When To Start a Biologic

Biologic treatment must be considered in all patients with fistulising Crohn's disease –
especially those with enterocutaneous fistula(e), rectovaginal fistula(e), or complex peri-anal fistula(e):

- Anti-TNFs are funded for 'top-down' treatment in fistulising Crohn's disease and should be started at diagnosis. Patients do not need to fail immunomodulators prior to anti-TNF treatment
- Infliximab is the most efficacious medical therapy for perianal Crohn's disease

Early biologic treatment should be considered in patients with high-risk features and is associated with more favourable outcomes, especially when there is:

- Fistulising disease
- Early stricturing disease
- Previous small bowel resections especially if >40cm or ileostomy
- Small bowel disease >40cm
- Large or deep ulcers on endoscopy

Biologics are not currently funded for upfront use in IBD patients outside fistulising Crohn's disease. A treat-to-target strategy should be adopted to allow rapid 'step-up' to biologic treatment especially in patients with high-risk features.

Dosing Regimen for Adults

	Dose	***Dose Optimisation/ Therapeutic Drug Monitoring*** * refer to TDM document	***Immunodulator (IMM) co-prescription***
	Loading:		
	Maintenance:		
Adalimumab (ADA) AMGEVITA adalimumab HUMIRA adalimumab	160mg sc stat 80mg sc in 2 weeks 40mg sc fortnightly	Increase dose and/or reduce dosing interval guided by clinical symptoms, end of dose effect, and TDM, maximum sc weekly Consider dose reduction if deep (histologic) remission and high trough levels	Moderately immunogenic. Consider co-prescribing thiopurine or methotrexate
Infliximab (IFX) Remicade INFLIXIMAB	5mg/kg IV at 0, 2, 6 weeks 5mg/kg IV Q8weekly	Increase dose and/or reduce dosing interval guided by clinical symptoms, end of dose effect, and TDM, maximum 10mg/kg Q4weekly Consider dose reduction if deep (histologic) remission and high trough levels	Immunogenic, co-prescribe thiopurine or methotrexate to reduce anti-drug antibodies
Ustekinumab (UST) Stelara (ustekinumab)	260mg IV if <55kg 390mg IV if 55-85kg 520mg IV if >85mg 90mg sc Q8weekly	TDM not currently available for UST. Liaise with Janssen for case-by-case compassionate access; *some patients have been granted Q4weekly maintenance*	Less immunogenic. Individualise IMM decision
Vedolizumab (VDZ) Entyvio vedolizumab	300mg IV at 0, 2, 6 weeks 300mg IV Q8weekly	TDM not currently available for VDZ. Liaise with Takeda for case-by-case compassionate access; *some patients have been granted Q4weekly maintenance*	Less immunogenic. Individualise IMM decision

Treat to Target:

*refer to TTT document (link to be added)

- Therapeutic intervention should be considered as part of a treat to target strategy, which changes the natural history of disease and improves long-term outcomes.
  - This applies to starting, dose optimising, or switching of biologic therapy
- Short, medium, and long term targets include symptomatic, biochemical, radiologic, and endoscopic response/remission, as well as improved quality of life, resolution of EIMs, and absence of disease complications
- Regular reassessments are required in both the active and quiescent phase of disease to ensure targets have been met
  - Frequent reassessments are needed in patients who are flaring of with phenotypically high-risk features