



Grŵp Strategaeth Meddyginiaethau Cymru Gyfan All Wales Medicines Strategy Group

One Wales Medicines Assessment Group Recommendation

Ustekinumab concentrate for solution for infusion and solution for injection (OW25)

Date of advice: February 2023

Date of last review: September 2026

AWTTC reference number: OW25

Using the agreed starting and stopping criteria ustekinumab can be made available within NHS Wales for the treatment of inflammatory bowel disease in children and young people aged from 6 to 17 years: for ulcerative colitis following loss of response, non-response or intolerance to anti-TNF therapies and vedolizumab; for Crohn's disease following loss of response, non-response or intolerance to anti-TNF therapies in children weighing less than 40 kg*.

*Ustekinumab for the treatment of children and young people aged less than 18 years with Crohn's disease and who weigh at least 40 kg is now licensed. It is expected that ustekinumab will continue to be made available for this cohort in accordance with the [AWMSG policy statement on paediatric licence extensions](#). Dose escalation beyond the licensed dose remains an off-label indication for this patient cohort. Refer to the starting and stopping criteria for further information on this One Wales advice.

The risks and benefits of the off-label use of ustekinumab for this indication should be clearly stated and discussed with the patient to allow informed consent.

This recommendation has been endorsed by the All Wales Medicines Strategy Group (AWMSG) and ratified by Welsh Government.

This advice will be reviewed after 12 months or earlier if new evidence becomes available.



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Clinician responsibility

Clinicians will be obliged to collect and monitor patient outcomes. Evidence of clinical outcomes will be taken into consideration when reviewing the One Wales Medicines Assessment decision.

Health board responsibility

Health boards will take responsibility for implementing One Wales Medicines Assessment Group decisions and ensuring that a process is in place for monitoring clinical outcomes

One Wales advice assists consistency of access across NHS Wales.

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Starting and stopping criteria for ustekinumab for the treatment of inflammatory bowel disease in children and young people aged 6 to 17 years: for ulcerative colitis following loss of response, non-response or intolerance to anti-TNF therapies and vedolizumab; for Crohn's disease following loss of response, non-response or intolerance to anti-TNF therapies in children weighing less than 40 kg

Starting criteria

Patients aged 6 to 17 years with ulcerative colitis following loss of response or non-response to anti-TNF inhibitors and vedolizumab or when anti-TNF inhibitors and vedolizumab cannot be tolerated or are contraindicated.

Patients aged 6 to 17 years with Crohn's disease following loss of response or non-response to anti-TNF inhibitors or when anti-TNF inhibitors cannot be tolerated or are contraindicated and who weigh less than 40 kg. Ustekinumab for the treatment of children and young people aged less than 18 years with Crohn's disease and who weigh at least 40 kg is now licensed and so outwith this criteria. It is expected that ustekinumab will continue to be made available for this cohort in accordance with the AWMSG policy statement on paediatric licence extensions. However, escalation beyond the licensed dose remains off-label and patients may continue to receive this via this One Wales recommendation.

Screening

Ustekinumab may have the potential to increase the risk of infections and reactivate latent infections. Caution should be exercised when considering the use of ustekinumab in patients with a chronic infection or a history of recurrent infection. Patients should be evaluated for tuberculosis infection and anti-tuberculosis therapy considered prior to initiation of ustekinumab in patients with a history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed^{1,2}.

Dose

Induction

Induction treatment is administered intravenously as a weight-based dose of about 6 mg per kg (maximum 520 mg, see also below) administered over one hour.

Child's weight	Dose to be prescribed
<55kg	260mg
55kg- 85kg	390mg
>85kg	520mg





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Maintenance

Maintenance treatment is administered as a subcutaneous injection, given at week 8 after induction. Adult patients receive a 90 mg injection, children should receive a body surface area-adjusted dose (considering a standard adult of 1.73 m²), see suggested dosing below:

Child's weight	Dose to be prescribed
<40kg	45mg
>40kg	90mg

After this, dosing every 12 weeks is recommended. Clinical benefit can be observed from 8 weeks following intravenous induction³. Patients who have not had an adequate response 8 weeks after the first subcutaneous dose (week 16) may have a second subcutaneous dose at this time, to allow for delayed response. Patients who lose response on 12-weekly dosing may benefit from an increase in dosing frequency to every 6-8 weeks, according to clinical judgement.

Subcutaneous maintenance doses may be administered at home by the patient or a carer following suitable training.

Outcome data, including dosing frequency and duration of treatment, should be collected to inform future policy changes.

Monitoring

- Infusion-related reactions including anaphylactic shock
- Systemic and respiratory hypersensitivity reactions
- Routine blood tests including FBC, U&E, LFTs, CRP and ESR at induction and 6-monthly thereafter.
- Extra blood tests including vitamins D and B12, folate and ferritin after 6 months of treatment and 6-monthly thereafter.
- Endoscopy (annual)
- Treatment response indicators at induction and 6-monthly thereafter
 - Faecal calprotectin levels
 - Mucosal or endoscopic healing
 - Patient height and weight
 - Paediatric Crohn's Disease Activity Index or Paediatric Ulcerative Colitis Activity Index scores (or appropriate scoring measurements used in clinical practice)

Stopping criteria

- Treatment failure, progression of symptoms or minimal response, including need for surgery



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- Toxicity to treatment (that cannot or does not respond to temporary treatment interruption)
- Patient request

Outcome data, including reasons for stopping treatment, should be collected to inform future policy changes.

Continuation of treatment

At 12 months, patients should be assessed to determine whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. Regular reassessment to determine whether continued treatment is justified should be done at least every 12 months.

References

1. Janssen-Cilag Ltd. STELARA®. 130 mg concentrate for solution for infusion. Summary of Product Characteristics. Feb 2022. Available at: <https://www.medicines.org.uk/emc/product/4412/smpc>. Accessed September 2026.
2. Janssen-Cilag Ltd. STELARA®. 90 mg solution for injection in pre-filled syringe. Summary of Product Characteristics. Oct 2022. Available at: <https://www.medicines.org.uk/emc/product/7638/smpc>. Accessed September 2026.
3. van Rhee PF, Aloï M, Assa A et al. The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update. Journal of Crohn's and Colitis. 2021;15(2):171-194. Accessed September 2026



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Second Review of One Wales Decision – June 2026

Ustekinumab for the treatment of inflammatory bowel disease in children and young people aged 6 to 17 years: for ulcerative colitis following loss of response, non-response, or intolerance to anti-TNF therapies and vedolizumab; for Crohn's disease following loss of response, non-response, or intolerance to anti-TNF therapies (OW25)

This report was prepared by the All Wales Therapeutics and Toxicology Centre in June 2026. It summarises any new evidence available and patient outcome data collected since the last review in April 2024.

Background: Ulcerative colitis (UC) and Crohn's disease (CD) are the two main forms of inflammatory bowel disease (IBD). They are lifelong, chronic, systemic conditions that follow an unpredictable relapsing and remitting course and can cause significant morbidity. IBD negatively affects the quality of life of children and adolescents due to its impact on the physical, emotional and social wellbeing of these patients, especially if poorly controlled.

Clinicians in Wales considered there to be an unmet need and identified a cohort of people who could benefit from this treatment. This included children and young people (CYP) aged 6 to 17 years who had failed current treatments in the pathway and where there is no alternative licensed therapy to meet their needs. These patients may be dependent on steroids to control the disease and would be at risk of complications and repeated surgical interventions if their inflammatory bowel disease is poorly controlled. This medicine was assessed via the One Wales process and supported for use; this is the second review of that advice.

Current One Wales Decision: [Supported](#)

Licence status: Ustekinumab was licensed by the MHRA for the treatment of moderately to severely active **Crohn's disease** in paediatric patients weighing **at least** 40 kg (around 12 years of age), who have had an inadequate response to, or were intolerant to either conventional or biologic therapy in September 2025. The European Union have recently extended the licence of ustekinumab to include the treatment of moderately to severely active Crohn's disease in paediatric patients from the age of 2 years and older ([EMA, 2026](#)). The UK licence date for this extension is currently unknown. [Commercial in confidence information removed].

In accordance with the [paediatric licence extension policy statement](#), AWMSG do not appraise medicines with a minor licence extension to treat children and adolescents (up to age 18 years) where existing advice from NICE or AWMSG applies in adults. Therefore, it is expected that health boards will continue to make these treatments available and the One Wales advice will no longer include the paediatric populations now covered by the licence.

Since the last review, a number of ustekinumab biosimilars are now available for prescribing in NHS Wales ([BNF](#)).

Guidelines: An update to guidelines originally published in 2018 by [Wine et al \(2025\)](#) focused on the management of ambulatory paediatric ulcerative colitis. These guidelines are a joint effort of the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) and the European Crohn's and Colitis Organisation (ECCO). Anti-p40 treatments including ustekinumab are recommended to be considered following failure of approved anti-TNF therapy. Supporting evidence for this recommendation is included two retrospective studies by [Cohen et al \(2024\)](#) and [Koudsi et al \(2023\)](#) as well as a phase III prospective study by [Dhaliwal et al \(2021\)](#). All of these studies have been reported in the [original evidence summary report](#) and subsequent reviews.

Licensed alternative medicines or Health Technology Assessment advice for alternative medicines:

[TA956](#) - Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over, when conventional or biological treatments cannot be tolerated, or the condition has not responded well enough, or lost response to treatment, March 2024

Effectiveness: A repeat literature search conducted by AWTTC identified three papers which analysed the clinical effectiveness of ustekinumab pertinent to the recommendation. These included two retrospective studies and a systematic review. Overall results are comparable to those seen in the original evidence report and indicate that the benefits from treatment with ustekinumab are sustained in the longer term.

The retrospective study by [Yamamoto et al \(2025\)](#) evaluated long-term clinical and endoscopic outcomes of ustekinumab in paediatric onset Crohn's disease after anti-TNF failure (n = 43). The median age at initiation of ustekinumab was 13.6 (interquartile range: 9.0 – 15.8) years and the median follow-up was 136 weeks. Following induction treatment, a maintenance subcutaneous (SC) dose of 90 mg every 8 – 12 weeks was given, shortened to 4-7 weeks for 7 patients with very early onset disease. The primary outcome was the continuation rates at weeks 8, 52 and 106 which were 100%, 91% and 80%, respectively. The incidence of discontinuation was 6.2% per patient-year of follow-up. The steroid-free remission rates were 44%, 71% and 80% at weeks 8, 52 and 106, respectively. The Simple Endoscopic Score for Crohn's Disease of patients in clinical remission at the last follow up showed a significant reduction ($p < 0.01$).

[Steiner et al \(2026\)](#) retrospectively evaluated the effectiveness and safety of ustekinumab in paediatric Crohn's disease using data collected from the ImproveCareNow (ICN) registry. 348 paediatric patients aged ≥ 2 to < 18 years old were treated with ustekinumab. Of these patients, at least 83.6% received previous anti-TNF treatment. The primary endpoint of this observational, real-world retrospective study was clinical remission defined as a short paediatric Crohn's disease activity index (sPCDAI) of ≤ 10 at week 52 (without intercurrent events). 264 out of 348 patients had a clinical remission assessment at week 52, of which 47.3% achieved clinical remission and 41.3% a corticosteroid-free clinical remission. Among a subset of patients with moderate to severely active Crohn's disease, similar proportions of paediatric patients achieved clinical remission (36.9%, 41/111) and

corticosteroid-free clinical remission (31.5%, 35/111). In addition, a clinical response was achieved by 60.9% (67/110) of paediatric patients with moderate to severe disease.

[Marques et al \(2025\)](#) conducted a systemic review of the long term effects of ustekinumab in children with IBD. However, no new findings were reported in this review and all supporting evidence has been previously reported in the [original evidence summary report](#) and subsequent reviews.

Safety: [Steiner et al \(2026\)](#) retrospectively evaluated the safety of ustekinumab in paediatric Crohn's disease using data collected from the ImproveCareNow registry (n = 348) and reported that ustekinumab was well tolerated, with no new safety signals identified. The most common adverse event was serious infections (7.5%) and rates of opportunistic infections were low (1.4%). One death was reported but deemed not to be related to IBD or ustekinumab treatment.

Cost-effectiveness: No relevant cost-effectiveness analyses identified in the repeat literature search.

Budget impact: Twelve patients were receiving treatment with ustekinumab commenced either before or after ustekinumab was recommended by One Wales in March 2024; ten at the tertiary centre in Cardiff and Vale UHB and [confidential information removed]. Of these, nine received ustekinumab off label although treatment subsequently became licensed for [confidential information removed]. The actual number of patients who received treatment over the past 17 months is lower than the original estimate of 22 new patients per year. Clinicians advise that treated patient numbers are lower than initially predicted as newer agents, such as risankizumab (used off label) and upadacitinib (used off label), may be used in preference to ustekinumab due to their quicker onset of action making them more appropriate for patients with severe flares of disease and/or recent and frequent courses of prednisolone. Since the last review, a number of ustekinumab biosimilars are now available for prescribing in NHS Wales. Contract prices exist for the biosimilars which means that the acquisition cost of ustekinumab has dropped significantly.

Impact on health and social care services: Minimal.

Patient outcome data: Of the 12 patients (age range at start of treatment 9-17) who have received ustekinumab, eight had Crohn's disease and [confidential information removed]. The length of time patients remained on treatment ranged from 1 month to over 5 years, with many receiving treatment for 2-3 years. Outcome data provided by the tertiary centre in Cardiff for nine patients [confidential information removed]. No further patient outcome data have been received.

Evaluation of evidence

No significant new evidence has been published which challenges the current One Wales advice. The number of children on treatment is lower than the budget impact estimates used in the evidence summary report due to the availability of newer treatments (albeit off label and not routinely available) with quicker onset of

action although ustekinumab is still used for some paediatric patients. AWTTC recommends continuing access in Wales to ustekinumab for the treatment of inflammatory bowel disease in children and young people aged from 6 to 17 years: for ulcerative colitis following loss of response, non-response or intolerance to anti-TNF therapies and vedolizumab; for Crohn's disease following loss of response, non-response or intolerance to anti-TNF therapies in children weighing less than 40 kg. As ustekinumab for the treatment of children and young people aged less than 18 years with Crohn's disease and who weigh at least 40 kg is now licensed, this One Wales recommendation no longer includes this patient group; it is expected that health boards in Wales will continue to make ustekinumab available for this cohort in accordance with the AWMSG policy statement on paediatric licence extensions. However, escalation beyond the licensed dose remains off-label and patients may continue to receive this treatment via the One Wales recommendation. AWTTC will continue to monitor for changes to the licence for ustekinumab and will update this advice accordingly.

Next review date: September 2027

References: a full reference list is available on request.

This document includes evidence published since the last review or full assessment of this medicine for the indication under consideration. It does not replace the original full evidence status report. Any previous reviews and the original full evidence status report are available on request by email to AWTTC@wales.nhs.uk.

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