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Health Technology Briefing
October 2025

Vedolizumab for treating moderate to severe active ulcerative colitis or Crohn's disease in paediatrics

Company/Developer	Takeda UK Ltd

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 29078	NICE ID: Not Available	UKPS ID: 673089

Licensing and Market Availability Plans

Currently in phase lll clinical development.

Summary

Vedolizumab is being developed as a treatment for moderate to severe ulcerative colitis and Crohn's disease. These conditions are chronic (long-term) and cause inflammation in the digestive system. Both conditions are types of inflammatory bowel disease, which affects the gut and can significantly impact daily life. Current treatment options can cause harmful side effects and may stop working overtime. Therefore, there is a need for new treatments that can directly control inflammation in the gut with less risk of side effects.

Vedolizumab is a type of medicine which is injected intravenously (into a vein). Vedolizumab attaches to a protein called 'alfa-4-beta-7 integrin', which is mostly found on the surface of certain white blood cells in the gut. In ulcerative colitis and Crohn's disease, these cells are involved in causing inflammation. By blocking alfa-4-beta-7 integrin, vedolizumab reduces inflammation in the gut and the symptoms of these diseases. This targeted approach may minimise the impact on the rest of the immune system. If approved, it could provide an additional treatment option for children and adolescents with ulcerative colitis and Crohn's disease, potentially improving their symptoms and overall quality of life.

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.

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Proposed Indication

Treatment of moderate to severe active ulcerative colitis or Crohn's disease in paediatric patients.[1]

Technology

Description

Vedolizumab (Entyvio) is a humanised monoclonal antibody that binds specifically to the α4β7 integrin, which is preferentially expressed on gut homing T helper lymphocytes. By binding to α4β7 integrin on certain lymphocytes, vedolizumab inhibits adhesion of these cells to mucosal adhesin cell adhesion molecule-1 (MAdCAM-1). MAdCAM-1 is mainly expressed on gut endothelial cells and plays a critical role in the homing of T lymphocytes to tissues within the gastrointestinal (GI) tract. The α4β7 integrin is expressed on a discrete subset of memory T helper lymphocytes which preferentially migrate into the GI tract and cause inflammation that is characteristic of UC and CD, both of which are chronic inflammatory immunologically mediated conditions of the GI tract. Vedolizumab reduces gastrointestinal inflammation in UC and CD.[2]

Vedolizumab is in clinical development for children and adolescent patients with moderate to severe active UC or CD. In the Phase III clinical trial (NCT04779320), during the induction phase and maintenance period, vedolizumab is administered via intravenous (IV) infusions on weeks 0, 2, and 6 with doses ranging from 150mg to 300mg depending on baseline weight ranging from 10kg- ≥30 kg.[1]

Key Innovation

Anti-TNFα agents are currently the only biologics used in the treatment of paediatric inflammatory bowel disease (IBD).[3] However, approximately 15–20% of patients with IBD do not respond to induction therapy with anti-TNF and another 30–40% stop responding; therefore, the use of unlicensed biologics is often required.[4,5] It is typically several years before biologics that are licensed for use in adults gain licensing for use in paediatric populations.[4]

A multicentre, prospective cohort study evaluated the effectiveness and safety of vedolizumab as induction therapy for children and adolescents with IBD. The study results suggest an improvement in disease activity as early as week six. Furthermore, 32% of children with CD and 42% of those with UC in steroid-free and exclusive enteral nutrition-free (all calories are received through a special nutrition formula and no regular food is eaten) met clinical remission at week 14.[4,6] Since vedolizumab targets the immune system in the gut, rather than the whole body, it is likely to have a lower risk of serious infections than systemic immunosuppressants that affect the whole body.[7] If approved, vedolizumab would offer an additional treatment option for children and adolescents with moderately to severely active UC and CD.

Regulatory & Development Status

Vedolizumab is currently marketed in the EU/UK as a monotherapy for the following indications:[8]

- treatment of adults with moderately to severely active UC who have had an inadequate response with lost response to, or were intolerant to either conventional therapy or a TNFα antagonist
- treatment of adults with moderately to severely active CD who have had an inadequate response with lost response to, or were intolerant to either conventional therapy or a TNFα antagonist
- treatment of adult patients with moderately to severely active chronic pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for UC, and have had an inadequate response with or lost response to antibiotic therapy

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Patient Group

Disease Area and Clinical Need

CD and UC are types of IBD. They can cause painful sores (ulcers) and inflammation in the gut. In CD the inflammation can be anywhere in the gut, from the mouth to the bottom. In UC the inflammation and ulcers are only in the large bowel. UC can occur anywhere in the colon and rectum. However, only the inner lining of the gut is inflamed.[9] Patients with moderate to severe UC or CD often experience frequent bowel movements or diarrhoea, occurring four or more times per day, accompanied by blood, mucus, or pus in the stool. Other common symptoms include severe abdominal cramping, persistent fatigue, and unexplained weight loss.[10,11] Children with UC or CD may grow more slowly or not grow as well as other children. They may start puberty later or have weaker bones. This may be caused by ongoing inflammation, fewer nutrients taken through the gut and some treatments including long term steroids.[12] While the exact cause of UC or CD is unknown, it is believed to be the result of a problem with the immune system.[13,14] Other risk factors include genetics, an imbalance between good and bad bacteria within the bowel and environmental factors such as location of residence.[14,15]

In the UK, the incidence of CD is approximately 83 per million people per year and 5.2 per 100,000 children per year. The prevalence of CD in the UK is 10.6 per 100,000 people per year.[16,17] UC is the most common form of IBD.[18] One in every 227 people in the UK has been diagnosed with UC. This amounts to an estimated 296,000 people. The condition can develop at any age, it is most commonly diagnosed between 15 and 25 years old.[19] The incidence of paediatric-onset UC, which represents about 15–20% of all UC cases, ranges from 1–4 per 100,000 per year in European regions.[18,20] In England 2024-25, there were 186,002 finished consultant episodes (FCEs) and 175,116 hospital admissions for CD [regional enteritis] (ICD-10 code K50), resulting in 87,020 Finished Consultant Episode (FCE) bed days and 161,517 day-cases. Additionally, there were 168,195 FCEs and 153,512 hospital admissions for UC (ICD-10 code K51), resulting in 92,026 FCE bed days and 140,186 day cases.[21]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) guidelines currently recommend the following pharmacological treatments for children and adolescents with moderately to severely active UC: [22]

- Etrasimod for treating moderately to severely active UC in young people aged 16 and 17 years when the condition has inadequately responded or lost response to conventional or biological treatment, or when such treatment cannot be tolerated.
- Infliximab for treating severely active UC in children and adolescents aged 6 to 17 years when the condition has inadequately responded to conventional treatment, or when such treatment cannot be tolerated, or it is contraindicated.

NICE currently recommends infliximab, within its licensed indication for the treatment of people aged 6 to 17 years with severe active CD whose disease has not responded to conventional therapy (including corticosteroids, immunomodulators and primary nutrition therapy), or who are intolerant of or have contraindications to conventional therapy. The need to continue treatment should be reviewed at least every 12 months. [23]

Clinical Trial Information

Trial	NCT03138655, 2015-001094-40; A phase 2, randomized, double-blind, dose-ranging study to determine the pharmacokinetics,	NCT03196427, 2017-002182-21; A phase 2b, extension study to determine the long-term

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	safety and tolerability of vedolizumab IV in paediatric subjects with ulcerative colitis or Crohn's disease **Phase II** – Completed **Location(s):** 6 EU countries, UK, USA, Canada, Isreal and Ukraine **Primary completion date:** June 2020	safety of vedolizumab IV in paediatric subjects With Ulcerative Colitis or Crohn's disease **Phase II** – Active, not recruiting **Location(s):** 3 EU countries, UK, USA, Israel and Ukraine **Primary completion date:** May 2025
Trial Design	Randomised, parallel assignment, triple masking	Randomised, parallel assignment, double blinded (participant, investigator).
Population	N=89; subjects with moderate to severe active ulcerative colitis or Crohn's disease aged 2 to 17 years old	N=59; subjects with moderate to severe active ulcerative colitis or Crohn's disease aged 2 to 17 years old
Intervention(s)	Vedolizumab 100mg-300mg (weight dependent) intravenous (IV)	Vedolizumab high dose: 200-300mg (weight dependent) IV Vedolizumab low dose: 100-150mg (weight dependent) IV
Comparator(s)	No comparator	No comparator
Outcome(s)	Primary outcome measure: • Area under the serum concentration-time curve [AUC] at week 14 • Average serum concentration during a dosing interval at week 14 • Observed serum concentration at the end of a dosing interval at week 14	Primary outcome measure: • percentage of participants with treatment-emergent adverse events [Time Frame: Baseline up to approximately 8 years]

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Results (efficacy)	Primary endpoints at Week 14: 1. AUC vedolizumab exposure increased in an approximately dose-proportional manner across weight groups. Doubling the dose in both weight groups led to roughly a two-fold increase in AUC. 2. Average concentration [Cavg] The average vedolizumab concentration over the dosing interval also approximately doubled with increased dosing. Higher doses yielded noticeably higher Cavg in both ulcerative colitis and Crohn's disease cohorts, reflecting efficient dose scaling in paediatric patients. 3. Observed serum concentration at the end of the dosing interval [Ctrough] Trough concentrations at Week 14 were consistently higher for patients receiving the higher vedolizumab doses, supporting an approximately dose-proportional increase. Clinical efficacy was a secondary endpoint Clinical Remission Results at Week 14: **- Ulcerative colitis:** Mayo score: clinical remission rates across dose and weight groups ranged from 20.0% to 38.5%. By paediatric ulcerative colitis Activity Index (PUCAI) score: remission rates ranged from 30.0% to 61.5%. **-Crohn's disease:** By adult Crohn's disease activity index (CDAI) score: clinical remission rates ranged from 50.0% to 63.6%. By paediatric Crohn's disease activity index (PCDAI) score: Remission rates ranged from 16.7% to 54.5%.	_

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Results (safety)	_ Vedolizumab was generally safe and well tolerated when administered at either 150 and 300 mg in paediatric patients weighing ≥30 kg or at 100 and 200 mg in patients weighing <30 kg, with a comparable safety profile in both weight groups. Fourteen per cent [12/88] of patients had treatment-related adverse events and 6.8% [6/88] had anti-drug antibodies. No new safety signals were identified.[24] The overall safety profile observed in this study is generally consistent with the known safety profile of vedolizumab in adults and with the common symptoms of inflammatory bowel disease (IBD).[24]		_
Clinical Trial Information			
Trial	NCT04779320, 2020-004301-31, A randomized, double-blind, phase 3 study to evaluate the efficacy and safety of vedolizumab intravenous as maintenance therapy in paediatric subjects with moderately to severely active Crohn's Disease who achieved clinical response following open-Label vedolizumab intravenous therapy **Phase III** – Active, recruiting **Location(s):** 10 EU countries, UK, USA, Canada and other countries **Primary completion date:** May 2026	NCT04779307, 2023-509018-12-00; A randomized, double-blind, phase 3 study to evaluate the efficacy and safety of vedolizumab intravenous as maintenance therapy in paediatric subjects with moderately to severely active ulcerative colitis who achieved clinical response following open-label vedolizumab intravenous therapy **Phase III** – Completed **Location(s):** 6 EU countries, UK, USA, Canada and other countries **Completion date:** July 2025	NCT05442567, 2021-000630-34; A phase 3b extension study to evaluate the long-term safety of vedolizumab intravenous in paediatric patients with Ulcerative Colitis or Crohn's Disease **Phase III** – Active, recruiting **Location(s):** 7 EU countries, UK, USA, Canada and other countries **Primary completion date:** August 2031
Trial Design	Randomised, parallel assignment, quadruple masking	Randomised, double-blind, open label	Non-randomised, parallel assignment, open label
Population	N=120; subjects with moderate to severe active ulcerative colitis or	N=121; subjects with moderate to severe active ulcerative colitis aged 2 to 17 years old	N=240; subjects with moderate to severe active ulcerative colitis or Crohn's disease aged 2 to 17 years old

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	Crohn's disease aged 2 to 17 years old		
Intervention(s)	Vedolizumab intravenous (IV)	Vedolizumab IV	Vedolizumab IV
Comparator(s)	No comparator	No comparator	No comparator
Outcome(s)	Primary outcome measure: • Percentage of participants with clinical remission at week 54 based on paediatric Crohn's disease activity index score ⩽10 [time frame: week 54] • Percentage of participants with endoscopic response at week 54 based on simple endoscopic score for Crohn's Disease score [Time frame: week 54] See trial record for full list of other outcomes.	Primary outcome measure: • Percentage of Participants with Clinical Remission at Week 54 Based on Modified Mayo Score [Time Frame: Week 54] See trial record for full list of other outcomes.	Primary outcome measure: • Treatment Cohort: Number of participants with at least one adverse event (AE) [Time Frame: From first dose of study drug up to approximately 5 years] • Observational Cohort: Number of participants with prespecified safety events [Time Frame: Up to approximately 2 years] See trial record for full list of other outcomes.
Results (efficacy)	-	-	-
Results (safety)	-	-	-
Clinical Trial Information			
Trial	NCT06100289; An open-label, phase 3 study to evaluate the pharmacokinetics, safety, and immunogenicity of vedolizumab subcutaneous in paediatric subjects with moderately to severely active Ulcerative Colitis or Crohn's Disease who achieved clinical response following open-label vedolizumab intravenous therapy **Phase III** – Active, not recruiting **Location(s):** 10 EU countries, USA, and other countries **Primary completion date:** June 2027		

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Trial Design	Non-randomised, parallel assignment, open label.
Population	N=70; subjects with moderate to severe active ulcerative colitis or Crohn's disease aged 2 to 17 years old
Intervention(s)	• Vedolizumab intravenous (IV) Vedolizumab subcutaneous (SC) injection
Comparator(s)	No comparator
Outcome(s)	Primary outcome measure: • Steady-state Median Observed Plasma Concentration at the End of a Dosing Interval for Vedolizumab at Week 34 [Time Frame: Predose at Week 34] Average Serum Concentration at Steady-state for Vedolizumab at Week 34 [Time Frame: Multiple time points prior to Week 34; pre-dose at Week 34]
Results (efficacy)	-
Results (safety)	-

Estimated Cost

Vedolizumab is already marketed in the UK for the treatment of CD and UC. The NHS indicative cost of one 300mg powder for concentrate for solution for infusion vial is £2,050.00.[25]

Relevant Guidance

NICE Guidance

- NICE technology appraisal. Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over (TA956). March 2024.
- NICE technology appraisal. Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (TA329). February 2015.
- NICE clinical guideline. Ulcerative colitis: management (NG130). May 2019.
- NICE clinical guideline. Crohn's disease: management (NG129). May 2019.
- NICE quality standard. Inflammatory bowel disease (QS81). February 2015.

NHS England (Policy/Commissioning) Guidance

- NHS England. 2013/14 NHS Standard Contract Paediatric Medicine: Gastroenterology, Hepatology and Nutrition. E03/S/c.

Other Guidance

- European Crohn's and Colitis Organisation (ECCO). Guidelines on therapeutics in Crohn's disease: medical treatment. 2024.[26]

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