main comparator to tocilizumab in the DMARD-IR population. Tocilizumab and etanercept have

equivalent annual drug acquisition costs, but tocilizumab is associated with additional drug administration costs due to a monthly intravenous (IV) infusion. Etanercept, by contrast, is administered by a once weekly subcutaneous (SC) self-injection.

As noted in section 4.9 of the FAD: *“It noted that the cost of etanercept was similar to tocilizumab, although etanercept is given as a subcutaneous injection and therefore incurs lower administration and monitoring costs than tocilizumab”*

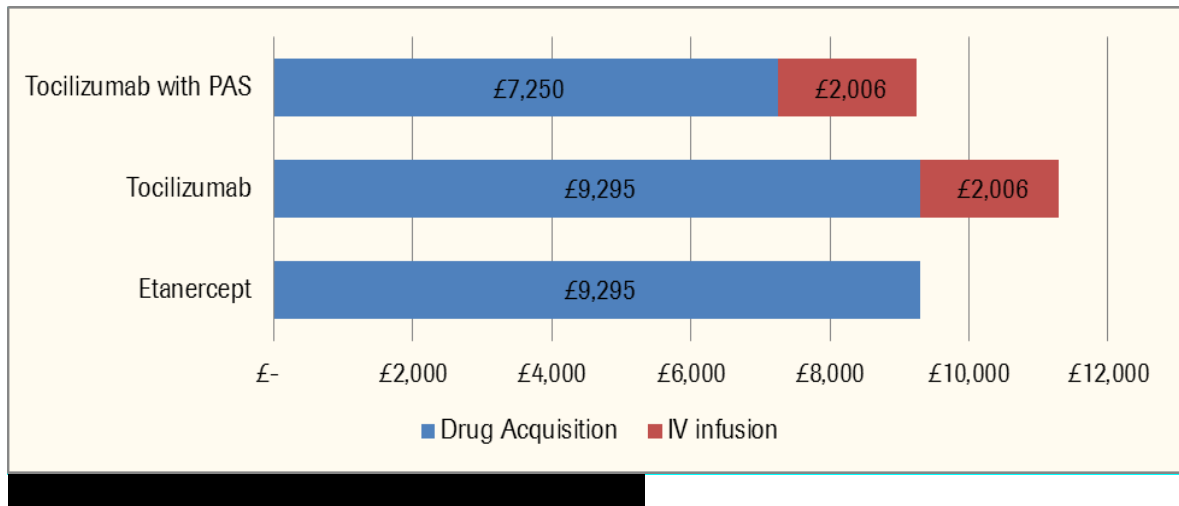
The PAS therefore aims to directly address this fundamental additive cost when comparing tocilizumab with etanercept by equalising the total cost of drug acquisition and drug administration costs between tocilizumab and etanercept by the provision of a simple discount.

In the longer term, to help address the cost discrepancy arising from additional drug administration, a sub-cutaneous formulation of tocilizumab is currently in development and is expected to receive EMA marketing authorisation in approximately [REDACTED]

The value of the discount is linked to the assumed tocilizumab drug administration cost, as reported in the FAD and included in the final economic model of £154.30. Section 4.13 of the FAD states: *“The Committee therefore considered that the ICERs from the incremental analysis in which the administration cost of tocilizumab had been doubled were not appropriate and concluded that the manufacturer’s revised estimate of £154 was acceptable”*



The costs described in this section and the basic principle and impact of PAS are summarised in Figure 1 below as annual, per-patient costs.



3.3 Please describe the type of patient access scheme, as defined by the PPRS.

This qualifies as a simple discount.

3.4 Please provide specific details of the patient population to which the patient access scheme applies. Does the scheme apply to the whole licensed population or only to a specific subgroup (for example, type of tumour, location of tumour)? If so:

The scheme applies to all populations for which tocilizumab has EMA marketing authorisation in both RA and sJIA indications.

3.5 Please provide details of when the scheme will apply to the population specified in 3.4. Is the scheme dependent on certain criteria, for example, degree of response, response by a certain time point, number of injections? If so:

The scheme will apply to all sales of tocilizumab after the date of final guidance publication.

3.6 What proportion of the patient population (specified in 3.4) is expected to meet the scheme criteria (specified in 3.5)?

The PAS is relevant to the whole license for tocilizumab, which includes adult RA and systematic juvenile idiopathic arthritis (sJIA). The scheme is a simple

discount and consequently will not be subject to limitation within specific disease sub-types.

- 3.7 Please explain in detail the financial aspects of the scheme. How will any rebates be calculated and paid?

The PAS is a simple discount scheme

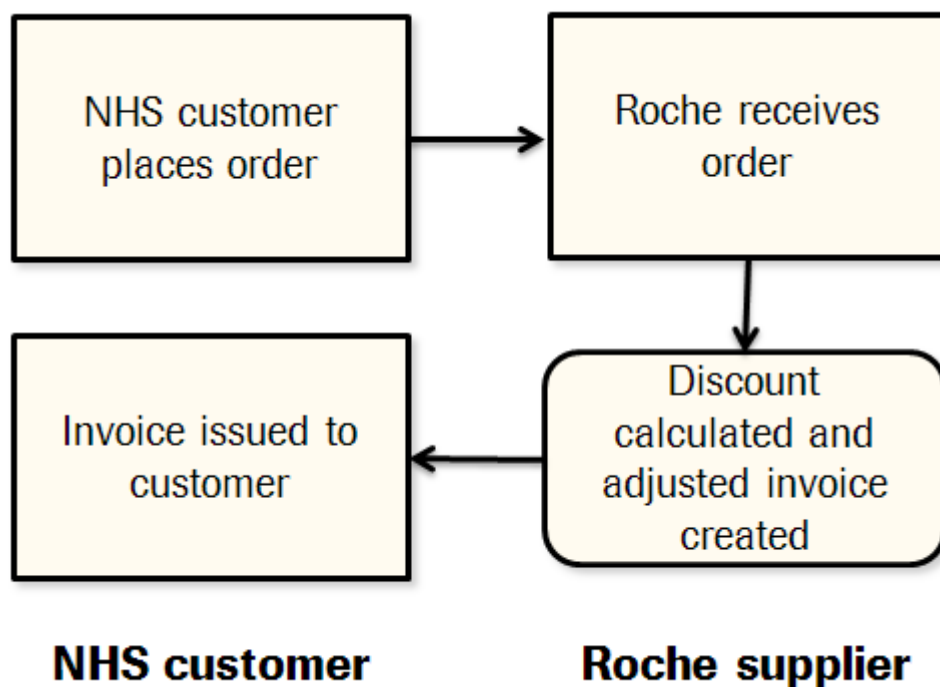
[REDACTED] The discount will be applied through adjustments to invoices rather than a reduction in drug list price [REDACTED]

- 3.8 Please provide details of how the scheme will be administered. Please specify whether any additional information will need to be collected, explaining when this will be done and by whom.

The discount will be applied through adjustments to invoices rather than a reduction in drug list price [REDACTED]

[REDACTED] No additional administration is required to qualify for the scheme. NHS customers and purchasing pharmacists will need to be notified of the discount level which will remain confidential in NICE and DH documents. This approach has been adapted for other patient access schemes, e.g. azacitidine for the treatment of myelodysplastic syndromes.

- 3.9 Please provide a flow diagram that clearly shows how the scheme will operate. Any funding flows must be clearly demonstrated.



Please note that all payment and funding arrangements may remain unchanged.

3.10 Please provide details of the duration of the scheme.

The scheme will remain in place until the publication of revised NICE guidance relating to tocilizumab. After any review, the scheme may be withdrawn or modified or carry on in its current form depending upon the outcome of the re-appraisal.

In any case and in line with best practice, Roche would provide a formal notice period of a minimum of 6 months to NHS Trusts regarding any proposed changes to the scheme following any NICE guidance review.

3.11 Are there any equity or equalities issues relating to the scheme, taking into account current legislation and, if applicable, any concerns identified during the course of the appraisal? If so, how have these been addressed?

None.

3.12 If available, please list any scheme agreement forms, patient registration forms, pharmacy claim forms/rebate forms, guides for pharmacists and physicians and patient information documents. Please include copies in the appendices.

None required.

3.13 In the exceptional case that you are submitting an outcome-based scheme, as defined by the PPRS, please also refer to appendix B.

N/A

4 Cost effectiveness

- 4.1 If the population to whom the scheme applies (as described in sections 3.4 and 3.5) has not been presented in the main manufacturer/sponsor submission of evidence for the technology appraisal (for example, the population is different as there has been a change in clinical outcomes or a new continuation rule), please (re-)submit the relevant sections from the 'Specification for manufacturer/sponsor submission of evidence' (particularly sections 5.5, 6.7 and 6.9). You should complete those sections both with and without the patient access scheme. You must also complete the rest of this template.

The scheme applies to all licensed populations for tocilizumab.

- 4.2 If you are submitting the patient access scheme at the end of the technology appraisal process, you should update the economic model to reflect the assumptions that the Appraisal Committee considered to be most plausible. No other changes should be made to the model.

Noted. Please see response to 4.3.

- 4.3 Please provide details of how the patient access scheme has been incorporated into the economic model. If applicable, please also provide details of any changes made to the model to reflect the assumptions that the Appraisal Committee considered most plausible.

In the economic model incorporating the PAS, we have adjusted the annual drug cost cells to reflect the discount applied to tocilizumab.

Having consulted the document produced by the Decision Support Unit (DSU) in April 2010 which relates to this appraisal, we have also updated and amended our economic model for tocilizumab to reflect the assumptions which the DSU and Appraisal Committee consider most plausible.

Section 3.3 of the DSU report presents four alternative Approaches to modelling, each describing a list of amendments to Roche's base case model.

We have assumed that all changes proposed by the DSU are additive in the sense that each of Approaches 1 through 4 progressively adds new assumptions whilst retaining assumptions of earlier.

From what we understand from the FAD, the Institute based its recommendations on DSU's Approach 4, and we have updated our model to reflect the changes therein as follows:

- As per the FAD, we have used 'unadjusted' American College of Rheumatology (ACR) response rate figures for our analysis.
- For the etanercept 'unadjusted' ACR response rates we have used pooled results from two studies, Weinblatt and Combe (73%, 47% and 22% for ACRs 20, 50 and 70 respectively)
- We adjusted downwards the ACR rates in the "inadequate response after two biologics" (2-Bio-IR) group, to match those seen in the "inadequate response to one TNF- α " (TNF-IR) group
- To match the consideration of the Appraisal Committee that a treatment used in 2nd line or 3rd line is likely to be associated with different ACR rates to the same treatment used in 1st line, Roche updated ACR figures in its response to ACD 3; these changes are also reflected in the current model

We believe the above 4 steps represent the DSU's Assumption 4.

- We also updated the model such that HAQ does not gradually improve over time on tocilizumab, but remains constant.

4.4 Please provide the clinical effectiveness data resulting from the evidence synthesis and used in the economic model which includes the patient access scheme.

Clinical Evidence

The final position of the committee was to utilise unadjusted ACR scores within the economic modelling, as the mixed treatment comparison was considered unreliable. Therefore the evidence synthesis relating to the unadjusted ACR inputs (originally supplied to the committee as part of the MTC technical appendix) are therefore reproduced on the following page:

Figure 2. ACR-20 observed response in conventional DMARDs inadequate responders

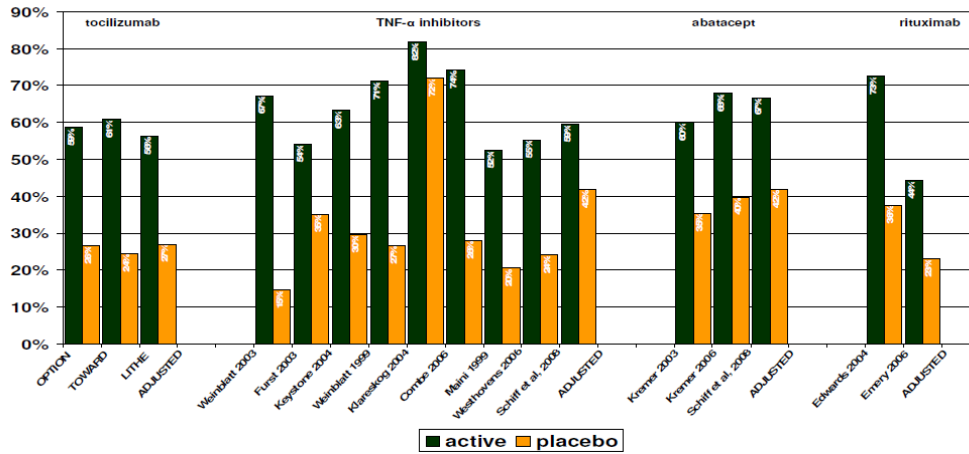


Figure 4. ACR-50 observed response in conventional DMARDs inadequate responders

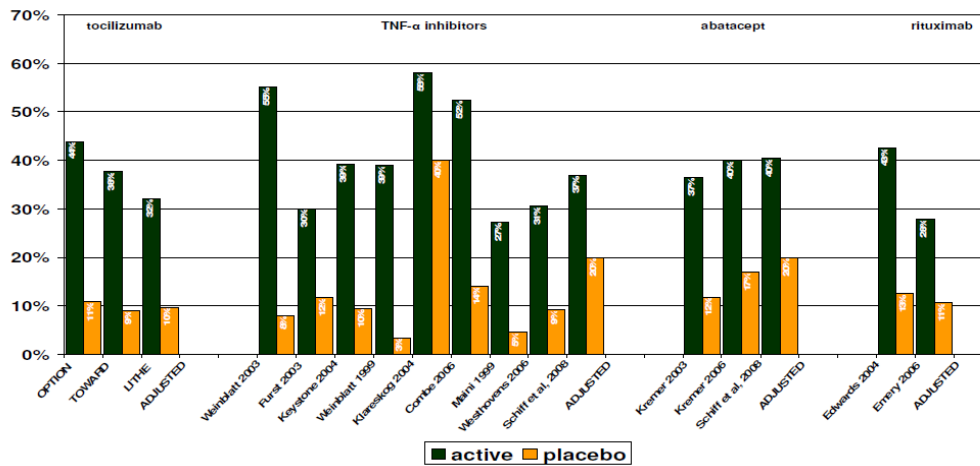
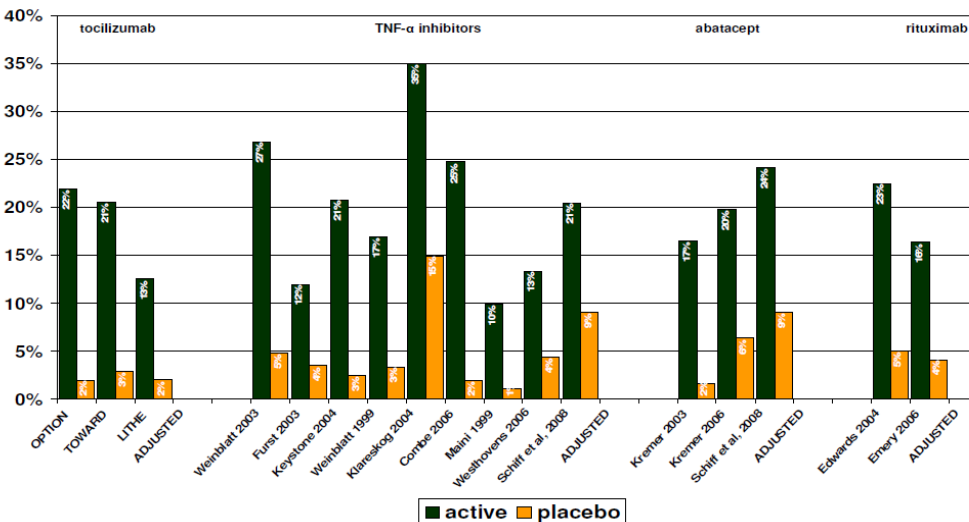


Figure 6. ACR-70 observed response in conventional DMARDs inadequate responders



Whilst there are observed differences in the point estimates of the various ACR categories and corresponding placebo outcomes, in the absence of a head to head randomised control trial an assumption of comparable efficacy

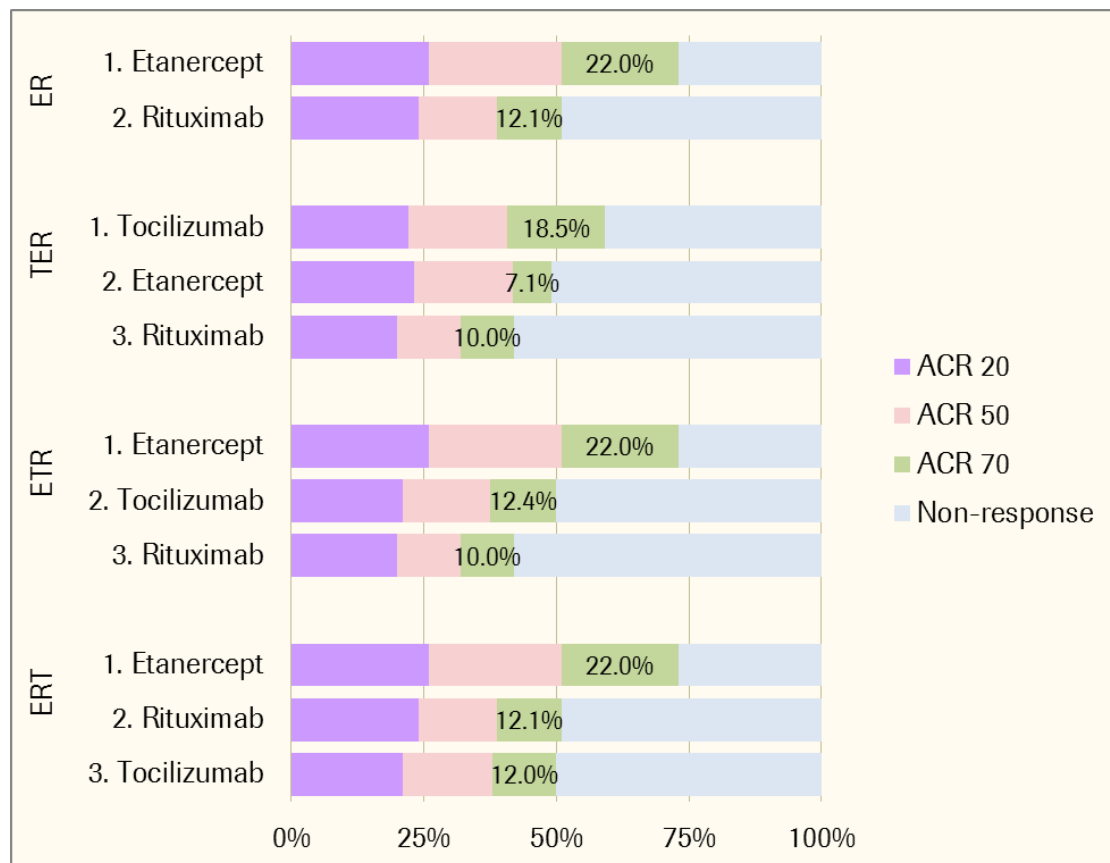
would appear reasonable, based upon the above unadjusted clinical effectiveness data.

Such an assumption would be consistent with the assumption made in other NICE appraisals of RA biologics (within the DMARD IR setting) when presented with similar observed differences in reported ACR results and no head to head RCT evidence.

Economic Model Clinical inputs

To help illustrate the ACR assumptions utilised by the DSU and within the final Guidance, we present a graphical summary of the breakdown of ACR responses for the evaluated treatment sequences in the figure below.

Figure 7. Assumed distribution of ACR response by treatment sequence within Final Guidance economic model



NOTES: each block of bars represents a treatment strategy denoted by the abbreviation (ERT etc). In each sequence the drugs given are listed from first to last administered. Proportions of patients falling into each category of ACR response are adjusted according to pre-defined assumptions about expected efficacy of biologics when used in first, second and third line.

Of particular importance to economic modelling are:

- the overall proportion of patients having any ACR response – this determines the estimated proportion of patients receiving ongoing treatment in each line.

- the proportion of patients achieving an ACR70 response – this outcome is associated with significant quality of life gains and extended time on treatment, an important driver of drug cost and QALY outcomes.

A tabular presentation of the ACR figures in each treatment sequence is shown below.

ER

	ACR 20 %	ACR 50 %	ACR 70 %	Non-response %
Etanercept	26.0	25.0	22.0	27.0
Rituximab (TNF-IR)	24.0	14.9	12.1	49.0

TER

	ACR 20 %	ACR 50 %	ACR 70 %	Non-response %
Tocilizumab	22.2	18.5	18.5	40.8
Etanercept (Bio-IR)	23.2	18.7	7.1	51.0
Rituximab (2xBio-IR)	20	12	10.0	58.0

ETR

	ACR 20 %	ACR 50 %	ACR 70 %	Non-response %
Etanercept	26.0	25.0	22.0	27.0
Tocilizumab (TNF-IR)	21.0	17.0	12.0	50.0
Rituximab (2xBio-IR)	20.0	12.0	10.0	58.0

ERT

	ACR 20 %	ACR 50 %	ACR 70 %	Non-response %
Etanercept	26.0	25.0	22.0	27.0
Rituximab (TNF-IR)	24.0	15.0	12.0	49.0
Tocilizumab (2xBio-IR)	21.0	17.0	12.0	50.0

- 4.5 Please list any costs associated with the implementation and operation of the patient access scheme (for example, additional pharmacy time for stock management or rebate calculations). A suggested format is presented in table 1. Please give the reference source of these costs. Please refer to section 6.5 of the 'Specification for manufacturer/sponsor submission of evidence'

Implementation of this PAS is not expected to be associated with any additional administration costs to the NHS.

- 4.6 Please provide details of any additional treatment-related costs incurred by implementing the patient access scheme. A suggested format is presented in table 2. The costs should be provided for the

intervention both with and without the patient access scheme.

Please give the reference source of these costs.

As this is a financial scheme, we do not expect any change in clinical management costs.

Summary results

Base-case analysis

4.7 Please present in separate tables the cost-effectiveness results as follows.¹

- the results for the intervention without the patient access scheme
- the results for the intervention with the patient access scheme.

A suggested format is shown below (table 3).

Results of the revised base-case model with and without PAS are shown in Table 1.

Table 1. Base-case cost-effectiveness results

	ER	TER	TER with PAS
Total costs (£)	88,244	95,407	
Difference in total costs (£)		7,164	
LYG	26.00	26.10	26.10
LYG difference		0.10	0.10
QALYs	8.466	8.618	8.618
QALY difference		0.1518	0.1518
ICER (£)		47,193	5,716

LYG: life-year gained; QALY: quality-adjusted life-year; ICER: incremental cost-effectiveness ratio.

Abbreviations used in treatment sequences: E: etanercept; R: rituximab; T: tocilizumab.

¹ For outcome-based schemes, please see section 5.2.8 in appendix B.

4.8 Please present in separate tables the incremental results as follows.²

- the results for the intervention without the patient access scheme
- the results for the intervention with the patient access scheme.

List the interventions and comparator(s) from least to most expensive. Present the incremental cost-effectiveness ratios (ICERs) in comparison with baseline (usually standard care), and the incremental analysis ranking technologies in terms of dominance and extended dominance. A suggested format is presented in table 4.

As the Committee's deliberations have been informed by evidence relating to the sequencing options of tocilizumab, we present incremental results which estimate the relative cost effectiveness of:

1. using no tocilizumab in the treatment sequence, i.e. only etanercept followed by rituximab (ER);
2. using tocilizumab as a first biologic agent followed by a TNF- α inhibiting biologic (we use etanercept as the example in our models) and then rituximab (TER);
3. using tocilizumab in patients who have previously received one TNF- α inhibiting biologic, (ETR);
4. using tocilizumab after rituximab in patients who have also previously received one TNF- α inhibiting biologic and rituximab (ERT).

When adopting an incremental approach it is important to consider that regardless of the cost of the intervention, one strategy will always produce a more favourable cost effectiveness scenario compared to the other two. This principle would still apply even if tocilizumab were to be discounted by 99% of its original cost.

Therefore the certainty, by which the committee can claim one clinical strategy is cost effective compared to the other two, would be critical if a restriction to the licensed population is to be made when all strategies appear cost effective compared to the previous standard of care.

We have now recalculated costs and QALYs associated with these alternative treatment sequences, with the PAS applied to tocilizumab regardless where it is utilised within its licensed indications. Results are shown in Table 2.

² For outcome-based schemes, please see section 5.2.9 in appendix B.

Table 2. Base case incremental results

Treatment sequences	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£) versus baseline (QALYs)	ICER (£) incremental (QALYs)
ER	88,244	8.466				
TER (with PAS)		8.618		0.152	5,716	5,716
ETR (with PAS)		8.984		0.366	23,396	30,716
ERT (with PAS)		9.066		0.082	21,293	8,134

QALY: quality-adjusted life-year; ICER: incremental cost-effectiveness ratio.

If the various treatment strategies are compared to one another in an incremental fashion, we observe the following with regard to ER, TER, ETR, and ERT sequences:

- TER compared to ER delivers more QALYs at a cost increase which is cost-effective (incremental ICER of £5,716/QALY)
- ETR compared to TER delivers more QALYs at a cost increase which is borderline cost-effective (incremental ICER of £30,716/QALY)
- ERT compared to ETR delivers more QALYs at a cost increase which is cost-effective (incremental ICER of £8,134/QALY)

Cost-effectiveness results are driven predominantly by the assumed clinical response (ACR) in each line of therapy, assumptions around which are illustrated in section 4.4. The notable differences between treatment strategies is the proportion of patients who are ACR responders, and within this the proportion who are ACR70 responders. These two outcomes are associated with longer mean treatment duration and thus increased treatment costs, as well as a greater QALY gain.

The listed ACR responses are unadjusted and therefore take no account of the performance of the placebo arm and thus differences in baseline characteristics across the trials used.

Differences in the assumed ACR figures explain not only the apparently small difference in total costs and total QALYs observable between the ER and TER sequences, but also the incremental increase in total cost which is apparent between TER and ETR sequences.

In conclusion with the PAS in place, all sequences involving tocilizumab represent cost-effective improvements on the current standard of care.

Sensitivity analyses

- 4.9 Please present deterministic sensitivity analysis results as described for the main manufacturer/sponsor submission of

evidence for the technology appraisal. Consider using tornado diagrams.

As this was a rapid review, no parameters were varied from those established in the FAD, except for those relevant to this PAS, therefore a deterministic sensitivity analysis has not been provided.

4.10 Please present any probabilistic sensitivity analysis results, and include scatter plots and cost-effectiveness acceptability curves.

Please see response to 4.9.

4.11 Please present scenario analysis results as described for the main manufacturer/sponsor submission of evidence for the technology appraisal.

Please see response to 4.9.

4.12 If any of the criteria on which the patient access scheme depends are clinical variable (for example, choice of response measure, level of response, duration of treatment), sensitivity analyses around the individual criteria should be provided, so that the Appraisal Committee can determine which criteria are the most appropriate to use.

N/A

Impact of patient access scheme on ICERs

4.13 For financially based schemes, please present the results showing the impact of the patient access scheme on the ICERs for the base-case and any scenario analyses. A suggested format is shown below (see table 5). If you are submitting the patient access scheme at the end of the appraisal process, you must include the scenario with the assumptions that the Appraisal Committee considered to be most plausible.

Please see table 2 in section 4.8

5 Appendices

5.1 *Appendix A: Additional documents*

- 5.1.1 If available, please include copies of patient access scheme agreement forms, patient registration forms, pharmacy claim forms/rebate forms, guides for pharmacists and physicians, patient information documents.

Not applicable as this is a simple discount PAS with a confidentiality arrangement.

Appendix B: Details of outcome-based schemes

5.1.2 If you are submitting a proven value: price increase scheme, as defined in the PPRS, please provide the following information:

- the current price of the intervention
- the proposed higher price of the intervention, which will be supported by the collection of new evidence
- a suggested date for when NICE should consider the additional evidence.

Response

5.1.3 If you are submitting an expected value: rebate scheme, as defined in the PPRS, please provide the following details:

- the current price of the intervention (the price that will be supported by the collection of new evidence)
- the planned lower price of the intervention in the event that the additional evidence does not support the current price
- a suggested date for when NICE should consider the additional evidence.

Response

5.1.4 If you are submitting a risk-sharing scheme, as defined in the PPRS, please provide the following details:

- the current price of the intervention (the price that will be supported by the collection of new evidence)
- the proposed relationship between future price changes and the evidence to be collected.

Response

5.1.5 For outcome-based schemes, as defined in the PPRS, please provide the full details of the new information (evidence) planned to be collected, who will collect it and who will carry the cost associated with this planned data collection. Details of the new information (evidence) may include:

- design of the new study
- patient population of the new study
- outcomes of the new study
- expected duration of data collection
- planned statistical analysis, definition of study groups and reporting (including uncertainty)
- expected results of the new study
- planned evidence synthesis/pooling of data (if applicable)
- expected results of the evidence synthesis/pooling of data (if applicable).

Response

5.1.6 If you are submitting a risk-sharing scheme, please specify the period between the time points when the additional evidence will be considered.

Response

5.1.7 Please provide the clinical effectiveness data resulting from the evidence synthesis and used in the economic modelling of the patient access scheme at the different time points when the additional evidence is to be considered.

Response

5.1.8 Please provide the other data used in the economic modelling of the patient access scheme at the different time points when the additional evidence is to be considered. These data could include cost/resource use, health-related quality of life and utilities.

Response

5.1.9 Please present the cost-effectiveness results as follows.

- For proven value: price increase schemes, please summarise in separate tables:
 - the results based on current evidence and current price
 - the anticipated results based on the expected new evidence and the proposed higher price.
- For expected value: rebate schemes, please summarise in separate tables:
 - the results based on the expected new evidence and the current price (which will be supported by the additional evidence collection)
 - the results based on the current evidence and the lower price (if the new evidence is not forthcoming).
- For risk-sharing schemes, please summarise in separate tables:
 - the results based on current evidence and current price
 - the results based on the expected new evidence and the current price (which will be supported by the additional evidence collection)
 - the results based on the current evidence and the lower price (if the new evidence is not forthcoming)
 - the anticipated results based on the expected new evidence and the proposed higher price.

A suggested format is shown in table 3, section 4.7.

5.1.10 Please present in separate tables the incremental results for the different scenarios as described above in section 5.2.8 for the type of outcome-based scheme being submitted.

List the interventions and comparator(s) from least to most expensive. Present the incremental cost-effectiveness ratios (ICERs) in comparison with baseline (usually standard care), and the incremental analysis ranking technologies in terms of dominance and extended dominance. A suggested format is presented in table 4, section 4.8.