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All Wales Therapeutics & Toxicology Centre

Evidence Status Report: infliximab to treat moderate to severe hidradenitis suppurativa that does not respond to licensed treatments or when licensed treatments are not suitable **(OW37)**

Report prepared by the All Wales Therapeutics and Toxicology Centre
August 2026

Key findings

Licence status
Infliximab is not licensed for treating hidradenitis suppurativa (HS); its use for this indication is off label.

Guidelines
Infliximab is recommended for the treatment of HS in guidelines published by the British Association of Dermatologists and European Hidradenitis Suppurativa Foundation.

Clinical evidence
One randomised controlled trial compared intravenous infliximab 5 mg/kg (on Weeks 0, 2 and 6, and then every eight weeks) with placebo in moderate-to-severe HS. In sub-analyses, infliximab showed significant improvement in HS Severity Index (HSSI) compared with placebo.

Safety
Side effects are in line with the licensed use of infliximab, though studies have reported cases of polyarthritis during infliximab therapy for HS, which resolved after treatment was discontinued.

Patient factors
Questionnaires submitted to AWTTC by people with HS refer to extreme pain, toll on mental health, impact on relationships and restrictions to everyday activities. Patients welcome any new treatment which may reduce flares and in particular the pain associated with this condition.

Cost effectiveness
No cost-effectiveness evidence was identified for this use of infliximab, and no analyses of cost effectiveness have been done.

Budget impact
The addition of infliximab is estimated to decrease the spend associated with this patient group in Wales by [Commercial in confidence text removed] in Year 1 and [Commercial in confidence text removed] in Year 2 compared with current last line biologics accessed through individual patient funding requests. Compared to best supportive care alone, infliximab would increase the budget impact by [Commercial in confidence text removed] in Year 1 and [Commercial in confidence text removed] in Year 2. However, this excludes any additional saving due to infliximab treatment, including reduced hospital admissions and additional procedures. An estimated budget impact for an increase in dose frequency to every four weeks for

patients with inadequate response has also been provided.

Impact on health and social care services
We would expect a minimal impact on health and social care services.

Innovation and/or advantages
Infliximab offers an additional much-needed treatment option for patients whose HS has stopped responding to standard therapies, and patients for whom standard therapies are not suitable.

Background

Clinicians in Wales consider there is an unmet need for treating moderate-to-severe hidradenitis suppurativa (HS; acne inversa) that does not respond to licensed and National Institute for Health and Care Excellence (NICE)-recommended treatments (adalimumab and secukinumab), or for when licensed treatments are not suitable. They have identified a cohort of patients who could benefit from infliximab treatment and requested that it is considered for off-label use in this indication. This request is supported by the British Association of Dermatologists (BAD), as evidenced by the BAD Guidelines.

The AWMSG Scrutiny Panel agreed that infliximab was suitable for assessment though the One Wales medicines process.

Target group

The indication under consideration is the off-label treatment of moderate-to-severe HS that does not respond to licensed treatments, or when licensed treatments are not suitable.

Marketing authorisation date: Not applicable, off label

Infliximab is not licensed to treat moderate-to-severe HS that does not respond to licensed treatments or when licensed treatments are not suitable. [Commercial in confidence text removed].

Dosing information

The proposed dose is 5 mg/kg by intravenous infusion over a 2-hour period at Week 0[1]. This dose is the recommended infliximab dose to treat most of the indications for which it is licensed. A second, and third dose may be given, two and six weeks later, and then every eight weeks. Due to risk of acute infusion-related reactions, patients should be monitored during and for at least one to two hours post-infusion[1]. Clinicians have requested that an option for increased dose frequency to every four weeks is considered for patients who have inadequate response after six months of treatment.

Clinical background

Hidradenitis suppurativa (HS) is a painful, long-term skin condition that causes abscesses and scarring on the skin[2]. The exact cause of HS is unknown[2]. Unlike a simple skin infection, HS is a complex condition that can form deep, painful lumps, nodules, and abscesses in skin-fold areas – most commonly the armpits, groin, buttocks, inner thighs, and under the breasts, although HS can occur anywhere on

the body[3]. Over time, these recurring episodes can form sinus tracts – persistent, draining tunnels under the skin[3].

The severity of HS is usually assessed using the Hurley staging system[4]. Patients with moderate HS (Hurley stage II) have recurrent lesions separated by normal skin with sinus tract formation and scarring. In severe HS (Hurley stage III) patients have multiple lesions coalescing into inflammatory plaques involving most of the affected area[4].

In the UK, two biologic therapies are approved by NICE to treat moderate to severe HS: adalimumab and secukinumab[5,6]. However, clinicians in Wales report that the effects of these biologics generally only last for one or two years[7,8], while HS can persist for many years.

Incidence/prevalence

The prevalence of HS is approximately 1% of the UK population[9]. It can affect anyone but is more common in women and in people with darker skin[9].

Clinicians in Wales estimate that about 40% of patients have moderate-to-severe (Hurley stage II to III) disease. Based on Secure Anonymised Information Linkage (SAIL) Databank figures, clinicians estimate that each year in Wales, about 10 patients with HS would be eligible for treatment with infliximab.

Current treatment options and relevant guidance

No licensed alternative treatments are routinely available for patients who have not responded to licensed and health technology assessment (HTA) approved treatments; bimekizumab (licensed for HS) or upadacitinib (currently off-[Commercial in confidence text removed]) are being considered for HTA and can only be requested through an individual patient funding request (IPFR). NICE terminated an appraisal of bimekizumab due to non-submission by the company[10], but the company are planning to submit for appraisal by the All Wales Medicines Strategy Group (AWMSG; date of advice to be determined). Upadacitinib has been topic selected by NICE and guidance is awaiting development[11]. Povorcitinib is undergoing appraisal with NICE for treatment of moderate to severe HS where a tumour necrosis factor (TNF)-alpha inhibitor is not suitable, did not work or has stopped working[12]. Infliximab is a TNF-alpha inhibitor therefore the patient cohort under consideration is different from that being considered for povorcitinib.

The British Association of Dermatologists (BAD) guideline for the treatment of HS, published in 2019, recommends initial treatment with topical clindamycin and oral tetracycline antibiotics plus dressings for lesions and lifestyle advice[4]. For HS that does not respond to these treatments, oral treatments such as acitretin and dapsone are recommended. For HS that continues not to respond, the guideline recommends adalimumab treatment. Infliximab 5 mg/kg every eight weeks may be considered in people with moderate-to-severe HS that is unresponsive to adalimumab therapy[4].

Since the publication of the BAD guideline, a second biologic, secukinumab, has been licensed and recommended by NICE for the treatment of moderate-to-severe HS if adalimumab is not suitable, did not work, or has stopped working[6].

The European Hidradenitis Suppurativa Foundation's updated 2025 guideline advises modifying therapy if there is no significant reduction in the inflammatory activity of the lesions or no improvement of the quality of life is observed after 12 weeks[13]. For moderate-to-severe HS the guideline recommends that intravenous infliximab may be considered as third-line treatment, after second-line treatment with licensed biologics (adalimumab, bimekizumab and secukinumab) has been unsatisfactory. The recommended dosage and duration of treatment are 5 mg/kg intravenous infliximab given at Weeks 0, 2 and 6, and then every eight weeks[13].

Summary of evidence on clinical effectiveness

The All Wales Therapeutics and Toxicology Centre (AWTTC) conducted a literature search during 27–29 July 2026, to look for evidence about the use of infliximab to treat moderate-to-severe HS.

Searches were conducted on 27 July 2026 in MEDLINE ALL (Ovid), Embase (Ovid) and the Cochrane Library from database inception to the most recent update available. Our search terms were: infliximab, renflexis, remicade, zessly, remsima, inflectra, flixabi; hidradenitis suppurativa; acne inversa. Pre-set search filters prepared by Canada's Drug Agency were used to search MEDLINE and Embase for economic evaluations and quality-of-life information.

The primary outcomes of interest were: symptom improvement or resolution in randomised controlled trials (RCT), systematic reviews, network meta-analyses, guidelines, case series, retrospective studies, health-related quality of life, economic evaluations, adverse events. No date restrictions were applied; results were restricted to English language. Targeted searches of Google and Google Scholar were also performed. Conference abstracts, letters and editorials were excluded. Clinical authors at AWTTC sifted and screened the results of the searches for clinical evidence, economic evaluations and quality of life. No relevant economic evaluations were identified.

The clinical literature search identified a total of 956 records, from which 172 duplicates were removed. The remaining 784 records were screened by inspecting titles and abstracts, and the full texts of 64 papers were reviewed for eligibility. We focused on studies that recorded the dose of infliximab as the dose recommended for most licensed indications in the Summary of Product Characteristics (SmPC; 5 mg/kg on Weeks 0, 2 and 6, and then every eight weeks) and the BAD guideline (5 mg/kg every eight weeks)[1,4]. An increased frequency of dosing to 5 mg/kg every four weeks was also included. We have not included studies using higher doses of infliximab, studies that focused on surgery, non-RCT studies that were included in the Shih et al. systematic review, single case reports, older guidelines and older studies with less than 10 patients. We identified six studies to include in this report, including one clinical trial of infliximab to treat HS, one systematic review, three retrospective studies and one study with increased dose frequency. See the PRISMA diagram in Appendix 1.

Efficacy

Randomised controlled trial

Grant et al. (2010) conducted a randomised, double-blind, placebo-controlled crossover trial of infliximab therapy in patients with moderate to severe HS[14]. The study recruited 38 adults with moderate to severe HS and at least one of the following: HS lasting more than one year; more than five steroid injections per year; failed systemic retinoid treatment; failed antibiotic treatment; or patients with a history of reconstructive surgery. Moderate to severe HS was defined by a HS Severity Index (HSSI) score greater than 8. HSSI is a composite score ranging from 0–19 assessing: number of sites involved; percentage of body surface involved; number of lesions; number of dressing changes; pain quantified by visual analogue scale (VAS). Thirty eight patients were randomised to receive infliximab (n = 15) at 5 mg/kg on Weeks 0, 2 and 6 and every eight weeks thereafter up to Week 22, or placebo (n = 23) on weeks 0, 2 and 6. Treatments were unblinded after Week 8 and patients in the placebo group could cross over to infliximab treatment. An observation phase followed from treatment end up to Week 52[14].

The primary endpoint was change in HSSI score at Week 8 from baseline[14]. Secondary endpoints included: change in Dermatology Life Quality Index (DLQI), VAS and Physician Global Assessment (PGA) at Week 8 from baseline; improvement in disease severity in patients in the placebo group crossing over to infliximab at Week 8 before and after cross over; and change in disease severity at Week 22 (end of infliximab treatment) and at Week 52 (end of study)[14].

The number of patients with ≥ 50% decrease from baseline in HSSI at Week 8 was higher in the infliximab group than in the placebo group, although the difference was not significant ($p = 0.092$)[14]. Post-hoc HSSI composite analysis of patients achieving between 25% and 50% decrease in HSSI from baseline showed a significant difference between groups ($p < 0.001$); 60% in the infliximab group (compared with 5.6% in the placebo group). Most patients treated with placebo (88.9%) had a < 25% decrease in HSSI from baseline compared with 13.3% of patients treated with infliximab. Infliximab showed significant improvements compared to placebo for DLQI, VAS and PGA[14].

Systematic review

Shih et al. (2022) conducted a systematic review and meta-analysis that identified 19 studies published between 2003 and 2021 that reported outcomes of infliximab use in patients with HS (n = 341)[15]. Studies included one randomised control trial (Grant et al., 2010; summarised above), four open-label trials and 13 cohort studies: one prospective and 12 retrospective). Patients with HS severity data (n = 299) had moderate-to-severe HS. Previously failed treatments, where reported, were varied and infliximab was not necessarily placed after failure of another biologic treatment. The dose of infliximab was 5 mg/kg for 10 studies. Five studies used infliximab at 5 mg/kg to 10 mg/kg with a frequency of maintenance dose between four and eight weeks[15].

The pooled response rate of HS to infliximab was 83% (95% confidence interval [CI]: 0.71 to 0.91) with 17 studies reporting a response rate > 50%[15]. There was significant heterogeneity between studies ($I^2 = 89\%$). The analysis concluded that overall, infliximab is an effective treatment for patients with moderate-to-severe HS[15].

Retrospective study

Le et al. (2026) conducted a retrospective study of 55 patients with Hurley Stage II or III HS who were treated with infliximab at a centre in the USA during July 2015–October 2025, and who had at least one measurement of serum infliximab trough concentration[16]. Thirty-nine (71%) patients had previously been exposed to biologic (adalimumab) therapy. Nineteen patients (35%) responded to infliximab therapy, 36 (65%) had suboptimal responses (19 primary and 17 secondary suboptimal responses). Baseline demographics, comorbidities, smoking, and prior adalimumab exposure (39/55; 70.9%) were similar across the responder groups. Hurley stage III was more prevalent among suboptimal responders than responders, occurring in 100% of patients with primary non-response and 94.1% of those with secondary non-response, compared with 63.2% of responders ($p = 0.002$)[16].

Anti-infliximab antibodies (ATIs) were detected exclusively among suboptimal responders, most often in secondary suboptimal responders (52.9%; $p = 0.0001$)[16]. The infliximab dose was escalated in nine patients with low infliximab trough concentrations and negative ATIs, with a subsequent clinical response observed in six patients. The mean duration of infliximab use was 8 months (range 4–19)[16].

Increased dosing frequency

Clinicians have requested consideration of an increase in frequency of dose to 5 mg/kg every 4 weeks for patients with insufficient response. Three studies were identified that included increased dose and/or frequency of infliximab and had not been included in the systematic review by Shih et al. (2022). In two studies the dose of infliximab had been increased to between 7.5 mg/kg 12.5 mg/kg and so will not be discussed further. A study by Srour et al. (2026) report on a retrospective cohort study of 40 HS patients treated in a single centre in Israel. All patients had Hurley Stage II or III HS and were treated with infliximab 5 mg/kg every four weeks following failure of adalimumab. Outcomes measured were HS clinical response (HiSCR) 50 (a ≥ 50% decrease in the number of abscesses and inflammatory nodules without an increase in abscesses or draining fistulas) and DLQI. HiSCR 50 was achieved in 29 patients (72.5%) at 24 weeks, response was maintained at 48 weeks in 26 patients (65%). A sustained response after 48 weeks of treatment was reported in in 86.2% of the 29 initial responders. Mean DLQI was significantly reduced from 19.55 at baseline to 12.4 at 24 weeks and 11.8 at 48 weeks ($p < 0.001$)[17].

Safety

The adverse event profile of infliximab in this indication is expected to be in line with that described in the summary of product characteristics (SmPC)[1]. Upper respiratory tract infection was the most common adverse drug reaction (ADR) reported in clinical trials, occurring in 25.3% of infliximab-treated patients compared with 16.5% of control patients. The most serious ADRs associated with the use of tumour necrosis factor blockers that have been reported for infliximab include hepatitis B virus reactivation, congestive heart failure, serious infections (including sepsis, opportunistic infections and tuberculosis), serum sickness (delayed hypersensitivity reactions), haematologic reactions, systemic lupus erythematosus or lupus-like syndrome and serious infusion reactions[1].

The very common (≥ 1 in 10) side effects reported from infliximab infusion across all indications for use include: viral infections (such as influenza, herpes virus infection),

headache, upper respiratory tract infection, sinusitis, and abdominal pain, nausea, infusion-related reaction and pain[1].

The recommended baseline monitoring for infliximab is complete metabolic profile, complete blood count with differential, tuberculosis test, serologic tests for hepatitis B and C, and HIV test for higher risk patients[18]. Ongoing monitoring needed is an annual tuberculosis test and liver function tests at three months after starting treatment then every 6 to 12 months afterwards[18].

In the randomised controlled trial of infliximab, no unexpected adverse events were reported during the study[14]. Likewise, in the meta-analysis by Shih et al. (2022) the most common adverse events were in line with the expected side effect profile for infliximab[15].

In the study by Srour et al. (2026) adverse events were noted in 22.5% of patients, most were mild and included muscle pain, transient elevated liver enzymes and infections requiring antibiotic treatment[17].

Acquacalda et al. (2015) and **Van Rappard et al. (2011)** both report cases of polyarthritis following treatment with infliximab for HS[19,20]. Acquacalda et al. noted three of 11 patients with severe, therapy-resistant HS developed an acute and painful polyarthritis, without systemic reaction, during infliximab infusion leading to the discontinuation of treatment[19]. In two of the cases polyarthritis developed soon after the 4th and 8th infliximab infusion and resolved 12 weeks after discontinuation in both. In the third case, polyarthritis developed two months after the 16th infusion infliximab and resolved after four months. In the three cases no rheumatological flare was reported 24, 26 and 12 months later[19].

In a retrospective study, van Rappard et al. reported five of 27 patients (18%) developed an acute and painful polyarthritis during treatment with infliximab for HS[20]. On average, the arthritis started after 12 months of treatment; it was not clearly associated with anti-infliximab antibodies and resolved in an average of four months. No patients had a history of arthritis and all showed a good skin response to infliximab. Arthritis was not observed in any of the control groups studied (227 patients with HS not treated with any biologic, 22 patients with HS treated with adalimumab, and 28 patients with psoriasis treated with infliximab). Compared with the adalimumab group the odds ratio of developing arthritis was calculated to be 7.241 (95% CI: 1.15 to 45.6), and compared with the psoriasis group, the odds ratio was 9.025 (95% CI: 1.45 to 55.82)[20].

Discussion

The highest quality evidence for efficacy is a single RCT of infliximab versus placebo in 38 patients with moderate-to-severe HS, conducted in 2010. No new clinical trials of infliximab in this indication have been conducted that compare infliximab with other biologics or placebo. The severity of HS was defined using an HSSI score which captures inflammatory burden, whilst Hurley staging focusses on the degree of scarring. Moderate and severe HS as defined by HSSI may not align with moderate to severe Hurley staging. At the time the RCT was conducted, no biologics were licensed to treat HS and infliximab was administered as a first-line biologic treatment. Limited data is available for later line use, in the retrospective cohort study by Le et al. (2026), prior treatment with adalimumab did not appear to significantly affect response to infliximab.

The RCT had a treatment period of eight weeks, with an observation period of a further 44 weeks. There are no data for longer-term treatment. Although the primary end point of a ≥ 50% decrease from baseline in HSSI after eight weeks was higher in the infliximab group than in the placebo group, the difference was not statistically significant. Post-hoc analyses showed a significant difference between the two groups for achieving a 25% to 50% decrease in HSSI from baseline with infliximab. The use of infliximab is recommended by the European Hidradenitis Suppurativa Foundation's guideline, predominantly based on the results of the RCT[13]. The guideline also recommends continued maintenance treatment beyond the initial eight-week treatment period that was included in the study, stating that evidence for long-term use (one year) is only based on a single-centre case series of eight patients with moderate-to-severe HS[13].

Clinicians in Wales note that no licensed biologics to treat HS have demonstrated long-term treatment success. Therefore, they have requested the assessment of infliximab to provide another option for patients in Wales for whose HS does not respond to, or has stopped responding to, licensed biologics; and also for patients for whom the licensed treatments are not suitable.

For patients who have an inadequate response to 5 mg/kg infliximab every eight weeks, clinicians have requested that the frequency of dose can be increased to up to every four weeks. The rationale provided is that in the marketing authorisation for secukinumab for treatment of HS there is the option to increase dose frequency from every four weeks to every two weeks based on clinical response. There is one study described where patients were initiated on four-weekly dosing regimen following failure of adalimumab treatment. The study reported an improvement in HS symptoms and quality of life at this dose[17]. Five of the ten studies included in the systematic review by Shih et al. (2022) included either increased dose of infliximab (up to 10 mg/kg) or increased frequency of dose (up to every four weeks). The findings were not stratified by regimen though infliximab was found to have an overall beneficial effect in treating moderate to severe HS.

Clinicians indicate that even if new biologics become available for HS in Wales, because of the chronic nature of HS and the relatively short drug survival times of biologics to treat it, there is still likely to be a place for infliximab in HS therapy.

The safety profile of infliximab has been established and in the majority of HS studies no new adverse effects were reported. The study by Srour et al. (2026) demonstrated that an increase in frequency to four weekly was well tolerated and adverse events were mild and manageable[17]. Two studies report that polyarthritis might be an unwanted effect that seems to occur in a small number of HS patients treated with infliximab[19,20]. It may be prudent to monitor and advise patients of this rare adverse event which typically occurs after 12 months of treatment and resolves on treatment discontinuation.

Cost-effectiveness evidence

No cost-effectiveness evidence was identified for this use of infliximab; no cost-effectiveness analyses have been undertaken.

Budget impact

The cost of infliximab is provided in Table 1 and is based on the weighted average of NHS Wales contract prices for the reference product and biosimilars with 2024 secondary care prescribing data. The standard dose of infliximab is 5 mg/kg on Weeks 0, 2 and 6 and every 8 weeks thereafter. Clinical experts estimate that in 30% of cases, HS will not respond or the treatment will not be tolerated and will be discontinued after the initial three doses of infliximab, assuming that a response has not been seen by Week 12. This 30% discontinuation rate has also been applied to the comparators.

Infliximab is to be reserved for patients whose HS has failed to respond or who have contraindications to treatment with licensed and approved biologic therapies. Active comparator treatments would be either bimekizumab or off-label upadacitinib accessed through IPFR. These would also be the only treatment options for patients whose HS does not respond to treatment with adalimumab or secukinumab, or for whom these treatments are unsuitable. Where these options are unavailable or unsuitable, patients will receive best supportive care (BSC), which may include continued treatment with topical or oral antibiotics, dapsone, retinoids, ciclosporin and antiandrogens. Treatments offered are tailored to the individual and courses of treatment may be cycled. Therefore, there is no standard BSC. Costs for BSC have been estimated based on the treatments included for the NICE TA935 appraisal of secukinumab, and durations of treatment from the European guidelines for HS treatment[6,13]. An average of all treatments was calculated to provide an estimate of the annual cost of BSC. The annual costs for comparators are provided in Table 2.

Bimekizumab is administered as a subcutaneous injection; the SmPC states that after proper training, patients may self-inject if their physician determines that it is appropriate[21]. Upadacitinib is an oral tablet, therefore there are no associated administration costs. The dose (15 mg or 30 mg) is based on individual patient presentation[22].

Clinicians estimate that 10 patients will receive infliximab per year. Each patient will receive treatment for up to two years. For simplicity the comparator biologics have been split 50:50 and the discontinuation rate rounded up or down to equate to the same number of patients as infliximab remaining on active treatment. The alternative scenario is BSC and all patients are assumed to remain on this treatment throughout the two years. Table 3 provides an estimate of the net annual cost of treating HS with infliximab as an alternative to bimekizumab or upadacitinib or BSC. The budget impact estimates that infliximab would incur savings of [Commercial in confidence text removed] in Year 1 and [Commercial in confidence text removed] in Year 2. Compared to BSC alone, infliximab would incur an additional cost of [Commercial in confidence text removed] in Year 1 and [Commercial in confidence text removed] in Year 2. Clinicians have requested consideration of an increase in dose frequency to 5 mg/kg infliximab up to every 4 weeks for patients who have an inadequate response. It is estimated that approximately half of all responders will require an increase in frequency after six months of the standard regimen. Costs and scenario analyses for increased frequency are provided in Tables 4 and 5. The estimated associated budget impact savings are [Commercial in confidence text removed] in Year 1 and [Commercial in confidence text removed] in Year 2. The cost incurred compared with BSC would be [Commercial in confidence text removed] in Year 1 and [Commercial in confidence text removed] in Year 2.

Table 1. Estimated annual cost of infliximab in Wales (per patient)

	Year 1	Year 2
Infliximab (100 mg vial)*	¶¶	¶¶
Annual drug administration costs†	¶¶	¶¶
Annual total cost	¶¶	¶¶

*Weighted average drug contract price; costs exclude VAT; 5 mg/kg body weight; average body weight 79 kg
†National Cost Collection Data: National Schedule 2024/25. HRG code SBZ12Z Deliver simple parenteral chemotherapy at first attendance (outpatient procedures)[23]
¶¶ Commercial in confidence data removed

Table 2. Estimated annual costs of comparators in Wales (per patient)

	Year 1	Year 2
Bimekizumab		
320 mg sub-cutaneous injection (320 mg every 2 weeks to week 16, every 4 weeks thereafter)*	¶¶	¶¶
Annual drug administration costs†	£423	NA
Annual total cost	¶¶	¶¶
Upadacitinib		
15 mg tablets (15 mg once daily)	¶¶	¶¶
15 mg, 30 mg tablets (15 mg daily for 28 days then 30 mg daily thereafter)	¶¶	¶¶
Average annual cost	¶¶	¶¶
Best supportive care		
Averaged cost of topical and oral antibiotics; dapsone; retinoids; ciclosporin; anti-androgens§	¶¶	¶¶

* Patient Access Scheme (PAS) price excludes VAT
†National Cost Collection Data: National Schedule 2024/25. Dermatology non-consultant led outpatient appointment. Assumed to be self-injecting after three appointments[23].
§British National Formulary (BNF) prices[24]
NA: not applicable
¶¶ Commercial in confidence data removed

Table 3. Estimated budget impact in Wales, standard dosing infliximab

	Year 1	Year 2
Scenario without infliximab - assuming treatment is with either bimekizumab or upadacitinib		
Number of patients given bimekizumab	5	10
Number of responders	3	6
Number of patients given upadacitinib	5	10
Number of responders	4	8
Scenario with infliximab – assuming displaces active comparators		
Number of patients given infliximab	10	10
Number of responders	7	14
Estimated costs of above scenarios		
Total annual costs without infliximab	¶¶	¶¶
Total annual costs with infliximab	¶¶	¶¶
Annual net cost compared with active comparators	¶¶	¶¶
Annual net cost compared with BSC	¶¶	¶¶
BSC: best supportive care ¶¶ Commercial in confidence data removed		

Table 4. Estimated annual cost of infliximab every 4 weeks in Wales (per patient)

	Year 1	Year 2
Infliximab (100 mg vial)*	¶¶	¶¶
Annual drug administration costs†	£3,916	£4,628
Annual total cost	¶¶	¶¶
*Weighted average drug contract price; costs exclude VAT; 5 mg/kg body weight; average body weight 79 kg †National Cost Collection Data: National Schedule 2024/25. HRG code SBZ12Z Deliver simple parenteral chemotherapy at first attendance (outpatient procedures)[23]. ¶¶ Commercial in confidence data removed		

Table 5. Estimated budget impact in Wales, scenario analysis with dose frequency increased to every four weeks after six months treatment

	Year 1	Year 2
Scenario without infliximab - assuming treatment is with either bimekizumab or upadacitinib		
Number of patients given bimekizumab	5	10
Number of responders	3	6
Number of patients given upadacitinib	5	10
Number of responders	4	8
Scenario with infliximab – assuming displaces active comparators		
Number of patients given infliximab	10	10
Number of responders standard dose	4	8
Number of responders with dosing frequency every 4 weeks at 6 months	3	6
Estimated costs of above scenarios		
Total annual costs without infliximab	¶¶	¶¶
Total annual costs with infliximab	¶¶	¶¶
Annual net cost compared with active comparators	¶¶	¶¶
Annual net cost compared with BSC	¶¶	¶¶
BSC: best supportive care ¶¶ Commercial in confidence data removed		

Budget impact issues

- Infliximab is estimated to be cost saving in the budget impact, compared with active comparators. The high cost of bimekizumab is the main driver of the budget impact. If bimekizumab is approved for use in Wales, the budget impact associated with infliximab may be neutral or cost incurring because the cost of upadacitinib is comparable to infliximab. An increase in dose frequency for patients who have inadequate response to treatment results in slightly reduced cost savings.
- Comparator biologic treatments, upadacitinib and bimekizumab, are accessed through IPFR. The budget impact assumes all IPFR applications are approved; therefore, offset costs may be an overestimate. Additionally, this scenario assumes all patients are receiving last-line treatment prior to BSC. It is feasible that some patients may receive more than one biologic at this stage and this could affect the budget impact. For the purposes of the budget

impact, there is an assumption that 50% or patients would receive bimekizumab and 50% would receive upadacitinib; of these, two patients on bimekizumab and one patient on upadacitinib would stop treatment after 12 weeks. This assumption may have resulted in an over-estimate or under-estimate of the budget impact, depending upon the proportion of patients receiving the different comparator treatments.

- BSC costs are likely to be underestimated, because they only include medicine costs. Wound dressings are likely to be an additional BSC cost which may be significant depending upon the number of affected sites and the extent and severity of disease. Dressings are changed daily and, in some cases, may be changed several times a day. For patients whose HS responds to treatment with infliximab, the offset costs may be considerably greater. Global HS registry data showed that fewer patients needed procedural interventions (steroid injections, drainage of boils, surgery), emergency department visits, hospital admissions, and visits to healthcare providers for HS in the six months after starting consistent (12 weeks or more) biologic therapy, compared with the six-month period before starting treatment[25].
- The budget impact assumes that all patients whose HS responds to treatment will continue treatment for two years. The two-year estimate is based on clinical expert opinion. In the study by Le et al., the mean duration of infliximab use was 8 months (range 4–19 months)[16]. It is likely that several patients could lose HS response and discontinue treatment before two years, and in others their HS might maintain response beyond two years. Therefore, a two-year duration of treatment is considered a reasonable estimate for the mean duration of treatment for patients whose HS responds.
- Administration costs have been included for infliximab. Costs for three outpatient appointments have been included for bimekizumab treatment; administration is assumed to be by self-injection thereafter.
- Adverse event costs and additional monitoring costs are not included. Clinicians state that no additional monitoring is required for patients treated with infliximab.

Patient factors

Garg et al. (2020) conducted a multinational survey of patients with HS during October 2017 to July 2018[26]. The Global Survey of Impact and Healthcare Needs (Global VOICE) project aimed to evaluate the unmet needs of patients with HS. Patients identified several critical unmet needs, including: delays in getting a formal diagnosis of HS (mean delay 10.2 ± 8.9 years); experiencing disease flare (daily flare reported by 23% of patients; weekly flare by 29.8% and monthly flare by 31.1%); HS-related pain (rated by 61.4% as moderate pain or higher, with 4.5% describing pain over the past week to be the worst possible); visiting the emergency department (18.3%) or being hospitalised (12.5%) five times or more for symptoms; and 43.3% (n = 563) reported an extreme impact on life, with 14.5% reporting they were disabled due to disease and unable to work. Patients also reported a high frequency of comorbidities, most commonly anxiety and depression. Many patients were dissatisfied with medical treatment (45.9%) or procedural treatments (34.6%) most commonly because of perceived poor efficacy and undesirable adverse effects. The level of optimism for having satisfactory control of symptoms within the next three months was low or very low in 45.9% of participants[26].

Results of the RCT showed significant improvements from baseline ($p < 0.005$) in DLQI scores in the infliximab group, with patients achieving more than 50% improvement compared with the placebo group[14].

Questionnaires submitted to AWTTC by HS patients echo the above findings with particular reference to extreme pain, toll on mental health, impact on relationships and restrictions to everyday activities. Patients welcome any new treatment which may reduce flares and, in particular, the pain associated with this condition.

Equality and health impact assessment

AWTTC has completed an Equality and Health Impact Assessment in parallel with each development stage of the project. This follows the five ways of working for public bodies, and work to achieving the wellbeing goals, outlined in the Well-Being of Future Generations (Wales) Act 2015.

It is not expected that infliximab will have a significant potential negative impact on people based on the protected characteristics of the Equality Act 2010.

Additional factors

Prescribing unlicensed medicines

Infliximab is not licensed to treat this indication and is therefore prescribed ‘off label’. Providers should consult the relevant guidance on prescribing unlicensed medicines before any off-label medicines are prescribed.

Care has been taken to ensure the information is accurate and complete at the time of publication. However, the All Wales Therapeutics and Toxicology Centre (AWTTC) do not make any guarantees to that effect. The information in this document is subject to review and may be updated or withdrawn at any time. AWTTC accept no liability in association with the use of its content. An Equality and Health Impact Assessment (EHIA) has been completed in relation to the medicine and has been published on the AWTTC website.

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References

1. Janssen-Cilag Ltd. Remicade®. 100 mg powder for concentrate for solution for infusion. Summary of Product Characteristics. Jul 2025. Available at: https://www.medicines.org.uk/emc/product/3831/smpc. Accessed Sep 2026.
2. National Health Service. Hidradenitis suppurativa. Mar 2023. Available at: https://www.nhs.uk/conditions/hidradenitis-suppurativa/. Accessed Sep 2026.
3. Living Life With HS. What is HS? Information about hidradenitis suppurativa (HS). 2026. Available at: https://livinglifewithhs.co.uk/what-is-hs/. Accessed Sep 2026.
4. Ingram JR, Collier F, Brown D et al. British Association of Dermatologists guidelines for the management of hidradenitis suppurativa (acne inversa) 2018. *British Journal of Dermatology.* 2019;180:pp1009–1017.
5. National Institute for Health and Care Excellence. Technology Appraisal TA392. Adalimumab for treating moderate to severe hidradenitis suppurativa. Jun 2016. Available at: https://www.nice.org.uk/guidance/ta392. Accessed Aug 2026.
6. National Institute for Health and Care Excellence. Technology Appraisal TA935. Secukinumab for treating moderate to severe hidradenitis suppurativa. Dec 2023. Available at: https://www.nice.org.uk/guidance/ta935. Accessed Aug 2026.
7. Prens LM, Bouwman K, Aarts P et al. Adalimumab and infliximab survival in patients with hidradenitis suppurativa: a daily practice cohort study. *British Journal of Dermatology.* 2021;185:177–184.
8. Ring HC, Thorsen J, Kirby B et al. Long-term drug survival of adalimumab, infliximab, secukinumab and ustekinumab in hidradenitis suppurativa: a Danish nationwide cohort study. *British Journal of Dermatology.* 2024;190(5):769–771.
9. British Skin Foundation. Hidradenitis suppurativa. 2026. Available at: https://www.britishskinfoundation.org.uk/conditions/hidradenitis-suppurativa. Accessed Sep 2026.
10. National Institute for Health and Care Excellence. Technology Appraisal TA1028. Bimekizumab for treating moderate to severe hidradenitis suppurativa (terminated appraisal). Jan 2025. Available at: https://www.nice.org.uk/guidance/ta1028. Accessed Sep 2026.
11. National Institute for Health and Care Excellence. ID6666. GID-TA11825. Upadacitinib for treating moderate to severe hidradenitis suppurativa in people 12 years and over. Sep 2025. Available at: https://www.nice.org.uk/guidance/awaiting-development/gid-ta11825. Accessed Sep 2026.
12. National Institute for Health and Care Excellence. ID6569. GID-TA11743. Povorcitinib for treating moderate to severe active hidradenitis suppurativa after a TNF-alpha inhibitor. Apr 2025. Available at: https://www.nice.org.uk/guidance/indevelopment/gid-ta11743. Accessed Sep 2026.
13. Zouboulis CC, Bechara FG, Behadou F et al. European S2k guidelines for hidradenitis suppurativa/acne inversa part 2: treatment. *Journal of the European Academy of Dermatology and Venereology.* 2025;39:899–941.
14. Grant A, Gonzalez T, Montgomery MO et al. Infliximab therapy for patients with moderate to severe hidradenitis suppurativa: a randomized, double-blind,

placebo-controlled crossover trial. *Journal of the American Academy of Dermatology.* 2010;62(2):205–217.
15. Shih T, Lee K, Grogan T et al. Infliximab in hidradenitis suppurativa: a systematic review and meta-analysis. *Dermatologic Therapy.* 2022;35(9):e15691.
16. Le DV, Tran HT, Shrestha R et al. Therapeutic infliximab levels are associated with improved clinical outcomes in hidradenitis suppurativa: a pilot retrospective cohort study. *Journal of the American Academy of Dermatology.* 2026.
17. Srour R, Shapiro J, Avitan-Hersh E et al. From Failure to Success: Evaluating Infliximab Efficacy After Adalimumab Failure in Hidradenitis Suppurativa. *Dermatologic Therapy.* 2026;9020978.
18. Holcomb ZE, Porter ML, and Kimball AB. A safety review of biologic therapies for the management of hidradenitis suppurativa and unmet needs. *Expert Opinion on Drug Safety.* 2021;20(10):1147–1161.
19. Acquacalda E, Roux CH, Albert C et al. New onset of articular inflammatory manifestations in patients with hidradenitis suppurativa under treatment with infliximab. *Joint Bone Spine.* 2015;82:362–364.
20. van Rappard DC, Mooij JE, Baeten DLP et al. New-onset polyarthritis during successful treatment of hidradenitis suppurativa with infliximab. *British Journal of Dermatology.* 2011;165:194–198.
21. UCB Pharma Limited. Bimzelx®. 160 mg solution for injection in pre-filled pen. Summary of Product Characteristics. Apr 2026. Available at: https://www.medicines.org.uk/emc/product/12834/smpc. Accessed Sep 2026.
22. AbbVie Ltd. RINVOQ®.15 mg prolonged-release tablets. Summary of Product Characteristics. Jun 2026. Available at: https://www.medicines.org.uk/emc/product/10972/smpc. Accessed Sep 2026.
23. NHS England. National Cost Collection Data Publication: National Schedule 2024/25. Nov 2025. Available at: https://www.england.nhs.uk/publication/2024-25-national-cost-collection-data-publication/. Accessed Sep 2026.
24. Haymarket Publications. Monthly Index of Medical Specialities (MIMS). Sep 2026. Available at: http://www.mims.co.uk/. Accessed Sep 2026.
25. Oliveira M, Rahawi K, Duan Y et al. Effect of biologics on the need for procedural interventions, systemic medications, and healthcare utilization in patients with hidradenitis suppurativa: real-world data from the UNITE registry. *Dermatology and Therapy.* 2023;13:1577–1585.
26. Garg A, Neuren E, Cha D et al. Evaluating patients' unmet needs in hidradenitis suppurativa: results from the Global Survey Of Impact and Healthcare Needs (VOICE) Project. *Journal of the American Academy of Dermatology.* 2020;82(2):366–376.

Appendix 1. PRISMA flow diagram

