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# Canadian Rheumatology Association Position Statement

## Criteria for Access to Targeted Agents for Rheumatoid Arthritis in Canada

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### Purpose

There are currently significant discrepancies between Canadian provinces and territories in the criteria for access to advanced targeted agents for rheumatoid arthritis (RA) treatment. Such targeted agents include biologic medications as well as small molecule inhibitors. In hopes of supporting universality and equity of care for rheumatoid arthritis patients in Canada, the Canadian Rheumatology Association Therapeutics Committee has reviewed the current provincial and territorial criteria (see Addendum) and makes the following recommendations for criteria to access advanced targeted agents for treatment of RA, both for public and private payers.

- Targeted agents should be available to patients with moderate-severely active RA. To access such medications, an objective measurement should ideally be provided. The best option would be the Clinical Disease Activity Index (CDAI) which adds the tender joint count (TJC), swollen joint count (SJC), patient global assessment (PGA) and physician global assessment or the Simplified Disease Activity Index (SDAI) which uses the same measurements but adds a C-reactive peptide (CRP).
  - Patients should demonstrate an inadequate response, intolerance or contraindication to methotrexate (MTX), whether oral or parenteral, in a dose of 20-25 mg/week (15 mg/week in patients  $\geq 65$  years of age). In patients with an inadequate response or intolerance to oral MTX, parenteral MTX may be considered, given the improved bioavailability of this formulation.
  - Combination treatment with MTX as the anchor drug should be used unless there is an intolerance or it is contraindicated. Options include Sulfasalazine (SSZ), Hydroxychloroquine (HCQ) or Leflunomide (LEF). Other options may be considered such as Mycophenolate (MMF). Treatment with LEF should not be mandatory.
  - Treatment duration should be for minimum 12 weeks as monotherapy or combination therapy.
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## Guidelines

The Canadian guidelines for the treatment of Rheumatoid Arthritis or RA, that were last updated in July 2024, state that treatment should aim to achieve remission and, when not feasible, minimal disease activity. In patients with persistent synovitis, disease modifying agents (DMARDs) should be introduced as soon as possible and Methotrexate (MTX) is the preferred DMARD with respect to efficacy and safety.

The recommended initial treatment is with Methotrexate, given orally (po) or intramuscularly/subcutaneous (IM/SQ), in a maximum dose of 25 mg/wk (15 mg/wk in patients  $\geq 65$  yrs of age). The current criteria in different provinces differ in the dose of MTX required; it varies from 20-25 mg a week and all provinces state it can be given po or IM/SQ except for BC which requires that MTX be given IM/SQ except in exceptional situations such as needle phobia.

The guidelines say that if patients have an inadequate response or intolerance to po MTX, parenteral administration should be considered. If patients had an inadequate response, defined as moderate to high disease activity despite 3 months of treatment at target dose, then patients should receive a combination of at least 2 DMARDs (including MTX unless contraindicated) in mono or combination therapy. MTX coprescription was recommended for improved efficacy. Choices for the DMARDs include Sulfasalazine (SSZ) +/- Hydroxychloroquine (HCQ) and Leflunomide (LEF). The provinces differ in terms of which DMARDs are required.

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## Provincial and Territorial Criteria for Access to Targeted Agents

The provinces differ somewhat in terms of what the activity of RA needs to be to apply for access to targeted agents with most saying that the patient needs to have moderate to severe disease activity although some say patients need to have severe disease activity and the provinces differ in what their definitions of activity are.

### ALBERTA:

#### Disease Activity Requirements:

In Alberta, patients need to have prespecified pre-treatment DAS28 and HAQ scores to qualify for targeted agents.

#### Prior Therapy Requirements:

New patients need to receive MTX po, SQ or IM, MTX with another DMARD other than LEF as well as LEF. MTX + SZ + HCQ has to be given for a minimum of 4 months and MTX + LEF for a minimum of 10 wks.

#### Additional Requirements:

Patients need to be maintained on MTX in combination with the required drug (except for Abatacept).

## BRITISH COLUMBIA

### Disease Activity Requirements:

In BC, patients must have moderate to severely active RA. Physicians must provide swollen joint count (SJC), tender joint count (TJC), erythrocyte sedimentation rate (ESR) or C-reactive protein (CRP), duration of early morning stiffness or EMS and physician global assessment or MDG.

### Prior Therapy Requirements:

Patients need to have tried MTX IM or SQ at a dose of 25 mg/wk (15mg/wk if  $\geq 65$ ) for a minimum of 8 weeks and at least 1 or more DMARDs (not including HCQ) and at least 1 DMARD combination (HCQ and 1 other DMARD not acceptable). For LEF, the duration of Rx needs to be at least 10 wks, SZ  $\geq 2$  gms/d for 3 months and AZA 2-3 mg/kg for 3 months. MTX + SZ + HCQ must be given for a minimum of 4 months and MTX + LEF for at least 10 wks.

### Additional Notes:

For Golimumab and Infliximab, the biologic must be given in combination with a DMARD (MTX or specify other).

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## MANITOBA

### Disease Activity Requirements:

In Manitoba, patients need to have moderate to severely active RA and the physicians have to provide SJC, TJC, ESR and CRP.

### Prior Therapy Requirements:

Patients have to have failed at least 3 DMARDs, one of which is MTX and /or LEF unless intolerance or contraindication is documented. One combination treatment with DMARDs must also be tried.

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## SASKATCHEWAN

### Disease Activity Requirements:

In Saskatchewan, patients need to have active RA but there is no requirement for any other criteria.

### Prior Therapy Requirements:

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Patients have to have failed or been intolerant to MTX and LEF. No dose or duration is required.

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## ONTARIO

### Prior Therapy Requirements:

In Ontario, patients need to have tried MTX in a dose of 20 mg/wk as well as the maximum dose of LEF and any DMARD combination for at least 3 months.

### Limited Use Codes:

Certain targeted agents, such as Tofacitinib and biosimilars, have specific limited use (LU) codes that enable physicians to access treatment. LU codes are linked to specific clinical criteria, such as a particular disease severity, the failure of previous treatments, or when a drug is used first-line under specific conditions. For Tofacitinib, for example, the LU code says that the clinical criteria is for the treatment of RA in patients who have severe active disease ( $\geq 5$  SJ and rheumatoid factor or RF +/- anti-cyclic citrullinated peptide antibodies or anti-CCP +, +/- have radiographic evidence of RA) and have experienced failure, intolerance, or have a contraindication to adequate trials of DMARD regimens, such as one of the following treatments: A) MTX 20 mg/wk for at least 3 months and LEF 20 mg/d for at least 3 months and an adequate trial of at least one combination of DMARDs for 3 months or B) MTX 20 mg/wk for at least 3 months and LEF with MTX for at least 3 months or C) MTX 20 mg/wk, SZ 2 gms/d and HCQ 400 mg for at least 3 months.

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## QUEBEC

### Disease Activity Requirements:

In Quebec, patients need to have moderate or severe RA and, upon initiation of treatment or the patient has been receiving therapy for < 5 months prior to the beginning of treatment, patients must have 8 or > joints with active synovitis and at least 1 of the following elements: +RF, radiographically measured erosions, HAQ >1,  $\uparrow$ CRP or  $\uparrow$ ESR.

### Prior Therapy Requirements:

Patients need to have tried 2 DMARDs, used either concomitantly or not, for at least 3 months each. Unless there is serious intolerance or serious contraindication, 1 of the 2 drugs must be MTX at a dose of 20mg or >/wk.

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## NOVA SCOTIA

### Disease Activity Requirements:

In Nova Scotia, patients need to have severely active RA.

**Prior Therapy Requirements:**

Patients need to be refractory or intolerant to MTX po or parenteral at a dose of  $\geq 20$  mg/wk (15 mg/wk if  $\geq 65$ ) or use of MTX in combo with another DMARD and MTX in combination with at least 2 other DMARDs eg SZ and HCQ, for a minimum of 12 wks.

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## NEW BRUNSWICK

**Disease Activity Requirements:**

In New Brunswick, patients need to have moderately to severely active RA.

**Prior Therapy Requirements:**

Patients must be refractory, intolerant or have contraindications to MTX po or parenteral alone at a dose of  $\geq 20$  mg/wk (15 mg/wk if  $\geq 65$ ) or in combination with another DMARD for a minimum of 12 wks and MTX in combination with at least 2 other DMARDs, such as HCQ and SZ, for a minimum of 12 wks.

**Additional Notes:**

For patients who do not demonstrate a clinical response to oral MTX, or who have experienced GI intolerance, a trial of parenteral MTX must be considered. For patients who have intolerances that prevent the use of triple DMARD Rx, these must be described and dual Rx with DMARDs must be tried.

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## PRINCE EDWARD ISLAND

**Prior Therapy Requirements:**

In PEI, patients must be refractory or intolerant to MTX po or parenteral at a dose of  $\geq 20$  mg/wk (15 mg/wk if  $\geq 65$ ) or in combination with another DMARD for a minimum of 12 wks. For patients who do not demonstrate a clinical response to oral MTX, or have experienced GI intolerance, a trial of parenteral MTX must be considered and patients must be refractory or intolerant to MTX in combination with 2 other DMARDs (triple therapy) for a minimum of 12 wks.

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## NEWFOUNDLAND

**Disease Activity Requirements:**

In Newfoundland, patients need to have severely active RA.

### **Prior Therapy Requirements:**

Patients need to have tried MTX, oral or parenteral, at a dose of  $\geq 20$  mg/wk (15 mg/wk if  $\geq 65$ ) for a minimum of 12 wks followed by MTX in combination with at least 2 other DMARDs, such as HCQ and SZ, for a minimum of 12 wks or initial use of triple DMARD therapy with MTX in combination with at least 2 other DMARDs, such as HCQ and SZ, for a minimum of 12 wks.

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## **NIHB PROGRAM**

### **Disease Activity Requirements:**

For NIHB, patients need to have severely active RA and they must have at least 2 of: 5 or more SJs, at least 1 joint proximal to, or including, the wrist or ankle, > 1 joint with an erosion on imaging and the daily use of corticosteroids.

### **Prior Therapy Requirements:**

Patients must have failed MTX po or parenteral at a dose of  $\geq 20$  mg/wk (15 mg/wk if  $\geq 65$ ) for a minimum of 12 wks. Patients who do not exhibit a clinical response to oral MTX or who experience GI intolerance may consider a trial of parenteral MTX. They must also take MTX in combination with at least 2 other DMARDs, such as SZ and HCQ, for a minimum of 12 wks.