Canada's Drug and Health Technology Agency

Biologics in Plaque Psoriasis

FMEC Responses to Questions From the Drug Programs

Table 1: Response Summary

Drug program questions	FMEC response
The review was focused on the adult population. Are there any considerations that could be extrapolated to the pediatric population (i.e., patients younger than 18 years)? The following biologics have approval for use in pediatrics in their product monographs: etanercept, ustekinumab, ixekizumab, and secukinumab.	FMEC agreed with the clinical experts that the evidence in this review would not be sufficient to answer this question.
Initial coverage criteria across jurisdictions generally require failure, intolerance, or contraindications to systemic therapies like methotrexate and cyclosporine, and lack of access to phototherapy. Stakeholder input from patient organizations has asked to "expand the project scope to include an evaluation of the safety and efficacy of newer biologics compared to 'pre-requisite therapies'." Has there been a change in the evidence to warrant a change in prerequisite therapies?	FMEC noted that the evidence in this review would not be sufficient to answer this question.
If there is rationale to prioritize new-generation biologics (anti-IL-17 and anti-IL-23) before old-generation biologics (anti-TNF and anti-IL-12/23), should the criteria be that at least 2 new-generation biologics are trialled before an old-generation biologic? This way, 2 biologics allow for the trial of 1 drug from the anti-IL-17 class and 1 drug from the anti-IL-23 class.	FMEC noted that the rationale for the use of multiple options from the class of new-generation biologics was uncertain. It was discussed that trialling 1 option from each new-generation class unnecessarily limits therapeutic options for prescribers. Therefore, FMEC agreed to trialling just 1 option from either class of anti-IL-17 or anti-IL-23.
Infliximab appears to stand out amongst the old-generation biologics (anti-TNF and anti-IL-12/23), yet there is a lack of direct evidence to support it and there is very little utilization. Is there reason to believe that infliximab is more comparable to the new-generation biologics (anti-IL-17 and anti-IL-23)?	FMEC noted that they could not comment beyond the data that suggested that there is comparable benefit under the parameters of the systematic review. However, 1 manufacturer identified that there are additional data that suggest that infliximab may not have a comparable benefit.
If the net price of old-generation biologics (anti-TNF and anti-IL-12/23 [e.g., biosimilars]) is lower than the net price of new-generation biologics (anti-IL-17 and anti-IL-12/23), is there reason to warrant a change in funding status or criteria for old-generation biologics?	FMEC noted that although biosimilar costs for old-generation drugs may be lower, there is no reason to prioritize them on the basis of cost alone, given the improved efficacy of new-generation drugs compared to old-generation drugs.

Drug program questions	FMEC response
One of the key findings from this streamlined class review was that a policy prioritizing the use of new-generation biologics (anti-IL-17 and anti-IL-12/23) compared to the status quo could result in budget neutrality or modest savings for drug programs. However, annual costs of new-generation biologics were compared to the annual costs of branded versions of old-generation biologics anti-TNF and anti-IL-12/23 (vs. annual costs of biosimilars), and the utilization analysis assessed average costs from claims in 2020, which may not fully capture the recent experience associated with savings accrued through jurisdictional biosimilar switching initiatives. If the net annual costs of new-generation biologics exceed the net annual costs of older-generation biosimilars, how would value be assessed, given there is no CUA in this case?	In the absence of a CUA, FMEC concluded that even if there was potentially no cost-savings or a slight cost increase attached to the prioritized use of new-generation biologics, the value appears to be demonstrated on clinical grounds alone. FMEC noted that there are costs associated with the use of lower-efficacy agents (e.g., dose optimization) that were not considered but are relevant in clinical practice.
Forcing prescribers to tier 1 biologic over another could be an implementation challenge. Importantly, preferential listing of products within the same therapeutic space on any formulary must be carefully balanced with patient preferences for treatment, product access, and prescriber autonomy for the choice of therapies appropriate for individual patients. Is that threshold met in this review?	FMEC concurs with the clinical experts that the threshold was met in this review.
Guselkumab and certolizumab are currently not funded for plaque psoriasis. Are they relevant comparators for this review?	FMEC noted that as long as there is no distinct difference between biologics within a class, which is what was assumed, then the data remain valid for comparator purposes irrespective of funding status.

CUA = cost utilization analysis; FMEC = Formulary Management Expert Committee; IL = interleukin; TNF = tumour necrosis factor.