# Vedolizumab Dose Escalation Policy for IBD

NHS
Bath and North East Somerset, Swindon and Wiltshire
Clinical Commissioning Group

## Introduction

This policy has been developed to support the decision making process associated with the allocation of resources for commissioning. In creating this policy BSW CCG has reviewed this treatment and the clinical conditions for which it is prescribed. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

## Background

Vedolizumab was approved by NICE for adults with moderately to severely active Crohn's Disease in July 2017[1] and for adults with moderately to severely active Ulcerative Colitis in June 2015[2]. The licensed maintenance dose for this indication is 300mg every 8 weeks[3]. However since the publication of NICE, the manufactures have extended the license to include 300mg every 4 weeks. The SPC sates 'Some patients who have experienced a decrease in their response may benefit from an increase in dosing frequency to Entyvio 300 mg every 4 weeks'. Therapeutic options for patients with Inflammatory Bowel Disease (IBD) are limited and so optimising drug therapy is essential to ensure patients get the maximum value from treatments. Patients without further drug options are likely to be left with a high symptom burden and require frequent hospital admissions and/or surgery.

## Proposal

In order to ensure that our patients across BSW CCG are dealt with in an equitable manner, this policy aims to provide clarity to acute provider trusts on how to deal with patients where dose escalation is being considered. Proposed commissioned dose escalation for vedolizumab in IBD:

- 300mg 4 weekly (outside of NICE)
- Criteria based access using blueteq.

We have identified that a proportion of vedolizumab treated patients experience a return in their IBD symptoms before their next dose at the licensed interval of 8 weekly. We propose that for a small number of patients increasing the dose to 3000mg 4 weekly would be beneficial. As a CCG we are aware that this dose escalation is utilised by IBD colleagues in tertiary centres. It is expected that the patients eligible for this escalation would have an appropriate recommendation from a tertiary centre based on assessment of their symptoms. This dose escalation is not within the original scope of NICE, however is within license.

The annual cost of 1 year of vedolizumab 300mg 8 weekly, is £13,488. When escalated to 300mg 4 weekly the average annual cost of treatment increases to £24,900. However, a small cohort of patients requiring 4 weekly injections has already been commissioned via tertiary referral and IFR applications. This change in policy would seek to align us with the current practice of tertiary colleagues and support the use of criteria based access for clinicians. The aim is to minimise the variation in dose escalation and assessment taking place and to unify practice across BSW.

## Evidence

There is a licensed dose escalation and as such an evidence review has not been conducted.

## Monitoring

To ensure that these patients are appropriate for initiating dose escalation, advice should be sought from a tertiary centre. It is expected that our clinicians would discuss the patient's condition, including clinical symptoms and inflammatory markers. Only following advice/recommendation from a tertiary centre may clinicians escalate a patient to 4 weekly vedolizumab. To determine if dose escalation has been successful, ongoing monitoring of the patients symptoms and inflammatory markers is required. If successful, then it is expected that the ongoing need for dose escalation will continue to be reviewed at the patient's annual review. If the patient is well maintained and asymptomatic, de-escalation of treatment should be considered by the clinician. Where the dose escalation has not improved the patient's condition, guidance should be sought from tertiary colleagues on when to consider discontinuing/ switching therapy. Further dose escalation beyond 4 weekly is not commissioned. BSW CCG will require secondary care service providers to embrace the policy and advise patient's accordingly. Adherence to this policy will be demonstrated by clinicians via Blueteq criteria based access. BSW CCG will monitor blueteq, alongside standard contractual process monitoring on an ongoing basis.

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**References**

[1] Vedolizumab for treating moderately to severely active Crohn's disease after prior therapy. NICE TA352. August 2015 https://www.nice.org.uk/guidance/ta352

[2] Vedolizumab for treating moderately to severely active ulcerative colitis. NICE TA342. June 2015 https://www.nice.org.uk/guidance/ta342

[3] Summary of product characteristics. Entyvio 300 mg powder for concentrate for solution for infusion (vedolizumab); date of revision of text 21 October 2020. Takeda UK Ltd. https://www.medicines.org.uk/emc/medicine/3236