NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Adalimumab for treating moderate to severe hidradenitis suppurativa

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of adalimumab within its marketing authorisation for treating moderate to severe hidradenitis suppurativa.

Background

Hidradenitis suppurativa (HS), also known as acne inversa or Verneuil's disease, is a chronic disorder of the skin. HS is caused by blocked apocrine (sweat) glands which are connected to hair follicles which become inflamed and filled with pus. The symptoms are subcutaneous nodules, papules or abscesses. These are painful and tender and can cause discomfort, itching, erythema, burning or excessive sweating. The nodules may spontaneously rupture or coalesce, forming painful, deep dermal abscesses and fistulae and eventually result in fibrosis, scarring and the formation of extensive sinus tracts. Symptoms begin around puberty and most commonly appear in the second or third decade of life. The disease affects areas with apocrine glands, such as axillae, the groin, the perineum, the inframammary region (in women), the perianal region, the inguinal region and the suprapubic region. The cause of HS is unclear but may be hormonal or the result of an underlying autoimmune disorder.

HS affects around 1 in 600 people in England. There are approximately 90,000 people with HS in England. The disease is more common in women than in men and people of African family origin have a higher incidence than people of European family origin.

There is no standard treatment pathway for this condition. Current treatment includes antibiotics (erythromycin, metronidazole, minocycline, clindamycin, cephalosporins and penicillins; long term antibiotics: erythromycin or tetracycline), steroids (High-dose oral steroids such as prednisolone; or intralesional corticosteroid injection in the acute phase of the disease), and oestrogens. Retinoids (such as acitretin), dapsone, and TNF-inhibitors (such as infliximab) are usually used in a later stage of the disease. Surgery may be considered for people with chronic HS to remove the apocrine glands in the affected areas of skin although the disease can reoccur after surgery.

The technology

Adalimumab (Humira, AbbVie) is a fully human recombinant monoclonal IgG1 antibody specific for tumour necrosis factor (TNF)-alpha. It blocks interaction with cell-surface receptors, thereby limiting the promotion of inflammatory pathways. It is administered by subcutaneous injection.

Adalimumab does not currently have a marketing authorization in the UK for hidradenitis suppurativa. It has been studied in clinical trials compared with placebo, in adults with moderate to severe hidradenitis suppurativa that has failed to respond to oral antibiotics.

Intervention(s)	Adalimumab
Population(s)	Adults with moderate to severe hidradenitis suppurativa.
Comparators	• High-dose oral steroids • Intralesional corticosteroid injection • Oestrogens • Retinoids • Dapsone
Outcomes	The outcome measures to be considered include: • Disease severity • Clinical response • Inflammation and fibrosis • Discomfort and pain • Adverse effects of treatment • Health-related quality of life.

Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any patient access schemes for the intervention or comparator technologies should be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	None
Related National Policy	NHS England: A12/S/a 2013/14 NHS Standard Contract For Specialised Dermatology Services (all ages) (2013) Department of Health: Department of Health (2013) NHS Outcomes Framework 2014-2015

Questions for consultation

Are current treatments for this condition correctly described in the background section? If not, what is the current treatment pathway for people with moderate to severe hidradenitis suppurativa? Are there different treatments for moderate or severe HS? Do antibiotics represent routine first line treatment for people with hidradenitis suppurativa?

Have all relevant comparators for adalimumab for treating hidradenitis suppurativa been included in the scope? Are retinoid and dapsone considered to be established clinical practice in the NHS for treating hidradenitis suppurativa?

Should oral antibiotics, TNF-inhibitors (other than adalimumab) or surgery be included as comparators?

Are retinoids, dapsone used in the same place in the treatment pathway as TNF-inhibitors and where does adalimumab fit into treatment pathway?

Are biosimilars likely to be established clinical practice for the treatment of hidradenitis suppurativa?

Are disease severity and clinical response two different outcomes? Should other specific clinical outcomes be considered?

Are there any subgroups of people in whom adalimumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

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 adalimumab will be licensed;

- 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.

Do you consider adalimumab 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)?

Do you consider that the use of adalimumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

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