

Special Authorization Request Form, for:

Infliximab Biosimilars (AVSOLA, REMDANTRY, RENFLEXIS)

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

- Rheumatoid Arthritis (RA)
- Psoriatic Arthritis
- Plaque Psoriasis
- Ankylosing Spondylitis (AS)
- Fistulising Crohn's Disease
- Crohn's Disease
- Pediatric Crohn's Disease
- Ulcerative Colitis
- Pediatric Ulcerative Colitis

Physician specialty

- Dermatologist
- Gastroenterologist
- Pediatric gastroenterologist
- Physician specializing in treatment of pediatric inflammatory bowel disease
- Rheumatologist

Criteria for initial coverage, confirm the following:

FOR RHEUMATOID ARTHRITIS (RA)

- Patient is 18 years of age or older; and
- Patient has severe active disease, as demonstrated by ≥ 5 swollen joints; and rheumatoid factor positive; or having radiographic evidence of RA; and
- Patient has failed to respond to two disease-modifying anti-rheumatic drugs (DMARDs) or patient has a documented intolerance or contraindication to DMARDs*

NOTE: Duration of initial approval is 1 year

*Please describe any intolerance or contraindications

FOR PSORIATIC ARTHRITIS

- Patient is 18 years of age or older; and
- Patient must be 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

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

*Please describe any intolerance or contraindications

FOR PLAQUE PSORIASIS

- Patient is 18 years of age or older; and
- Patient must be 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.

*Please describe any intolerance or contraindication

FOR ANKYLOSING SPONDYLITIS (AS)

- Patient is 18 years of age or older; and
- Patient must be diagnosed with moderate to severe Ankylosing Spondylitis**; and
- Patient has evidence of active disease as defined by BASDAI (Bath Ankylosing Spondylitis Disease Activity Index) score ≥ 4 while on standard therapy; and
- Patient has axial symptoms and has failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation, or in whom NSAIDs are contraindicated; or
- Patient has peripheral symptoms and has failed to respond to, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 3 months observation and has had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD

**Ankylosing Spondylitis is defined by at least two of the following clinical criteria:

- Low back pain and stiffness for > 3 months that improves with exercise but is not relieved by rest; or
- Limitation of motion of the lumbar spine in both the sagittal and frontal planes; or
- Limitation of chest expansion relative to normal values correlated for age and sex

NOTE: Duration of initial approval is 1 year

FOR FISTULISING CROHN'S DISEASE

- Patient is 18 years of age or older; and
- Patient must be diagnosed with fistulising Crohn's Disease; and
- Patient has an actively draining perianal or enterocutaneous fistula(e) that have recurred or persisted despite a course of antibiotic therapy (*metronidazole* as monotherapy or in combination with *ciprofloxacin*)

NOTE: Duration of initial approval is 3 months

FOR CROHN'S DISEASE

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

NOTE: Duration of initial approval is 3 months

*Please describe any intolerance or contraindications

FOR PEDIATRIC CROHN'S DISEASE

- Patient is between 9-17 years of age; and
- Patient diagnosed with moderately to severely active Crohn's disease ; and
- Patient has failed to respond or is intolerant to conventional treatment (corticosteroids and/or aminosalicylate and/or an immunosuppressant)*

Corticosteroids: *prednisone, prednisolone, budesonide*

Immunosuppressant agents: *azathioprine, 6-Mercaptopurine, methotrexate, or cyclosporine*

NOTE: Duration of initial approval is 3 months

*Please describe any intolerance or contraindications

FOR ULCERATIVE COLITIS

- 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 ≥ 2 based on endoscopy performed within the last year; and
- Patient failed 2 weeks of oral *prednisone* ≥ 40 mg; or
- Patient stabilized with 2 weeks of oral *prednisone* ≥ 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

*Please describe any intolerance or contraindications

FOR PEDIATRIC ULCERATIVE COLITIS

- Patient is between 6-17 years of age; and
- Patient must be diagnosed with moderate or severe disease Ulcerative Colitis; and
- Mayo score 6-12; and
- Patient has had an inadequate response or was unable to tolerate an adequate trial of an immunosuppressant (e.g., systemic corticosteroid, 6-mercaptopurine, azathioprine) and/or aminosalicylate*

NOTE: Duration of initial approval is 3 months

*Please describe any intolerance or contraindications

Request for continuation of therapy, confirm the following:

FOR RHEUMATOID ARTHRITIS

- Patient demonstrates continued therapeutic benefit, such as objective evidence of at least 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 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 PLAQUE PSORIASIS

- Patient demonstrates continued therapeutic benefit, outweighing any potential risks

NOTE: Duration of continued approval is 1 year

FOR ANKYLOSING SPONDYLITIS

- Patient demonstrates a positive response to therapy defined by a 50% relative change or absolute change of 2 (scale 0-10) in BASDAI score from baseline; or
- Patient has documented significant functional improvement from the ongoing therapy with biologic (e.g. measured by outcomes such as HAQ or “ability to return to work”)

NOTE: Duration of continued approval is 1 year

FOR FISTULISING CROHN'S DISEASE

- Patient has resolution of fistula(e)

NOTE: Duration of continued approval is 1 year

FOR CROHN'S DISEASE

- Patient demonstrates 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 PEDIATRIC CROHN'S DISEASE

- Patient demonstrates clinical response (clinical response was defined as a decrease in the weighted Pediatric Crohn's Disease Activity Index by at least 17.5 points, or a decrease in Physician's Global Assessment from moderate or severe to mild)

NOTE: Duration of continued approval is 1 year

FOR ULCERATIVE COLITIS

After 3 loading doses of infliximab

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

NOTE: Duration of continued approval is 1 year

FOR PEDIATRIC ULCERATIVE COLITIS

- Patient must have a clinical response, defined as a decrease in Mayo score by ≥30% and ≥3 points

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? _____

Date: March 2025