

SPECIALISED COMMISSIONING – RESPONSE TO AMENDMENTS REQUESTED TO EVIDENCE REVIEW DURING ENGAGEMENT OR CONSULTATION

URN	1862
POLICY TITLE	Vedolizumab for refractory ulcerative colitis in pre-pubescent children
CRG:	Paediatric Medicine
NPOC:	Women and Children
Date	Sept 2019

Description of comments during consultation (If studies have been suggested please provide a list of references)	See below
Action taken by Public Health lead	<p>All references reviewed (see below)</p> <p>Hamel B, Wu M, Hamel E et al. (2018) Outcome of tacrolimus and vedolizumab after corticosteroid and anti-TNF failure in paediatric severe colitis, BMJ open gastroenterology, 5, 1, e000195. Reason for exclusion from ER - Intervention – vedolizumab plus concomitant tacrolimus study.</p> <p>Schneider AM, Weghuber D, Hetzer B et al. (2018) Vedolizumab use after failure of TNF-alpha antagonists in children and adolescents with inflammatory bowel disease, BMC gastroenterology, 18, 1, 140 Reason for exclusion from ER - Case series with a small proportion of participants with ulcerative colitis for whom outcomes were not reported separately from those with unclassified inflammatory bowel disease and reporting no additional outcomes of interest.</p> <p>Conrad M, Stein R, Maxwell E et al. (2016) Vedolizumab Therapy in Severe Pediatric Inflammatory Bowel Disease, Inflammatory bowel diseases, 22, 10, 2425-31 Reason for exclusion from ER - Case series with a small proportion of participants with ulcerative colitis for whom outcomes were not reported separately from those with unclassified inflammatory bowel disease and reporting no additional outcomes of interest.</p> <p>Singh N, Rabizadeh S, Jossen J et al. (2016) Multi-Center Experience of Vedolizumab Effectiveness in Pediatric</p>

	<p>Inflammatory Bowel Disease, Inflammatory bowel diseases, 22, 9, 2121-6</p> <p>Reason for exclusion from ER - Population – 18% had not previously been treated with TNF-alpha inhibitors. The authors reported a greater response to vedolizumab in TNF-alpha inhibitor-naïve participants compared with those who were not, but the outcomes for each of these groups were not reported separately.</p> <p>Colombel. J-F BMJ, Sands E, Rutgeerts E: The safety of vedolizumab for ulcerative colitis and Crohn’s disease, Gut 2017 66:839-851 – This was an observational safety study where participants were adults and children over 17 (but not specified). Outcomes were not reported separately for children thus does not fit inclusion criteria based on PICO</p> <p>Sandborn W, Vedolizumab as induction and maintenance therapy for Chron’s disease, 2013 N ENG J Med 369:8 – This open label randomised double blind study reported outcomes for adult participants only this does not fit the PICO selection criteria</p> <p>Turner A: Use of placebo in paediatric inflammatory bowel disease: a position paper form ESPGHAN, ECCO, PIBDnet, and the Canadian Children IBD Network, JPGN volume 62, Number 1, January 2016 – Opinion paper thus not accepted as per PICO</p> <p>Conclusion – The above-mentioned evidence does not present material change to the current policy.</p>
<p>Outcome for studies suggested during consultation</p>	
<p>1. Evidence already identified during the evidence review</p>	<p>Hamel EO, et al. Outcome of tacrolimus and Vedolizumab after corticosteroid and anti-TNF failure in paediatric severe colitis. BMJ Open Gastro2018;5:e000195. doi:10.1136/bmjgast-2017-000195</p> <p>Schneider AM, Weghuber D, Hetzer B, Entenmann A, Müller T, Zimmermann G, Schütz S, Huber WD, Pichler J.</p> <p>Singh N, Rabizadeh S, Jossen J, Pittman N, Check M, Hashemi G, Phan BL, Hyams JS, Dubinsky MC.</p> <p>Conrad MA, Stein RE, Maxwell EC, Albenberg L, Baldassano RN, Dawany N, Grossman AB, Mamula P, Piccoli DA, Kelsen JR.</p>

<p>2.New evidence identified by stakeholders that does not fall within PICO and search methodology</p>	<p>Colombel J-F, Sands BE, Rutgeerts P, et al. Safety of vedolizumab for ulcerative colitis and Crohn’s disease. Gut 2017;66:839–851.</p> <p>Sandborn WJ, Feagan BG, Rutgeerts P, Hanauer S, Colombel JF, Sands BE, Lukas M, Fedorak RN, Lee S, Bressler B, Fox I, Rosario M, Sankoh S, Xu J, Stephens K, Milch C, Parikh A, GEMINI 2 Study Group.</p> <p>Vedolizumab as induction and Maintenance therapy for Crohn’s disease.</p> <p>Turner et al. Use of Placebo in Pediatric Inflammatory Bowel Diseases: A Position Paper From ESPGHAN, ECCO, PIBDnet, and the Canadian Children IBD Network. JGPN Vol 62, No. 1. 2016.</p>
<p>3.New evidence identified by stakeholders that falls within PICO and search methodology but does not materially affect the conclusions of the existing evidence review</p>	<p>None</p>
<p>4.New evidence identified by stakeholders that falls within PICO and search methodology, that does materially affect the conclusions of the existing evidence review. Updated evidence review to be undertaken (agreed with CET)</p>	<p>Doudouliaki, T et al. Experience and Outcomes in Paediatric Inflammatory Bowel Disease (pIBD) on Vedolizumab with Biomarker and Therapeutic Drug Monitoring (TDM). Gastroenterology – Inflammatory Bowel Disease (unpublished).</p> <p>See above - unpublished study so not accepted as per PICO.</p>