Bristol, North Somerset and South Gloucestershire
Integrated Care Board

Reference: FOI.ICB-2223/022

Subject: Dose escalation of Ustekinumab for treating Ulcerative Colitis

*I can confirm that the ICB **does hold the information requested**; please see responses below:*

QUESTION	RESPONSE
We've had a patient group contact us regarding the maintenance dosing schedule of Ustekinumab for treating moderately to severely active ulcerative colitis, specifically mentioning your ICS. I am looking to sense check the details that they have provided in their letter and so I am hoping you can provide me with the following information: 1. The maintenance schedule that you currently fund for Ustekinumab 2. In what instances you would release funding for maintenance dose escalation to prevent a relapse in symptoms, if at all. 3. Upon agreement of a dose escalation, the minimum number of weeks in between doses that you fund.	1. Ustekinumab is included on the Bristol, North Somerset and South Gloucestershire (BNSSG) Joint Formulary in accordance with the NICE TA633 - https://www.nice.org.uk/guidance/ta633 for treating moderately to severely active ulcerative colitis within its marketing authorisation. Therefore, the dosage schedule that is funded within BNSSG would be within the product license. 2. Dose escalation for maintenance treatment outside of the marketing authorisation would be unlicensed, not within the remit of NICE guidance, or the BNSSG Formulary, and therefore not routinely funded within BNSSG. There are 2 mechanisms for potential release of funding for maintenance dose escalation: i. Individual patient - if a specialist determines there is a clinical need to escalate the dose more frequently than the licensed dosing and has considered the quality of evidence for safety and efficacy of a dosage schedule outside the product license, the route by which the specialist may apply for funding for an individual patient is through the submission of an Exceptional

	Funding Request (EFR). https://bnssgccg.nhs.uk/individual-funding-requests-ifr/ ii. Cohort application to the BNSSG Joint Formulary Group (JFG) - if the local specialist teams feel that there is a cohort of patients in BNSSG that would benefit from a maintenance dose escalation that is outside of the product license, they may complete a new drug request defining the intended dose escalation and submit this along with supportive clinical evidence to the BNSSG Joint Formulary Group (JFG). This application is then assessed against the following criteria: • Patient safety • Clinical effectiveness • Strength of evidence • Cost effectiveness or resource impact • Place in therapy relative to available • National guidance and priorities • Local health priorities • Equity of access If the JFG support the application for the defined maintenance dose escalation, a process for financial approval through the ICB will need to be sought before addition to the BNSSG Joint Formulary. 3. a. EFR - where an EFR application has been approved the minimum number of weeks in between doses that is funded would be discussed at the EFR panel meeting based on the

	patient information and evidence submitted by the requesting specialist. This decision is made on an individual patient basis. An appropriate timeframe is set for clinical review of effect and consideration of continued funding based on clinical response b. BNSSG Joint Formulary - the minimum number of weeks in between doses that is funded would be determined during the decision-making process for the cohort of patients, based on the formulary application and supporting evidence. This would then be reflected in the BNSSG Joint Formulary.

The information provided in this response is accurate as of 9 August 2022 and has been approved for release by Joanne Medhurst, Chief Medical Officer for NHS Bristol, North Somerset and South Gloucestershire ICB.