NHS Greater Glasgow and Clyde

CLINICAL GUIDELINE

Advanced Therapies - Ulcerative Colitis (UC)

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Does this version include changes to clinical advice:	Yes
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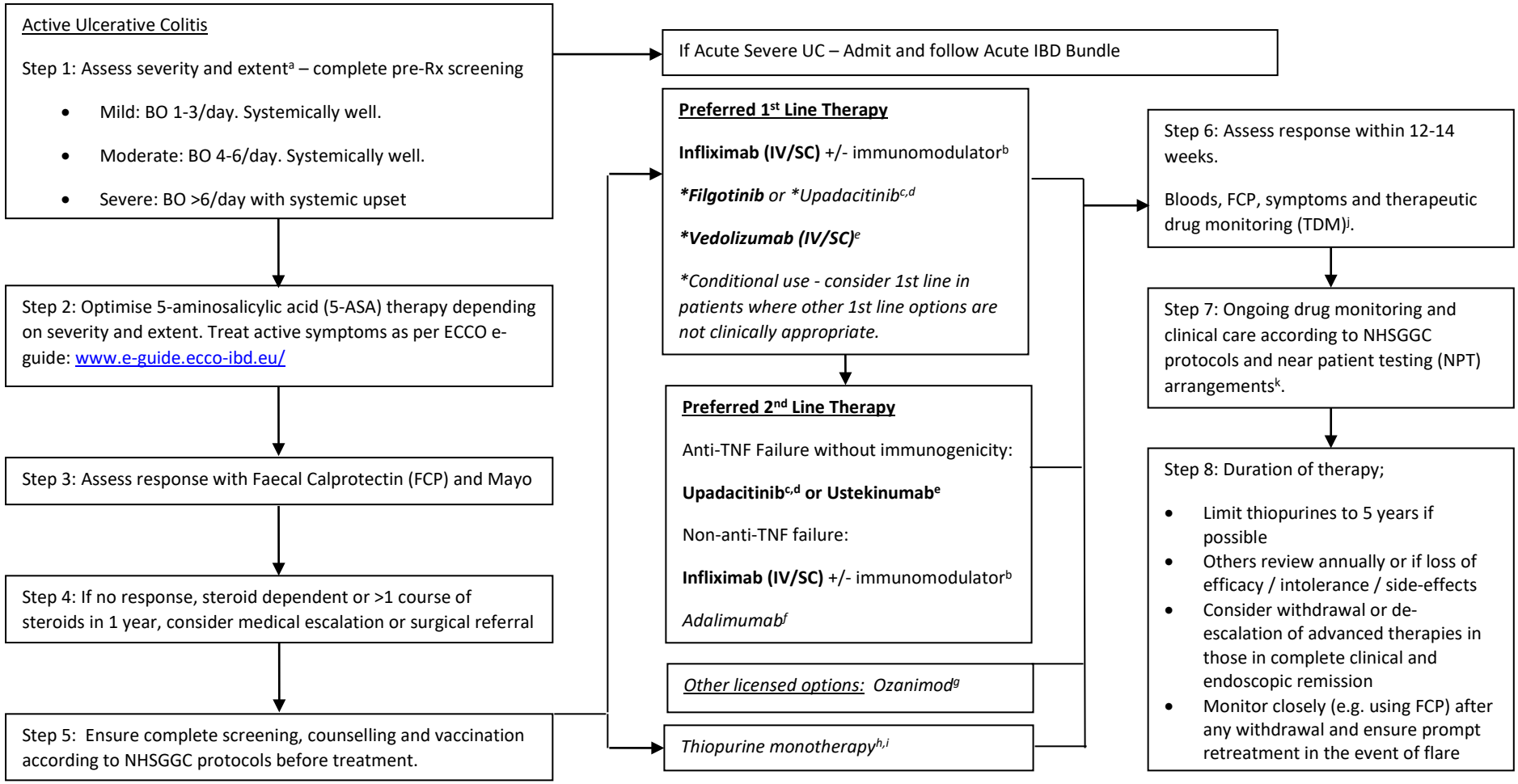
Approval Group:	Medicines Utilisation Subcommittee of ADTC

Important Note:

The Intranet version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Treatment with advanced therapies should be initiated and reviewed by specialist clinicians with experience of these agents and of managing Ulcerative Colitis. The British Society of Gastroenterology has established eligibility criteria for the use of these agents. This is the standard used in GGC and is accessible via www.bsg.org.uk. This document is designed to guide treatment decisions but these should be individualised where possible and made in line with SMC and GGC formulary restrictions.



Consider clinical trials at every step in the treatment pathway.

Email: GastrointestinalTeam.Gcrf@ggc.scot.nhs.uk

or Call: 0141-232-7599

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Prescribing Notes

a) Endoscopic assessment should ideally be done before treatment with serial biopsies, multiple photographs and an appropriate endoscopy scoring system used. However, this should not delay the start of therapy in those with a confirmed diagnosis of IBD.

b) Co-prescription of an immunomodulator may be less important when subcutaneous (SC) anti-TNF agents are used.

c) Consider using a JAK-inhibitors 1st line in patients unsuitable for or unwilling to take prednisolone. Consider Upadacitinib 1st line in patients with more severe disease flare / higher inflammatory burden. JAK-inhibitors may interact with some drugs (e.g. Carbamazepine and Phenytoin) so check with IBD Pharmacist if any concerns.

d) The MHRA advice about the use of JAK-inhibitors with regard to venous thrombo-embolism, major adverse cardiovascular events and malignancies should be adhered to and discussed with patients. It should only be used in those over 65y, current or previous smoker and those with other risk factors for cardiovascular disease or malignancy if no other alternative exists.

e) Consider Vedolizumab 1st line and Ustekinumab 2nd line in the elderly/frail, those with a past history of cancer or significant co-morbidity that would make other first line options unsuitable.

f) Adalimumab use in UC should be reserved for those patients who have achieved deep remission on Infliximab but have secondary loss of response due to immunogenicity.

g) Ozanimod may be appropriate for use in selected patients including those with co-existing multiple sclerosis where it may provide dual benefit.

h) Thiopurine monotherapy has a limited role in the management of IBD but remains an option as maintenance therapy in some patients with steroid-responsive but steroid-dependent UC.

i) Thiopurines should be used with caution in Epstein-Barr Virus (EBV) negative young males, history of lymphoma, skin cancer, cervical neoplasia and those >50 years.

j) Define treatment goals at the start of treatment which for most patients should be steroid free, clinical and biochemical remission. Non-response should precipitate treatment change and not procrastination.

k) The subsequent drug choice should take in to account any initial response to existing treatment including symptoms and objective markers of response together with therapeutic drug monitoring where available. Primary non-response is often best addressed by moving treatment to a different class of drug.

Factors to Consider When Making Treatment Choices

1. Route of administration
2. Speed of response
3. Potential immunogencity and need for combination therapy
4. Family planning – consider avoiding JAK-inhibitors or Ozanimod in females planning pregnancy within 5 years
5. Side effects including risk of cancer
6. Persistence of drug therapy
7. Availability of infusion facilities and TDM
8. Extra-intestinal manifestations and co-existing immune-mediated inflammatory diseases with the potential for dual benefit from some treatments
9. Overall Cost