Canada's Drug and
Health Technology Agency

Updated CADTH Reimbursement Recommendations From a Streamlined Drug Class or Therapeutic Review

Biologics for Plaque Psoriasis

Streamlined Drug Class Review

On August 24, 2023, the Formulary Management Expert Committee (FMEC) deliberated on a streamlined drug class review for biologics in plaque psoriasis (TS0001).

Rationale for Updates to CADTH Reimbursement Recommendations

FMEC concluded that the current evidence supports the improved efficacy of anti-interleukin (IL)-17 and anti-IL-23 biologics compared to anti-tumour necrosis factor (TNF) and anti-IL-12/23 biologics in the treatment of plaque psoriasis.

As described in the procedures, FMEC may provide updates to previous CADTH Reimbursement Recommendations, which can include the recommendation status and/or criteria or conditions, as appropriate.

FMEC deemed it appropriate to update the previous criteria or conditions set out by the Canadian Expert Drug Advisory Committee (CEDAC) or CADTH Canadian Drug Expert Committee (CDEC) for biologics in plaque psoriasis based on the conclusions of the streamlined drug class review.

Updates to CADTH Reimbursement Recommendations

The CADTH recommendations in this document now supersede the previously published recommendations for the following biologics: bimekizumab, tildrakizumab, certolizumab pegol, brodalumab, risankizumab, infliximab, guselkumab, ixekizumab, secukinumab, ustekinumab, adalimumab, and etanercept.

Refer to Table 1 for the updated CADTH Reimbursement Recommendations for these drugs, which includes the previous final recommendation (by CEDAC or CDEC) and update by FMEC.

Table 1

Why Did FMEC Make This Recommendation?

Generic name (brand name)	Indication under review and date final recommendation (CDEC) issued	Final recommendation (CEDAC or CDEC)	Addition to CEDAC or CDEC recommendation (by FMEC)
Bimekizumab (Bimzelx) **SR0698**	For the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. March 30, 2022	CDEC recommends that bimekizumab (Bimzelx) be reimbursed for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy only if the conditions listed are met. **Conditions for reimbursement** **Initiation:** Eligibility for reimbursement of bimekizumab should be based on the criteria used by each of the public drug plans for reimbursement of other IL-17 inhibitors for the treatment of adult patients with moderate to severe plaque psoriasis. **Renewal:** Bimekizumab should be renewed in a similar manner to other IL-17 inhibitors currently reimbursed for the treatment of adult patients with moderate to severe plaque psoriasis. **Prescribing:** Patients should be under the care of a dermatologist. Bimekizumab should not be used in combination with other biologic treatments for moderate to severe plaque psoriasis. **Pricing:** Price reduction. **Feasibility of adoption:** The feasibility of adoption of bimekizumab must be addressed. Bimzelx Reimbursement Recommendation	FMEC affirms that bimekizumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** For patients who are biologic-naive who have yet to be treated with any biologic, a drug from the anti-IL-17 or anti-IL-23 class should be trialled before a drug from the anti-TNF or anti-IL-12/23 class (if the FMEC pricing condition is met). **Pricing:** Drug plan cost per patient should be no more than the least expensive biologic (originator or biosimilar) used to treat moderate to severe plaque psoriasis.

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Tildrakizumab (Ilumya) **SR0624**	Proposed: Adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. June 21, 2021	CDEC recommends that tildrakizumab (Ilumya) be reimbursed for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy only if the following conditions are met. **Conditions for reimbursement** **Initiation:** Eligibility for tildrakizumab should be based on the criteria used by each of the public drug plans for reimbursement of other biologics for moderate-to-severe plaque psoriasis. **Renewal:** Treatment with tildrakizumab may be renewed for patients who exhibit a response to treatment after 12 to 16 weeks. A response to treatment is defined as an achievement of at least a 75% reduction in the PASI score (PASI 75). **Prescribing:** Patient should be under the care of a dermatologist. Tildrakizumab should not be used in combination with other systemic or biologic treatments for moderate-to-severe plaque psoriasis. **Pricing:** The drug plan cost of tildrakizumab should not exceed the drug plan cost of treatment with the least costly biologic therapy reimbursed for the treatment of moderate-to-severe plaque psoriasis. Ilumya Reimbursement Recommendation	FMEC affirms that tildrakizumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** For patients who are biologic-naive who have yet to be treated with any biologic, a drug from the anti-IL-17 or anti-IL-23 class should be trialled before a drug from the anti-TNF or anti-IL-12/23 class (if the FMEC pricing condition is met). **Pricing:** Drug plan cost per patient should be no more than the least expensive biologic (originator or biosimilar) used to treat moderate to severe plaque psoriasis.

Generic name (brand name)	Indication under review and date final recommendation (CDEC) issued	Final recommendation (CEDAC or CDEC)	Addition to CEDAC or CDEC recommendation (by FMEC)
Certolizumab pegol (Cimzia) **SR0587**	Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy. November 20, 2019	Reimburse for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy if the following conditions are met: **Conditions for reimbursement** **Initiation criteria:** Adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy. **Discontinuation criteria:** Treatment should be discontinued if a response to treatment with certolizumab pegol has not been demonstrated by 16 weeks. A response to treatment is defined as an achievement of at least a 75% reduction in PASI score (PASI 75). **Prescribing conditions:** Patient should be under the care of a dermatologist. **Pricing conditions:** The drug plan cost of treatment with certolizumab pegol should result in cost-savings compared with the drug plan cost of treatment with the least costly alternative biologic therapy reimbursed for the treatment of moderate-to-severe plaque psoriasis. Cimzia Reimbursement Recommendation	FMEC affirms that certolizumab pegol should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** Drugs in the anti-TNF class (such as certolizumab pegol) could be considered for use if there is a contraindication, failure, or intolerance to a biologic from the anti-IL-17 or anti-IL-23 class.
Risankizumab (Skyrizi) **SR0583**	Treatment of moderate to severe plaque psoriasis in adults. May 24, 2019	List for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy if the following conditions are met. **Conditions:** In a manner similar to other biologics reimbursed for the treatment of moderate to severe plaque psoriasis. Treatment should be discontinued if a response to risankizumab has not been demonstrated by 16 weeks. The drug plan cost for risankizumab should not exceed the drug plan cost of treatment with the least costly biologic therapy reimbursed for the treatment of moderate to severe plaque psoriasis. Risankizumab Recommendations and Reasons	FMEC affirms that risankizumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** For patients who are biologic-naive who have yet to be treated with any biologic, a drug from the anti-IL-17 or anti-IL-23 class should be trialled before a drug from the anti-TNF or anti-IL-12/23 class (if the FMEC pricing condition is met). **Pricing:** Drug plan cost per patient should be no more than the least expensive biologic (originator or biosimilar) used to treat moderate to severe plaque psoriasis.

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Brodalumab (Siliq) **SR0547**	Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. June 20, 2018	List for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy if the following criteria and conditions are met. **Criteria:** Reimburse in a manner similar to other biologics reimbursed for the treatment of moderate to severe plaque psoriasis. Discontinue treatment if a response has not been demonstrated after 12 weeks to 16 weeks. **Condition:** Drug plan cost of treatment should not exceed the cost of the least expensive biologic therapy reimbursed for plaque psoriasis. Brodalumab Reimbursement Recommendation	FMEC affirms that brodalumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** For patients who are biologic-naive who have yet to be treated with any biologic, a drug from the anti-IL-17 or anti-IL-23 class should be trialled before a drug from the anti-TNF or anti-IL-12/23 class (if the FMEC pricing condition is met). **Pricing:** Drug plan cost per patient should be no more than the least expensive biologic (originator or biosimilar) used to treat moderate to severe plaque psoriasis.
Infliximab SB2 (Renflexis) **SE0532**	Treatment of adult patients with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy. For patients with chronic moderate plaque psoriasis, Renflexis should be used after phototherapy has been shown to be ineffective or inappropriate. When assessing the severity of psoriasis, the physician should consider the extent of involvement, location of lesions, response to previous treatments, and impact of disease on the patient's quality of life. February 20, 2018	List in accordance with the Health Canada-approved indications for the treatment of rheumatoid arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, fistulising Crohn's disease, adult and pediatric ulcerative colitis, psoriatic arthritis, and plaque psoriasis, if the following criterion and condition are met: **Criteria:** For use in patients for whom infliximab is considered to be the most appropriate treatment option. **Condition:** The cost of treatment with Renflexis should provide significant cost savings for jurisdictions compared with the cost of treatment with existing infliximab products. Renflexis Reimbursement Recommendation	FMEC affirms that infliximab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** Drugs in the anti-TNF class (such as infliximab) could be considered for use if there is a contraindication, failure, or intolerance to a biologic from the anti-IL-17 or anti-IL-23 class.

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Guselkumab (Tremfya) **SR0530**	Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. February 21, 2018	List for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, with the following criteria and condition. **Criteria:** Reimburse in a manner similar to other biologics for the treatment of moderate to severe plaque psoriasis. Treatment should be discontinued if a response to treatment with guselkumab has not been demonstrated after 16 weeks. **Condition:** Drug plan cost for guselkumab should not exceed the drug plan cost of treatment with the least costly biologic reimbursed for moderate to severe plaque psoriasis. Guselkumab Reimbursement Recommendation	FMEC affirms that guselkumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** For patients who are biologic-naive who have yet to be treated with any biologic, a drug from the anti-IL-17 or anti-IL-23 class should be trialled before a drug from the anti-TNF or anti-IL-12/23 class (if the FMEC pricing condition is met). **Pricing:** Drug plan cost per patient should be no more than the least expensive biologic (originator or biosimilar) used to treat moderate to severe plaque psoriasis.
Ixekizumab (Taltz) **SR0481**	Treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. October 25, 2016	List for the treatment of patients with moderate to severe plaque psoriasis with the following criteria and condition. **Criteria:** Limited to patients with a documented inadequate response, contraindication, or intolerance to conventional systemic therapies, such as methotrexate and cyclosporine. Treatment should be discontinued if a response to treatment with ixekizumab has not been demonstrated after 12 weeks. **Condition:** Reduced price. Taltz Recommendations and Reasons	FMEC affirms that ixekizumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** For patients who are biologic-naive who have yet to be treated with any biologic, a drug from the anti-IL-17 or anti-IL-23 class should be trialled before a drug from the anti-TNF or anti-IL-12/23 class (if the FMEC pricing condition is met). **Pricing:** Drug plan cost per patient should be no more than the least expensive biologic (originator or biosimilar) used to treat moderate to severe plaque psoriasis.

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Secukinumab (Cosentyx) **SR0407**	Treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. October 28, 2015	Listed for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy, if the following clinical criterion and condition are met. **Clinical criterion:** Treatment discontinued if a PASI 75 response has not been demonstrated after 12 weeks. **Condition:** The drug plan cost for secukinumab should not exceed the drug plan cost of the least costly biologic reimbursed for the treatment of moderate to severe plaque psoriasis. Cosentyx Recommendations and Reasons	FMEC affirms that secukinumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** For patients who are biologic-naive who have yet to be treated with any biologic, a drug from the anti-IL-17 or anti-IL-23 class should be trialled before a drug from the anti-TNF or anti-IL-12/23 class (if the FMEC pricing condition is met). **Pricing:** Drug plan cost per patient should be no more than the least expensive biologic (originator or biosimilar) used to treat moderate to severe plaque psoriasis.
Infliximab (Inflectra) **SE0384**	Treatment of adult patients with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy. For patients with chronic moderate plaque psoriasis, Inflectra should be used after phototherapy has been shown to be ineffective or inappropriate. When assessing the severity of psoriasis, the physician should consider the extent of involvement, location of lesions, response to previous treatments, and impact of disease on the patient's quality of life. December 19, 2014	List in accordance with the Health Canada–approved indications for the treatment of rheumatoid arthritis, ankylosing spondylitis, plaque psoriasis, and psoriatic arthritis, if the following conditions are met. **Conditions:** For use in patients for whom infliximab is considered to be the most appropriate treatment option. List in a manner similar to Remicade. Inflectra Psoriasis Recommendations and Reasons	FMEC affirms that infliximab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** Drugs in the anti-TNF class (such as infliximab) could be considered for use if there is a contraindication, failure, or intolerance to a biologic from the anti-IL-17 or anti-IL-23 class.

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Ustekinumab (Stelara) **SR0156**	Indicated in adult patients for the treatment of chronic moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. June 17, 2009	List for patients with severe, debilitating psoriasis who meet all of the following criteria: • BSA involvement of > 10% and/or significant involvement of the face, hands, feet, or genital region • failure to respond to, contraindications to, or intolerant to methotrexate and cyclosporine • failure to respond to, intolerant to, or unable to access phototherapy. Stelara Psoriasis Recommendations and Reasons	FMEC affirms that ustekinumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** Drugs in the anti-IL-12/23 class (such as ustekinumab) could be considered for use if there is a contraindication, failure, or intolerance to a biologic from the anti-IL-17 or anti-IL-23 class.
Adalimumab (Humira) **SR0130**	Treatment of adult patients with chronic moderate to severe psoriasis who are candidates for systemic therapy. For patients with chronic moderate plaque psoriasis, should be used after phototherapy has been shown to be ineffective or inappropriate. October 16, 2008	List for patients with severe, debilitating psoriasis who meet all of the following criteria: • BSA involvement of > 10% and/or significant involvement of the face, hands, feet, or genital region • failure to respond to, contraindications to, or intolerant of methotrexate and cyclosporine • failure to respond to, intolerant to, or unable to access phototherapy. Humira Psoriasis Recommendations and Reasons	FMEC affirms that adalimumab should be reimbursed with criteria or conditions. The following additional conditions for reimbursement will now apply. **Initiation:** Drugs in the anti-TNF class (such as adalimumab) could be considered for use if there is a contraindication, failure, or intolerance to a biologic from the anti-IL-17 or anti-IL-23 class.
Etanercept	Etanercept was not reviewed by CADTH for the treatment of moderate to severe plaque psoriasis, and therefore does not have a Final Recommendation (CDEC) to be updated.		FMEC recommends that etanercept be reimbursed with criteria or conditions for the treatment of moderate to severe plaque psoriasis for adults who are candidates for phototherapy or systemic therapy. The following additional conditions for reimbursement will also apply. **Initiation:** Drugs in the anti-TNF class (such as etanercept) could be considered for use if there is a contraindication, failure, or intolerance to a biologic from the anti-IL-17 or anti-IL-23 class.

BMI = body mass index; BSA = Body Surface Area; CDEC = CADTH Canadian Drug Expert Committee; CEDAC = Canadian Expert Drug Advisory Committee; FMEC = Formulary Management Expert Committee; IL = interleukin; PASI = Psoriasis Area Severity Score; TNF = tumour necrosis factor.

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November 2023