

## South East Regional Medicines Optimisation Group (SERMOG) policy recommendation

<b>Title:</b>	Inflammatory bowel disease (IBD) high cost-drug pathway for adults
<b>Number:</b>	SERMOG-06
<b>Category:</b>	Treatment pathway
<b>Date determined by SERMOG:</b>	November 2025

### Introduction

This pathway is a guideline for the initiation and maintenance of high cost drugs (biologicals and small molecules) for the treatment of inflammatory bowel disease (IBD) in adults where the patient has had an inadequate response, intolerance or contraindication to optimised conventional therapy (non-biological therapy e.g. aminosalicylates, corticosteroids and immunomodulators), taken for an adequate period. The pathway follows NICE Technology Appraisal (TA) guidance alongside additional recommendations for dose escalation considered by the SERMOG. The use of HCDs for the treatment of IBD is only approved in line with this pathway and the dosing regimens outlined in tables 4 and 5. Any dose regimens outside of these recommendations are not routinely funded, as detailed in SERMOG-02 (Overarching policy on licensed doses or dosing schedules of high-cost drugs not considered in NICE Technology Appraisal (TA) guidance). Where dose escalations are off-label or unlicensed, the guidance for off-label use of HCDs as detailed in box 3 should be followed. See Box 1 for considerations when choosing treatment and Box 2 on assessing response and effective maintenance. Definitions for terms used in the pathway are set out in Tables 1 and 2. Where biosimilars are available, these should be used, as detailed in SERMOG-03 (Overarching policy on switching between biosimilars).

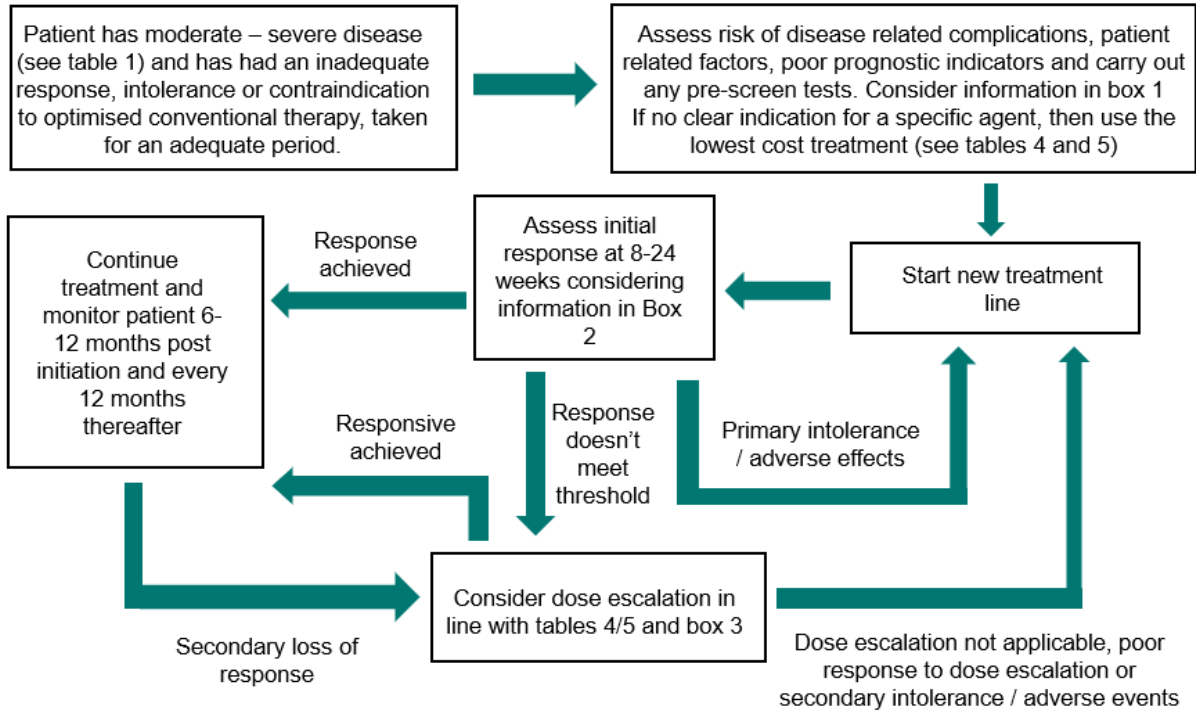
The use of dual-biological therapy for IBD is not routinely funded, as detailed in SERMOG-01.

The most appropriate treatment should be chosen after discussing the advantages and disadvantages of the treatments available with the person having treatment. If patients and clinicians consider more than one treatment to be suitable, choose the least expensive treatment (taking into account drug administration costs, dose needed and frequency, and product price per dose). The lowest cost treatments in each mode of action are highlighted in table 3.

According to a Regional Medicines Optimisation Committee (RMOC) Advisory Statement on the sequential use of biologic medicines (May 2020), when a treatment fails, guidance from specialist bodies suggests switching to a biologic with a new mechanism of action is more effective than switching within class. The exception to this is secondary failure of anti-TNF treatment due to formation of anti-drug antibodies, in which case switching within class may be a valid treatment option. In situations where the appropriateness of further treatment options is undecided, a peer multidisciplinary team discussion may be helpful.

Any new high cost drug (HCD) which receives a positive recommendation from NICE between document iterations will be approved through local ICB processes and will be included in future pathway updates.

**Figure 1. High cost drug pathway for IBD**



**Table 1. Definitions of moderate – severe disease (one or more may be applicable)**

Crohn's disease	Ulcerative Colitis
<ul style="list-style-type: none"> <li>• Crohn's disease activity index (CDAI) score <math>\geq 220</math></li> <li>• Harvey Bradshaw Index (HBI) <math>\geq 8</math>.</li> <li>• Where CDAI / HBI is not a relevant indicator of disease severity alternative objective measures (e.g. colonoscopy, stoma output, C-reactive protein, Faecal calprotectin, video capsule) should be provided to confirm moderate to severe disease</li> </ul>	<ul style="list-style-type: none"> <li>• Mayo score <math>\geq 6</math></li> <li>• Partial Mayo score <math>\geq 5</math></li> <li>• Simple Clinical Colitis Activity Index (SCCAI) <math>\geq 6</math></li> <li>• Ulcerative Colitis Endoscopic Index of Severity (UCEIS) <math>\geq 5</math></li> <li>• Faecal calprotectin can be used to detect inflammation and check for biochemical response</li> </ul>

**Table 2. Pathway definitions and actions**

Description	Definition	Action
Response does not meet threshold	Level of improvement does not meet the thresholds above, or the agreed clinical outcome. Includes primary non response and partial response.	Dose escalate or switch mode of action. Switch within class acceptable if loss of response considered to be treatment specific.

Secondary loss of response	Where the improvement meets initial thresholds, but this response is lost over time	Dose escalate or switch mode of action. Switch within class acceptable if loss of response considered to be treatment specific.
Primary intolerance or adverse events	Where treatment is discontinued within the initial time period defined by the NICE TA due to inability to tolerate side-effects of treatment	If class specific or a severe adverse event change to a new mode of action. Otherwise consider changing to another option from the same treatment line.
Secondary intolerance or adverse events	Where treatment is discontinued outside of the initial time period defined by the NICE TA due to inability to tolerate side-effects of treatment	Change to a new mode of action. Switch within class acceptable if loss of response considered to be treatment specific.

**Table 3. Drug treatment options (lowest acquisition cost option highlighted<sup>1</sup>)**

Mode of action		Drug	Indication	
			Ulcerative colitis	Crohn's disease
TNF alpha inhibitor		Adalimumab	✓	✓
		Infliximab	✓	✓
		Golimumab	✓	✗
Interleukin (IL) inhibitor	IL 12/23	Ustekinumab	✓	✓
	IL 23	Mirikizumab	✓	✓
		Guselkumab <sup>2</sup>	✓	✓
		Risankizumab	✓	✓
Integrin $\alpha$ 4 $\beta$ 7 receptor antagonist		Vedolizumab	✓	✓
Janus Kinase (JAK) inhibitor (oral)	JAK 1	Filgotinib	✓	✗
	JAK 1 and JAK 3	Tofacitinib	✓	✗
	JAK 1	Upadacitinib	✓	✓
Sphingosine 1-phosphate (S1P) receptor modulator	Subtype 1 and 5	Ozanimod	✓	✗
	Subtype 1,4 and 5	Etrasimod	✓	✗

**Box 1. Considerations when choosing and starting treatment**

The most appropriate treatment should be chosen after discussing the advantages and disadvantages of the treatments available with the person having treatment. If patients and clinicians consider more than one treatment to be suitable, choose the least expensive treatment (taking into account drug administration costs, dose needed and frequency, and product price per dose). The lowest cost treatments (based on drug acquisition cost) in each class are highlighted in table 3.

<sup>1</sup> Due to differences in dosing regimens between ulcerative colitis and Crohn's disease there are differences in year 1 drug acquisition costs. As such, the IL23's in table 3 are not in ascending drug acquisition cost order for Crohn's disease. Table 5 is in cost-acquisition order based on year 1 costs. Correct at time of recommendation.

<sup>2</sup> Guselkumab has a number of differing dosing regimens (see tables 4 and 5). The use of more intensive dosing regimens incurs a higher cost which makes treatment more costly.

Where subcutaneous and intravenous (IV) preparations are available, subcutaneous preparations are preferred where there is not a clinical need for an IV preparation.

When initiating a treatment, the treatment aims should be discussed and agreed with the individual. This should include a specified outcome and a definition of achieving this. Examples include:

- CD – A decrease in HBI  $\geq 3$  points or a decrease in CDAI  $\geq 70$  points
- UC – Reduction of baseline Mayo score by  $\geq 3$  points and a decrease of 30% from the baseline score with a decrease of at least one point on the rectal bleeding subscale or an absolute rectal bleeding score of 0 or 1, or a decrease in partial Mayo score from baseline  $\geq 2$  points and  $\geq 25\%$  AND Decrease in rectal bleeding sub-score from baseline of  $\geq 1$  point OR absolute rectal bleeding sub-score 0 – 1, or a change in UCEIS  $\geq 3$  points, or a reduction in faecal calprotectin to less than 250 mcg/g

## Box 2. Assessing response and effective maintenance

Response should be initially assessed 8-24 weeks after initiation (specific time frame as detailed in NICE TA/SPC) where it should be ascertained if the response meets the treatment aims set out at initiation. If this aim has been met, treatment should be continued and reviewed again at 6-12 months. If the aim has not been met, consideration may be given to dose escalation or switching treatment.

Response should be re-assessed 6-12 months (or earlier if recommended by NICE TA) after treatment was commenced to determine whether ongoing treatment is still clinically appropriate.

Treatment should only be continued at this point if there is evidence of on-going adequate or partial response and active disease, determined by clinical symptoms / physicians' assessment and biological markers and/or evidence of endoscopic/imagery and histological disease activity,

If there is evidence of ongoing disease, the treatment may be dose escalated in line with pathway recommendations, or if more appropriate the patient may move to the next step in the treatment pathway.

If the patient is in a stable clinical remission, consideration may be given to stopping or dose tapering treatment. This decision should follow a discussion with the patient regarding the risk of inflammatory exacerbations (with and without drug treatment) and the potential side effects of drug treatment. Treatment may be re-started if the patient relapses.

Drug levels and antibody testing should be used where appropriate to guide optimal patient care, including the management of secondary loss of response and at annual review.

## Box 3. Using off-label dose escalations

The use of licenced dosing of high cost drugs (HCD) including biologics and small molecules for the treatment of inflammatory bowel disease (IBD) is the preferred treatment option. However, it is acknowledged that there are instances where off-label dose escalation may be most clinically appropriate for the individual.

The use of off-label dose escalations as detailed within the SER IBD HCD pathway is supported if all the following criteria are met, response is monitored and treatment discontinued if adequate response is not achieved. The prescriber must take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment.

### **Criteria for use**

- There is ongoing active disease despite escalated dosing in line with the licenced, locally approved or TA recommended escalations.
- There is consensus at MDT that off-label dose escalation is the most clinically appropriate treatment option for the individual.
- If escalating anti-TNF medications, where antibody testing is available, the results are indicative that treatment escalation has a good chance of therapeutic effect
- There is clear reasoning for continuing the current treatment over switching to another treatment option (e.g. response has been previously achieved, and it is considered likely that escalation will recapture response)
- The individual has optimised concomitant treatment where appropriate (e.g. immunomodulators)
- There is recorded informed consent from the individual being treated

### **Assessment of response**

- Response should be assessed after 3 months.
- If no improvement has been achieved (30% improvement in Mayo score point, a 70 point reduction in CDAI score or evidence of endoscopic response) treatment should be stopped and the individual switched to an alternative treatment option (if available).
- If the individual responds at 3 months, response should be re-assessed at 6-12 months in line with box 5.
- If there has been a secondary loss of response, then treatment should be stopped and the individual switched to an alternative treatment option.

### **Monitoring**

The use of off-label dose escalations should be recorded. This record should include details on MDT approval, response, outcomes and adverse events.

**Table 4. TA recommendations and local dose escalation agreements for Crohn's disease (grouped by mechanism of action, in drug acquisition cost order within each mode of action<sup>3</sup>)**

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
Adalimumab SC	<a href="#">TA187</a> (2010)	Yes	Moderately <sup>4</sup> - severely active Crohn's disease whose disease has not responded to conventional therapy (including immunosuppressive and/or corticosteroid treatments), or who are intolerant of or have contraindications to conventional therapy	Yes	<ul style="list-style-type: none"> <li>80mg at week 0, then 40mg at week 2</li> </ul>	<ul style="list-style-type: none"> <li>40mg every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>40mg weekly or 80mg every 2 weeks</li> <li>80mg every week (unlicensed)</li> </ul>
Infliximab IV		Yes		Yes	<ul style="list-style-type: none"> <li>5mg/kg at weeks 0, 2, and 6. Then 8 weekly</li> </ul>	<ul style="list-style-type: none"> <li>5mg/kg 8 weekly</li> </ul>	<ul style="list-style-type: none"> <li>10mg/kg every 8 weeks</li> <li>5mg/kg every 4 or 6 weeks (off-label)</li> <li>10mg/kg every 4 or 6 weeks (off-label)</li> </ul>
Infliximab SC		SERMOG recommendation		No	<ul style="list-style-type: none"> <li>5mg/kg IV at weeks 0 and 2, then 120mg SC at week 6</li> </ul>	<ul style="list-style-type: none"> <li>120mg every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>240mg every 2 weeks</li> </ul>
Ustekinumab	<a href="#">TA456</a> (2017)	Yes	Moderately to severely active Crohn's disease, that is, for adults who have had an inadequate response with, lost response to, or were intolerant to either	Yes	<ul style="list-style-type: none"> <li>&lt; 56kg – 260mg IV, then 90mg SC at 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>90mg every 12 weeks</li> </ul>	<ul style="list-style-type: none"> <li>90mg every 8 weeks</li> <li>90mg every 4 or 6 weeks (off-label)</li> </ul>

<sup>3</sup> Based on year 1 drug acquisition costs only assuming only standard maintenance dosing regimens are used.

<sup>4</sup> NICE TA187 states use in severe disease only and to consider stopping treatment at 12 months. Inclusion of patients with moderate disease and treatment beyond 12 months (if adequate response is still being achieved) has been recommended by SERMOG.

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
			conventional therapy or a TNF-alpha inhibitor or have medical contraindications to such therapies		<ul style="list-style-type: none"> <li>• 56-85kg – 390mg IV, then 90mg SC at 8 weeks</li> <li>• &gt;86kg – 520mg IV then 90mg SC at 8 weeks</li> </ul>		
Guselkumab	<a href="#">TA1095</a> (2025)	No	Moderately to severely active Crohn's disease in adults, when: conventional or biological treatment has not worked (that is, the condition has not responded well enough or lost response to treatment), or cannot be tolerated, and a tumour necrosis factor (TNF)-alpha inhibitor has not worked, cannot be tolerated or is not suitable.	No	<ul style="list-style-type: none"> <li>• 200mg IV at week 0,4 and 8</li> </ul> OR <ul style="list-style-type: none"> <li>• 400mg SC at weeks 0, 4 and 8</li> </ul>	<ul style="list-style-type: none"> <li>• 100mg SC every 8 weeks from week 16</li> </ul>	<ul style="list-style-type: none"> <li>• 200mg SC every 4 weeks from week 12<sup>5</sup></li> </ul>
Mirikizumab	<a href="#">TA1080</a> (2025)	No	Moderately to severely active Crohn's disease in adults, only if the disease has not responded well	No	<ul style="list-style-type: none"> <li>• 900mg IV at weeks 0,4 and 8</li> </ul>	<ul style="list-style-type: none"> <li>• 300mg SC every 4 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

<sup>5</sup> Consideration should be given to discontinuing treatment in patients who have shown no evidence of therapeutic benefit after 24 weeks of treatment. Note this dose escalation has a significantly higher drug acquisition cost than a 100mg dose.

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
			enough or stopped responding to a previous biological treatment, or a previous biological treatment was not tolerated, or tumour necrosis factor (TNF)-alpha inhibitors are not suitable.				
Risankizumab	<a href="#">TA888</a> (2023)	No	Moderately to severely active Crohn's disease in people 16 years and over, only if the disease has not responded well enough or lost response to a previous biological treatment, or a previous biological treatment was not tolerated, or tumour necrosis factor (TNF)-alpha inhibitors are not suitable.	No	<ul style="list-style-type: none"> <li>600mg IV at weeks 0,4 and 8, then 360mg SC at week 12</li> </ul>	<ul style="list-style-type: none"> <li>360mg SC every 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Vedolizumab SC	SERMOG recommendation	No	Moderately to severely active Crohn's disease only if a tumour necrosis factor-alpha inhibitor has failed (that is, the disease has responded inadequately or has lost response to treatment) or a tumour necrosis factor-alpha	No	<ul style="list-style-type: none"> <li>300mg IV at weeks 0 and 2, then 108mg SC at week 4</li> </ul>	<ul style="list-style-type: none"> <li>108mg every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Vedolizumab IV	<a href="#">TA352</a> (2015)	No		No	<ul style="list-style-type: none"> <li>300mg IV at week 0, 2 and 6</li> </ul>	<ul style="list-style-type: none"> <li>IV – 300mg IV every 8 weeks after</li> </ul>	<ul style="list-style-type: none"> <li>300mg IV every 4<sup>7</sup> (licenced) or 6 weeks (off-label)</li> </ul>

<sup>7</sup> Due to the high acquisition cost of this dosing regimen, it is recommended that MDT support is obtained to ensure it is the most appropriate treatment option.

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
			inhibitor cannot be tolerated or is contraindicated <sup>6</sup>				
Upadacitinib <sup>8</sup>	<a href="#">TA905</a> (2023)	No	Moderately to severely active Crohn's disease in adults, only if the disease has not responded well enough or lost response to a previous biological treatment or a previous biological treatment was not tolerated or tumour necrosis factor (TNF)-alpha inhibitors are contraindicated.	No	<ul style="list-style-type: none"> <li>• 45mg daily at 12 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• 15 or 30mg daily based on individual patient presentation</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

<sup>6</sup>. Vedolizumab should be given as a planned course of treatment until it stops working or surgery is needed, or until 12 months after the start of treatment, whichever is shorter. At 12 months, people should be reassessed to determine whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. People who continue vedolizumab should be reassessed at least every 12 months to decide whether continued treatment is justified.

<sup>8</sup>. [Janus kinase \(JAK\) inhibitors: new measures to reduce risks of major cardiovascular events, malignancy, venous thromboembolism, serious infections and increased mortality.](#)

**Table 5. TA recommendations and local dose escalation agreements for Ulcerative Colitis (grouped by mechanism of action, in drug acquisition cost order within each mode of action<sup>3</sup>)**

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
Adalimumab SC	<a href="#">TA329</a> (2015)	Yes	Moderately to severely active ulcerative colitis in adults whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies.	Yes	<ul style="list-style-type: none"> <li>• 160mg at week 0, 80mg at week 2, then 40mg at week 4</li> </ul>	<ul style="list-style-type: none"> <li>• 40mg every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• 40mg weekly or 80mg every 2 weeks</li> <li>• 80mg weekly (off-label)</li> </ul>
Infliximab IV		Yes		Yes	<ul style="list-style-type: none"> <li>• 5mg/kg at weeks 0, 2, 6 and 14 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• 5mg/kg 8 weekly</li> </ul>	<ul style="list-style-type: none"> <li>• 10mg/kg every 8 weeks (off-label)</li> <li>• 5mg/kg every 4 or 6 weeks</li> </ul>
Infliximab SC	SERMOG recommendation	Yes		No	<ul style="list-style-type: none"> <li>• 5mg/kg at weeks 0, 2 then 120mg SC at week 6</li> </ul>	<ul style="list-style-type: none"> <li>• 120mg every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Golimumab SC	<a href="#">TA329</a> (2015)	Yes		Yes	<ul style="list-style-type: none"> <li>• &lt;80kg – 200mg at week 0, 100mg at week 2, then 50mg at week 6</li> <li>• ≥80kg – 200mg at week 0,</li> </ul>	<ul style="list-style-type: none"> <li>• 50mg every 4 weeks</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
					100mg at week 2, then 100mg at week 6	<ul style="list-style-type: none"> <li>100mg every 4 weeks</li> </ul>	
Ustekinumab	<a href="#">TA633</a> (2020)	No	Moderately to severely active ulcerative colitis in adults when conventional therapy or a biological agent cannot be tolerated, or the disease has responded inadequately or lost response to treatment, only if a tumour necrosis factor-alpha inhibitor has failed (that is the disease has responded inadequately or has lost response to treatment) or a tumour necrosis factor-alpha inhibitor cannot be tolerated or is not suitable,	Yes	<ul style="list-style-type: none"> <li>&lt; 56kg – 260mg IV, then 90mg SC at 8 weeks</li> <li>56-85kg – 390mg IV, then 90mg SC at 8 weeks</li> <li>&gt;86kg – 520mg IV then 90mg SC at 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>90mg SC every 12 weeks</li> </ul>	<ul style="list-style-type: none"> <li>90mg SC every 8 weeks</li> <li>90mg SC every 4 or 6 weeks (off-label)</li> </ul>
Mirikizumab	<a href="#">TA925</a> (2023)	No	Moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or the condition has not responded well enough or lost response to treatment, only if a tumour necrosis factor (TNF)-alpha inhibitor has not worked (that is the condition has not responded well enough or has lost response to treatment) or a TNF-alpha	No	<ul style="list-style-type: none"> <li>300mg IV at weeks 0, 4 and 8 then 200mg SC at week 12</li> </ul>	<ul style="list-style-type: none"> <li>200mg SC every 4 weeks</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
			inhibitor cannot be tolerated or is not suitable				
Guselkumab	<a href="#">TA1094</a> (2025)	No	Moderately to severely active ulcerative colitis in adults, when: conventional treatment, biological treatment or JAK inhibitor has not worked (that is, the condition has not responded well enough or lost response to treatment), or cannot be tolerated, and a tumour necrosis factor (TNF)-alpha inhibitor has not worked, cannot be tolerated or is not suitable.	No	<ul style="list-style-type: none"> <li>• 200mg IV at week 0,4 and 8</li> </ul> OR <ul style="list-style-type: none"> <li>• 400mg SC at weeks 0, 4 and 8</li> </ul>	<ul style="list-style-type: none"> <li>• 100mg SC every 8 weeks from week 16</li> </ul>	<ul style="list-style-type: none"> <li>• 200mg SC every 4 weeks from week 12<sup>9</sup></li> </ul>
Risankizumab	<a href="#">TA998</a> (2024)	No	Moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or the condition has not responded well enough or has lost response to treatment, only if a tumour necrosis factor (TNF)-alpha inhibitor has not worked (that is the condition has not responded well enough or has lost response to treatment), or cannot be tolerated or is not suitable	No	<ul style="list-style-type: none"> <li>• 1200mg IV at weeks 0, 4 and 8 then 360mg at week 12</li> </ul>	<ul style="list-style-type: none"> <li>• 180mg every 8 weeks</li> <li>• 360mg every 8 weeks if inadequate initiation response</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

<sup>9</sup> Consideration should be given to discontinuing treatment in patients who have shown no evidence of therapeutic benefit after 24 weeks of treatment. Note this dose escalation has a larger cost acquisition cost than a 100mg 8 weekly regimen.

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
Vedolizumab SC	SERMOG recommendation	Yes		No	<ul style="list-style-type: none"> <li>300mg IV at weeks 0 and 2, then 108mg SC at week 4</li> </ul>	<ul style="list-style-type: none"> <li>108mg every 2 weeks</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Vedolizumab IV	<a href="#">TA342</a> (2015)	Yes	Moderately to severely active ulcerative colitis <sup>10</sup>	No	<ul style="list-style-type: none"> <li>300mg IV at week 0, 2 and 6</li> </ul>	<ul style="list-style-type: none"> <li>IV – 300mg every 8 weeks</li> </ul>	<ul style="list-style-type: none"> <li>IV – 300mg every 4<sup>7</sup> (licenced) or 6 (off-label) weeks</li> </ul>
Filgotinib <sup>8</sup>	<a href="#">TA792</a> (2022)	Yes	Moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or if the disease has not responded well enough or has stopped responding to these treatments	No	<ul style="list-style-type: none"> <li>200mg daily</li> <li>100mg daily for adults at higher risk of VTE, MACE and malignancy</li> </ul>	<ul style="list-style-type: none"> <li>200mg daily</li> <li>100mg daily for adults at higher risk of VTE, MACE and malignancy</li> </ul>	<ul style="list-style-type: none"> <li>N/A</li> </ul>
Tofacitinib <sup>8</sup>	<a href="#">TA547</a> (2018)	Yes	Moderately to severely active ulcerative colitis in adults when conventional therapy or a biological agent cannot be tolerated or the disease has	No	<ul style="list-style-type: none"> <li>10mg twice daily for 8 weeks<sup>11</sup></li> </ul>	<ul style="list-style-type: none"> <li>5mg twice daily</li> </ul>	<ul style="list-style-type: none"> <li>10mg twice daily</li> </ul>

<sup>10</sup> Vedolizumab should be given until it stops working or surgery is needed. At 12 months after the start of treatment, people should be reassessed to see whether treatment should continue. Treatment should only continue if there is clear evidence of ongoing clinical benefit. For people in complete remission at 12 months, consider stopping vedolizumab, resuming treatment if there is a relapse. People who continue vedolizumab should be reassessed at least every 12 months to see whether continued treatment is justified.

<sup>11</sup> May be extended for 8 weeks if adequate therapeutic benefit not achieved by week 8

Treatment	TA	Can be used first line	NICE TA indication	Biosimilar available	Induction dose	Maintenance dose	Approved dose escalations
			responded inadequately or lost response to treatment				
Upadacitinib <sup>8</sup>	<a href="#">TA856</a> (2023)	Yes	Moderately to severely active ulcerative colitis in adults when conventional or biological treatment cannot be tolerated, or if the condition has not responded well enough or has stopped responding to these treatments	No	<ul style="list-style-type: none"> <li>• 45mg daily for 8 weeks<sup>12</sup></li> </ul>	<ul style="list-style-type: none"> <li>• 15mg or 30mg once daily</li> </ul>	<ul style="list-style-type: none"> <li>• 30mg once daily</li> </ul>
Ozanimod	<a href="#">TA828</a> (2022)	Yes	Moderately to severely active ulcerative colitis in adults, only if conventional treatment cannot be tolerated or is not working well enough and infliximab is not suitable, or biological treatment cannot be tolerated or is not working well enough	No	<ul style="list-style-type: none"> <li>• 0.23mg daily on days 1-4, 0.46mg daily on days 5-7</li> </ul>	<ul style="list-style-type: none"> <li>• 0.92mg daily</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>
Etrasimod	<a href="#">TA956</a> (2024)	Yes	Moderately to severely active ulcerative colitis in people aged 16 years and over when conventional or biological treatments cannot be tolerated or the condition has not responded well enough, or lost response to treatment.	No	<ul style="list-style-type: none"> <li>• 2mg daily</li> </ul>	<ul style="list-style-type: none"> <li>• 2mg daily</li> </ul>	<ul style="list-style-type: none"> <li>• N/A</li> </ul>

<sup>12</sup> May be extended for 8 weeks if adequate therapeutic benefit not achieved by week 8

**Version control:**

Version 1 – Policy developed March 2025

Version 2 – Update for new TA recommendations, new biosimilar availability and following consideration of some recommendations of the British Society of Gastroenterology – Issued to ICBs 27/11/2025

**Notes:**

This policy recommendation will be reviewed when new information becomes available that is likely to have a material effect on the current recommendation.

South East region ICBs will always consider appropriate individual funding requests (IFRs) through their IFR processes.