

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Single Technology Appraisal

### Adalimumab for treating moderate to severe hidradenitis suppurativa

#### Final scope

#### 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 inflammatory skin disorder. HS is caused by blocked hair follicles which are connected to apocrine sweat glands. This stops sweat from escaping onto the skin and leads to the formation of pus-filled abscesses which can become infected. These are painful and can cause itching, redness, burning, excessive sweating, and eventually scarring. In severe cases the pus tunnels deep under the surface of the skin and forms widespread networks of interconnected channels that can break out on the surface and leak pus. Symptoms begin around puberty and most commonly appear in the second or third decade of life. The disease affects areas with apocrine sweat glands such as the groin and genitals, buttocks and inner thighs, armpits and below the breasts (in women). The cause of HS is unclear but may be hormonal or the result of an underlying autoimmune disorder.

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 clinical management includes antibiotics (including combination treatment with clindamycin plus rifampicine), retinoids (such as acitretin), ciclosporin, dapson, and tumour necrosis factor (TNF)-inhibitors (such as infliximab plus methotrexate). None of these treatments have a marketing authorisation in the UK for HS. Surgery may be considered for people with chronic HS to remove the sweat 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 TNF-alpha. It blocks interaction with cell-surface receptors, thereby limiting the promotion of inflammatory pathways. It is administered by subcutaneous injection.

Adalimumab has a marketing authorisation in the UK for treating active moderate to severe hidradenitis suppurativa in adults whose disease has not responded to conventional systemic hidradenitis suppurativa therapy.

<b>Intervention(s)</b>	Adalimumab
<b>Population(s)</b>	Adults with active moderate to severe hidradenitis suppurativa which has not responded to conventional therapy
<b>Comparators</b>	Established clinical management without adalimumab
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• Disease severity</li> <li>• Clinical response</li> <li>• Inflammation and fibrosis</li> <li>• Discomfort and pain</li> <li>• Adverse effects of treatment</li> <li>• Health-related quality of life.</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<b>Other considerations</b>	<p>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.</p>
<b>Related NICE recommendations and NICE Pathways</b>	None
<b>Related National Policy</b>	<p>NHS England:  A12/S/a <a href="#">2013/14 NHS Standard Contract For Specialised Dermatology Services (all ages)</a> (2013)</p>

