Request for Biologics for Rheumatoid Arthritis (RA) Exceptional Access Program (EAP)

Not for Other Inflammatory Disorders
Not for Paediatric Cases

Ontario Rheumatology Association

To avoid delays, please ensure that all appropriate information for each section is provided.

For rituximab (Rituxan®), please use the RA Rituxan EAP form. For tofacitinib (Xeljanz™), please refer to LU code #480

Section 1 – Physician Information

First Name	Initial	Last Name

Street #	Street Name

City	Postal Code

Fax	Telephone (Back Line)

Section 2 – Patient Information

First Name	Initial	Last Name

Ontario Health Insurance Number	

Gender ◯ Male ◯ Female	Current Weight (kg)

Date of Birth (DD/MM/YYYY)

Request Type ◯ Initial Request (Complete all sections) ◯ Renewal Request (Complete sections 3, 4B) | EAP #

Section 3 – Drugs, Dose and Regimen Requested *(attach additional sheets if more space is required)*

◯ **abatacept** (Orencia™) 500 mg (<60 kg), 750 mg (60-100 kg), 1000 mg (>100 kg) IV at 0, 2, 4 weeks then every 4 weeks or 125 mg SC once weekly +/- initial IV loading

◯ **adalimumab** (Humira®)* 40 mg SC every two weeks

◯ **anakinra** (Kineret®)* 100 mg SC per day

◯ **certolizumab** (Cimzia™) 400 mg SC at 0, 2, 4 weeks, followed by 200 mg SC every other week (400 mg SC every 4 weeks may be considered for maintenance therapy only)

◯ **golimumab** (Simponi®) 50 mg SC once monthly

◯ **sarilumab** (Kevzara®) 200 mg SC once every 2 weeks

Reduced dose of 150 mg once every 2 weeks is recommended for patients with neutropenia, thrombocytopenia, or with elevated liver enzymes.

◯ **tocilizumab** (Actemra®) 4 mg/kg/dose IV every 4 weeks followed by an increase to 8 mg/kg/dose IV based on clinical response; not to exceed 800 mg/dose

Patients < 100 kg weight, starting dose of 162 mg SC every other week. May increase to weekly dose based on clinical response > 100 kg weight, 162 mg every week

◯ **etanercept** (Enbrel®)* 25 mg SC twice weekly or 50 mg SC once weekly. ◯ **infliximab** (Remicade®)* Maintenance therapy of 3 mg/kg IV every 8 weeks.

The Ministry will no longer fund initial requests for reference biologics that have a biosimilar listed on the formulary for the same condition in patients treatment naïve to the reference biologic or in patients who were initiated and stabilized through manufacturer supported funding when the biosimilar could have been an option. Requests for renewal of the reference biosimilars with existing EAP approvals will be assessed according to established renewal criteria.

Dosage	Dosing Frequency	Route of Administration: ◯ SC ◯ IV ◯ PO

*Higher than listed dosages should be accompanied by the rationale for the need for non-standard dosing levels.
Please provide additional documentation (i.e. objective evidence) regarding the patient's response, including the swollen joint count, to the standard dosing regimen vs the higher dosing regimen.

Section 4A
Indication of Active Disease

Diagnosis of active RA:

- ☐ ≥ 5 Swollen Joints
- ☐ Rheumatoid Factor Positive
- ☐ Anti-CCP Positive
- ☐ Radiographic Evidence of RA

if < 5 swollen joints, provide location of swollen joints

Section 4B
Response to Treatment

Renewal requests should demonstrate a 20% reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For renewals beyond the second year, objective evidence of the preservation of treatment effect must be provided.

Clinical Marker	Before Initiation of a Biologic	Prior-to Requested Biologic	Renewal 1	Renewal 2	Renewal 3	Renewal 4
Swollen Joint Count						
Date (DD/MM/YYYY)						

Section 5 – Previous/Current Disease Modifying Anti-Rheumatic Drug (DMARD) and Biologic Therapies

1. Provide details of use and response to separate courses of maximum dose methotrexate (i.e. 20 mg/week) AND maximum dose leflunomide (i.e. 20 mg/day), AND any DMARD combination for at least 3 months each. If maximum doses of methotrexate and leflunomide have not been tried, details of the patient's intolerance or contraindication to these two agents must be given AND details of another DMARD tried in each one's place for at least 3 months should be provided. ***OR***
2. Provide details of use and response to methotrexate 20 mg/week and leflunomide 20 mg/day in combination for at least 3 months. ***OR***
3. Provide details of use and response to triple disease modifying anti-rheumatic drug (DMARD) therapy, defined as methotrexate (20 mg/week), sulfasalazine (2 g/day) and hydroxychloroquine (400 mg/day - dose based by weight up to 400 mg per day) for at least 3 months. Note: In cases where the patient could not receive an adequate trial of triple DMARD therapy with methotrexate, sulfasalazine and hydroxychloroquine due to intolerance, then the regular DMARD trial criteria must be met. (i.e. #1 or #2)
4. Combination biologics is not funded.

NAME OF DRUG	DOSING REGIMEN	START DATE (DD/MM/YYYY)	END DATE (DD/MM/YYYY)	REASON FOR DISCONTINUATION Details of intolerance, contraindication, or failure at maximum dose must be provided
methotrexate				
leflunomide				
Combination DMARD regimen				

Physician Signature (Mandatory)	CPSO Number	Date (DD/MM/YYYY)

Please fax the completed form and/or any additional relevant information to **416-327-7526** or toll free **1-866-811-9908**; or send to the Drug Programs Delivery Branch, 3rd Floor, 5700 Yonge Street, North York, Ontario, M2M 4K5. For copies of EAP forms, please visit: http://ontariorheum.ca/drug-forms-and-codes/eap-forms