

## INTRODUCTION

- Remicade® (infliximab) was first approved in Canada in June 2001 for Crohn's disease & subsequently received approval for 4 additional indications.
- Since then, 5 associated biosimilars made their entry to the Canadian market, their uptake aided by implementation of biosimilar switching policies across the country.
- In addition to increasing biosimilar uptake through switching policies, other initiatives have been implemented to reduce barriers to accessing biosimilars.
- Canada's Drug Agency (CDA)'s streamlined biosimilar review process, initially launched Feb. 2018 to evaluate & issue reimbursement recommendations, was no longer offered as of June 1, 2019, to prevent potential delays to access to new biosimilars.
  - As such, submissions for biosimilars are currently filed directly with pan-Canadian Pharmaceutical Alliance (pCPA) & jurisdictions unless there is a special case where the biosimilar should be reviewed by CDA (e.g., new indication not approved for the biologic originator or a new formulation).
- While CDA no longer reviews biosimilars, the *Institut national d'excellence en santé et services sociaux* (INESSS) continues to review biosimilars; the process for listing & coverage of biosimilars by the Quebec public drug plan remains unmodified.

## OBJECTIVE

To describe Canadian health technology assessment (HTA) decisions, pricing negotiations, and reimbursement of originator biologic Remicade® (infliximab) and associated biosimilars across indications and jurisdictions.

## METHODS

- HTA recommendations for Remicade® and associated biosimilars were retrieved from the CDA website; corresponding submissions for these products were retrieved from the INESSS website.
- Information on the following were retrieved from CDA HTA reports:
  - Product information (brand or generic drug name, manufacturer, dosage, route of administration, & indication)
  - Clinical evidence submitted (pivotal trial name, study design, trial phase, comparator)
  - Original & updated reimbursement decisions (review type, indication under review, recommendation type)
  - Reimbursement conditions (general criteria, condition, initiation, renewal, discontinuation, prescribing, pricing)
- Reimbursement decisions by public drug plans and pCPA negotiation status for these products were also retrieved.

## RESULTS

### Identification of CDA/INESSS recommendations

- Eight relevant CDA HTA reports were identified (for: Remicade® (1), Inflectra® (2), Remsima™ SC (3; & 1 withdrawn), Renflexis® (1)).
- All 6 CDA HTAs evaluating infliximab biosimilars for up to 6 indications concluded with positive recommendations. One biosimilar, Remsima™ SC, was withdrawn by the manufacturer (Fresenius). In corresponding INESSS submissions, all biosimilars received a positive recommendation. INESSS conducted HTAs for 2 additional biosimilars (Ixfi® and Avsola®), which both received a positive recommendation. Remicade® received a negative recommendation from CDA & INESSS for the treatment of ulcerative colitis (UC) (Table 1).

Table 1. CDA/INESSS recommendations concordance for infliximab & biosimilars

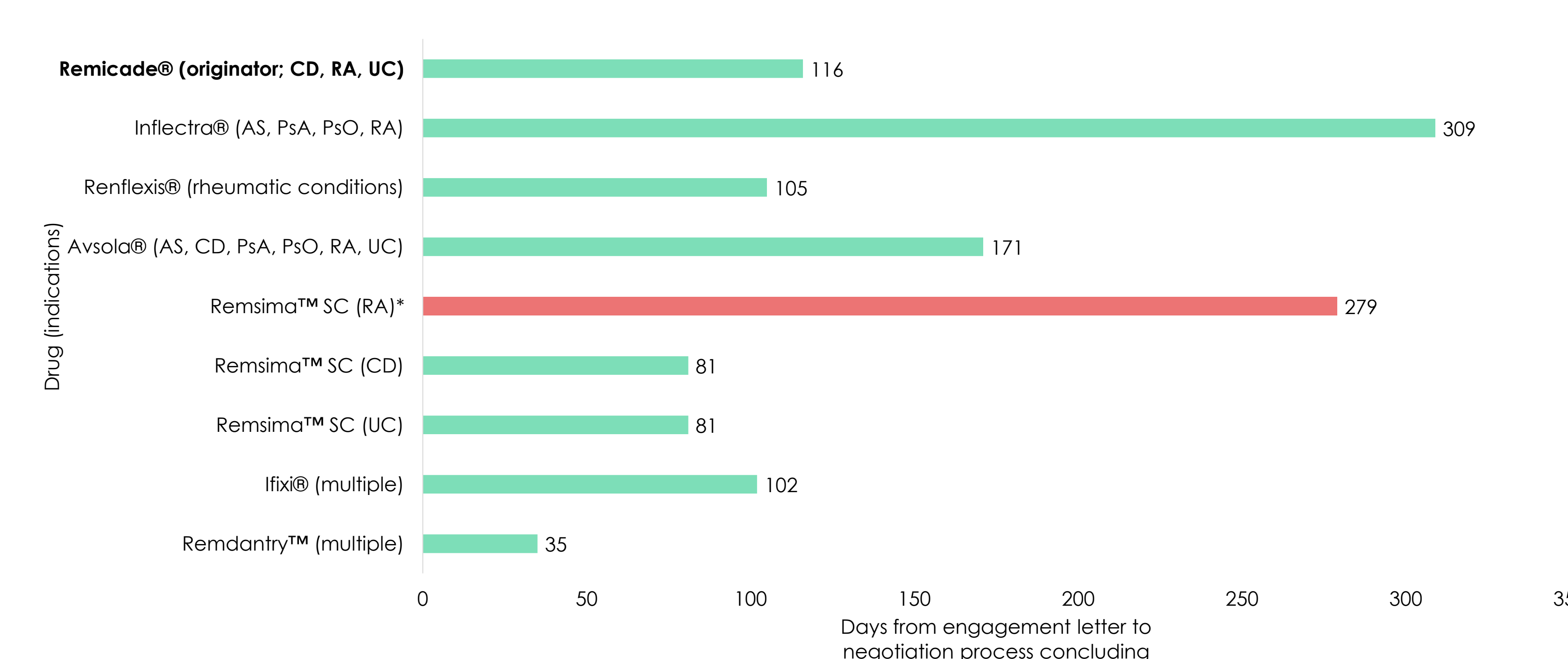
Drug (indications)	CDA recommendation	INESSS recommendation	Concordance / Discordance
Remicade® (UC)	Do not reimburse	Do not reimburse	Concordant (Negative)
Remicade® (AS, CD, PsA, PsO, RA)	N/A	Reimburse with conditions	N/A
Inflectra®/ Remdantry™ (AS, CD, PsA, PsO, RA, UC)*	Reimburse with clinical criteria and/or conditions	Reimburse with conditions	Concordant (Positive)
Renflexis® (AS, CD, PsA, PsO, RA, UC)	Reimburse with clinical criteria and/or conditions	Reimburse with clinical criteria and/or conditions	Concordant (Positive)
Avsola® (AS, CD, PsA, PsO, RA, UC)	N/A	Reimburse with conditions	N/A
Remsima™ SC (CD, RA, UC)	Reimburse with clinical criteria and/or conditions	Reimburse with conditions	Concordant (Positive)
Ixfi® (AS, CD, PsA, PsO, RA, UC)	N/A	Reimburse with conditions	N/A

Note: this table focuses on adult indications only. \* Inflectra® was discontinued and replaced by Remdantry™. Abbreviations: AS: ankylosing spondylitis; CD: Crohn's disease; CDA: Canada's Drug Agency; INESSS: Institut national d'excellence en santé et en services sociaux; N/A: not applicable; PsA: psoriatic arthritis; PsO: plaque psoriasis; RA: rheumatoid arthritis; UC: ulcerative colitis.

### pCPA negotiations

- Inflectra®, the first biosimilar introduced to market, had the longest pCPA negotiation process duration (309 days) compared with Remicade® and other biosimilars (Fig. 1).

Figure 1. Days from engagement letter to negotiation process concluding for infliximab and its biosimilars



Received an LOI (green bar), Did not receive an LOI (red bar). \* Remsima™ SC for the RA indication was re-submitted for pCPA negotiations on November 26, 2024, and received an LOI on the same day.<sup>3</sup> Abbreviations: AS: ankylosing spondylitis; CD: Crohn's disease; LOI: letter of intent; PsA: psoriatic arthritis; PsO: plaque psoriasis; RA: rheumatoid arthritis; UC: ulcerative colitis.

### Public drug plan listings

- Biosimilar switching policy has been implemented in all provinces, the Northwest Territories (NWT), Yukon, and federal Non-Insured Health Benefits (NIHB) program (Table 2).
- As of Jan. 2026, 5 infliximab biosimilars were covered by all provincial/territorial drug plans, except Yukon, which only covered 2 biosimilars (Renflexis® & Remdantry™). Remicade® was only covered by 5 public drug plans for select indications, which require special authorization for reimbursement (Table 2).

Table 2. Public drug plan listing status for infliximab and its biosimilars

	BC	AB	SK	MB	ON	QC	NB	NS	PEI	NL	YT	NWT	NIHB	CAF	VAC
Remicade®	Not listed	Not listed	Not listed	Not listed	Not listed	Listed for most (≥50%) indications	Not listed	Not listed	Not listed	Not listed	Listed for all indications	Listed for most (≥50%) indications	Listed for all indications	Listed for all indications	Listed for all indications
Inflectra®/ Remdantry™* Renflexis®	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications
Avsola®	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Not listed	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications
Remsima™ SC	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications	Listed for most (≥50%) indications
Ixfi®	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications	Listed for all indications

Listed for all indications (green), Listed for most (≥50%) indications (yellow), Not listed (red), Information not available (grey). Note: this figure focuses on adult indications only. \* Inflectra® was discontinued and replaced by Remdantry™. Abbreviations: AB: Alberta; BC: British Columbia; CAF: Canadian Armed Forces; MB: Manitoba; NB: New Brunswick; NIHB: Non-Insured Health Benefits; NL: Newfoundland and Labrador; NS: Nova Scotia; NWT: Northwest Territories; ON: Ontario; QC: Quebec; SK: Saskatchewan; VAC: Veterans Affairs Canada; YT: Yukon Territory.

## DISCUSSION & CONCLUSIONS

- Biosimilar market entry has provided patients with additional treatment options for indications that were not originally reimbursed by public drug plans for the originator.
- Policies supporting biosimilar use have allowed provinces and federal drug plans to expand access to biologic therapies for more patients within cost constraints.
- Biosimilar access has also improved due to a shorter overall process, including shorter pCPA negotiations.

## REFERENCES

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## DISCLOSURES

Authors have no conflicts of interest to declare.

