Government of Saskatchewan

Saskatchewan Ministry of Health
Drug Plan and Extended Benefits Branch

Exception Drug Status Request
Ankylosing Spondylitis Drugs

Please ensure each section is completed to avoid delays.

Section 1 – Prescriber Information		Section 2 – Patient Information
First Name **Last Name**		**First Name** **Last Name**
Mailing Address		**Date of Birth** _____ (day/month/year)
Telephone Number	**Fax Number**	**Health Services Number**

Section 3 – Requested Drug Regimen and Clinical Information (see Appendix A for specific EDS criteria)

Exception Drug Status will be approved for patients who are assessed and meet the following criteria.

Drug Requested: _____

Initial Application

Initial coverage will be granted for a 12-week medication trial (or 16 weeks for Cosentyx (secukinumab)).

- The patient has already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at maximum tolerated or recommended doses for four weeks without symptom control; **AND**
- The patient satisfies New York diagnostic criteria:
  - A score ≥ 4 on the BASDAI* **AND**
  - A score ≥ 4cm on the 0-10cm spinal pain VAS** on two occasions at least 12 weeks apart without any change of treatment.

☐ YES ☐ NO

	BASDAI	VAS #1	VAS #2
	☐	☐	☐
Date:	_____	_____	_____

Second Application

Following the initial 12- or 16-week approval, requests will be considered for a one-year approval timeframe.

- The patient has had an adequate response to treatment assessed at 12 weeks (or 16 weeks for Cosentyx (secukinumab)) defined by:
  - At least 50% reduction in the pre-treatment baseline BASDAI* score or by ≥ 2 units **AND**
  - A reduction of ≥ 2cm in the spinal pain VAS**

	BASDAI	VAS
	☐	☐
Date:	_____	_____

Subsequent Annual Renewal Application

Subsequent applications will be considered for a one-year approval timeframe.

- The patient's BASDAI* score does not worsen (i.e. remains within two units of the second assessment) **AND** remains at least two units less than the initial application's BASDAI* score.

	BASDAI
	☐
Date:	_____

Criteria Notes:

- Requests for coverage for this indication must be made by a rheumatologist.
- Coverage may be provided for one switch for patients transitioning to another biologic agent following an adequate trial of the first agent if the patient fails to respond, if there is a loss of response, or is intolerant, to the first agent. Approval will be subject to the published Exception Drug Status criteria for the requested biologic agent.
- Patients will not be permitted to switch back to a previously trialed biologic if they were deemed unresponsive to therapy.
- Patients are limited to receiving one biologic agent at a time regardless of the indication for which it is being prescribed.

*BASDAI (Bath Ankylosing Spondylitis Disease Activity Index); **VAS (Visual Analogue Scale)

Signature (Required)	**Date:** _____ (day/month/year)

Please submit the completed form by:

- Fax to 306-798-1089; or
- Email to DPEB@health.gov.sk.ca; or
- Mail to the Drug Plan and Extended Benefits Branch, 2nd floor, 3475 Albert Street, Regina, SK S4S 6X6

If you have any questions, please call 306-787-8744 (in Regina) or 1-800-667-2549 (toll-free).