

North East London

Treatment Pathway for Inflammatory Bowel Disease in adults

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Document version history	
Date / Version	Comments / Changes
September 2023 v1.2	Addition of Risankizumab to Crohn's pathway Addition of Upadacitinib to Crohn's and UC pathways
Sept 2025 v1.3	Addition of Etrasimod, Mirikizumab and Risankizumab to the UC pathway. Addition of Mirikizumab for Crohn's disease. Information added re: cardiac and eye complications. Box 9 added for info relating to pregnancy/breastfeeding. Change mode of action on vedolizumab.

With thanks and acknowledgement to South East London ICS, their IBD pathway was adapted in the production of this pathway.

NB: *This pathway is correct at the time of publication. Any NICE Technology Appraisals which are published after this date in relation to IBD (adults) will be commissioned in line with the TA implementation recommendations.*

**Patients 16-18 years old should be referred to the specialist young adult IBD clinic at RLH*

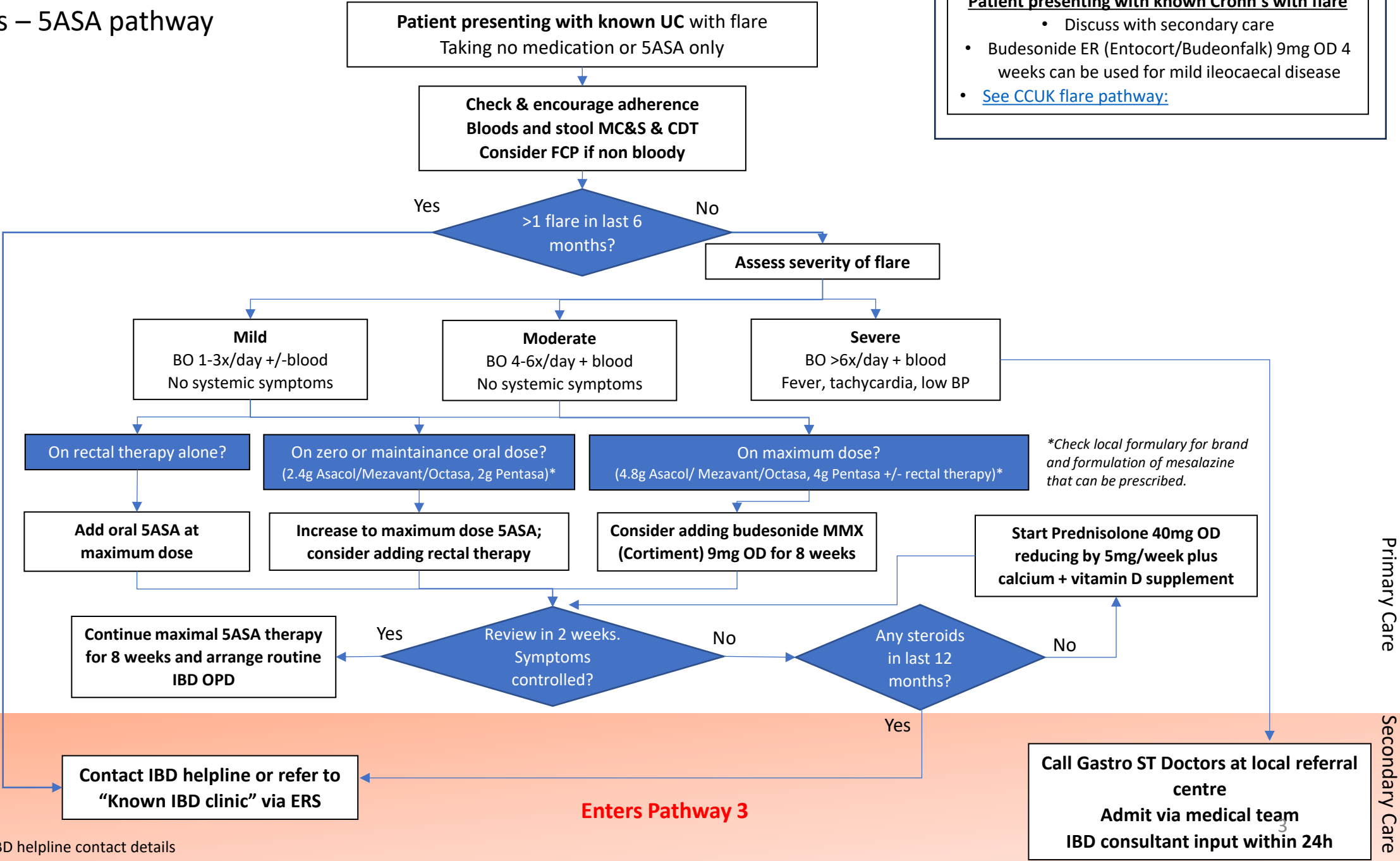
See CCUK flare pathway



IBD pathway 2:
Ulcerative colitis – 5ASA pathway

Rectal therapy:
- Suppository for proctitis
- Enema for left sided UC

Enema can be added for
pancolitis



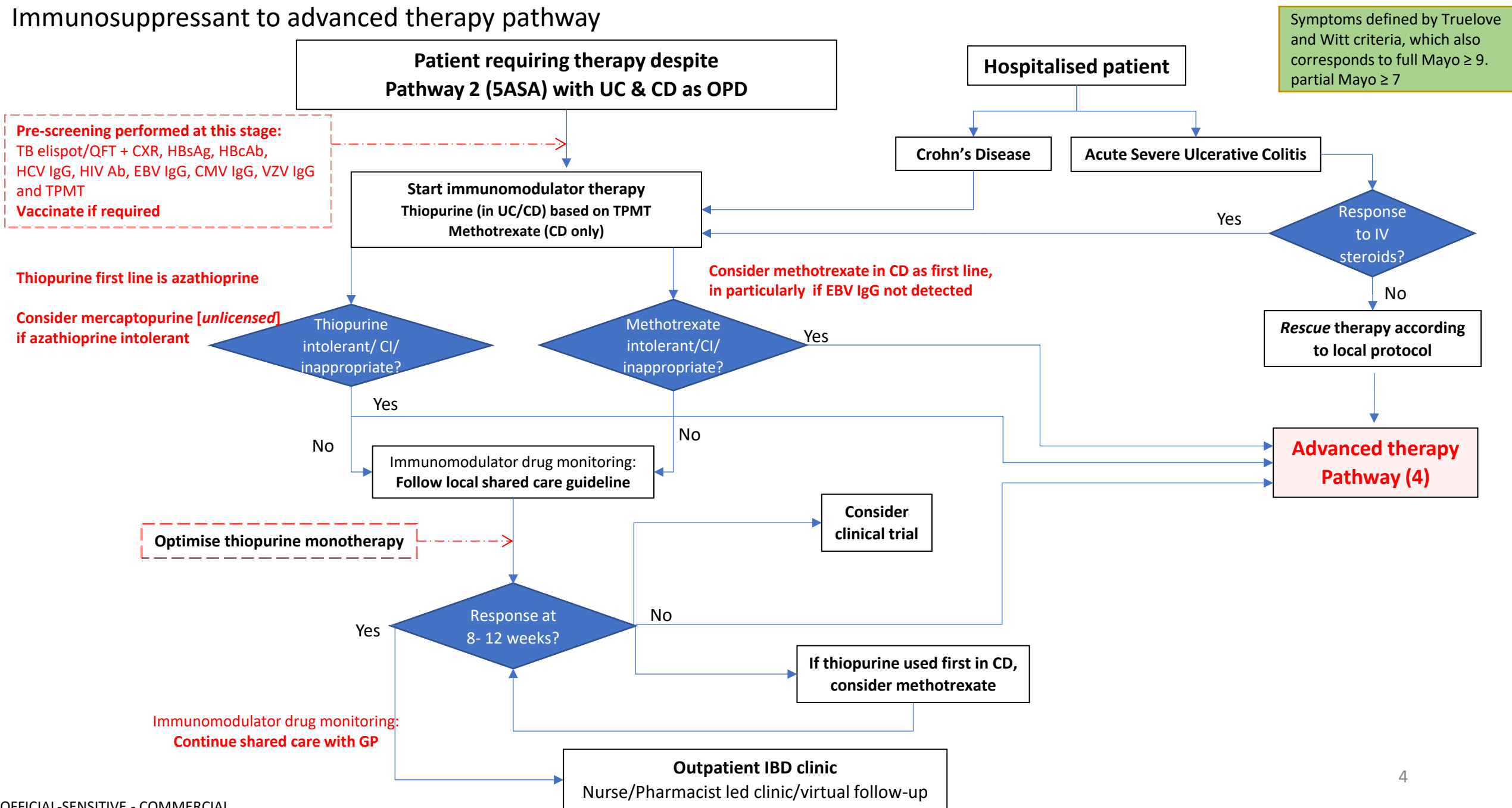
Patient presenting with known Crohn's with flare

- Discuss with secondary care
- Budesonide ER (Entocort/Budeonfalk) 9mg OD 4 weeks can be used for mild ileocaecal disease
- [See CCUK flare pathway:](#)

Call Gastro ST Doctors at local referral
centre
Admit via medical team
IBD consultant input within 24h

IBD pathway 3

Immunosuppressant to advanced therapy pathway



IBD pathway 4:
Advanced therapy pathway

Patient requiring therapy despite Pathway 3

Ulcerative Colitis

Clinical Trial?

Moderate/ severe Crohn's Disease +/- fistula

See boxes 2 and 3

Hospitalised with acute severe UC

Symptoms defined by Truelove and Witt criteria, which also corresponds to full Mayo ≥ 9 , partial Mayo ≥ 7

Chronic moderate/ severe active UC

See box 1

See Box 4 for further notes

Adalimumab^{1,3} (TA329) Tofacitinib* (TA547)
Infliximab^{1,2,3} (TA329) Upadacitinib* (TA856)
Golimumab (TA329) Filgotinib* (TA792)
Vedolizumab² (TA342) Etrasimod** (TA956)

Ozanimod** (TA828) [If IFX not suitable]
Ustekinumab¹ (TA633) [If anti-TNF not suitable]
Mirikizumab (TA925) [If anti-TNF not suitable]
Risankizumab (TA998) [If anti-TNF not suitable]

If more than 1 suitable, the least expensive treatment should be chosen.

Follow NICE guidance:

Consider cost, efficacy, route of administration, patient preference.

*consider PRAC recommendations for JAKi ([here](#))

** See box 5 overleaf

If on Ada/IFX, consider combination therapy with immunomodulator for immunogenicity prevention (Pathway 3)

See box 4 for further notes

Adalimumab^{1,6} (TA187)

Infliximab^{1,2,6,7} (TA187)

Ustekinumab¹ (TA456)

Upadacitinib* (TA905) [If anti-TNF not suitable]

Risankizumab (TA888) [If anti-TNF not suitable]

Vedolizumab^{2,4} (TA352) [If anti-TNF not suitable]

Mirikizumab (TA1080) [If anti-TNF not suitable]

No
Clinical Response by day 7?

Colectomy?

Start thiopurine (Pathway 3)

Consider trial withdrawal or dose de-escalate
If disease relapses, consider restart biologic/ dose escalation

Maintain treatment
Reassess patient every 12 months. Consider 6-12 months reviews for patients on escalated dosing
Follow pathway for secondary loss of response

On ciclosporin

On infliximab x 3 doses (TA 163)

Yes
Thiopurine naïve?

If ciclosporin CI/ clinically inappropriate

Stable clinical remission?

Evidence of active disease (see box 8)?

If on IFX or Vedo IV – consider switch to SC

Annual therapy review

Initial response at 12 – 16 weeks? (see box 6 overleaf)

Adequate response
See box 7 for post-initiation dosing

Partial response

Trial dose optimisation (see box 7) +/- TDM/Ab levels

Outpatient IBD clinic
Nurse led clinic/virtual follow-up

Secondary loss of response?

No response

Switch therapy (TDM based decision)
Surgery/
Clinical trial

Response in 16 weeks?

Where patient is dose escalated, review regularly at 6-12 monthly intervals

Trial dose optimisation (see box 7) +/- TDM/Ab levels

Not appropriate or already on escalated dose

IBD pathway 4: Advanced therapies pathway (notes)

Box 1. Ulcerative colitis- access criteria and definition of disease

Patients would need to have had:

- Inadequate response/ intolerance/ contraindication to optimised conventional therapy taken for an adequate period, including:
 - Corticosteroids **and/or**
 - Azathioprine/ 6-mercaptopurine
- Moderate to severe active UC, **normally corresponds to a Mayo score ≥ 6 , partial Mayo score ≥ 5 or SCCAI ≥ 6**

If an alternative disease severity scoring system is used, evidence of correlation with disease severity (e.g. endoscopy or radiology results, faecal calprotectin) and response criteria needs to be provided by the clinician.

Box 2. Crohn’s Disease access criteria and definition of disease

Patients would need to have had:

- Inadequate response/ intolerance/ contraindication to optimised conventional therapy taken for an adequate period, including:
 - Immunosuppressants (e.g. azathioprine/6-mercaptopurine/methotrexate) **and/or**
 - Corticosteroids
- Moderate to severe active CD, **normally corresponds to a Crohn’s disease activity index (CDAI) score ≥ 220 or Harvey-Bradshaw (HBI) score ≥ 6**

If an alternative disease severity scoring system is used, evidence of correlation with disease severity (e.g. colonoscopy, stoma output, faecal calprotectin) and response criteria needs to be provided by the clinician.

Box 3: Fistulising Crohn’s disease- treatment options

Infliximab is the only treatment option (NICE TA 187), provided that the disease has not responded to conventional therapy (including antibiotics, drainage and immunosuppressive treatments), or who are intolerant of or have contraindications to conventional therapy. From clinical practice, it is very rare that patients would present with pure fistulising disease without meeting the moderate/ severe Crohn’s criteria

Box 4: Choice of therapy

¹Biosimilars available. Use best value brand.

²Subcutaneous = clinically approved and commissioned locally. Not evaluated by NICE TAs

³Consider combination therapy with immunomodulator for immunogenicity prevention (Pathway 3)

⁴Only if anti-TNF failed/ not tolerated/ contraindicated as per NICE TAs

⁵Moderate disease not included in the economic analysis for NICE TA187 but clinically approved and commissioned locally (pending)

⁶Infliximab is first choice in perianal disease

Box 5: Etrasimod and Ozanimod: Cardiac and eye complications

1. ECG monitoring:

Etrasimod: Prior to treatment initiation, an electrocardiogram (ECG) should be obtained in all patients to assess for pre-existing cardiac abnormalities.

Ozanimod: Prior to treatment initiation, an electrocardiogram (ECG) should be obtained in all patients to assess for pre-existing cardiac abnormalities. In patients with certain pre-existing conditions, 6-hour monitoring is required following first-dose. Monitoring for signs and symptoms of symptomatic bradycardia is recommended in patients with resting HR <55bpm, second-degree [Mobitz type I], AV block or a history of myocardial infarction or heart failure.

Cardiologist advice may be required before initiation of Etrasimod or Ozanimod.

Ophthalmic monitoring:

Etrasimod: An ophthalmic evaluation of the fundus, including the macula, is recommended within 3-4 months of starting treatment in all patients and at any time if there is any change in vision while taking Etrasimod. This is due to the associated increased risk of macular oedema.

Ozanimod: Ophthalmological evaluation prior to treatment initiation will be required in patients with pre-existing risk factors or comorbid conditions (history of uveitis, diabetes mellitus or underlying/co-existing retinal disease). This is due to macular oedema with or without visual symptoms being observed. Patients who present with visual symptoms of macular oedema should be evaluated and, if confirmed, treatment with Ozanimod should be discontinued. A decision on whether Ozanimod should be re-initiated after resolution needs to take into account the potential benefits and risks for the individual patient.

Box 6: Definition of response

Adequate response (UC):

Complete Mayo:

- decrease in full Mayo score from baseline by ≥ 3 points and $\geq 30\%$, AND
- decrease in rectal bleeding sub-score from baseline by ≥ 1 point, OR absolute rectal bleeding sub-score of 0 or 1.

Partial Mayo (where further endoscopy not considered necessary/appropriate):

- decrease in partial Mayo score from baseline of ≥ 2 points and $\geq 25\%$ AND
- decrease in rectal bleeding sub-score from baseline of ≥ 1 point OR absolute rectal bleeding sub-score of 0 or 1.

Adequate response (CD) - decrease in HBI ≥ 3 points or CDAI ≥ 70 points

•**Partial response-** any improvement in HBI/CDAI/Mayo/partial Mayo that does not meet adequate response criteria

Box 6 continues on the next page.

IBD pathway 4: Advanced therapies pathway (notes continued)

Box 6 – continued

• **No response** – worsening/ no change of HBI/CDAI/ Mayo/partial Mayo

If alternative disease severity scoring system used, evidence of treatment response (e.g. endoscopy or radiology results, faecal calprotectin) to be provided.

Box 7: Dose escalation

Note adalimumab, infliximab IV or mirikizumab dose escalation is allowed **if there is a partial response during the induction period**

Adalimumab: 40mg weekly

Infliximab IV: 10mg/kg 8 weekly OR 5mg/kg 4 weekly OR 5mg/kg 6 weekly

Mirikizumab in UC: If adequate response not achieved at week 12 of induction dosing 300mg by intravenous infusion may be continued at weeks 12, 16 and 20 (extended induction therapy). If therapeutic benefit is achieved with these additional achieved, then patients may initiate mirikizumab subcutaneous dosing of 200mg every 4 weeks, starting at week 24.

Risankizumab in UC: A dose of 360mg administered by subcutaneous injection is recommended for patients with inadequate improvement disease activity after induction.

Tofacitinib: 10mg twice daily (consider VTE risk)

Ustekinumab: 90mg 8 weekly

Upadacitinib in UC: 45 mg once daily for 8 weeks. Patients who do not achieve adequate response by week 8, 45 mg once daily may be continued for an additional 8 weeks.

Vedolizumab: 300mg 4 weekly. (Use of vedolizumab TDM for dose adjustments is unvalidated at time of writing)

Mirikizumab, Ustekinumab and Upadacitinib dosing post-initiation:

- Ustekinumab can be administered every 8 weeks or 12 weeks according to SPC post-initiation provided **adequate response is demonstrated. If patient is not in remission by week 14, use 8 weekly dosing.**
- Mirikizumab in UC: Patients experiencing a loss of therapeutic response during maintenance phase may received 300mg mirikizumab by intravenous infusion every 4 weeks for a total of 3 doses. If clinical response is achieved dosing resumes subcutaneously every 4 weeks.
- The recommended Upadacitinib maintenance dose is 15mg or 30mg once daily based on individual presentation, see the [SPC](#) for further information. The **lowest effective dose** should be used whenever possible, whilst considering the patient's risk factors.

Golimumab: ≥80kg: Initial dose of 200mg , followed by 100mg at week 2, then 100mg every 4 weeks.

Box 8: Disease reassessment at 12 months

Treatment should only be continued if there is evidence of ongoing adequate response and active disease, or it is considered clinical inappropriate to withdraw therapy. Ongoing active disease may be determined by:

- Clinical symptoms and
- Biological markers and
- Investigations, including endoscopy, imaging if necessary.

Clinical Remission:

UC: Normally defined as complete Mayo ≤2 with no subscore >1, partial Mayo ≤1 or SCCAI ≤2

CD: Normally defined as HBI ≤ 4 or CDAI ≤ 150

Box 9: Conception, pregnancy and lactation

- Patients must be advised to liaise with their IBD team in advance of planning conception so that treatment can be optimised
- Due to potential teratogenic risks, effective contraception must be used during and for a period after treatment with methotrexate, upadacitinib, filgotinib, tofacitinib, etrasimod and ozanimod – consult SPCs for contraceptive guidelines
- Due to limited safety data, effective contraception is recommended as a sensible precaution with Vedolizumab, Ustekinumab, Risankizumab, and Mirikizumab. However, in select cases, these agents may be continued in patients wishing to conceive but only following a thorough discussion with the relevant consultant. Please consult the SPCs for further guidance.
 - Follow local protocols regarding specialist obstetric input in the event of inadvertent foetal exposure
- Immunosuppressant medications may affect use of live vaccines in the exposed newborn – contact pharmacy or Trust Medicines Information departments for advice

SPCs;

[Adalimumab](#)
[Golimumab](#)
[Ozanimod](#)
[Upadacitinib](#)

[Etrasimod](#)
[Infliximab](#)
[Risankizumab](#)
[Ustekinumab](#)

[Filgotinib](#)
[Mirikizumab](#)
[Tofacitinib](#)
[Vedolizumab](#)

Appendix 1. Drug factors to consider (including modes of action)

The table below provides an approximate drug cost for each biologic based upon first year of therapy, with the loading dose schedule taken into consideration. The cost will vary depending upon commercial arrangements and access to short-term free of charge supplies, which has not been taken into consideration for this guidance.

Mode of action	Drug name	Indicated for	TA (other indications)	Reviewed within	Drug cost
Anti-TNFα	Adalimumab (subcutaneous injection)	<u>TA187 – Crohn’s disease</u> Severe active Crohn’s: which has not responded/ intolerant/ contraindication to conventional therapy (immunosuppressive and/or corticosteroid treatments)	TA199 – Psoriatic arthritis TA195 – Rheumatoid arthritis TA373 – JIA TA375 – Rheumatoid arthritis TA383 – Ankylosing spondylitis and non-radiographic axial spondylitis TA392 – Hidradenitis suppurativa TA715 – Rheumatoid arthritis	12 weeks	£
		<u>TA329 – Ulcerative colitis</u> Moderate to severe active ulcerative colitis: which has not responded/ intolerant/ contraindication to conventional therapy including corticosteroids and mercaptopurine/ azathioprine.		2-8 weeks	
	Golimumab (subcutaneous injection)	<u>TA329 – Ulcerative colitis</u> Moderate to severe active ulcerative colitis: which has not responded/ intolerant/ contraindication to conventional therapy including corticosteroids and mercaptopurine/ azathioprine.	TA220 – Psoriatic arthritis TA225 – Rheumatoid arthritis TA375 – Rheumatoid arthritis TA383 – Ankylosing spondylitis and non-radiographic axial spondylitis TA497 – Ankylosing spondylitis	12-14 weeks	££
	Infliximab (biosimilar) (subcutaneous injection or intravenous injection)	<u>TA163 – Ulcerative colitis (acute)</u> Acute exacerbations of ulcerative colitis: which has not responded/ intolerant/ contraindication to conventional therapy including corticosteroids and mercaptopurine/ azathioprine. <u>TA329 – Ulcerative colitis</u> Moderate to severe active ulcerative colitis: which has not responded/ intolerant/ contraindication to conventional therapy including corticosteroids and mercaptopurine/ azathioprine.	TA195 – Rheumatoid arthritis TA199 – Psoriatic arthritis TA375 – Rheumatoid arthritis TA383 – Ankylosing spondylitis and non-radiographic axial spondylitis TA715 – Rheumatoid arthritis	3 doses (acute ulcerative colitis) 14 weeks (ulcerative colitis)	£
		<u>TA187 – Crohn’s disease</u> Severe active Crohn’s: which has not responded/ intolerant/ contraindication to conventional therapy (immunosuppressive and/or corticosteroid treatments) Active fistulising Crohn’s disease which has not responded/ intolerant/ contraindication to conventional therapy (including antibiotics, drainage and immunosuppressive treatments).		2 doses (Crohn’s disease) 3 doses (fistulising Crohn’s disease)	
					8

Mode of action	Drug name	Indicated for	TA (other indications)	Reviewed within	Drug cost
JAK inhibitors	Tofacitinib (oral)	<u>TA547 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis when conventional therapy of biological agent cannot be tolerated, or the disease has responded inadequately or lost response to treatment.	TA735 – JIA TA480 – Rheumatoid arthritis TA543 – Psoriatic arthritis	16 weeks	££
	Filgotinib (oral)	<u>TA792 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis: which has not responded/ intolerant/ contraindication to conventional or biological treatment.	TA676 – Rheumatoid arthritis	10 weeks	£
	Upadacitinib (oral)	<u>TA856 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis: which has not responded/ intolerant/contraindication to conventional or biological treatment.	TA829 – Ankylosing spondylitis TA665 – Severe Rheumatoid arthritis TA744 – Moderate Rheumatoid arthritis TA861 – Non-radiographic axial Spondyloarthritis TA768 - Psoriatic arthritis TA814 – Atopic dermatitis	8 weeks (UC) <i>[which may be followed by a further 8 weeks for inadequate responders]</i>	££ 15mg dose
		<u>TA905 – Crohn’s disease</u> Moderately to severely active Crohn’s disease when a previous biological agent cannot be tolerated/ has responded inadequately to/ lost response or a TNF alpha- inhibitor is contraindicated.		12 weeks (Crohn’s)	££££ 30mg dose
α4β7 integrin antagonist	Vedolizumab (subcutaneous injection or intravenous injection)	<u>TA352 – Crohn’s disease</u> Moderately to severely active Crohn’s disease when a TNF-alpha inhibitor cannot be tolerated, or the disease has responded inadequately, lost response to treatment or is contraindicated. To be provided with the discount agreed in the patient access scheme.		14 weeks	££ SC
		<u>TA342 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis when conventional therapy or a TNF-alpha inhibitor cannot be tolerated, or the disease has responded inadequately or lost response to treatment. To be provided with the discount agreed in the patient access scheme.		10 weeks	££££ IV
IL-12 and IL-23 inhibitor	Ustekinumab (subcutaneous injection) *	<u>TA456 – Crohn’s disease</u> Moderately to severely active Crohn’s disease when conventional therapy or a TNF-alpha inhibitor cannot be tolerated, or the disease has responded inadequately or lost response to treatment.	TA180 – Psoriasis TA340 – Psoriatic arthritis	16 weeks	££ Biosimilar
		<u>TA633 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis when a TNF-alpha inhibitor cannot be tolerated, or the disease has responded inadequately, lost response to treatment or is not suitable.			££££

Mode of action	Drug name	Indicated for	TA (other indications)	Reviewed within	Drug cost
IL-23 inhibitor	Risankizumab (subcutaneous injection)	<u>TA905 – Crohn’s disease</u> Moderately to severely active Crohn’s disease when a previous biological agent cannot be tolerated/ has responded inadequately to/ lost response or a TNF alpha- inhibitor is contraindicated. <u>TA998 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis when a TNF-alpha inhibitor cannot be tolerated, or the disease has responded inadequately, lost response to treatment or is not suitable.	TA596 – Psoriasis TA803 – Psoriatic arthritis	12 weeks	£££
	Mirikizumab (Intravenous infusion then subcutaneous injection)	<u>TA925 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis when conventional and TNF-alpha inhibitor cannot be tolerated, or the disease has responded inadequately, lost response to treatment or is not suitable.		12 weeks	£££***
		<u>TA1080 – Crohn’s Disease</u> moderately to severely active Crohn's disease in adults only if, the disease has not responded well 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.		24 weeks	£££***
Sphingosine 1-phosphate (S1P) receptor modulator	Etrasimod (Oral)	<u>TA956 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis: which has not responded/ intolerant/ contraindication to conventional or biological treatment.		12 weeks	£
	Ozanimod (oral)	<u>TA828 – Ulcerative colitis</u> Moderately to severely active ulcerative colitis when 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 and the company provides it according to the commercial arrangement.	TA706 – Relapsing-remitting multiple sclerosis	10 weeks	£

***subject to change once PAS price is available

Pathway 1

Abbreviation	Name
CDT	Clostridium difficile test
GI	Gastrointestinal
IBD	Inflammatory bowel disease
MC&S	Microscopy, culture and sensitivity
FCP	Faecal calprotectin
FBC	Full blood count
LFT	Liver function test
CRP	C-reactive protein
TFT	Thyroid function test
IBS	Irritable bowel syndrome
ERS	Electronic referral system
STT	Straight to test
PIFU	Patient Initiated Follow-Up

Pathway 4

Abbreviation	Name
Ada	Adalimumab
IFX	Infliximab
Vedo	Vedolizumab
SC	Subcutaneous
TDM	Therapeutic drug monitoring
Ab	Antibody
IBD	Inflammatory bowel disease

Pathway 2

Abbreviation	Name
BO	Bowels open
BP	Blood pressure
5ASA	Aminosalicylates
OD	Once daily
OPD	Out-patient department

Pathway 3

Abbreviation	Name
HBsAg	Hepatitis B surface antigen
HBcAb	Hepatitis B core antibody
HCV IgG	Hepatitis C virus antibody
TB elispot/QFT	Tuberculosis elispot/quantiferon test
HIV Ab	Human immunodeficiency virus antibody
EBV IgG	Epstein-Barr virus antibody
CMV IgG	Cytomegalovirus antibody
VZV IgG	Varicella zoster virus antibody
TPMT	Thiopurine S-methyltransferase
IV	Intravenous
CI	Contraindicated
MTX	Methotrexate

IBD contact details

Barts Health NHS Trust

Royal London and Mile End hospitals:

Adult service Tel: 020 3594 3700 email: bhnt.ibdhelpline@nhs.net

Paediatric service Tel: 020 3594 0402 email: bartshealth.pibd.helpline@nhs.net

Whipps Cross hospital

Tel: 0208 539 5522 ext 4210 email: bartshealth.wxhibdhelpline@nhs.net

Newham hospital

Tel: 07761405192

Homerton Healthcare NHS Foundation Trust

Adult service Tel: 0208 5105906 email: Huh-tr.homertonibdcns@nhs.net

Barking, Havering and Redbridge University Hospitals NHS Trust:

Adult service Tel QH: 01708 435 347 for KGH: 028 970 8161 email: bhrut.ibdhelp@nhs.net