NHS
Coventry and Warwickshire
Integrated Care Board

Ustekinumab dose Escalation in Crohn's Disease Policy

Reference Number:	This will be applied to all new ICB-wide PPSs by the Governance and Corporate Affairs Team and will be retained throughout its life span.
Version:	Version 1.0
Name of responsible Committee and date approved or recommended to Integrated Care Board Board:	Audit Committee
Date approved by the Integrated Care Board (if applicable):	1 July 2022
Next Review Date:	1 April 2024
Expiry Date:	1 October 2024
Name of author and title:	Jas Sagoo Medicines Optimisation Lead Pharmacist
Name of reviewer and title:	Angela Brady, Chief Medical Officer, ICB
Department:	Corporate Office

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.

Coventry & Warwickshire ICB

Position Statement: Ustekinumab Dose Escalation in patients with Crohn's Disease

Date:	October 2021
Requested Intervention:	Ustekinumab 90mg every 4 or 6 weeks in patients with Crohn's Disease who have not responded to standard dosing
ICB decision:	Ustekinumab 90mg every 4 or 6 weeks is approved as an alternative to Ustekinumab every 8 weeks in patients who initially responded to every 8 weeks but lost response. Any dose increase must be agreed at the MDT meeting and documented in the patient's clinical notes
Evidence Summary:	Limited amount of moderate strength evidence (level 2, retrospective, observational cohort studies) was found to support Ustekinumab dose intensification in refractory Crohn's disease
Criteria for Use (if applicable):	• Failure on anti-Tumour Necrosis Agents (Infliximab, Adalimumab) and/or Vedolizumab • Initial response to Ustekinumab 90mg every 8 weeks, subsequently lose response and who continue to have active disease either on MRI scan or colonoscopy or persistently raised faecal calprotectin of > 250mg/kg • Dose escalation approved at MDT meeting and documented in patient's notes • Regular monitoring of objective markers of inflammation (CRP and FCP), repeated imaging (MRI/CT) and colonoscopy. • A falling trend in FCP is considered a positive response and a faecal calprotectin < 100 mg/kg is indicative of remission • Regular review via MDT forum including consideration of stepping dose back down
Discontinuation:	• Adverse event due to Ustekinumab **or** • No evidence of therapeutic benefit after dose adjustment – maximum 6 months
Further Information	• An audit will take place prior to the policy review date to ensure compliance with this policy and to assess patient response to treatment/success criteria; namely; o a falling trend in FCP is considered a positive response and a faecal calprotectin < 100 mg/kg is indicative of remission o Improvement in objective markers of inflammation (CRP and FCP), repeated imaging (MRI/CT) and colonoscopy.

	• This policy will be reviewed in light of new evidence or guidance.