Health Technology Briefing
April 2026

Lutikizumab for hidradenitis suppurativa in adults and adolescents

Company/Developer	AbbVie Ltd

☒ New Active Substance ☐ Significant Licence Extension (SLE)

NIHRIO ID: 41371	NICE ID: Not Available	UKPS ID: 675335

Licensing and Market Availability Plans

Currently in phase III clinical trial.

Summary

Lutikizumab is being developed for the treatment of adult and adolescent patients with moderate to severe hidradenitis suppurativa (HS). HS is a painful, long-term skin condition that causes repeated painful nodules and abscesses (lumps with pus) and can leave scars if not treated adequately. Its exact cause is not fully known, but it develops around hair roots where there are sweat glands, and usually affects areas like the groin, bottom, under the breasts and the armpits. HS can affect anyone, but it is more common in women and in people with darker skin. HS is difficult to manage and is associated with a high morbidity burden and disability, as well as a significant unmet medical and socioeconomic need.

Lutikizumab is a new type of medicine made from human antibodies and injected under the skin. It works by blocking two proteins in the body, called IL-1 alpha and IL-1 beta, which are involved in causing inflammation. If licensed, lutikizumab may provide a new treatment option for the adult and adolescent patients with moderate to severe HS.

Proposed Indication

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

Treatment of adults and adolescents with moderate to severe hidradenitis suppurativa (HS).[1]

Technology

Description

Lutikizumab (ABT-981) is a novel human dual variable domain immunoglobulin that has been shown to bind and inhibit interleukin 1α and 1β (IL-1α and IL-1β).[2,3] Lutikizumab binds 2 human IL-1α and 2 human IL-1β molecules simultaneously. IL-1α and IL-1β are structurally distinct cytokines that bind to the same receptor, IL-1RI, to induce distinct physiological effects, including expression of cytokines, chemokines, nitric oxide synthase, and matrix metalloproteinases. Since IL-1α and IL-1β are upregulated in skin lesions of patients with HS, inhibition of IL-1α and IL-1β by lutikizumab is expected to improve the signs and symptoms associated with HS compared with inhibition of IL-1α or IL-1β alone.[4]

Lutikizumab is currently in development for the treatment of adult and adolescent patients with moderate to severe HS. In a phase III clinical trial (Intrepid; NCT06468228), participants received subcutaneous administration of lutikizumab weekly for 16 weeks (Period 1), followed by a further weekly or every other week administration for 36 weeks (Period 2) up to 52 weeks.[1] Participants will subsequently continue to receive lutikizumab subcutaneously using the same assigned dosing regimen from the end of Period 2 for another 16 weeks, followed by open-label lutikizumab every other week for a further 140 weeks. This is a total trial time of 208 weeks.

Key Innovation

HS is difficult to manage and is associated with a high morbidity burden and disability, as well as a significant unmet medical and socioeconomic need.[5-8] It has been shown that IL-1α and IL-1β are elevated in HS.[3,9] Lutikizumab offers a dual function of binding and neutralising IL-1α and IL-1β to relieve the pain and dysfunctional symptoms caused by the elevated IL-1α and IL-1β.[10,11] In a phase II clinical trial, patients with moderate to severe HS who were treated with lutikizumab, achieved greater numerical improvement in their draining tunnels.[12] If licensed, lutikizumab may provide a new treatment option for adult and adolescent patients with moderate to severe HS.

Regulatory & Development Status

Lutikizumab does not currently have Marketing Authorisation in the EU/UK for any indication.

Lutikizumab is currently in phase II/III clinical development for the following indications as a monotherapy or in combination with other therapy:[13]

- Rheumatoid arthritis
- Atopic dermatitis
- Psoriatic arthritis

Patient Group

Disease Area and Clinical Need

HS is a painful, long-term skin condition that causes skin abscesses and scarring on the skin. The exact cause of HS is unknown, but it occurs near hair follicles where there are sweat glands, usually around the groin, bottom, breasts and armpits.[14] The symptoms of HS range from mild to severe and may include boil-like lumps, blackheads, cysts, scarring and channels in the skin that leak pus.[14] HS can affect anyone but is

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

more common in women and in people with darker skin.[15] Smoking and obesity are both strongly associated with HS, and HS runs in families in about 1 in 3 cases.[14]
HS affects around 1% of the UK population.[15] In England (2024-25) there were 3,063 finished consultant episodes (FCEs) and 2,810 finished admission episodes for HS (ICD-10 code L73.2), which resulted in 1,706 day cases and 3,075 FCE bed days.[16]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) recommends the following for the treatment of moderate to severe HS:[17,18]

- Adalimumab
- Secukinumab

Clinical Trial Information

Trial	**Intrepid**; NCT06468228; EUCT 2024-510730-40-00; A Phase 3 Multicentre, Randomised, Double-Blind Placebo-Controlled Study to Evaluate the Efficacy and Safety of Lutikizumab in Adult and Adolescent Subjects with Moderate to Severe Hidradenitis Suppurativa (HS). **Phase III** – Recruiting **Location(s)**: Twenty-one EU countries, UK, USA, Canada, Australia and others **Primary completion date**: December 2026
Trial Design	Randomised, triple masking, parallel assignment, placebo-controlled.
Population	N=1280; participants aged 12 years and older with moderate to severe HS
Intervention(s)	Subcutaneous administration of lutikizumab every week for 16 weeks, followed by a further weekly or every other week administration up to 52 weeks.
Comparator(s)	Matched placebo
Outcome(s)	• Primary outcome measure: Percentage of Participants Achieving Hidradenitis Suppurative Clinical Response (HiSCR) 75 [Time frame: at week 16] See the trial record for a full list of other outcomes.
Results (efficacy)	-
Results (safety)	-

Estimated Cost

The cost of lutikizumab is not yet known.

Relevant Guidance

NICE Guidance

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

- NICE technology appraisal awaiting development. Upadacitinib for treating moderate to severe hidradenitis suppurativa in people 12 years and over (GID-TA11825). Expected publication date to be confirmed
- NICE technology appraisal guidance. Secukinumab for treating moderate to severe hidradenitis suppurativa (TA935). December 2023
- NICE technology appraisal guidance. Adalimumab for treating moderate to severe hidradenitis suppurativa (TA392). June 2016

NHS England (Policy/Commissioning) Guidance

- NHS England. NHS Clinical Commissioning Policy: Infliximab for the treatment of hidradenitis suppurativa. 16018/P

Other Guidance

- The British Association of Dermatologists. Guidelines for the management of hidradenitis suppurativa (acne inversa) 2018. 2019.[19]

Additional Information

References

1 ClinicalTrials.gov. *A Study to Assess Disease Activity and Safety of Lutikizumab in Adult and Adolescent Participants With Moderate to Severe Hidradenitis Suppurativa (Intrepid)*. *Trial ID: NCT06468228*. 2024. Status: Recruiting. Available from: https://clinicaltrials.gov/study/NCT06468228 [Accessed 16 February, 2026].

2 Fleischmann RM, Bliddal H, Blanco FJ, Schnitzer TJ, Peterfy C, Chen S, et al. A Phase II Trial of Lutikizumab, an Anti-Interleukin-1α/β Dual Variable Domain Immunoglobulin, in Knee Osteoarthritis Patients With Synovitis. *Arthritis & Rheumatology*. 2019;71(7):1056-69. Available from: https://doi.org/10.1002/art.40840.

3 Abbvie - News Centre. *Lutikizumab Showed Positive Results in a Phase 2 Trial of Adults with Moderate to Severe Hidradenitis Suppurativa as Program Advances to Phase 3*. 2024. Available from: https://news.abbvie.com/2024-01-08-Lutikizumab-Showed-Positive-Results-in-a-Phase-2-Trial-of-Adults-with-Moderate-to-Severe-Hidradenitis-Suppurativa-as-Program-Advances-to-Phase-3 [Accessed 16 February, 2026].

4 Kimball AB, Sawicki KT, Ackerman L, Lima H, Giamarellos-Bourboulis EJ, Zhan T, et al. Lutikizumab in Adults With Moderate to Severe Hidradenitis Suppurativa After Anti-TNF Therapy Failure: A Phase 2 Randomized Clinical Trial. *JAMA Dermatology*. 2026. Available from: https://doi.org/10.1001/jamadermatol.2026.0155.

5 Ingram JR, Bettoli V, Espy JI, Kokolakis G, Martorell A, Villani AP, et al. Unmet clinical needs and burden of disease in hidradenitis suppurativa: real-world experience from EU5 and US. *Journal of the European Academy of Dermatology and Venereology*. 2022;36(9):1597-605. Available from: https://doi.org/10.1111/jdv.18163.

6 Dufour DN, Emtestam L, Jemec GB. Hidradenitis suppurativa: a common and burdensome, yet under-recognised, inflammatory skin disease. *Postgraduate Medical Journal*. 2014;90(1062):216-21; quiz 20. Available from: https://doi.org/10.1136/postgradmedj-2013-131994.

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.

7 Kirby JS, Miller JJ, Adams DR, Leslie D. Health care utilization patterns and costs for patients with hidradenitis suppurativa. *JAMA Dermatol*. 2014;150(9):937-44. Available from: https://doi.org/10.1001/jamadermatol.2014.691.

8 Jemec GB, Kimball AB. Hidradenitis suppurativa: Epidemiology and scope of the problem. *Journal of the American Academy Dermatology*. 2015;73(5 Suppl 1):S4-7. Available from: https://doi.org/10.1016/j.jaad.2015.07.052.

9 van der Zee HH, de Ruiter L, van den Broecke DG, Dik WA, Laman JD, Prens EP. Elevated levels of tumour necrosis factor (TNF)-α, interleukin (IL)-1β and IL-10 in hidradenitis suppurativa skin: a rationale for targeting TNF-α and IL-1β. *British Journal of Dermatology*. 2011;164(6):1292-8. Available from: https://doi.org/10.1111/j.1365-2133.2011.10254.x.

10 Cao Z, Li Y, Wang W, Jie S, Hu X, Zhou J, et al. Is Lutikizumab, an Anti-Interleukin-1α/β Dual Variable Domain Immunoglobulin, efficacious for Osteoarthritis? Results from a bayesian network meta-analysis. *BioMed Research International*. 2020;2020:9013283. Available from: https://doi.org/10.1155/2020/9013283.

11 Galozzi P, Bindoli S, Doria A, Sfriso P. The revisited role of interleukin-1 alpha and beta in autoimmune and inflammatory disorders and in comorbidities. *Autoimmunity Reviews*. 2021;20(4):102785. Available from: https://doi.org/10.1016/j.autrev.2021.102785.

12 Kimball A, Ackerman L, Lima H, Kirby B, Zhan T, Gamelli A, et al. 63539 Improvement in Draining Tunnels in Response to Lutikizumab Treatment in Adult Patients with Moderate-to-Severe Hidradenitis Suppurativa Who Have Failed Anti-TNF Therapy. *Journal of the American Academy of Dermatology*. 2025;93(3):AB55. Available from: https://doi.org/10.1016/j.jaad.2025.05.224.

13 ClinicalTrials.gov. *Lutikizumab | Phase 2,3*. 2026. Available from: https://clinicaltrials.gov/search?term=Lutikizumab&viewType=Table&aggFilters=phase:2%203 [Accessed 17 February, 2026].

14 National Health Service (NHS). *Hidradenitis suppurativa (HS)*. 2023. Available from: https://www.nhs.uk/conditions/hidradenitis-suppurativa/ [Accessed 17 February, 2026].

15 British Association of Dermatologists. *Hidradenitis suppurativa*. 2025. Available from: https://www.bad.org.uk/pils/hidradenitis-suppurativa [Accessed 17 February, 2026].

16 National Health Service (NHS) Digital. *Hospital Admitted Patient Care Activity, 2024-25*. 2025. Available from: https://digital.nhs.uk/data-and-information/publications/statistical/hospital-admitted-patient-care-activity/2024-25 [Accessed 09 February, 2026].

17 National Institute for Health and Care Excellence (NICE). *Secukinumab for treating moderate to severe hidradenitis suppurativa*. 2023. Available from: https://www.nice.org.uk/guidance/TA935/chapter/1-recommendations [Accessed 17 February, 2026].

18 National Institute for Health and Care Excellence (NICE). *Adalimumab for treating moderate to severe hidradenitis suppurativa (TA392)*. 2016. Available from: https://www.nice.org.uk/guidance/ta392 [Accessed 15 April, 2026].

19 Ingram JR, Collier F, Brown D, Burton T, Burton J, Chin MF, et al. British Association of Dermatologists guidelines for the management of hidradenitis suppurativa (acne inversa) 2018. *British Journal of Dermatology*. 2019;180(5):1009-17. Available from: https://doi.org/10.1111/bjd.17537.

NB: This briefing presents independent research funded by the National Institute for Health and Care Research (NIHR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

Copyright © National Institute for Health and Care Research Innovation Observatory, The University of Newcastle upon Tyne.