NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Appraisal consultation document

Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF inhibitor

The Department of Health has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using certolizumab pegol in the NHS in England. The appraisal committee has considered the evidence submitted by the company and the views of non-company consultees and commentators, clinical experts and patient experts.

This document has been prepared for consultation with the consultees. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the consultees and commentators for this appraisal and the public. This document should be read along with the evidence (see the committee papers).

The appraisal committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

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Note that this document is not NICE's final guidance on this technology. The recommendations in section 1 may change after consultation.

After consultation:

- The appraisal committee will meet again to consider the evidence, this appraisal consultation document and comments from the consultees.
- At that meeting, the committee will also consider comments made by people who are not consultees.
- After considering these comments, the committee will prepare the final appraisal determination (FAD).
- Subject to any appeal by consultees, the FAD may be used as the basis for NICE's guidance on using certolizumab pegol in the NHS in England.

For further details, see NICE's guide to the processes of technology appraisal.

The key dates for this appraisal are:

Closing date for comments: 5pm Tuesday 2 August 2016.

Second appraisal committee meeting: Wednesday 10 August 2016

Details of membership of the appraisal committee are given in section 7.

1 Recommendations.

- 1.1 Certolizumab pegol, in combination with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults who have had an inadequate response to, or who cannot tolerate, other diseasemodifying antirheumatic drugs (DMARDs), including at least 1 tumour necrosis factor-alpha (TNF-alpha) inhibitor, only if:
 - disease is severe, that is, a disease activity score (DAS28) greater than
 5.1 and
 - the person cannot have rituximab therapy because rituximab is contraindicated or not tolerated and
 - the company provides certolizumab pegol with the discount agreed in the patient access scheme
- 1.2 Certolizumab pegol can be used as monotherapy for people who have had an inadequate response to, or who cannot tolerate, other disease-modifying antirheumatic drugs (DMARDs), including at least 1 tumour necrosis factor-alpha (TNF-alpha) inhibitor and who cannot have rituximab therapy because methotrexate is contraindicated or not tolerated and where the criteria in 1.1 are met.
- 1.3 Continue treatment only if there is a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months
- 1.4 After initial response within 6 months, withdraw treatment if a moderate EULAR response is not maintained
- 1.5 When using DAS28, healthcare professionals should take into account any physical, sensory or learning disabilities, communication difficulties, or disease characteristics that could adversely affect patient assessment and make any adjustments they consider appropriate.

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1.6 This guidance is not intended to affect the position of patients whose treatment with certolizumab pegol was started within the NHS before this guidance was published. Treatment of those patients may continue without change to whatever funding arrangements were in place for them before this guidance was published until they and their NHS clinician consider it appropriate to stop.

2 The technology

Description of the technology	Certolizumab pegol solution for injection (Cimzia, UCB pharma). PEGylated, Fc-free (fragment crystallisable) inhibitor of tumour necrosis factor-alpha (TNF-alpha), a pro-inflammatory mediator that is partly responsible for damage to the joints in rheumatoid arthritis.
Marketing authorisation	Certolizumab pegol has a marketing authorisation in the UK for the treatment of 'moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying antirheumatic drugs (DMARDs) including MTX (methotrexate), has been inadequate'. Certolizumab pegol can be used 'as monotherapy in case of intolerance to MTX or when continued treatment with MTX is inappropriate' (see the summary of product characteristics).
Adverse reactions	Certolizumab pegol is associated with common bacterial and viral infections and eosinophilic and leukopenia disorders. More uncommon infections that may limit its use include tuberculosis and sepsis. For full details of adverse reactions and contraindications, see the summary of product characteristics.
Recommended dose and schedule	Loading doses of 400 mg at weeks 0, 2 and 4; maintenance doses of 200 mg every 2 weeks or 400 mg every 4 weeks, once clinical response is confirmed.
Price	£715.00 per 2-syringe pack (excluding VAT; 'British national formulary' [BNF] edition 71). The company has agreed a patient access scheme with the Department of Health. This scheme provides a discount where the first 12 weeks of treatment is provided free of charge for certolizumab pegol which is equivalent to 10 vials. The acquisition cost is £6,793 in the first year of treatment and £9,295 per year thereafter. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS.

3 Evidence

The appraisal committee (section 7) considered evidence submitted by UCB Pharma and a review of this submission by the evidence review group (ERG). See the <u>committee papers</u> for full details of the evidence.

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4 Committee discussion

The appraisal committee reviewed the data available on the clinical and cost effectiveness of certolizumab pegol, having considered evidence on the nature of rheumatoid arthritis and the value placed on the benefits of certolizumab pegol by people with the condition, those who represent them, and clinical experts. It also took into account the effective use of NHS resources.

Clinical need and practice

- 4.1 The committee understood that the remit for this appraisal is to consider certolizumab pegol when the response to other DMARDS, including a TNF inhibitor, has been inadequate. It was reminded of existing NICE guidance at this point in the treatment pathway. NICE technology appraisal guidance for adalimumab, etanercept, infliximab, rituximab and abatacept for rheumatoid arthritis recommends rituximab plus methotrexate after inadequate response to, or intolerance to, other DMARDs, including at least 1 TNF-alpha inhibitor. The committee was aware that the guidance provides alternative options where either rituximab or methotrexate is contraindicated or withdrawn. The committee heard from the clinical and patient experts that response to treatment is difficult to predict, as responses to bDMARDs differ between individuals. The clinical expert emphasised the importance of a range of options for bDMARD treatments, particularly where rituximab plus methotrexate cannot be offered because of well-documented risks of adverse events occurring (i.e. after infusion). The committee concluded that an additional treatment option to treat rheumatoid arthritis that has not responded to a TNF inhibitor would be valued by both patients and clinicians.
- 4.2 The committee was aware that the marketing authorisation covers the use of certolizumab pegol in moderate to severe rheumatoid arthritis and that measures of response to treatment include the disease activity score

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(DAS28), developed in Europe. This was the recommended measure of treatment in NICE guidance <u>adalimumab</u>, <u>etanercept</u>, <u>infliximab</u>, <u>rituximab</u> <u>and abatacept for the treatment of rheumatoid arthritis</u>. It is calculated using a formula that includes counts for tender and swollen joints, an evaluation of general health by the person (on a scale of 0–100), and erythrocyte sedimentation rate or C-reactive protein. A DAS28 score greater than 5.1 indicates high disease activity, between 3.2 and 5.1 indicates moderate disease activity, and less than 3.2 indicates low disease activity. A score of less than 2.6 indicates disease remission. The European League Against Rheumatism (EULAR) response criteria use the degree of change in DAS28 score and the DAS28 score reached to determine good, moderate or non-response. It is the recommended measure of continuing response in NICE guidance for <u>adalimumab</u>, <u>etanercept</u>, <u>infliximab</u>, <u>certolizumab</u> <u>pegol</u>, <u>golimumab</u>, <u>tocilizumab</u> and abatacept for rheumatoid arthritis.

Decision problem

- 4.3 The committee considered the comparators for certolizumab pegol set out in the scope. It noted that the comparator was rituximab plus methotrexate. It was aware that, in line with existing NICE guidance (see section 4.1) alternative bDMARD treatment options were listed as comparators for those people for whom rituximab or methotrexate are contraindicated or withdrawn. The committee noted that the company had presented the evidence for 3 distinct populations, all of whom have been treated with a TNF-alpha inhibitor:
 - people for whom rituximab is contraindicated or not tolerated
 - people for whom methotrexate is contraindicated or not tolerated
 - people for whom rituximab plus methotrexate is a treatment option.

The committee concluded it was appropriate to consider the 3 groups as distinct from each other, and went on to discuss the company's choice of comparators for each group.

- 4.4 The committee was aware that past appraisals in this disease area have used a treatment sequence approach for comparing the intervention and comparator (see section 4.4). For this appraisal the company presented treatment sequences for the defined populations, which reflected the clinical pathway for people with severe active rheumatoid arthritis, who have had an inadequate response to, or who cannot tolerate, other DMARDs, including at least 1 TNF-alpha inhibitor. A sequence including certolizumab pegol (the intervention) was compared against a sequence including the comparator bDMARD. For the populations for whom methotrexate or rituximab is contraindicated, the comparator bDMARDs were:
 - Abatacept, adalimumab, etanercept, golimumab, infliximab and tocilizumab (each plus methotrexate) when rituximab is contraindicated or not tolerated
 - Adalimumab monotherapy, etanercept monotherapy or tocilizumab monotherapy when rituximab therapy cannot be given because methotrexate is contraindicated or not tolerated.

The certolizumab pegol and comparator treatment sequences were the same length, the only difference being that certolizumab pegol replaced the other bDMARD in the first line of the sequence. The committee accepted these sequences. However, for the population for whom rituximab plus methotrexate is a treatment option, the company had placed certolizumab pegol before rituximab in the intervention sequence, creating a longer intervention sequence to be compared against a shorter comparator sequence. This placed certolizumab pegol plus methotrexate in the treatment pathway before rituximab (and after a TNF-alpha

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inhibitor). The committee noted that this sequencing did not show a strict comparison with rituximab because it did not replace it, as with the other populations defined in the scope (see section 4.3).

- 4.5 The committee heard evidence from the clinical expert on the use of biosimilar bDMARDs in clinical practice. It heard that the infliximab biosimilar is not used in rheumatology and that the etanercept biosimilar has only been launched recently. The consensus among rheumatologists is that the etanercept biosimilar should be used in preference to the branded form because it has lower acquisition costs. The committee concluded that, because the etanercept biosimilar is being used in clinical practice, it was an appropriate to consider it in its decision making.
- 4.6 The committee was aware that the marketing authorisation for certolizumab pegol covers both moderate and severe disease and that existing NICE guidance specifies that a person must have severe disease to have treatment with a bDMARD. Severe disease is defined by a disease activity score (DAS28) greater than 5.1 (see section 4.2).

Clinical effectiveness

4.7 The committee considered the company's clinical evidence, noting that all the trials compared certolizumab pegol with placebo. It accepted that the results showed that certolizumab pegol was more clinically effective than placebo. The committee understood that the only evidence available on the comparative effectiveness of certolizumab pegol with the bDMARDs was from the company's mixed treatment comparisons. The committee heard that there were problems with the methods used for these comparisons. Heterogeneity was not appropriately accounted for. This could lead to an over-estimation of effect, favouring certolizumab pegol. The committee heard that the evidence review group (ERG) would have preferred to see random effects models throughout, rather than fixed effects models, because these can adequately capture the heterogeneity

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expected from the studies included in the analysis. The results from the mixed treatment comparisons are academic in confidence and cannot be included here. The committee concluded that there are uncertainties from the methods used and it could not reliably conclude whether certolizumab pegol was more clinically effective than the comparator bDMARDs on the basis of the mixed treatment comparisons presented by the company. However the committee heard from the clinical expert that certolizumab pegol is considered to be neither better nor worse than other TNF-alpha inhibitors. The committee concluded on the basis of the clinical expert's comments that certolizumab pegol has a similar efficacy to other available bDMARDs.

4.8 The committee saw no evidence to support the use of certolizumab pegol in people who have moderate disease. A comparison with conventional DMARDs (well-established treatments for moderate disease) was not made. The committee concluded that it should focus on the use of certolizumab pegol for people with severe disease.

Cost effectiveness

4.9 The committee considered the cost-effectiveness evidence for the 3 populations defined in the company's submission (see section 4.1).

People for whom rituximab is contraindicated or not tolerated

4.10 Given similar clinical efficacy between certolizumab pegol and other bDMARDs, the committee queried the base case incremental costeffective ratio (ICER) in the company's submission of £3,527 per quality-adjusted life year (QALY) gained. It would have expected to see similar QALY gains to other bDMARDs, yet the incremental QALY gain for certolizumab pegol plus methotrexate was 0.260, which was not in agreement with what the committee had already concluded on bDMARD efficacy (see section 4.10). The committee then considered the results of the ERG's scenario analysis in which it had been assumed that

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certolizumab pegol had equal efficacy with etanercept, adalimumab and infliximab (all plus methotrexate). The committee noted that the biosimilar of etanercept had been included in this sequence and agreed that this was appropriate. However, in the incremental analysis, certolizumab pegol was dominated by the biosimilar of etanercept, that is, certolizumab pegol plus methotrexate was more expensive but just as effective as the comparator bDMARDs. When the committee looked at the incremental increase in total costs between certolizumab and the biosimilar of etanercept it noted that there was very little difference so equivalence among bDMARDs could be accepted. The committee considered the ICERs which incorporated confidential patient access schemes for abatacept and tocilizumab, the results of which cannot be shown here. Even when these schemes were taken into account, the committee concluded that certolizumab pegol plus methotrexate can be considered a cost-effective use of NHS resources for people for whom rituximab is contraindicated or not tolerated.

People for whom methotrexate is contraindicated or not tolerated

4.11 The committee considered that the company's base case estimate ICER of £6,213 for people for whom methotrexate is contraindicated or not tolerated. Again, despite assumed equivalence of efficacy between certolizumab pegol and other bDMARDS, the company's base case results suggested a QALY gain of 0.260 for certolizumab pegol monotherapy. In the ERG's scenario analysis which assumed equal efficacy for certolizumab pegol with etanercept and adalimumab, certolizumab pegol was dominated by the etanercept biosimilar. However, the committee noted that the difference in total costs between the 2 treatment strategies was very small (less than £200). The committee was aware of the confidential patient access schemes for abatacept and tocilizumab. Even when these schemes were taken into account, the committee concluded that certolizumab pegol monotherapy can be

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considered a cost-effective use of NHS resources for people for whom methotrexate is contraindicated or not tolerated.

People for whom rituximab plus methotrexate is a treatment option

4.12 The committee had concerns about the company's approach to evaluating the cost effectiveness of certolizumab pegol plus methotrexate for this population. In particular, it was not persuaded that an intervention treatment sequence containing certolizumab pegol and 6 other treatments should be compared with the same sequence without certolizumab pegol (see section 4.6). The committee was aware from past technology appraisals that using different sequence lengths can increase modelling parameter uncertainties. In addition, it heard that the ERG's exploratory model resulted in some counterintuitive results; the clinical benefit (shown by the QALY gain) appeared to be greater if a person had received rituximab plus methotrexate than if a person had received both certolizumab pegol plus methotrexate and rituximab plus methotrexate. The committee also understood that not all possible treatment sequences for this population had been included in the company's analysis. It therefore considered the ERG exploratory analyses that included 2 additional sequences in which certolizumab pegol plus methotrexate was placed after, and instead of, rituximab plus methotrexate. The committee considered that these were appropriate sequences to include. In this analysis, certolizumab pegol plus methotrexate was dominated, that is, it resulted in fewer total QALYs and a greater total cost, when placed both instead of rituximab and before rituximab. The committee reasoned that it could not be considered a cost-effective treatment in these positions in the sequence. The ICER for certolizumab pegol plus methotrexate placed after rituximab plus methotrexate was around £27,500 per QALY gained; however, this did not take into account the confidential patent access scheme discount for tocilizumab, a treatment included in the treatment sequence after rituximab. When the confidential

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discount for tocilizumab was included, the ICER was higher than could be considered a cost-effective use of NHS resources. The ICER is commercial in confidence and cannot be reported here. In summary, the committee concluded that certolizumab pegol plus methotrexate could not be considered a cost-effective use of NHS resources when rituximab plus methotrexate is a treatment option.

Pharmaceutical price regulations scheme (PPRS) 2014

4.13 The committee was aware of NICE's position statement on the Pharmaceutical Price Regulation Scheme (PPRS) 2014, and in particular the PPRS payment mechanism. It accepted the conclusion 'that the 2014 PPRS payment mechanism should not, as a matter of course, be regarded as a relevant consideration in its assessment of the cost effectiveness of branded medicines'. The committee heard nothing to suggest that there is any basis for taking a different view about the relevance of the PPRS to this appraisal. It therefore concluded that the PPRS payment mechanism was not relevant in considering the cost effectiveness of the technology in this appraisal.

Summary of appraisal committee's key conclusions

TAXXX	Appraisal title: Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF Inhibitor	Section
Key conclusion		
Certolizumab pegol, i	n combination with methotrexate, is	1.1
recommended as an	option for treating active rheumatoid arthritis in	
adults who have had an inadequate response to, or who cannot		
tolerate, other disease-modifying antirheumatic drugs (DMARDs),		
including at least 1 tumour necrosis factor-alpha (TNF-alpha)		
inhibitor, only if; disea	ase is severe, that is, a disease activity score	

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(DAS28) greater than	5.1, the person cannot have rituximab therapy	
because rituximab is contraindicated or not tolerated and the		
company provides certolizumab pegol with the discount agreed in the		
patient access scheme	e.	
Certolizumab pegol ca	an be used as monotherapy for people who	1.2
have had an inadequa	ate response to, or who cannot tolerate, other	
disease-modifying ant	irheumatic drugs (DMARDs), including at least	
1 tumour necrosis fact	tor-alpha (TNF-alpha) inhibitor and cannot have	
rituximab therapy beca	ause methotrexate is contraindicated or not	
tolerated and where th	ne criteria in 1.1 are met.	
Current practice		
Clinical need of	The committee heard from the clinical and	4.1
patients, including	patient expert that response to treatment is	
the availability of	difficult to predict as patients responses differ	
alternative	to certain biologics. The clinical expert	
treatments	expressed that a range of additional options of	
	bDMARDs is valued at the positions in the	
	pathway within existing NICE guidance. It is	
	especially useful to have a range of biologics	
	when rituximab plus methotrexate cannot be	
	considered as rituximab has well documented	
	infusion related adverse event risks.	
The technology		
Proposed benefits of	No evidence was presented to suggest that	-
the technology	there are additional innovative benefits that	
How innovative is	have not already been captured in the	
the technology in its	estimate of the QALY.	

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potential to make a		
significant and		
substantial impact		
on health-related		
benefits?		
What is the position	People who have had an inadequate	4.1
of the treatment in	response to treatment with a TNF-alpha	
the pathway of care	inhibitor. This is at the same point as the	
for the condition?	existing NICE guidance for <u>adalimumab</u> ,	
	etanercept, infliximab, rituximab and	
	abatacept for the treatment of rheumatoid	
	arthritis.	
A di conse que e atione e	No constitue and identities	
Adverse reactions	No specific committee considerations	-
Evidence for clinical	effectiveness	
Availability, nature	The committee understood that the trials only	4.7
and quality of	showed a comparison of certolizumab pegol	
evidence	with placebo and accepted it was clinically	
	effective over placebo. The committee	
	understood that there were no trials	
	comparing certolizumab pegol with	
	comparing certolizumab pegol with comparator bDMARDs and that only mixed	
	comparator bDMARDs and that only mixed treatment comparisons were available.	
Relevance to	comparator bDMARDs and that only mixed	-
Relevance to general clinical	comparator bDMARDs and that only mixed treatment comparisons were available.	-
	comparator bDMARDs and that only mixed treatment comparisons were available. There were no direct head to head trials with	-

Uncertainties	The committee was aware of the uncertainties	4.7
generated by the	generated from the mixed treatment	
evidence	comparisons and that the use of a fixed	
	effects model does not adequately account for	
	heterogeneity between studies. As such the	
	committee accepted the clinical expert view	
	that certolizumab pegol was neither better nor	
	worse than existing bDMARDs used in	
	practice.	
A no the analysis	No analis accepting a social actions	
Are there any	No specific committee considerations	-
clinically relevant		
subgroups for which		
there is evidence of		
differential		
effectiveness?		
Estimate of the size	The committee noted the effect size estimates	4.7
of the clinical	from the company's mixed treatment	
effectiveness	comparison, comparing certolizumab pegol	
including strength of	with comparator bDMARDs, were uncertain	
supporting evidence	and concluded from the view of the clinical	
	expert there was similar efficacy among the	
	bDMARDs.	
Evidence for cost eff	inativanana	
Evidence for cost en	ectiveness	
Availability and	The committee noted that the treatment	4.4
nature of evidence	sequences presented by the company for	
	people for whom rituximab plus methotrexate	
	is a treatment option placed certolizumab	
	pegol plus methotrexate before rituximab and	
	did not reflect the comparison set out in the	
	I	

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	scope.	
Uncertainties around	The committee noted that the ERGs scenario	4.4,
and plausibility of	analysis applied an assumption of equal	4.10
assumptions and	efficacy among some of the bDMARDS and	and
inputs in the	this resulted in the ICERs being dominated,	4.11
economic model	that is certolizumab pegol was more	
	expensive but just as effective as the	
	comparator bDMARDs, for the population for	
	whom rituximab plus methotrexate is	
	contraindicated or not tolerated and for whom	
	methotrexate is contraindicated or not	
	tolerated. The committee noted the similarities	
	in costs and its conclusions on comparative	
	efficacy so that equivalence among	
	bDMARDs could be accepted.	
	The committee heard that company compared	4.12
	a longer intervention sequence which included	
	another 6 treatments with a comparator	
	sequence without the intervention. It was	
	aware that differential sequence lengths can	
	exacerbate modelling parameter uncertainties	
	and as such, skews the results in favour of the	
	intervention causing bias.	

Incorporation of	No other health-related benefits have been	-
health-related	identified that have not been captured in the	
quality-of-life	QALY calculation.	
benefits and utility		
values		
Llove ony petential		
Have any potential		
significant and		
substantial health-		
related benefits been		
identified that were		
not included in the		
economic model,		
and how have they		
been considered?		
Are there specific	No specific committee consideration.	-
groups of people for		
whom the		
technology is		
particularly cost		
effective?		
What are the key	The committee paid particular attention to the	4.4 and
drivers of cost	treatment sequence used by the company for	4.12
effectiveness?	the population for whom rituximab plus	
	methotrexate is a treatment option and noted	
	that placing certolizumab pegol plus	
	methotrexate before rituximab plus	
	methotrexate was not a valid comparison as it	
	did not replace it.	
	The committee noted the comparative efficacy	4.10

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	assumptions placed on bDMARDs in the analysis for people for whom rituximab plus methotrexate or methotrexate is contraindicated or not tolerated resulted in ICERs that were dominated for certolizumab pegol, in the ERGs scenario analysis, that is certolizumab pegol is more costly but just as	and 4.11
	effective compared with comparator bDMARDs.	
Most likely cost-	The committee concluded from the ERG	4.10
effectiveness	scenario analyses that there was little	and
estimate (given as	difference in costs between comparator	4.11
an ICER)	bDMARDs and certolizumab pegol so that	
	equivalence among bDMARDs can be	
	accepted for people for whom rituximab is	
	contraindicated or not tolerated, and for	
	people for whom methotrexate is	
	contraindicated or not tolerated.	
	The committee concluded that the most likely	4.12
	ICER for people for whom rituximab plus	
	methotrexate is a treatment option was above	
	the normal range that would be considered a	
	cost effective use of NHS resources. The	
	most plausible ICER cannot be reported here	
	due to the confidential patient access	
	schemes for tocilizumab and abatacept.	
Additional factors ta	ken into account	
Patient access	Patient access schemes were taken into	-
	account for certolizumab pegol, golimumab,	

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schemes (PPRS)	tocilizumab and abatacept.	
End-of-life considerations	Not applicable	-
Equalities considerations and social value judgements	There were no equality issues raised during the Committee discussion.	-

5 Implementation

- 5.1 Section 7(6) of the National Institute for Health and Care Excellence

 (Constitution and Functions) and the Health and Social Care Information

 Centre (Functions) Regulations 2013 requires clinical commissioning

 groups, NHS England and, with respect to their public health functions,
 local authorities to comply with the recommendations in this appraisal

 within 3 months of its date of publication.
- The Welsh Assembly Minister for Health and Social Services has issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 3 months of the guidance being published.
- 5.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has severe rheumatoid arthritis and the doctor responsible for their care thinks that certolizumab pegol is the right treatment, it should be available for use, in line with NICE's recommendations.

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6 Proposed date for review of guidance

6.1 NICE proposes that the guidance on this technology is considered for review by the guidance executive 3 years after publication of the guidance. NICE welcomes comment on this proposed date. The guidance executive will decide whether the technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

Professor Andrew Stevens Chair, appraisal committee July 2016

7 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee C.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The <u>minutes</u> of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

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