**Adalimumab for treating moderate to severe hidradenitis suppurativa [ID812]**

**Comments on Appraisal Consultation Document, March 2016**

**John Ingram, on behalf of the British Association of Dermatologists**

**Has all of the relevant evidence been taken into account?**

We note that RCT data regarding adalimumab 40mg weekly therapy compared to placebo is also available from the phase II trial (Kimball et al 2012). Could any of this data be added to the results of PIONEER I and II for the purposes of modelling, or is this prevented by lack of HiSCR outcome data?

There is some confusion about the source of evidence for current hidradenitis suppurativa (HS) clinical practice in the UK. Two surveys have been conducted but in some places are not differentiated:

1) Ingram JR, McPhee M. Management of hidradenitis suppurativa: a UK survey of current practice. Br J Dermatol 2015; 173: 1070-2.
2) Abbvie-sponsored survey of management of moderate to severe HS, the full results of which have not yet been published in a peer reviewed journal.

The survey by Ingram and McPhee sets out the order of most frequently used medical therapies for HS (however note that while isotretinoin is included, evidence suggests that this is ineffective for most HS patients). The survey sponsored by Abbvie was used by the company to estimate the number of surgical procedures required in a HS patient's lifetime.

**Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?**

Yes, the summaries are comprehensive and reasonable. The report includes the issue of uncertainties surrounding surgery for HS, which remains difficult to estimate accurately. In particular, it may be that three or four wide excisions are required on average during the lifetime of a patient with moderate to severe HS, rather than the estimate of two wide excisions included in the ERG report.

In terms of further clarification of the surgery and wound care issues, reduction in suppuration in those patients who respond to adalimumab should decrease wound dressings costs, which can be a substantial component of the costs of supportive care. In addition there should be a reduction in the number of smaller procedures, such as incision and drainage and narrow margin excisions. It is uncertain whether there would be any change to the number of wide excisions because we do not have enough experience of how adalimumab will be used in practice, with the potential to use both adalimumab and wide excision surgery in some patients.

**Are the recommendations sound and a suitable basis for guidance to the NHS?**

Regarding stopping rules, we agree that it is reasonable to continue adalimumab treatment for partial response, defined as a 25-50% reduction in inflammatory lesions, with no increase in abscesses or draining fistulas. We also agree that it is inappropriate to continue treatment for a

further 12 weeks in non-responders, defined as a reduction of less than 25% in the number of inflammatory lesions. It is counterintuitive that, in the pharmacoeconomic model, removal of the rule to continue adalimumab therapy for 12 weeks in non-responders made adalimumab less cost effective.

The BAD wishes to stress that moderate to severe HS represents a large unmet patient need in the NHS, particularly when surgery is impractical due to involvement of several different skin regions. At the moment, clinicians are required to submit individual funding requests for anti-tumour necrosis factor alpha (anti-TNFα) therapies to treat HS, which generates inequalities in HS care provision across the UK. Anti-TNFα therapy represents a step change in HS care and adalimumab is currently the only licenced intervention available for HS.

**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?**

No.