National Institute for Health and Clinical Excellence

Psoriatic arthritis – etanercept, infliximab and adalimumab (review of 104 & 125)

Comment 1: the draft scope

Section	Consultees	Comments	Action
Background information	British Association of Dermatologists	Adequate	Comment noted.
	British Society for Rheumatology	Gold and anti-malarial drugs are very rarely used. Indeed hydroxychloroquine is relatively contra-indicated due to exacerbation of psoriasis. We do not know of anyone using phototherapy and would recommend these comments be removed in line with current practice. The other disease modifying drugs are not reserved for individuals with severe or progressive disease, but are increasingly used early in disease to try to prevent joint damage.	Comment noted. Scope amended accordingly.
	Psoriasis and Psoriatic Arthritis Alliance	Yes	Comment noted.
	Schering-Plough	No comments	Comment noted.
	Wyeth Pharmaceuticals	The background is accurate.	Comment noted.
The technology/ intervention	British Association of Dermatologists	Yes	Comment noted.
	British Society for Rheumatology	None	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	Yes	Comment noted.
	Schering-Plough	No comments	Comment noted.

Section	Consultees	Comments	Action
	Wyeth Pharmaceuticals	The description of the technologies is accurate.	Comment noted.
Population	British Association of Dermatologists	Yes and No	Comment noted.
	British Society for Rheumatology	In regards to the spectrum of disease in terms of peripheral joint involvement – there is no clear serological or radiological markers to define subgroups. There could be a case for considering predominant psoriatic spondyloarthritis with little or no peripheral joint involvement separately. Psoriatic arthritis is a heterogeneous disease. About a third of patients have a mild form of the disease. Recognising the other two thirds is difficult at onset, but the number of swollen joints at presentation is important – the more joints the worse prognosis. However, within this group is another, rapidly progressive group. Again this group is hard to predict at onset but it is likely that the clinical trials to date have at some point included some of these patients who are more likely to have erosions at presentation. The anti-TNF drugs may be particularly cost-effective in this group.	Comment noted. Subgroups are required to be biologically or clinically plausible and supported by a robust evidence base to be considered. Please see the NICE Guide to the methods of technology appraisal section 5.10
	Psoriasis and Psoriatic Arthritis Alliance	Yes, this reflects guidelines and licence indications.	Comment noted.
	Schering-Plough	No comments	Comment noted.
	Wyeth Pharmaceuticals	The population is defined appropriately.	Comment noted.
Comparators	British Association of Dermatologists	Yes	Comment noted.
	British Society for Rheumatology	No other anti-TNF agents currently.	Comment noted.

Section	Consultees	Comments	Action
	Psoriasis and Psoriatic Arthritis Alliance	Yes, these are the current comparators.	Comment noted.
	Schering-Plough	No comments	Comment noted.
	Wyeth Pharmaceuticals	These are the standard treatments.	Comment noted.
Outcomes	British Association of Dermatologists	Yes	Comment noted.
	British Society for Rheumatology	Yes. Presumably there will be tender and swollen joint counts included in outcome measures. Physician and patient global scores would also be needed if PsARC is still to be utilised.	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	Yes, but maybe a closer look at the effects, adverse events of the technologies on other non-skin/psoriasis co-morbidity risk.	Comment noted.
	Schering-Plough	Effect on nail psoriasis should also be considered. It is an important outcome for patients and some of the comparators have specific data on benefit on nail psoriasis	Comment noted.
	Wyeth Pharmaceuticals	It will be important, that the measurement of utility includes an accurate weighting of joint and skin involvement.	Comment noted.
Economic analysis	British Association of Dermatologists	None	Comment noted.
	British Society for Rheumatology	No time horizon given.	Comment noted.

Section	Consultees	Comments	Action
	Psoriasis and Psoriatic Arthritis Alliance	This is an interesting point given that 2 'separate' diseases might benefit from the technologies, therefore giving a better overall cost effective outcome by including (if psoriasis is also present with the psoriatic arthritis) the cost, for comparison, of other treatments used, or if neither disease qualifies separately but would equally benefit when considered together, by adding PASI score to the disability and QoL issues.	Comment noted. Effect on concomitant skin condition is included as an outcome and has been added as a subgroup.
	Schering-Plough	Costs specific to treatment of skin component should also be considered for the relevant population.	Comment noted. Effect on concomitant skin condition is included as an outcome and has been added as a subgroup.
	Wyeth Pharmaceuticals	The aspects are appropriate.	Comment noted.
Equality and Diversity	British Association of Dermatologists	None	Comment noted.
	British Society for Rheumatology	None	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	No comments on this.	Comment noted.
	Schering-Plough	No comments	Comment noted.
	Wyeth Pharmaceuticals	NA	Comment noted.

Section	Consultees	Comments	Action
Other considerations	British Association of Dermatologists	The important matter which ought now to be considered explicitly is how to incorporate joint AND skin disease into a composite evaluation of "incremental cost per quality-adjusted life year". This has not been achieved as yet in NICE Guidance and some thought needs to be given as to how it could be. Patients who may just fail the hurdle for eligibility when assessed by either joint or skin disease alone but who may well have more quality of life impairment than many patients with predominant skin or joint disease. This is particularly true when PASI is used for assessment of the skin as this underestimates the psychosocial and functional disability from acral, facial or flexural disease. It may not be easy to come up with a satisfactory formula. Nevertheless we shall be failing patients if we do not address this matter.	Comment noted. Effect on concomitant skin condition is included as an outcome and has been added as a subgroup.
	British Society for Rheumatology	None	Comment noted.
	Psoriasis and Psoriatic Arthritis Alliance	Nothing to add.	Comment noted.
	Schering-Plough	There is growing evidence of vial sharing in UK centres. Where the evidence allows, vial optimization should be considered.	Comment noted.
	Wyeth Pharmaceuticals	NA	Comment noted.
Questions for consultation	British Association of Dermatologists	Answer to both questions at the end of appendix A: No	Comment noted.

Section	Consultees	Comments	Action
	British Society for Rheumatology	There is no evidence that these drugs are any more clinically effective in certain subgroups than others, but they do seem to be effective across the clinical spectrum of disease, e.g. enthesitis, spondyloarthritis, peripheral arthritis. There may be a case for examining predominant spondyloarthritis separately in terms of outcome measures and qualification criteria. Cost effectiveness is likely to be higher if given early to patients who have severe disease before irreversible damage occurs. There are markers of poor prognosis: there are erosions at diagnosis and high numbers of swollen joints.	Comment noted. Subgroups are required to be biologically or clinically plausible and supported by a robust evidence base to be considered. Please see the NICE Guide to the methods of technology appraisal section 5.10
	Psoriasis and Psoriatic Arthritis Alliance	Nothing to add	Comment noted.
	Schering-Plough	Patients with predominantly skin component involvement should be considered separately.	Comment noted.
	Wyeth Pharmaceuticals	See comments above.	Comment noted.
Additional comments on the draft scope.	British Society for Rheumatology	None	Comment noted.

Comment 2: Regulatory issues

Section	Consultees	Comments		Action
Remit	Abbott Laboratories	*Does the wording of the remit reflect the current or proposed marketing authorisation? If not, please suggest alternative wording.*	Yes.	
Current or proposed marketing authorisation	Abbott Laboratories	*What are the current indications for the technology?*	For the treatment of moderate to severe rheumatoid arthritis, psoriatic arthritis, psoriasis, and ankylosing spondylitis and the treatment of severe Crohn's disease, plus for the treatment of juvenile idiopathic arthritis in adolescents aged 13 to 17.	
		What are the planned indications for the technology?	N/A	
		FOR EACH PLANNED INDICATION:		
		What is the target date (mm/yyyy) for regulatory submission?	N/A	
		Which regulatory process are you following?	N/A	
		What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable) and regulatory approval?	N/A	

Section	Consultees	Comments		Action
		Please indicate whether the information you provide concerning the proposed marketing authorisation is in the public domain and if not when it can be released. All commercial in confidence information must be highlighted and underlined.	N/A – adalimumab is available for the treatment of PsA.	

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

The Psoriasis Association

Abbott Laboratories