

Figure 1. Clinical decision support tool for use and positioning of advanced therapies in the management of adult outpatients with moderate to severely active ulcerative colitis.

Adult outpatients with moderate-to-severely active Crohn’s Disease

- Moderate to severely active CD** defined as:
- Moderate to severe abdominal pain and/or diarrhea due to inflammation
 - Mild symptoms, with high burden of inflammation
 - Patients with corticosteroid-dependence, or refractory to oral corticosteroids
 - Significant extent of disease or upper gut involvement

SUGGEST early use of advanced therapies, rather than step up after corticosteroids and/or immunomodulator monotherapy
(Conditional recommendation, very low certainty of evidence)

RECOMMEND using any of the following, over no treatment:
Infliximab, adalimumab, ustekinumab, risankizumab, guselkumab, mirikizumab, or upadacitinib*
(Strong recommendation, moderate to high certainty of evidence)

SUGGEST using any of the following, over no treatment:
Certolizumab pegol, vedolizumab
(Conditional recommendation, moderate certainty of evidence)

Implementation considerations:

1. Biosimilars of infliximab, adalimumab, and ustekinumab can be considered equivalent to their originator drug in their efficacy in terms of therapy selection.
2. Subcutaneous formulations of infliximab and vedolizumab have shown comparable efficacy to the respective intravenous maintenance doses.
3. In some patients, particularly those with more severe disease, extended induction regimens or dose escalation may be beneficial for certain agents.
4. There are two dosing options available for maintenance therapy for risankizumab, guselkumab and upadacitinib. Higher maintenance doses may be preferred in patients with high burden of inflammation and/or more severe disease, and those who have previously failed TNF antagonists.

Advanced therapy-naïve patients (First-line therapy)

SUGGEST using a HIGHER efficacy rather than a lower efficacy medication.
(Conditional recommendation, low to high certainty of evidence)

HIGHER EFFICACY MEDICATIONS: Infliximab, Adalimumab, Vedolizumab, Ustekinumab, Risankizumab, Mirikizumab, Guselkumab

LOWER EFFICACY MEDICATIONS: Certolizumab Pegol, Upadacitinib*

Prior exposure to one or more advanced therapies, particularly TNF antagonists

SUGGEST using a HIGHER efficacy, or INTERMEDIATE efficacy medication, rather than a lower efficacy medication. (Conditional recommendation, low to moderate certainty of evidence)

HIGHER EFFICACY MEDICATIONS: Adalimumab, Risankizumab, Guselkumab, Upadacitinib

INTERMEDIATE EFFICACY MEDICATIONS: Ustekinumab, Mirikizumab

LOWER EFFICACY MEDICATIONS: Certolizumab Pegol, Vedolizumab

*The FDA label recommends the use of JAK inhibitors only in patients with prior failure or intolerance to TNF antagonists.