Appendix C

National Institute for Health and Clinical Excellence

Adalimumab for the treatment of psoriasis

Response to consultee and commentator comments on the draft scope

Comment 1: the draft remit

Section	Consultees	Comments	Action
Appropriateness	The Psoriasis Association	Adalimumab is a new, as yet unlicensed treatment for psoriasis and it is important that clear guidelines are issued as soon as possible to improve options for patients and to help prescribers. We do have some concerns that a number of new treatments for psoriasis are being considered in isolation without a co-ordinated look at the patient pathway and all available treatments.	Comments noted.
Wording	Abbott Laboratories Ltd	Wording is appropriate	Comment noted.
	The Psoriasis Association	Wording is appropriate	Comment noted.
	Serono Ltd.	This STA will not address an unmet need as there are 2 other anti-TNF drugs already available. In order to reduce repetition of work, we suggest that NICE prepare Guidance for use of Biologics in Chronic Plaque Psoriasis covering all anti-TNF therapies and T-Cell modulators	The Department of Health has considered that guidance for the NHS is needed as soon as adalimumab has received marketing authorisation.
	Wyeth Pharmaceuticals	The terms moderate and severe should be defined in terms of PASI and DLQI score to ensure comparability with current NICE Guidance TA103	Comment noted. This has been added to the scope under 'other considerations'.
Timing Issues	Abbott Laboratories Ltd	The suggested timing for submission of evidence is appropriate for this appraisal.	Comment noted.

Section	Consultees	Comments	Action
	Serono Ltd.	There does not appear to be any urgency based on current evidence of efficacy of adalimumab compared to currently licenced anti-TNF therapies. Especially if MA for adalimumab is not expected until 2008	Comment noted.
	Wyeth Pharmaceuticals	Given that NICE guidance on the use of biologics in psoriasis is already in place, consideration should be given to appraising adalimumab as part of the scheduled review of the existing MTA (TA 103).	The Department of Health has considered that guidance for the NHS is needed as soon as adalimumab has received marketing authorisation.
Additional comments on the draft remit	Abbott Laboratories Ltd	Given the existing guidance for etanercept and efalizumab and ongoing appraisal of infliximab, it is important that this topic is considered for appraisal by NICE to ensure equal access to treatments for psoriasis.	Comments noted.

Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	The Psoriasis Association	Seems OK	Comment noted.
	Serono Ltd.	Para7 should describe the available biologic therapies, etanercept, infliximab and efalizumab without reference to the NICE TAG as para6 does for the other systemic therapies.	Scope amended.

Section	Consultees	Comments	Action
	Wyeth Pharmaceuticals	The text in the first paragraph of this section is inconsistent with the final (post-consultation) scope for the infliximab STA issued to stakeholders. This text should be made consistent. It is not made sufficiently clear that the last paragraph refers to biologic agents, distinct from the topical and systemic treatments discussed in the foregoing two paragraphs. Suggest the addition of a sentence at the beginning of this paragraph to clarify (e.g. "Recently, several biologic agents have received licences for the treatment of psoriasis"). Also, there is no mention of infliximab although it appears in the list of comparators.	Scope amended. Scope amended.
The technology/ intervention	Abbott Laboratories Ltd	Description of the technology/ies is accurate	Comment noted.
	The Psoriasis Association	Description of the technology/ies is accurate	Comment noted.
	Serono Ltd.	Confirm that adalimumab is being studied in mod-severe chronic plaque psoriasis	This is included under 'population'.
Population	Abbott Laboratories Ltd	Population defined appropriately	Comment noted.
	The Psoriasis Association	Population defined appropriately	Comment noted.
	Serono Ltd.	Population should be chronic plaque psoriasis	Scope amended.
	Wyeth Pharmaceuticals	Should be "Adults with moderate to severe plaque psoriasis" The terms moderate and severe should be defined in terms of PASI and DLQI, to ensure comparability with current NICE guidance TA103.	Scope amended. Scope amended under 'other considerations'

Appendix C

Section	Consultees	Comments	Action
Comparators	Abbott Laboratories Ltd	The list of comparators should be updated to the following: etanercept efalizumab infliximab Standard treatment without a TNF inhibitor or efalizumab.	The comparators section lists the relevant comparators.
	The Psoriasis Association	The comparators listed are standard treatments used in the NHS with which the technology should be compared to.	Comment noted.
	Serono Ltd.	How can Infliximab be used as it doesn't yet have an STA?	Infliximab is licensed for this indication and may be currently used for this indication in the NHS. It is therefore an appropriate comparator.
	Wyeth Pharmaceuticals	"PUVA" is the more usual term, rather than "photochemotherapy"	Added to scope.
Outcomes	Abbott Laboratories Ltd	Outcomes capture the most health related benefits (and harms) of the technology. The remission rate should also be included as an outcome in this appraisal.	Scope amended.
	Serono Ltd.	Ensure that adequate weight is given to the cost of adverse events on the QALY Long term efficacy is important as Psoriasis is a chronic condition. Short term studies would not suffice. Safety should not be with psoriasis patients, not historical data in a different patient population e.g. RhA	This level of detail is not included in the scope but will be considered as part of the appraisal. Added to scope.

Section	Consultees	Comments	Action
	Wyeth Pharmaceuticals	PASI and DLQI are the appropriate measures of disease severity to ensure consistency with TA103. Long-term efficacy and safety should be taken into account; particularly the clinical and cost-effectiveness implications of potential neutralising antibody development resulting in increased dose and/or dosing frequency to maintain clinical efficacy.	Added to scope under 'Other considerations'. Added to scope.
Economic analysis	Abbott Laboratories Ltd	It will be important to take a lifetime perspective to ensure all important costs and benefits are captured in the economic evaluation.	The time horizon of the economic analysis is not defined in the scope but will be considered as part of the appraisal.
Other considerations	Abbott Laboratories Ltd	The cost effectiveness of adalimumab for the treatment of psoriasis from a societal perspective.	The Guide to the Methods of Technology Appraisal states that cost effectiveness should be estimated from the perspective of the NHS and Personal and Social Services. Additional analyses, where considered relevant, may also be considered. See http://www.nice.org.uk/page.aspx?o=201973
	Serono Ltd.	Consider all anti-TNFs together as it is inappropriate to change a patient from one failed therapy to another of the same class	The clinical and cost effectiveness of adalimumab will be compared with other anti-TNFs, as defined in the comparators section of the scope.
	Wyeth Pharmaceuticals	It would be inappropriate for any recommendations from this appraisal to impact upon existing guidance (TA103) without giving consultees in TA103 the opportunity to fully participate, as consultees, in this process. The scope of the appraisal should specifically preclude the Appraisal Committee from making recommendations which would impact upon existing guidance.	This appraisal will make recommendations about adalimumab only and will not replace the NICE guidance on TA103.

Section	Consultees	Comments	Action
Questions for consultation	Serono Ltd.	A Single Technology Appraisal for adalimumab will not add greatly to the current body of evidence and will not enhance patient choice nor will it assist clinicians. NICE should consider all biologics in their real world usage. Ensure consistency with TAG 103 to allow comparisons to be made.	Comparisons with other anti- TNFs will be carried out in line with the appraisal process.

Comment 4: Regulatory issues

Section	Consultees	Comments	Action
Remit	Abbott Laboratories Ltd	Wording of remit reflects the current or proposed marketing authorisation	Comment noted.

Section	Consultees	Comments	Action
Current or proposed marketing authorisation	Abbott Laboratories Ltd	Rheumatoid arthritis - Humira in combination with methotrexate, is indicated for the treatment of moderate to severe, active rheumatoid arthritis in adult patients when the response to disease-modifying anti-rheumatic drugs including methotrexate has been inadequate. Humira is also indicated for the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate. Humira can be given as monotherapy in case of intolerance to methotrexate or when continued treatment with methotrexate is inappropriate. Humira has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function, when given in combination with methotrexate. Psoriatic arthritis - Humira is indicated for the treatment of active and progressive psoriatic arthritis in adults when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate. Ankylosing spondylitis - Humira is indicated for the treatment of adults with severe active ankylosing spondylitis who have had an inadequate response to conventional therapy.	Comments noted.

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

1. The British National Formulary
2. British Association of Dermatologists
3. National Public Health Service for Wales
4. NHS Quality Improvement Scotland
5. Psoriatic Arthropathy Alliance
6. Roche Products Ltd
7. Royal College of Nursing
8. Royal College of Physicians

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