NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Secukinumab for treating moderate to severe hidradenitis suppurativa [ID4039]

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of secukinumab 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 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. The cause of HS is unclear but may be hormonal or the result of an underlying autoimmune disorder.

HS affects around 1 in 130 people in the United Kingdom, although approximately one in three cases go unrecognised.[1] There are approximately 435,000 people with HS in England.[1,2] The disease is more common in women than in men. People of African-Caribbean family background have a higher incidence than people of European family background.

There are no tests used to diagnose HS and a diagnosis is usually based on the typical signs or symptoms of the disease, although a GP may do tests to rule out other conditions with similar signs and symptoms.[3] The British Association of Dermatologists guidelines recommend initial treatment with oral tetracyclines (such as doxycycline or lymecycline), followed by combination treatment with oral clindamycin and rifampicin in people whose disease has not responded. Retinoids (such as acitretin) and dapsone are recommended for people whose disease does not respond to antibiotic therapy.[4] NICE technology appraisal 392 recommends adalimumab as an option for treating active moderate to severe HS in adults whose disease has not responded to conventional systemic therapy. An NHS England Clinical Commissioning Policy states that there is not enough evidence to make infliximab available to treat HS. Surgery may also be considered for people with chronic HS that cannot be controlled by medicine.[3,4]

The technology

Secukinumab (Cosentyx, Novartis) is administered by subcutaneous injection.

Secukinumab does not currently have a marketing authorisation in the UK for HS. It is being studied in clinical trials, compared with placebo, in adults with moderate to severe HS.

Intervention(s)	Secukinumab
Population(s)	Adults with moderate to severe hidradenitis suppurativa
Comparators	• Adalimumab • Best supportive care
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 commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account. The availability and cost of biosimilar and generic products 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	**Related Technology Appraisals:** Adalimumab for treating moderate to severe hidradenitis suppurativa (2016). NICE Technology appraisal guidance 392. Review date May 2019.

Related National Policy	NHS England (2019). The NHS Long Term Plan NHS England (2016). Infliximab for the treatment of hidradenitis suppurativa. Clinical Commissioning Policy. Reference 16018/P. NHS England (2013) 2013/14 NHS standard contract for specialised dermatology services (all ages). Service specification no. A12/S/a

Questions for consultation

What is the current treatment pathway for people with moderate to severe hidradenitis suppurativa? Where do you consider secukinumab will fit into the existing care pathway for hidradenitis suppurativa?

Are there different treatments for moderate or severe hidradenitis suppurativa?

Have all relevant comparators for secukinumab for treating hidradenitis suppurativa been include in this scope?

Is infliximab considered to be established clinical practice in the NHS for treating hidradenitis suppurativa?

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

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

What does best supportive care for moderate to severe hidradenitis suppurativa consist of?

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

Would secukinumab be a candidate for managed access?

Do you consider secukinumab 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 secukinumab can result in any potential 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 committee to take account of these benefits.

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 secukinumab 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.

NICE intends to evaluate this technology through its Single Technology Appraisal process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost-comparison methodology for this topic?

- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?

- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?

- Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?

References

1. Ingram JR, Jenkins-Jones S, Knipe DW et al. (2018) Population-based Clinical Practice Research Datalink study using algorithm modelling to identify the true burden of hidradenitis suppurativa. British Journal of Dermatology 178(4):917-924.

2. Office for National Statistics (25 June 2021) Population estimates for the UK, England and Wales, Scotland and Northern Ireland: mid-2020

3. NHS (2019). Hidradenitis Suppurativa. Accessed May 2022.

4. Ingram JR, Collier F, Brown D et al. (2019) British Association of Dermatologists guidelines for the management of hidradenitis suppurativa (acne inversa) 2018. British Journal of Dermatology 180(5):1009-1017.