

## Special Authorization Request Form, for:

### **Adalimumab Biosimilars (AMGEVITA, HADLIMA, HULIO, IDACIO, SIMLANDI, YUFLYMA)**

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)
- Ankylosing Spondylitis (AS)
- Psoriatic Arthritis
- Plaque Psoriasis
- Crohn's Disease
- Pediatric Crohn's Disease
- Ulcerative Colitis (UC)
- Pediatric Ulcerative Colitis (UC)
- Active Polyarticular-course Juvenile Idiopathic Arthritis (JIA)
- Hidradenitis Suppurativa

- Non-infectious Uveitis
- Chronic Non-Infectious Uveitis

**Physician specialty**

- Dermatologist
- Gastroenterologist
- Ophthalmologist
- Pediatrician
- Rheumatologist
- Other physician with experience treating non-infections uveitis
- Other physician with experience treating chronic uveitis in pediatric patients
- Other physician specializing in treatment of pediatric inflammatory bowel disease

**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  $\geq 5$  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

**FOR ANKYLOSING SPONDYLITIS (AS)**

- Patient is 18 years of age or older; and
- Patient 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  $\geq 4$  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 PSORIATIC ARTHRITIS

- Patient is 18 years of age or older; and
- Patient diagnosed with Psoriatic Arthritis; and
- Patient has severe active disease ( $\geq 5$  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 PLAQUE PSORIASIS

- Patient is 18 years of age or older; and
- Patient diagnosed with severe Plaque Psoriasis (PASI score  $\geq 12$  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 CROHN'S DISEASE

- 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 PEDIATRIC CROHN'S DISEASE

- Patient should be between 13-17 years of age and weighing  $\geq 40$  kg; and
- Patient diagnosed with 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

#### 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  $\geq 2$  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

#### FOR PEDIATRIC ULCERATIVE COLITIS

- Patient should be between 5-17 years of age; and
- Patient diagnosed with Ulcerative Colitis, with moderate or severe disease (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

#### FOR ACTIVE POLYARTICULAR-COURSE JUVENILE IDIOPATHIC ARTHRITIS

- Patient is 2 years of age or older; and
- Patient must be diagnosed with active polyarticular-course Juvenile Idiopathic Arthritis; and
- Patient is intolerant to, has contraindications to, or has inadequate response to methotrexate

**NOTE:** Duration of initial approval is 1 year

#### FOR HIDRADENITIS SUPPURATIVA

- Patient is 12 years of age or older and weighing 30 kg or more; and
- Patient diagnosed with moderate to severe hidradenitis suppurativa; and
- Patient has tried and failed a course of systemic therapy for 10 weeks (e.g., systemic antibiotics, acitretin, dapsone, corticosteroids)

**NOTE:** Duration of initial approval is 16 weeks

#### FOR NON-INFECTIOUS UVEITIS

- Patient is 18 years of age or older; and
- Patient has diagnosis of non-infectious uveitis (intermediate, posterior or panuveitis); and
- Patient is refractory to treatment with more than 10 mg/day of *prednisone* (or equivalent) and at least two immunomodulatory drugs (e.g., *azathioprine*, *mycophenolate mofetil*, *methotrexate*); or
- Patient unable to continue treatment with a corticosteroid plus immunomodulatory drug due to severe intolerance or toxicity; or
- Patient has severe, aggressive disease with risk of rapid, permanent and profound vision loss

**NOTE:** Duration of initial approval is 6 months

#### FOR CHRONIC NON-INFECTIOUS UVEITIS

- Patient should be 2 - 18 years of age; and
- Patient has diagnosis of non-infectious chronic uveitis; and

- Patient is refractory to treatment with *methotrexate* or another DMARD (e.g., *azathioprine*, *cyclosporin A*, *mycophenolate mofetil*); or
- New inflammation-related complications of uveitis occur despite DMARD treatment

**NOTE:** Duration of initial approval is 6 months

**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 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 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 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 severe to mild)

**NOTE:** Duration of continued approval is 1 year

#### FOR ULCERATIVE COLITIS

After 3 loading doses of adalimumab:

- 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  $\geq 30\%$  and  $\geq 3$  points

**NOTE:** Duration of continued approval is 1 year

#### FOR ACTIVE POLYARTICULAR-COURSE JUVENILE IDIOPATHIC ARTHRITIS

- Patient demonstrates continued therapeutic benefit, outweighing any potential risks

**NOTE:** Duration of continued approval is 2 years

#### FOR HIDRADENITIS SUPPURATIVA

- Patient must have clinical response to therapy (i.e., HS-PGA score of clear, minimal or mild with at least a 2-grade improvement relative to baseline score according to Hidradenitis Suppurativa Physician's Global Assessment Scale)

**NOTE:** Duration of continued approval is 1 year

#### FOR NON-INFECTIOUS UVEITIS

- Patient must maintain continued evidence of benefit (i.e., no progression of the underlying disease)

**NOTE:** Duration of continued approval is 1 year

#### FOR CHRONIC NON-INFECTIOUS UVEITIS

- Patient must maintain continued evidence of benefit (i.e., no progression of the underlying disease)

**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? \_\_\_\_\_

\_\_\_\_\_

Update: November 2023