NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

RPP decision paper

Review of TA199; Etanercept, Infliximab, and Adalimumab for the treatment of psoriatic arthritis, TA220; Golimumab for the treatment of psoriatic arthritis, and TA340; Ustekinumab for treating active psoriatic arthritis

Final recommendation post consultation
The guidance should be transferred to the 'static guidance list'.

1. Background

TA199 was issued in August 2010, TA220 was issued in April 2011, and TA340 was issued in June 2015.

At the GE meeting of 19 July 2016 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

TA199, TA220 and TA340 should be transferred to the 'static guidance list'.

3. Rationale for selecting this proposal

There remains an absence of evidence from head-to-head comparisons between biologic treatments in people with psoriatic arthritis. Regarding the research recommendations of TA199, TA220 and TA340 for data from registries of long-term outcomes and adverse events there was no new evidence that would change the recommendations. The availability of biosimilars of infliximab and etanercept will not change the recommendations.

4. Summary of consultee and commentator responses

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.

Respondent: Psoriasis Association **Response to proposal:** No objection We have no objection to the proposal to move the guidance to the static list, as it is understood that the guidance may be transferred back to the active list for further appraisal should significant new evidence become available in the future. We would like to take this opportunity to reiterate comments we have made in previous Technology Appraisals, regarding the clear need for further research into the longer term safety, efficacy and patient experience of biologics for psoriatic arthritis – i.e. research outside of clinical trials. There is a clear need for a biologics register for the psoriatic arthritis population. It is felt that the opportunity to incorporate the guidance into the clinical guideline for spondyloarthropathies would be of benefit.	**Comment from Technology Appraisals** Comment noted. Psoriatic arthritis is included as a population in the scope of the spondyloarthritis guideline, currently in development, although the effectiveness of biological disease-modifying anti-rheumatic drugs for psoriatic arthritis will not be included. No action required.

Respondent: Merck, Sharp & Dohme **Response to proposal:** Agree We have no comments on this proposal and agrees with NICE's approach and plan to move the existing guidance for Psoriatic Arthritis treatments to the static list.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Janssen **Response to proposal:** Agree Janssen accepts NICE's recommendation to transfer TA340, TA220 and TA199 to the 'static guidance list'.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Pfizer **Response to proposal:** Agree Pfizer support this decision.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: British Association of Dermatologists **Response to proposal:** No comment	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Abbvie **Response to proposal:** Agree Abbvie agree with the proposal to move the existing guidance to the static list.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Psoriasis and Psoriatic Arthritis Alliance **Response to proposal:** Agree As an organisation that represents people affected by psoriasis and psoriatic arthritis, we support the opportunity for patients to get access to the latest therapies to alleviate their symptoms and limit disease progression. We also would like to see patients get better outcomes, fewer side effects and more convenient administration, therefore reducing the burden of being a patient, tied to frequent interventions, and dosage. We also acknowledge that the cost of treating each patient within the NHS has to be fair and equitable and any new treatment has to provide value for money and not have a detrimental effect on the service provided to others treated within the NHS. The decision to move the existing guidance to the static list, given the current changing treatment environment is sensible in our view. The only issue we have is the continual lack of head-to-head trials of the biologic agents and the lack of new data, to help people with psoriatic arthritis make and decision regarding the most appropriate therapy for their circumstances. Given that targeted agents act differently alone and in sequence, it would be useful if this was included within any future appraisal scope, and manufacturers could be encouraged to look at the broader view of matching treatment to individual patient needs. We also believe that in the future, a full review of all the psoriatic arthritis treatments should be completed, which includes higher target threshold of benefit, to encourage the manufacturers to provide more up-to-date relevant data.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: Novartis **Response to proposal:** Agree We agree with the guidance executive's proposal to move the named guidance to the static list. We note the following information which requires updating: • On page 5 of Appendix B- GE proposal paper, the text states 'Secukinumab does not yet have a marketing authorisation, but it is expected to be granted in…'. Please note, the marketing authorisation for secukinumab (Cosentyx) in psoriatic arthritis was granted in November 2015. The wording is as follows: Cosentyx, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate.	**Comment from Technology Appraisals** Comment noted. The secukinumab marketing authorisation information has been updated in Appendix B - GE proposal paper.

Paper signed off by: Frances Sutcliffe, 07/09/2016

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