National Institute for Health and Care Excellence

Technology Appraisal (STA)

Tocilizumab for treating giant cell arteritis

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

Please note: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Comment 1: the draft remit

Section	Consultee/ Commentator	Comments [sic]	Action
Appropriateness	British Society of Rheumatology	This appraisal proposal is appropriate as there is an ongoing need for alternatives in the treatment of GCA in individuals who are either resistant or are at high-risk of treatment-related side effects to the current standard of treatment with a slow-tapering course of high-dose glucocorticoids.	Thank you for your comments. No action required.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	We consider that the remit is appropriate because the existing standard of care (prolonged treatment with glucocorticosteroid prednisolone) is associated with substantial health impact. This impact includes risk of diabetes, thinning of the skin and soft tissues, damage to bones. The population susceptible to GCA is particularly vulnerable to the effects of long term steroids when they have pre-existing multiple conditions.	Thank you for your comments. No action required.
	Roche Products	GCA is a serious but rare condition. With no licensed treatment options available for GCA patients in the UK, we consider there to be a high need for effective licensed treatments	Thank you for your comments. No action required.

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	Royal College of Ophthalmologists	Yes, this is a timely and appropriate question. Tocilizumab plus glucocorticoids had greater efficacy than glucocorticoids alone in the induction and maintenance of remission in patients with giant cell arteritis (GCA) in a single-centre phase 2 randomized controlled trial reported this year (Villiger, P. M. et al. Tocilizumab for induction and maintenance of remission in giant cell arteritis: a phase 2, randomised, double-blind, placebo-controlled trial. Lancet http://dx.doi.org/10.1016/S0140-6736(16)00560-2 (2016)) Tocilizumab plus glucorticoids has been reported in a Phase 3 trial to be superior to treatment with corticoidsteroids alone (American College of Rheumatology, Nov 2016), currently awaiting publication.	Thank you for your comments. No action required.
	Vasculitis UK	YES As stated in the draft remit, GCA is a serious systemic disease which affects around 4,500 people annually in the UK. Currently these are treated with long term high dose steroids which frequently cause serious side effects and co-morbidities.	Thank you for your comments. No action required.
Wording	British Society of Rheumatology	Yes	Thank you for your comments. No action required.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	No specific issues.	Thank you for your comments. No action required.

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	Roche Products	Yes	Thank you for your comments. No action required.
	Royal College of Ophthalmologists	Yes	Thank you for your comments. No action required.
	Vasculitis UK	Yes	Thank you for your comments. No action required.
Timing Issues	British Society of Rheumatology	It is important that the data of the GiACTA trial (J Stone et al, ACR/ARHP Meeting, 2016, Abstract No 911) is published in a peer-reviewed format compliant with CONSORT criteria) within the time frame of this appraisal.	Thank you for your comments. No action required.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	No specific timing issues, although the absence of any other generally effective alternative treatment for this condition other than steroids does impose a certain urgency.	Thank you for your comments. No action required.
	Roche Products	We are not aware of any specific timing issues aside from the general urgency conferred by the unmet medical need in GCA and high burden to patients of current treatment practice	Thank you for your comments. No action required.
	Royal College of Ophthalmologists	It would need to be within the next year – 18 months I assume to align with regulatory approvals, so that there is not a large lag between approvals and ability for the NHS to use the technology.	Thank you for your comments. Once an appraisal topic has been referred from the Department of Health, NICE aims to provide

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			guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted.

Comment 2: the draft scope

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Background information	British Society of Rheumatology	'Headache' is best considered the 'most common' rather than 'main' symptom as not all patients experience headaches. Regarding the incidence: The original paper by L Smeeth et al, Ann Rheum Disease, 2006) reports on a GPRD cohort of subjects over 40 years of age: It should therefore read 'Around 1 in 4,500 people over the age of 40 years develop giant cell arteritis every year'. Regarding current treatment: 'Prolonged corticosteroid treatment is usually required, tapering gradually over a period of 18-24 months; adverse effects of treatment are common'.	Thank you for your comments. The background section of the scope has been updated.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	"Low-dose aspirin and drugs that suppress the immune system (including methotrexate, azathioprine or tumour necrosis factor-alpha inhibitors) may also be used to reduce the risk of symptoms returning and complications developing." - not entirely correct - see below.	Thank you for your comments. The workshop attendees agreed that aspirin is not a relevant comparator for tocilizumab and that tumour necrosis factor-

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			alpha inhibitors are not normally used to treat giant cell arteritis. The background section of the scope has been updated.
	Roche Products	We believe that GCA may be associated with the rapid onset of severe headache and jaw claudication. We would also add extremity pain and night sweats to the other common symptoms. There are currently no licensed treatments for GCA, therefore any treatments used as standard of care are being prescribed off-label. We do not believe that low-dose asirin and immunosuppressive agents (such as methotrexate, azathioprine and antiTNFs) have positive randomised control evidence to support their use in GCA, and also these are used as steroid-sparing agents. The third paragraph of the Background section may therefore be misleading as to what are the relevant comparators. GiACTA is the largest randomised controlled trial for the treatment of GCA patients conducted, so provides the most robust evidence base for a treatment comparison with corticosteroids – the most relevant standard of care for this appraisal. Also, clinical trials of methotrexate and antiTNFs have not shown statistically significant clinical benefit. We anticipate the British Society for Rheumatology could soon update their published guidelines for the treatment of GCA, with it being likely that these will be available prior to the start of this appraisal. The systematic literature review conducted as part of their guideline review will likely provide evidence of treatments used off-label to treat GCA.	Thank you for your comments. The background section is intended to provide a brief summary of the disease and how it is managed. It is not designed to be exhaustive, and therefore the list of symptoms has not been amended. The workshop attendees agreed that aspirin is not a relevant comparator for tocilizumab and that tumour necrosis factor-alpha inhibitors are not normally used to treat giant cell arteritis. The background section of

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			the scope has been updated.
	Royal College of Ophthalmologists	I am surprised they cite tumour necrosis factor-alpha inhibitors as from my experience I felt Rheumatologist did not use this for refractory GCA. In our practice mostly patients who relapse or who have co-morbidities tend to end up on Methotrexate.	Thank you for your comments. The workshop attendees agreed that tumour necrosis factor-alpha inhibitors are not normally used to treat giant cell arteritis. The background section of the scope has been updated. The workshop attendees acknowledged that methotrexate is the most commonly used immunosuppressant for giant cell arteritis, but agreed that other immunosuppressive agents such as azathioprine and leflunomide are also part of established clinical practice.

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	Vasculitis UK	A realistic summary	Thank you for your comments. No action required.
The technology/ intervention	British Society of Rheumatology	The randomised, placebo-controlled trials have looked at 'newly diagnosed or relapsed/ refractory disease'.	Thank you for your comments. Relapsed disease has been added to the description of clinical trials in the technology section; refractory or newly diagnosed disease were already included.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	Adequate	Thank you for your comments. No action required.
	Roche Products	The GiACTA clinical trial includes patients with newly diagnosed GCA and relapsed/refractory GCA. [redacted]	Thank you for your comments. Relapsed disease has been added to the description of clinical trials in the technology section; refractory or newly diagnosed disease were already included.

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	Royal College of Ophthalmologists	Yes, growing evidence for use (as above I have cited the RCTs).	Thank you for your comments. No action required.
	Vasculitis UK	Yes	Thank you for your comments. No action required.
Population	British Society of Rheumatology	Yes, but see further comments below.	Thank you for your comments. See response to further comments below.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	Adequate	Thank you for your comments. No action required.
	Roche Products	No comments.	No action required.
	Royal College of Ophthalmologists	Yes adults with GCA.	Thank you for your comments. No action required.
	Vasculitis UK	The peak incidence is over age 65	Thank you for your comments. No action required.

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Comparators	British Society of Rheumatology	Yes	Thank you for your comments. No action required.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	Comparators do not reflect clinical practice. All patients are treated with corticosteroids. There is no evidence for aspirin as a treatment for GCA as shown by a recent Cochrane Review. There is no evidence for any immunosuppressant or tumour necrosis factor alpha antagonist, apart from methotrexate. Suggest rewording to “including corticosteroids either alone or in combination with methotrexate”.	Thank you for your comments. It is anticipated that tocilizumab will be an add on to standard of care treatment with corticosteroids. This is reflected in the updated scope.
	Roche Products	There are no licensed treatments for GCA, although off-label use of corticosteroids is generally regarded as the standard of care. We do not believe there is strong clinical evidence to support the use of immunosuppressive agents in GCA. In addition, we believe that the immunosuppressants NICE consider to be relevant should be listed here for clarity, also stating which are used in combination with corticosteroids.	Thank you for your comments. It is anticipated that tocilizumab will be an add-on to standard of care treatment with corticosteroids. This is reflected in the updated scope.
	Royal College of Ophthalmologists	Yes corticosteroids is the main stay of treatment	Thank you for your comments. No action required.

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	Vasculitis UK	Yes	Thank you for your comments. No action required.
Outcomes	British Society of Rheumatology	In addition to the mentioned outcomes, morbidity (e.g. visual loss, strokes per treatment group/ comparator, development or exacerbation of diabetes, serious infections, hypertension, low trauma fracture related to acquired osteoporosis) need consideration. Deterioration of pre-morbid (ie before the diagnosis and treatment of GCA) conditions (e.g. diabetes mellitus, osteoporosis) should also, if possible, be considered. Currently the adverse effects of steroids required to control GCA, particularly in relapsing or resistant cases, confer significant morbidity and reduction in these would be important considerations regarding a newer technology.	Thank you for your comments. The workshop attendees agreed that morbidity should be added to the scope as an outcome. The other outcomes you have suggested are captured within the outcomes in the draft scope.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	The key outcome is the reduction in adverse health impact brought about by a reduction in cumulative glucocorticoid dosage over the course of the disease. Adverse effects of long term corticosteroids are poorly captured by standard clinical trial reporting as they include things that are important but hard to measure e.g. psychological adverse effects, impact of prednisolone-related weight gain on quality of life/mobility, certain medical complications of prednisolone therapy that are uncommon but potentially devastating for the patient. So the QALY method may not properly reflect the real benefit of these drugs.	Thank you for your comments. The scope has been updated to include “adverse effects of long term corticosteroid treatment” as an outcome. The company is encouraged to make a case, in its submission, for any significant and substantial impacts on health-related benefits of tocilizumab that are

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			unlikely to be included in the quality-adjusted life year (QALY) calculation.
	Roche Products	We agree with the outcome measures suggested by NICE, but would ask how disease remission will be measured as we believe there is no standard definition. We believe corticosteroid treatment should be described as dose, duration, tapering and cumulative burden. We anticipate that the adverse effects of treatment should specifically include steroid-related adverse events	Thank you for your comments. The cumulative burden and tapering of corticosteroid treatment is captured by the outcomes “adverse effects of treatment” and “health-related quality of life. The scope has been updated to include “adverse effects of long term corticosteroid treatment” as an outcome. The company should provide a definition of disease remission, with rationale, in its submission.
	Royal College of Ophthalmologists	These, but more importantly the long term use of corticosteroids causes significant toxicity and health related costs from fractures to diabetes and cataracts.	Thank you for your comments. The scope has been updated to include “adverse effects

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			of long term corticosteroid treatment" as an outcome.
	Vasculitis UK	Yes	Thank you for your comments. No action required.
Economic analysis	British Society of Rheumatology	Some side effects of corticosteroid treatment may not manifest within a trial or economic appraisal time frame, e.g. accelerated bone loss, which may add to fracture risk over the remaining life time.	Thank you for your comments. The company is encouraged to make a case for any significant and substantial impacts on health-related benefits of tocilizumab that are unlikely to be included in the QALY calculation in its submission.
	Roche Products	No comments	No action required.
	Vasculitis UK	Yes – Inclusion of NHS & Personal Social Service costs highly relevant	Thank you for your comments. No action required.
Equality and Diversity	British Society of Rheumatology	We do not see any a-priori problems of equality in general. Some pre-existing conditions such as complicated diabetes or chronic infections might put patients at risk of additional adverse impact.	Thank you for your comments. Any potential equality issues will be considered

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			during the course of the appraisal and the committee will consider whether its recommendations could have a different impact on people protected by the equality legislation than on the wider population. No action required.
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	The equality issue here is that the population that typically suffers from GCA is older adults (mean age at diagnosis c 76 years), and there is some perception that there has been a reliance on treatment solely with glucocorticosteroids for several years, in spite of the evident health burden imposed. Changes in pension legislation will inevitably mean that the proportion of GCA patients of working age and in employment will rise.	Thank you for your comments. The committee will consider whether its recommendations could have a different impact on people protected by the equality legislation than on the wider population (such as older people). In line with the NICE reference case, the perspective of the analysis on costs should be that of the NHS and Personal Social Services

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			perspective. This does not include indirect costs such as lost work productivity. The committee, at its discretion, may consider non-reference case analyses if appropriate.
	Roche Products	No comments	No action required.
	Royal College of Ophthalmologists	No this treatment assessment should not have any adverse risk to equality.	Thank you for your comments. No action required.
	Vasculitis UK	GCA has the highest incidence and prevalence of all types of vasculitis, but has received little attention in the past due to the age demographic - the incidence is almost entirely among the elderly population. As the mean age of the general population rises, one might expect a corresponding increase in this condition. Failure to fully appraise this new technology might easily be construed as discrimination on grounds of age.	Thank you for your comments. The committee will consider whether its recommendations could have a different impact on people protected by the equality legislation than on the wider population (such as older people).
Other considerations	British Society of Rheumatology	One of the questions that needs addressing is, which subgroups of patients are relatively most likely to benefit from the proposed intervention: e.g. a) patients with primary steroid-refractory disease; b) patients with early	Thank you for your comments. The workshop attendees

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		relapse whilst still on more than low doses of corticosteroids (in other words: patients at risk of high cumulative steroid exposure) ; and c) patients with pre-morbid conditions such as complicated diabetes mellitus and established osteoporosis.	agreed that primary refractory disease is extremely rare, and therefore refractory disease is grouped with relapsed disease. The subgroups in the draft scope were considered appropriate.
	Roche Products	We would define the subgroups as: • newly diagnosed, and; • relapsed/refractory GCA patients. Refractory GCA patients are those not responding to corticosteroids and relapsed GCA patients are those whose GCA flares in response to cortisteroid tapering. We recommend including the joint British Society for Rheumatology and British Health Professionals in Rheumatology guidelines for the management of GCA published in 2010: Dasgupta B, et. al. BSR and BHPR Guidelines for the management of giant cell arteritis. Rheumatology 2010; 49(8):1594-1597.	Thank you for your comments. The wording of the subgroups have been updated for clarity. The related National Policy section focusses on policies from NHS England and the Department of Health. The company and other consultees are encouraged to provide details of UK treatment guidelines in their submissions.
	Vasculitis UK	GCA is frequently very debilitating, especially vision loss, as are the side effects of the treatment. GCA is now considered to be part of a spectrum of Large Vessel Vasculitis which includes Takayasu Arteritis, affecting predominantly young females	Thank you for your comments. The remit of the appraisal committee is to appraise a technology within its

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		and PMR (Polymyalgia Rheumatica), which affects mainly middle aged females and is serologically similar to GCA. PMR is treated with long term corticosteroids and in some cases progresses to full GCA. Future trials with tocilizumab may demonstrate significant benefits for treating both Takayasu arteritis and PMR.	marketing authorisation. Based on the clinical trials of tocilizumab in giant cell arteritis, it is expected that its initial marketing authorisation will not include Takayasu's arteritis and therefore NICE cannot make recommendations for tocilizumab in this indication. The company noted at the scoping workshop that the clinical trial of tocilizumab in giant cell arteritis included people with polymyalgia rheumatic (PMR). No action required.
Innovation	British Society of Rheumatology	The technology is innovative in principle for this indication and would be a major breakthrough in the treatment options for GCA. In particular the potential reduction in adverse effects related to the large doses of steroids currently used would be a very significant benefit if proved.	Comment noted. The company and other consultees will be able to fully describe why they consider tocilizumab to be innovative in their evidence submissions, which will then be considered by the
	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	Yes. Tocilizumab does represent a real step-change in management of this condition as the evidence for even methotrexate as an adjunct to prednisolone is not strong, and methotrexate is poorly tolerated by many patients; tocilizumab is the first biologic drug that has ever shown efficacy in clinical trials in GCA and could revolutionise the way this disease is treated.	

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	Roche Products	There are no licensed treatments for GCA, and the GiACTA trial is the largest randomised clinical trial conducted in GCA patients. Therefore we consider tocilizumab to be an innovative treatment to address the unmet needs of GCA patients.	appraisal committee. No action required.
	Royal College of Ophthalmologists	This is the first treatment other than corticosteroids that will have a significant impact on GCA management, since corticosteroids were first used for the condition.	
	Vasculitis UK	This is most definitely a step change technology rather than marginally incremental benefit. It would represent the first treatment developed specifically for Large Vessel Vasculitis. Much of the aim in introducing new drugs for treating the various types of vasculitis focuses on reduction of steroid use.	
Questions for consultation	British Society of Rheumatology	Is tocilizumab expected to be: • administered in combination with corticosteroids to treat giant cell arteritis? **YES** • used to treat giant cell arteritis that has relapsed following corticosteroid treatment (but is not refractory to corticosteroids)? **YES, IF RELAPSE OCCURS AT A MODERATE DOSE OR HIGHER.** • used to treat non-active giant cell arteritis? That is, to prevent a relapse? **NO** • offered to people who cannot tolerate corticosteroids? **YES, AND ALSO IF THEY ARE REFRACTORY TO CORTICOSTEROIDS** Which treatments are considered to be established clinical practice in the NHS for active giant cell arteritis: • in people who have been recently diagnosed with the disease?	Thank you for your comments. Please see responses to comments on other sections, above.

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		HIG-DOSE CORTICOSTEROIDS PLUS LOW-DOSE ASPIRIN; PLUS/MINUS METHOTREXATE (MTX) OR AZATHIOPRINE (AZP) • in people whose disease has not responded to corticosteroids? **MTX, AZP OR LEFLUNOMIDE (LEFL)** • in people who cannot tolerate corticosteroids? **MTX, AZP AND LEFL.** In current practice in the UK, immunosuppressants (including tumour necrosis factor-alpha inhibitors) may be used to treat giant cell arteritis. • Which biological treatments are used? **INFLIXIMAB, ADALUMIMAB** • Are immunosupressants used in combination with corticosteroids? **MTX, AZP ANDF LEFL.** Are there any subgroups of people for whom immunosuppressants would be used alone? **THOSE WHO ARE INTOLERANT TO CORTICOSTEROIDS.** Have all relevant comparators for tocilizumab been included in the scope? **YES** Are the outcomes listed appropriate? **SEE COMMENT FORM** Are the subgroups suggested in 'other considerations' appropriate? Are there any other subgroups of people in whom tocilizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately? **SEE COMMENT FORM** NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope: • could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which tocilizumab will be licensed;	

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		• could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology; • could have any adverse impact on people with a particular disability or disabilities. Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts. **NO CONCERNSANTICIPATED.** Do you consider tocilizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)? **YES** Do you consider that the use of tocilizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation? **SEE COMMENT FORM.** Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits. **THE GIACTA TRIAL** NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction) **APPROPRIATE.**	

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		1 NHS Choices website. Giant cell arteritis - overview [accessed September 2016]	
	Roche Products	*Is tocilizumab expected to be:* • *administered in combination with corticosteroids to treat giant cell arteritis?* [redacted] Tocilizumab is initially expected to be administered in combination with corticosteroids, however the primary and key secondary endpoints of GiACTA are to demonstrate sustained remission after steroid taper. • *used to treat giant cell arteritis that has relapsed following corticosteroid treatment (but is not refractory to corticosteroids)?* Yes, and this is reflected in the study design. • *used to treat non-active giant cell arteritis? That is, to prevent a relapse?* This is likely to be at the discretion of the treating physician who may feel it appropriate to maintain tocilizumab therapy after the patient has reached remission. • *offered to people who cannot tolerate corticosteroids?* This would require input from clinicians, although tocilizumab will be the only licensed treatment for GCA. *In current practice in the UK, immunosuppressants (including tumour necrosis factor-alpha inhibitors) may be used to treat giant cell arteritis.* • *Which biological treatments are used?*	Thank you for your comments. Please see responses to your comments on other sections, above.

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		We believe no biologics are used in the UK for the routine treatment of GCA patients, and none are licensed in GCA. • *Are immunosupressants used in combination with corticosteroids? Are there any subgroups of people for whom immunosuppressants would be used alone?* We believe if immunosupressants are used in GCA patients then this is in combination with corticosteroids. • *Have all relevant comparators for tocilizumab been included in the scope?* Yes, along with some comparators we do not consider to be appropriate or relevant • *Are the outcomes listed appropriate?* We believe a key outcome for consideration will be corticosteroid-related adverse events. • *Do you consider tocilizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?* There are no licensed treatments for GCA, and the GiACTA trial is the largest randomised clinical trial conducted in GCA patients. Therefore we consider tocilizumab to be an innovative treatment to address the unmet needs of GCA patients. • *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits*	

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		In addition to the joint British Society for Rheumatology and British Health Professionals in Rheumatology guidelines for the management of GCA published in 2010 (referenced above), we recommend that the following articles include information of relevance to this scoping meeting: Villiger PM, *et. al.* Tocilizumab for induction and maintenance of remission in giant cell arteritis: a phase 2, randomised, double-blind, placebo-controlled trial. The Lancet 2016; 387(10031): 1921–1927. Stone JH, Tuckwell K, Dimonaco S, Klearman M, Aringer M, Blockmans D, Brouwer E, Cid MC, Dasgupta B, Rech J, Salvarani C, Spiera RF, Unizony SH, Collinson N. Efficacy and Safety of Tocilizumab in Patients with Giant Cell Arteritis: Primary and Secondary Outcomes from a Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial [abstract]. Arthritis Rheumatol. 2016; 68 (suppl 10). http://acrabstracts.org/abstract/efficacy-and- safety-of- tocilizumab-in- patients-with-giant-cell- arteritis-primary- and-secondary- outcomes-from- a-phase- 3-randomized-double-blind- placebo-controlled- trial/. Accessed December 16, 2016. Unizony, SH, *et. al.* Design of the Tocilizumab in Giant Cell Arteritis Trial. Int J Rheumatol, 2013; Article ID 912562, 10 pages.	
	Royal College of Ophthalmologists	The trial evidence thus far has used corticosteroids with TCZ. At least initially we would assume corticosteroids plus TCZ, then a taper of the steroids. I would assume the taper to be within weeks of diagnosis and treatment commencing. As above, offered to those refractory, relapsing or have co-morbidities. The evidence from the phase 3 study may provide evidence for newly diagnosed GCA as well. Current UK Ophthalmology practice is corticosteroids, if relapsing or co-morbidity then referral to rheumatology for methotrexate.	Thank you for your comments. Please see responses to comments on other sections, above.

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		I am unaware of anybody in our area using TNF treatment for GCA.	
Additional comments on the draft scope	Polymyalgia Rheumatica and Giant Cell Arteritis UK (PMRGCAuk)	Our informal survey research of patient members of our organisation in 2012 revealed that the adverse effects of cumulative long term steroid intake are the major preoccupation of patients as their disease proceeds.	Thank you for your comments. No action required.
	Vaculitis UK	We (Vasculitis UK) would warmly welcome the opportunity to present a sample of true patient reported outcomes ie a synopsis of the anecdotal personal evidence from both those who have experienced both conventional treatment and the new technology (through clinical trials)	Thank you for your comments. If this appraisal topic is referred by the Department of Health, all consultees will be invited to submit a statement when the company is invited to makes its evidence submission.

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

AbbVie
Department of Health
Pfizer