

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

URN	1861
POLICY TITLE	Ustekinumab for refractory Crohn’s disease 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>Chavannes M et al. Management of Paediatric Patients With Medically Refractory Crohn’s Disease Using Ustekinumab;I A Multi-Centred Cohort Study. J Crohns Colitis. 2019 Apr 26;13(5):578-584. Included in the review.</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.Consensus recommendations for research in children with IBD. Opinion paper thus not accepted as per PICO.</p> <p>STEP-CD study: STElara Use in Paediatric Crohn’s Disease. A Multicentre Retrospective Study from Paediatric IBD Porto Group of ESPGHAN Unpublished study so not accepted as per PICO.</p> <p>Dayan JR, Dolinger M, Benkov K, Dunkin D, Jossen J, Lai J, Phan BL, Pittman N, Dubinsky MC. Real World Experience With Ustekinumab in Children and Young Adults at a Tertiary Care Pediatric Inflammatory Bowel Disease Center. J Pediatr Gastroenterol Nutr. 2019 Jul;69(1):61-67.</p> <p>This was a retrospective non-comparative study of 52 children,81% of whom had Crohn’s Disease and included in the study because they were being treated with ustekinumab. This would not have been included in the evidence review because it would not fit the PICO: outcomes not reported separately for those under 18 years of age; over half of the patients with CD were started on ustekinumab while in clinical remission i.e. not</p>

	<p>refractory; and the study was published in 2019, outside of the PICO search period (2008-2018);</p> <p>Conclusion – The above-mentioned evidence does not present material change to the current policy.</p>
Outcome for studies suggested during consultation	
1. Evidence already identified during the evidence review	<p>Chavannes M et al. Management of Paediatric Patients With Medically Refractory Crohn’s Disease Using Ustekinumab; I A Multi-Centred Cohort Study. J Crohns Colitis. 2019 Apr 26;13(5):578-584. Included in the evidence review.</p>
2. New evidence identified by stakeholders that does not fall within PICO and search methodology	<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>Consensus recommendations for research in children with IBD. Opinion paper thus not accepted as per PICO.</p> <p>STEP-CD study: STElara Use in Paediatric Crohn’s Disease. A Multicentre Retrospective Study from Paediatric IBD Porto Group of ESPGHAN</p> <p>From the abstract, this study is a retrospective review of 104 patients with a spectrum of severity of CD and an average age of 15.5 years. Only 25% of the study population appear to be pre-pubescent. It is not possible to ascertain what the outcomes were for pre-pubescent children or by disease severity. This was a conference abstract so not accepted as per PICO.</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	Not applicable.
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>STEP-CD study: STElara Use in Paediatric Crohn’s Disease. A Multicentre Retrospective Study from Paediatric IBD Porto Group of ESPGHAN</p> <p>See above - unpublished study so not accepted as per PICO.</p>