Request for Biologics for Ankylosing Spondylitis(AS)/Psoriatic Spondylitis (PS) Exceptional Access Program (EAP)

Not for Other Inflammatory Disorders

ORA 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, 7)

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.

Requests for renewal of Enbrel in patients with AS who initiated therapy prior to July 31, 2017 will be assessed according to established renewal criteria. New requests will not be accepted. Note that Brenzys (LU code 499) and Erelzi (LU code 513) are considered for AS in patients meeting LU criteria.

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

☐ **infliximab** (Remicade®) Maintenance therapy of 3-5 mg/kg IV every 6-8 weeks.

Requests for renewal of Remicade in patients with AS who initiated therapy prior to February 24, 2016 will be assessed according to established renewal criteria. New requests will not be accepted. Note that Inflectra (LU code 469) and Renflexis (LU code 542) are considered for patients with AS meeting LU criteria.

☐ **secukinumab** (Cosentyx®) 150 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 AS/PS

☐ Age of onset ≤ 50

AND

☐ Low back pain and stiffness for > 3 months that improves with exercise and not relieved by rest

AND

☐ Failure of or intolerance to at least 2 NSAIDs tried for at least 4 weeks each (fill section 5)

AND

☐ BASDAI score ≥ 4 after at least 4 weeks of standard therapy

AND

☐ Radiographic report confirmed by:

- ☐ X-ray/CT of SI Joint featuring:
  - ☐ Erosions/Widening ☐ Fusion ☐ Ankylosis
- ☐ MRI of SI Joint featuring:
  - ☐ Edema ☐ Inflammation ☐ Erosions

OR

- ☐ X-ray/CT/MRI confirming NY classification:
  - ☐ Sacroiliitis grade ≥ 2 bilateral
  - ☐ Sacroiliitis grade > 2 unilateral

Section 4B: Response to Treatment

Renewal requests should demonstrate a 50% reduction in BASDAI score or ≥ 2 absolute point reduction in BASDAI score. Indicate whether there has been a reduction in pain medication since initiating the biologic. For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.

Clinical Marker	Pre-biologic	Renewal 1	Renewal 2	Renewal 3
BASDAI score				
Date (DD/MM/YYYY)				
PAIN MEDICATION *(if prescribed for AS/PS)*				
	None ☐	None ☐	None ☐	None ☐
	Drug and strength	Drug and strength	Drug and strength	Drug and strength
	Dose/Frequency	Dose/Frequency	Dose/Frequency	Dose/Frequency

Section 5 - Previous NSAIDs/COXIBs used

Provide details of use and response to NSAIDs and COXIBs used in the past

NAME OF NSAID/COXIB	DOSING REGIMEN	START DATE (DD/MM/YYYY)	END DATE (DD/MM/YYYY)	REASON FOR DISCONTINUATION Details of intolerance, contraindication, failure at maximum dose or inadequate response must be provided

Section 6 - DMARD trial if predominantly peripheral arthritis present or N/A ☐

DMARD	DOSING REGIMEN	START DATE (DD/MM/YYYY)	END DATE (DD/MM/YYYY)	RESPONSE

Section 7 - List all current medications relevant to rheumatic diagnosis, including dosage and indication

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