

Special Authorization Request Form, for:

***Ustekinumab* Biosimilars**

(OTULFI, OTULFI I.V., STEQEYMA, STEQEYMA I.V.)

The purpose of this form is to obtain medical information required to assess your request for a drug on the Special Authorization (SA) list of the Reformulary. Please ensure that all information, including contact information, is complete. Completing this form is not a guarantee of approval.

PART 1: COMPLETE THIS INFORMATION

Information about plan member

First name: _____ Last name: _____

Group number: _____ Certificate number: _____

Date of birth (DD/MM/YY): _____ Gender: _____

Address: _____

City/Town: _____ Province: _____ Postal code: _____

Email: _____ Phone: _____

COORDINATION OF BENEFITS

Coverage through another health benefit plan or provincial plan

Do you or your dependents have drug coverage through another health benefits, insurance company or provincial plan? Yes No

If yes, provide the following: Name of plan member: _____

Policy/Plan number: _____ Certificate number: _____

Patient assistance program

Have you enrolled in a patient assistance program? Yes No

If yes, provide your patient assistance program ID number: _____

Provide the patient assistance program:

Contact name: _____ Phone: _____

PART 2: TO BE COMPLETED BY YOUR DOCTOR (PHYSICIAN)

Physician Information

First name: _____ Last name: _____

License: _____ Phone: _____

Address: _____

City/Town: _____ Province: _____ Postal code: _____

Physician's signature: _____

(confirming the below information to be correct)

Drug being requested through Special Authorization

New request Request for continuation of therapy

DIN: _____ Product name: _____

Strength: _____ Dosage: _____

Site of Administration

- Home Private clinic Hospital
 Doctor's office Cancer centre LTC facility

CLINICAL INFORMATION

Diagnosis

- Plaque Psoriasis
 Psoriatic Arthritis
 Crohn's Disease
 Ulcerative Colitis

Physician specialty

- Dermatologist
 Gastroenterologist
 Rheumatologist

Criteria for initial coverage, confirm the following:

FOR PLAQUE PSORIASIS (OTULFI, STEQEYMA)

- Patient is 18 years of age or older; and
- Patient diagnosed with severe Plaque Psoriasis (PASI score ≥ 12 and BSA involvement $\geq 10\%$); and
- Patient is intolerant to, has contraindications to, or has inadequate response to either *methotrexate* or *acitretin* after at least a 6-month trial; and
- Patient has failed to respond to, is intolerant to or unable to access at least a 12-week trial of phototherapy

NOTE: Duration of initial approval is 12 weeks

Important note: Patient should be monitored to determine if continuation of therapy beyond 12 weeks is required. Patient not responding adequately at 12 weeks should have treatment discontinued.

FOR PSORIATIC ARTHRITIS (OTULFI, STEQEYMA)

- Patient is 18 years of age or older; and
- Patient diagnosed with Psoriatic Arthritis; and
- Patient has severe active disease (≥ 5 swollen joints and radiographic evidence of psoriatic arthritis) despite treatment with *methotrexate*, *leflunomide* or *sulfasalazine* for at least 3 months

NOTE: Duration of initial approval is 1 year

Important note: If patient has documented contraindications or intolerance to *methotrexate*, then patient must have tried either *leflunomide* or *sulfasalazine* for at least 3 months.

FOR CROHN'S DISEASE (OTULFI, OTULFI I.V., STEQEYMA, STEQEYMA I.V.)

- Patient is 18 years of age or older; and
- Patient diagnosed with moderate to severe Crohn's Disease; and
- Patient has failed to respond to conventional treatment with glucocorticoids (*prednisone*, *prednisolone*, *budesonide*); and
- Patient has failed to respond to an immunosuppressive agent (*azathioprine*, *6-Mercaptopurine*, *methotrexate*, or *cyclosporine*) tried for at least 3 months; and
- Harvey Bradshaw Index (HBI) score greater than or equal to 8

NOTE: Duration of initial approval is 3 months

FOR ULCERATIVE COLITIS (OTULFI, OTULFI I.V., STEQEYMA, STEQEYMA I.V.)

- Patient is 18 years of age or older; and
- Patient diagnosed with Ulcerative Colitis, with moderate or severe disease

Moderate disease:

- Mayo score between 6 and 10 (inclusive); and
- Endoscopic subscore of 2 based on endoscopy performed within the last year; and
- Patient failed 2 weeks of oral prednisone \geq 40 mg and 3 months of *azathioprine* (AZA)/ *6-Mercaptopurine* (6-MP) (or where the use of immunosuppressants is contraindicated); or
- Patient stabilized with 2 weeks of oral *prednisone* \geq 40 mg but the *prednisone* dose cannot be tapered despite 3 months of AZA/6-MP, (or where the use of immunosuppressants is contraindicated)

Severe disease:

- Mayo score $>$ 10; and
- Endoscopic subscore \geq 2 based on endoscopy performed within the last year; and
- Patient failed 2 weeks of oral *prednisone* \geq 40 mg; or
- Patient stabilized with 2 weeks of oral *prednisone* \geq 40 mg but the *prednisone* dose cannot be tapered despite 3 months of AZA/6-MP, (or where the use of immunosuppressants is contraindicated)

NOTE: Duration of initial approval is 3 months

Request for continuation of therapy, confirm the following:

FOR PLAQUE PSORIASIS

- Patient demonstrates continued therapeutic benefit, outweighing any potential risks

NOTE: Duration of continued approval is 1 year

FOR PSORIATIC ARTHRITIS

- Patient demonstrates continued therapeutic benefit, such as a 20% reduction in swollen joint count and a minimum improvement in 2 swollen joints over the previous year

NOTE: Duration of continued approval is 1 year

FOR CROHN'S DISEASE

- Clinical response (e.g., HBI score 5 or less, or decrease in HBI score of 4 or more)

NOTE: Duration of continued approval is 1 year

FOR ULCERATIVE COLITIS

After 3 loading doses of ustekinumab:

- Patient has Mayo score < 6; and
- Patient has 50% reduction in prednisone from the starting dose

NOTE: Duration of continued approval is 1 year

SPECIAL NOTES

Describe any intolerances to therapy: _____

Are there any other comments, diagnoses, symptoms, medications tried or failed, and/or any other information that the physician believes is important to this review? _____

