Request for Biologics for Psoriatic Arthritis (PsA)/Seronegative Arthritis Exceptional Access Program (EAP)

Not for Other Inflammatory Disorders

Ontario Rheumatology Association

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

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 - Drug, Dose and Regimen Requested

☐ **adalimumab** (Humira®)	40 mg SC every two weeks
☐ **certolizumab** (Cimzia™)	400 mg SC at 0, 2 and 4 weeks followed by maintenance therapy of 200 mg every 2 weeks OR 400 mg every 4 weeks
☐ **etanercept** (Enbrel®)	25 mg SC twice weekly or 50 mg SC once weekly
☐ **golimumab** (Simponi®)	50 mg SC once monthly
☐ **infliximab** (Remicade®)	maintenance therapy[1] of 3-5 mg/kg/dose IV every 8 weeks

[1]Requests for Remicade in patients with PsA who initiated Remicade therapy on or prior to February 24, 2016 will be grandparented and screened according to established renewal criteria. Note that Inflectra (LU code 470) and Renflexis (LU code 543) are considered for patients with PsA meeting LU criteria.

☐ **ixekizumab** (Taltz®) 80 mg/1.0 ml SC, 160 mg SC at week 0, followed by 80 mg every 4 weeks

For patients with PsA and coexistent mild plaque psoriasis. To be used as monotherapy OR in combination with a conventional DMARD (i.e. MTX).
For PsA patients with coexistent moderate-to severe plaque psoriasis (PPs), refer to ODB formulary for access upon meeting the Limited Use criteria for PPs; EAP authorization not required. PPs dosing: 80 mg/1.0 ml SC, 160 mg SC at week 0, 80 mg every 2 weeks for 6 doses (wk 2, 4, 6, 8, 10, 12) followed by 80 mg every 4 weeks.

☐ **secukinumab** (Cosentyx®) 150 mg SC at weeks 0, 1, 2 and 3 followed by monthly maintenance dosing starting at week 4

If a patient is an anti-TNF alpha inadequate responder and continues to have active psoriatic arthritis, consider using the 300 mg SC dose.
For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis (i.e. 300 mg SC at weeks 0, 1, 2, and 3, followed by monthly maintenance dosing starting at week 4).

Dosage

Dosing Frequency

Route of Administration: ☐ SC ☐ IV

Section 4A
Indication of Active Disease

Diagnosis of active PsA

☐ ≥ 5 swollen joints
AND
☐ Diagnostic imaging evidence of PsA (x-rays, U/S, MRI)

if < 5 swollen joints, provide location of swollen joints

If not PsA, please specify diagnosis and enclose copies of relevant diagnostic imaging and bloodwork

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	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) Therapy

Provide details of use and response to treatment with Methotrexate (20 mg/wk) for at least 3 months and either leflunomide (20 mg/day) **OR** sulfasalazine (1gm twice daily) for at least 3 months. If patient has documented contraindications or intolerances to methotrexate, then only one of leflunomide or sulfasalazine for at least 3 months is required. Details of contraindications and intolerances must be provided.

NAME OF DMARD	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				
sulfasalazine				

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 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