# Record of the Gastrointestinal Advisory Committee Meeting held on 13 March 2026

Gastrointestinal Advisory Committee records are published in accordance with the Terms of Reference for the Specialist Advisory Committees 2021.

**Note that this document is not necessarily a complete record of the Gastrointestinal Advisory Committee meeting**; only the relevant portions of the meeting record relating to Gastrointestinal Advisory Committee discussions about an application or Pharmac staff proposal that contain a recommendation are generally published.

The Gastrointestinal Advisory Committee may:

(a) recommend that a pharmaceutical be listed by Pharmac on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that Pharmac decline to list a pharmaceutical on the Pharmaceutical Schedule.

Pharmac Advisory Committees make recommendations, including priority, within their therapeutic groups of interest.

The record of this Advisory Committee meeting will be reviewed by PTAC at an upcoming meeting.

Specialist Advisory Committees and PTAC may differ in the advice they provide to Pharmac, including recommendations' priority, due to the committees' different, if complementary, roles, expertise, experience, and perspectives.

Pharmac is not bound to follow the recommendations made below. Applications are prioritised by Pharmac against other funding options and progressed accordingly. The relative priority of any one funding choice is dependent on a number of factors, including (but not limited to) the recommendation of PTAC and/or Specialist Advisory Committees, the mix of other applications being assessed, the amount of funding available, the success of commercial negotiations and/or the availability of clinical data.

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## 1. Attendance

**Present**
Bruce King – Chair
Catherine Stedman
James Fulforth
James Le Fevre
Michael Shultz
Murray Barclay
Sarah McLean-Orsborn

**Apologies**
Jon Bishop
Russell Walmsley

## 2. The role of Specialist Advisory Committees and records of meetings

2.1. This meeting record of the Gastrointestinal Advisory Committee is published in accordance with the Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) 2021 and Specialist Advisory Committees 2021.Terms of Reference describe, *inter alia*, the establishment, activities, considerations, advice, and the publication of such advice of Specialist Advisory Committees and PTAC.

2.2. Conflicts of Interest are described and managed in accordance with section 6.4 of the SAC Terms of Reference.

2.3. The Gastrointestinal Advisory Committee is a Specialist Advisory Committee of Pharmac. The Gastrointestinal Advisory Committee, PTAC and other Specialist Advisory Committees have complementary roles, expertise, experience, and perspectives. The Gastrointestinal Advisory Committee and other Specialist Advisory Committees may therefore, at times, make recommendations for treatments for the Gastrointestinal Therapeutic Group that differ from PTAC's, including the priority assigned to recommendations, when considering the same evidence. Likewise, PTAC may, at times, make recommendations for treatments for the Gastrointestinal

Therapeutic Group that differ from the Gastrointestinal Advisory Committee's, or Specialist Advisory Committees may make recommendations that differ from other Specialist Advisory Committees'.

Pharmac considers the recommendations provided by both the Gastrointestinal Advisory Committee and PTAC and any other relevant Specialist Advisory Committees when assessing applications for treatments for the Gastrointestinal Therapeutic Group.

## 3. Welcome and introduction

3.1. The Chair welcomed the Committee with a karakia followed by whakawhanaungatanga.

## 4. Pharmac update

4.1. The Committee noted the Pharmac update.

4.2. The Committee acknowledged the recent changes in Pharmac kaimahi and ongoing leadership and strategic changes, including the new Chief Executive who started at Pharmac in mid-September and the recent release of the 2025/2026 Letter of Expectations.

4.3. The Committee noted an update about the organisation reset programme and acknowledged that more information can be found on the Pharmac Website.

4.4. The Committee noted the following updates to the record processes:

4.4.1. 30-day provisional recommendation trial update.

4.4.2. The Committee noted the removal of second committee reviews, with targeted reviews to be used as required, and supported the use of direct engagement with Discussion Leads to resolve outstanding issues.

4.5. The Committee acknowledged that Pharmac is working on process improvements to improve timelines and transparency including piloting new approaches to seek clinical advice.

## 5. Matters Arising – Biologics Procurement update

### Discussion

5.1. The Committee noted that Pharmac has previously run request for proposal (RFP) processes for a number of biologic treatments including adalimumab, rituximab and infliximab.

5.2. The Committee noted the biologic treatments to be included in the 2026 hospital biologics RFP process, and that the RFP would be for principal supply status for the relevant items. Members noted that the potential outcomes for each treatment will depend on the bids received.

5.3. The Committee noted Pharmac's RFP process allows the agency to compete the market for biosimilar therapies when there are several suppliers who may be able to supply. The Committee noted RFP evaluation criteria would include aspects including costs and savings, supply continuity capability/planning, and implementation plans and education.

5.4. The Committee considered that, in the event of a brand change for infliximab, an exemption allowing patients who lose response to switch back to the reference brand of infliximab would be required. Relevant patient numbers are likely to be within standard alternative brand allowance parameters.

5.5. The Committee considered that if a subcutaneous brand of infliximab were to be funded, approximately 50-80% of individuals would be expected to uptake subcutaneous administration.

5.6. The Committee considered subcutaneous infliximab has a range of suitability benefits, such as shorter administration times for individuals and decreased pressure on infusion services. The Committee considered the suitability advantages associated with subcutaneous administration would be particularly meaningful for people who live rurally and would contribute to uptake on the higher end of the expected range.

5.7. The Committee noted that the optimised pharmacokinetic profile associated with subcutaneous administration may enable patients to achieve a similar outcome with standard dosing as with escalated IV administration dosing.

5.8. The Committee noted that some individuals value the wrap-around care that can be part of receiving an infusion and that delivery via infusion provided clarity around adherence.

5.9. The Committee noted that in the event a subcutaneous brand of infliximab was funded, an IV presentation of infliximab would need to remain available for a proportion of patients for whom self-administration could be difficult or otherwise not be clinically appropriate.

5.10. The Committee considered that support with implementation by the relevant supplier would be valuable if individuals on maintenance therapy would need to transition to a different product or presentation. Implementation of a subcutaneous presentation would require training with individuals on how to administer the medicine.

5.11. The Committee noted that open listing of rituximab would result in a small increase in use by gastroenterologists for hepatitis, lymphoproliferative disorder, and potentially a variety of other niche indications.

5.12. The Committee considered it had no concerns in relation to the proposed RFP process for tocilizumab.

## 6. Matters Arising – Biologics escalated dosing for Inflammatory Bowel Disease – infliximab and vedolizumab update advice to inform budget impact assessment

### Discussion

*Infliximab*

6.1. The Committee noted that Pharmac received a clinician-initiated application in 2018 proposing amendments to the Special Authority criteria for infliximab in the treatment of inflammatory bowel disease (IBD), including an amendment that would enable dose escalation.

6.1.1. Members noted the proposal was first reviewed by the Gastrointestinal Advisory Committee (formerly the Gastrointestinal Subcommittee) at its meeting in October 2018, who recommended amending renewal criteria for adalimumab and infliximab in gastrointestinal indications, to allow higher maximum doses in patients who have undergone therapeutic drug monitoring (TDM) and where a recent test indicated a higher dose would be beneficial.

6.1.2. Members noted that the October 2018 recommendation was not accepted by PTAC at its meeting in February 2019, which led to the proposal's consideration by PTAC in November 2019, where the Committee recommended the funding criteria for infliximab for currently funded inflammatory bowel disease indications be amended to allow for a higher

maximum dose (up to 10mg/kg every 8 weeks or equivalent as clinically indicated), with a **medium** priority.

6.1.3. The Committee noted that the proposal regarding infliximab dose escalation was ranked on Pharmac's Options for Investment list in June 2020. The proposal was subsequently removed from the OFI pending further assessment. The Committee noted that consideration at this meeting was to provide advice to support Pharmac's ongoing assessment.

6.2. The Committee noted that some individuals receive infliximab doses greater than 10 mg/kg every eight weeks and that the proportion expected to require such dosing remains uncertain. However, members noted that in settings without dose restrictions and with access to TDM, the average infliximab dose across the IBD population is approximately 7.5 mg/kg every eight weeks (Clemente Bautista et al. Pharmaceutics. 2024;16:1577). The Committee considered that an average dose of 7.5 mg/kg every eight weeks would be a reasonable estimate of infliximab use were unrestricted dose escalation to be funded.

6.3. The Committee discussed the likely uptake of escalated infliximab dosing in people who experience a loss of response. Members noted that it is best practice to use TDM to guide dosing decisions in the event of loss of response to infliximab (e.g. people with antibody mediated loss of response may not receive escalated dosing). The Committee noted that between a third and half of people experiencing loss of response would be antibody negative. The Committee noted that between 30-50% of people lose response to infliximab depending on the time horizon, and that in settings with TDM, approximately 20-30% of all people using infliximab would be expected to trial escalated dosing. The Committee noted that this proportion would be higher in settings without TDM. The Committee considered that TDM is widely used by gastroenterologists in NZ, and that it would be appropriate to assume that TDM is being used to guide escalated dosing in NZ.

6.4. The Committee considered it would not expect uptake of escalated dosing to differ by treatment line.

6.5. The Committee noted TDM improves the cost-effectiveness of using infliximab in the IBD setting.

6.6. The Committee noted that Pharmac received an application requesting funding for a subcutaneous formulation of infliximab, which PTAC recommended for funding with a **high priority** at its meeting in August 2023. The proposal is currently ranked to Pharmac's Cost-Neutral / Cost-Saving priority list.

6.7. The Committee considered that the existing infliximab special authority criteria regarding dose escalation for IBD are not appropriate. Members noted that limiting access to escalated dosing to three doses may allow some people who experienced inadequate benefit on standard dosing to trial a temporarily effective higher dose, only to be required to return to a dose that had already proven ineffective.

6.8. The Committee discussed escalated dosing in the context of subcutaneous infliximab.

6.8.1. Members considered that the proportion of people using subcutaneous infliximab who would require escalated dosing would be lower than for those receiving intravenous infliximab. The Committee considered that approximately 10–15% of people using subcutaneous infliximab may be expected to trial escalated dosing. The Committee considered that rates of escalated dosing would likely be lower in a real world setting than in the LIBERTY-UC and LNERTY-CD studies, where dose escalation rates were 28% for UC and 17% for CD (Danese et al. Gastroenterology. 2024;166:S13).

6.8.2. The Committee was uncertain regarding what the average dose of

subcutaneous infliximab would be in a setting with no restrictions on dose escalation but considered the proportion would be less than that associated with intravenous infliximab.

6.8.3. The Committee reiterated their concerns regarding the existing infliximab special authority criteria, and considered they should not be used to restrict access to escalated dosing on subcutaneous infliximab if the proposal were to be funded. The Committee considered if subcutaneous infliximab were funded and the restrictions regarding escalated dosing had to be maintained, then the equivalent dosing scheme for the subcutaneous administration would be 6 months of weekly dosing with subcutaneous infliximab.

6.8.4. The Committee considered that individuals receiving adequate benefit from escalated dosing with intravenous infliximab may be less likely to switch to subcutaneous administration were it to become available. However, the Committee was made aware of evidence that it was possible to switch from escalated dosing on intravenous infliximab to standard subcutaneous dosing without observing a material loss of response. The Committee considered this to be associated with the improved pharmacokinetic profile of subcutaneous administration compared to intravenous administration. The Committee noted that if access to escalated dosing were not available, most people requiring escalated dosing would likely switch to subcutaneous infliximab.

*Vedolizumab*

6.9. The Committee noted that vedolizumab has been funded since February 2023 for the treatment of IBD that has not responded to prior treatments, subject to Special Authority Criteria.

6.10. The Committee noted Pharmac received correspondence from vedolizumab's supplier and from the New Zealand Inflammatory Bowel Disease Nurses Group requesting the eligibility criteria be amended to enable dose escalation (300 mg every 4 weeks) for people whose disease has not responded (primary non-response) or lost response to treatment (secondary loss of response). Vedolizumab dose-escalation for IBD was considered by PTAC at its meeting in February 2024, PTAC made the following recommendations:

6.10.1. The Committee **recommended** the funding criteria for vedolizumab for currently funded inflammatory bowel disease indications be amended to allow a fourth induction dose at week 10, and subsequently a maintenance dose frequency escalation (up to four-weekly dosing as clinically indicated), in individuals with primary non-response to vedolizumab at week six, with a **low** priority.

6.10.2. The Committee **recommended** that the funding criteria be amended to allow for a maintenance dose frequency escalation (up to four-weekly dosing as clinically indicated) in individuals with secondary loss of response to vedolizumab, with a **high** priority.

6.11. The Committee was made aware of the findings of the ENTERPRET study (Jairath et al. Clin Gastroenterol Hepatol. 2024;22:1077-86), a randomised controlled trial that investigated vedolizumab dose escalation in the treatment of ulcerative colitis among individuals who had early nonresponse. Participants receiving standard vedolizumab dosing who demonstrated high drug clearance at week 5 (serum concentration <50 µg/mL) and non-response at week 6 were randomised to receive either escalated dosing or continue standard dosing. There was no statistically significant difference between the study arms regarding the proportion of participants achieving endoscopic improvement at week 30. The Committee considered these findings to align with the

growing body of evidence suggesting vedolizumab dose escalation is unlikely to have benefit for those with early non-response.

6.12. The Committee considered that among the proportion of people with a primary non-response to vedolizumab the proportion expected to receive dose escalation would be very small were it funded without dose restriction. The Committee considered it was not common practice in New Zealand to escalate people who experience primary non-response.

6.13. The Committee considered that therapeutic drug monitoring is not yet widely implemented for vedolizumab in New Zealand. The Committee noted that validated pharmacokinetic targets for vedolizumab have been established, and that approximately 30% of people would not meet the therapeutic window on standard dosing. The Committee considered that dose escalation can have a meaningful impact for individuals who are not achieving the therapeutic target on standard dosing.

6.14. The Committee considered there would be a small group of people who lose response to vedolizumab towards the end of the dose interval who would be likely to receive escalated dosing with vedolizumab. The Committee noted available evidence and suggested that approximately 20–30% of people may receive dose escalation in settings without dose restrictions (Panaccione et al. Adv Ther. 2023;40:2051-81). The Committee considered that uptake in the New Zealand context may be toward the lower end of this range, and that the expectations of benefit would be lower than with infliximab dose escalation.

6.15. The Committee was made aware of the findings of Mcnamara et al. J Crohns Colitis. 2024;18:i1732, which reported that in an Australasian cohort of people receiving vedolizumab for IBD, over a quarter received vedolizumab dose escalation. In this study, vedolizumab dose escalation correlated with improved endoscopic and biomarker remission rates at 12 months with reduced steroid use. The Committee considered the body of evidence regarding vedolizumab dose escalation generally has not demonstrated improvements in endoscopic/ biomarker-related outcomes, and that there remains uncertainty regarding the overall health benefits associated with dose escalation.

## 7. Matters Arising – Adalimumab, infliximab, vedolizumab for patients requiring EEN

### Recommendations

7.1. The Committee recommended the following amendments (in **bold**) to the infliximab Special Authority Criteria for children with Crohn's disease:

> Initial application – Crohn's disease (children)
>
> Applications from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
>
> All of the following:
>
> 1. Paediatric patient has active Crohn's disease; and
> 2. Either:
>
>  2.1 Patient has a PCDAI score of greater than or equal to 30; or
>
>  2.2 Patient has extensive small intestine disease; and
> 3. Patient has tried, but experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and **either** corticosteroids **or a course of Exclusive Enteral Nutrition (EEN)**, or
> 4. **Immunomodulators, corticosteroids and Exclusive Enteral Nutrition (EEN) are contraindicated.**

7.2. The Committee recommended the following amendments (in **bold**) to the adalimumab Special Authority Criteria for children with Crohn's disease:

> Initial application – Crohn's disease (children)
>
> Applications from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
>
> All of the following:
>
> 1. Paediatric patient has active Crohn's disease; and
> 2. Either:
>
> 2.1 Patient has a PCDAI score of greater than or equal to 30; or
>
> 2.2 Patient has extensive small intestine disease; and
>
> 3. Patient has tried, but experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and **either** corticosteroids **or a course of Exclusive Enteral Nutrition (EEN)**, or
>
> **4. Immunomodulators, corticosteroids and Exclusive Enteral Nutrition (EEN) are contraindicated**

7.3. The Committee recommended the following amendments (in **bold**) to the vedolizumab Special Authority Criteria for children with Crohn's disease:

> Initial application – Crohn's disease (children)
>
> Applications from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:
>
> All of the following:
>
> 1. Paediatric patient has active Crohn's disease; and
> 2. Either:
>
> 2.1 Patient has had an initial approval for prior biologic therapy and has experienced intolerable side effects of insufficient benefit to meet renewal criteria (unless contraindicated); or
>
> 2.2 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
>
> 2.3 Patient has extensive small intestine disease; and
>
> 3. **Either:**
>
> 3.1 **Patient has tried, but experienced an inadequate response to, or intolerable side effects from, prior therapy with either immunomodulators, corticosteroids or a course of Exclusive Enteral Nutrition (EEN), or**
>
> 3.2 **Immunomodulators, corticosteroids and Exclusive Enteral Nutrition (EEN) are contraindicated**

## Discussion

7.4. The Committee noted that access to first-line biologic therapies for Crohn's disease is currently contingent on prior treatment with immunomodulators and corticosteroids.

7.5. The Committee noted consultation feedback relevant to exclusive enteral nutrition (EEN) during the 2021 adalimumab request for proposals (RFP), wherein paediatric gastroenterologists considered that the current funded access criteria for adalimumab (and similarly infliximab and vedolizumab) do not adequately reflect contemporary management of paediatric Crohn's disease.

7.5.1. The Committee considered the feedback noted that EEN is an appropriate alternative to corticosteroids, such that children could qualify for biologic therapy after receiving both immunomodulators, and either EEN or corticosteroids.

7.6. The Committee noted that amending the access criteria to recognise use of EEN as an alternative to corticosteroids would be unlikely to materially change the number of paediatric patients who go on to receive biologic treatment.

7.6.1. The Committee further noted that children who receive insufficient benefit

from, or relapse following, EEN would progress to biologic therapy regardless of whether corticosteroids are used.

7.6.2. The Committee noted that corticosteroid use in paediatrics is typically avoided, where possible, due to growth-related and other harms.

7.6.3. The Committee considered that approximately half of children treated with EEN experience insufficient benefit or relapse, and that current corticosteroid prescribing practices were considered to result in a short delay (approximately one month) to biologic initiation rather than acting as a clinically appropriate long-term alterative to biologic treatment.

7.6.4. The Committee noted that avoiding corticosteroid exposure in children, where clinically appropriate, is associated with positive health outcomes, particularly given the known adverse effects of corticosteroids.

7.7. The Committee noted that, from both equity and clinical perspectives, it would be reasonable for the adult Special Authority Criteria to also recognise EEN as an alternative to corticosteroids for induction therapy, analogous to paediatric Special Authority Criteria amendments.

7.7.1. Members considered that individuals in their late teens often meet adult access criteria but may still use EEN as part of their clinical management.

7.7.2. The Committee noted that recognising EEN as an alternative induction option, for both children and adults, would provide additional clinical flexibility without materially affecting overall biologic utilisation.