June 1, 2021
Bulletin #200
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# SASKATCHEWAN FORMULARY BULLETIN

## Update to the 62nd Edition of the Saskatchewan Formulary

***Exception Drug Status (EDS) Benefit According to the Following Criteria:***

- **adalimumab**
  **Effective June 1, 2021, new patients (i.e., patients *without* previous EDS approval for Humira) will only be eligible for one of the listed biosimilar formulations of adalimumab.**
  - **Amgevita, adalimumab, pre-filled syringe, 20mg/0.4mL, 40mg/0.8mL; 40 mg/0.8mL auto injector (Amgevita-AMG)**
  - **Hadlima, adalimumab, pre-filled syringe 40mg/0.8mL; autoinjector, 40 mg/0.8mL auto injector (Hadlima-MRK)**
  - **Hulio, adalimumab, pre-filled syringe, 40mg/0.8mL; autoinjector, 40 mg/0.8mL (Hulio-BGP)**
  - **Hyrimoz, adalimumab, pre-filled syringe, 20mg/0.4mL, 40mg/0.8mL; autoinjector, 40 mg/0.8mL (Hyrimoz-SDZ)**
  - **Idacio, adalimumab, autoinjector, 40 mg/0.8mL (Idacio-FCL)**

**Note: These products are not interchangeable. When requesting coverage, please state which specific adalimumab product is being prescribed to avoid administrative and assessment delays.**

| Indication | Criteria |
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| **Rheumatoid arthritis** | For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Psoriatic arthritis** | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Anykylosing Spondylitis** | For the treatment of ankylosing spondylitis (AS) according to the following criteria:<br>**Initial Application (for a 12-week medication trial):**<br>o For patients who have 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<br>o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.<br>**Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):**<br>o Adequate response to treatment assessed at 12 weeks defined as at least |

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| | 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.<br>**Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):**<br>o The 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.<br>**Notes:**<br>o Requests for coverage for this indication must be made by a rheumatologist.<br>o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website. |
| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate **OR** cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br>*Coverage will be approved initially for the induction phase of up to 16 weeks*.<br>*Coverage can be renewed in patients who have responded to therapy.*<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Juvenile idiopathic arthritis** | For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have inadequate response to one or more non-biologic, disease-modifying anti-rheumatic drugs (DMARDs).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Crohn's disease** | For the treatment of moderate to severely active Crohn's disease in patients refractory to or with contraindications to an adequate course of corticosteroids and other immunosuppressive therapy.<br>Clinical response should be assessed after the induction regimen. Ongoing coverage of maintenance therapy will only be provided for responders, and for doses not exceeding 40mg every two weeks.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Ulcerative Colitis** | For the treatment of ulcerative colitis in patients unresponsive to high dose steroids.<br>Initial clinical response should be assessed after three months of therapy. Ongoing coverage will only be provided for those who respond to therapy.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Hidradenitis suppurativa** | For the treatment of patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy (including systemic antibiotics) and who have met the following:<br>o A total abscess and nodule count of 3 or greater;<br>o Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III;<br>o An inadequate response to a 90 day trial of oral antibiotics;<br>o Prescribed by a specialist with expertise in the management of patients with HS.<br>**Note:** Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment. |

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| **Uveitis** | For the treatment of:<br>○ Severe chronic non-infectious uveitis in patients unresponsive to, or unable to take, systemic corticosteroids.<br>○ Moderate chronic non-infectious uveitis in patients unresponsive to, or unable to take, systemic corticosteroids and a non-biologic immunosuppressant.<br>**Note:** This product should be used in consultation with a specialist in this area. |

- **dupilumab, solution for injection, 200mg/1.14mL pre-filled syringe, 300mg/2mL pre-filled syringe, 300mg/2mL pre-filled pen (Dupixent-GZY)**

  For the treatment of moderate to severe[1] atopic dermatitis in patients 12 years of age and older who:

  - Are inadequately controlled with topical prescription therapies, or where these treatments are not appropriate, AND
  - Have had an adequate trial with an inadequate response, or were intolerant, or are ineligible for each of the following therapies: phototherapy (where available), methotrexate and cyclosporine.

  Requests must include documentation of the Eczema Area and Severity Index (EASI) score and Physician Global Assessment score.

  Initial approval: Six (6) months.

  **Renewal criteria**

  Renewal requests will be considered for patients where there has been a 75% or greater improvement from baseline in the EASI score (EASI-75) six months after treatment initiation and where this response is maintained thereafter every six months.
  Renewal requests must include recent EASI score.

  Renewal approval: Six (6) months.

  Requests for coverage for this indication must be made by, or in consultation with a dermatologist.

  *[1]Moderate to severe atopic dermatitis is defined as an EASI score of 16 points or higher; or a Physician Global Assessment score of 3 or 4.*

- **tafamidis meglumine, capsule, 20mg (Vyndaqel-PFI)**

  For the treatment of adult patients with documented cardiac disease due to transthyretin (TTR)-mediated amyloidosis cardiomyopathy (ATTR-CM), wild-type[1] or hereditary[2], who meet all of the following criteria:

  - History of heart failure, defined as at least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic; and
  - Heart failure symptoms classified as New York Heart Association (NYHA) Class I to III.

  Patients must be under the care of a specialist with experience in the diagnosis and management of ATTR-CM.

  <u>Exclusion Criteria (at therapy initiation):</u>

  - Patients classified as NYHA class IV; or

- Patients who have received a heart or liver transplant; or
- Patients with an implanted cardiac mechanical assist device (CMAD); or
- Patients receiving other disease-modifying treatments for ATTR (including interfering ribonucleic acid drugs such as Tegsedi [inotersen] or Onpattro [patisiran]).

Initial approval duration: Nine (9) months

Discontinuation Criteria:
Patients should be regularly reassessed to determine ongoing treatment benefit of tafamidis. Treatment with Vyndaqel should be discontinued for patients who:

- Progress to NYHA class IV; or
- Receive a heart or liver transplant; or
- Receive an implanted CMAD; or
- Require end-of-life care[3].

After initial approval, renewal requests not meeting the discontinuation criteria will be considered for a six (6) month approval duration.

Notes:
[1]Documented wild-type ATTR-CM consists of all of the following: absence of a variant TTR genotype; evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac); and TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry.
[2]Documented hereditary ATTR-CM consists of all of the following: presence of a variant TTR genotype associated with cardiomyopathy and presenting with a cardiomyopathy phenotype; evidence of cardiac involvement by echocardiography with end diastolic interventricular septal wall thickness of greater than 12 mm; presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac).

[3]End-of-life care is defined as care in the late stages of a terminal illness, where life expectancy is measured in months, and treatment aimed at cure or prolongation of life is no longer deemed appropriate, but care is aimed at improving or maintaining the quality of remaining life (e.g. management of symptoms such as pain, nausea and stress).

***Revised Exception Drug Status Criteria:***

**cyclosporine, capsule, 10mg, 25mg, 50mg, 100mg; liquid, 100mg/mL (Neoral-NVR)**
For treatment of:
(a) Nephrotic syndrome.
(b) Severe active rheumatoid arthritis in patients for whom classical slow-acting anti-rheumatic agents are inappropriate or ineffective.
(c) For induction and maintenance of remission of severe psoriasis in patients for whom conventional therapy is ineffective or inappropriate.
(d) *For treatment of patients with atopic dermatitis who have not responded, or are intolerant, to topical treatment (such as steroids, tacrolimus, pimecrolimus). Treatment should be initiated in consultation with a specialist in this area.*
*(e)For the treatment of mild to moderate chronic non-infectious uveitis in patients unresponsive to, or unable to take, systemic corticosteroids and a non-biologic conventional immunosuppressant.*

*Note: This medication should be used in consultation with an ophthalmologist experienced in the management of chronic non-infections uveitis.*

For the above indications prescriptions are subject to deductible (where applicable) and co-payment as for other drugs covered under the Drug Plan. Pharmacies note: claims on behalf of these patients must use the following identifying numbers (not the DIN):
10mg - 00950792
25mg - 00950793
50mg - 00950807
100mg - 00950815
100mg/mL - 00950823

**The biologic criteria for ankylosing spondylitis and plaque psoriasis have been further revised. To summarize the changes for these conditions are:**

- Ankylosing spondylitis – remove the restriction to limit patients to just one therapeutic switch between biologic treatment options.
- Plaque psoriasis – provide access to biologic treatment options where there has been a trial of cyclosporine or methotrexate rather than a trial of both cyclosporine and methotrexate.

In addition to these criteria revisions, The Exception Drug Status (EDS) criteria for a variety of biologic medications have been reformatted to improve clarity for prescribers, pharmacists and patients. The updated format for these drugs is provided below and has been posted on Appendix A located on the Formulary website https://formulary.drugplan.ehealthsask.ca/EDStProg

**abatacept, powder for solution, 125mg/mL pre-filled syringe (Orencia-BMY); 250mg/vial (Orencia-BMY)**

| Indication | Criteria |
|---|---|
| Rheumatoid arthritis (125 mg/mL & 250mg/vial) | For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.<br><br>Coverage will not be provided when used in combination with tumor necrosis factor inhibitors**.**<br><br>**Note:** This product should be used in consultation with a specialist in this area. |
| Juvenile idiopathic arthritis (250 mg/vial only) | For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have not had an adequate response from etanercept.<br><br>Initial coverage for treatment induction will be limited to a maximum of 16 weeks.<br>Coverage of retreatment will only be considered for children who had an adequate initial treatment response and subsequently experience a disease flare. |

**adalimumab, pre-filled syringe, 40mg/0.8mL (Humira-ABV); pre-filled pen, 40mg/0.8mL (Humira Pen-ABV)**

**Effective June 1, 2021, all listed Humira indications have a biosimilar adalimumab option. As such, new patients (i.e., patients without previous EDS approval for Humira) will be eligible only for a listed biosimilar formulation of adalimumab.**

| Indication | Criteria |
|---|---|
| **Rheumatoid arthritis** | For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Psoriatic arthritis** | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Anykylosing Spondylitis** | For the treatment of ankylosing spondylitis (AS) according to the following criteria:<br>**Initial Application (for a 12-week medication trial):**<br>o For patients who have 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<br>o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.<br>**Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):**<br>o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.<br>**Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):**<br>o The 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.<br>**Notes:**<br>o Requests for coverage for this indication must be made by a rheumatologist.<br>o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website. |
| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br>*Coverage will be approved initially for the induction phase of up to 16 weeks*.<br>*Coverage can be renewed in patients who have responded to therapy.*<br>**Note:** This product should be used in consultation with a specialist in this area. |

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| **Juvenile idiopathic arthritis** | For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have inadequate response to one or more non-biologic, disease-modifying anti-rheumatic drugs (DMARDs).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Crohn's disease** | For the treatment of moderate to severely active Crohn's disease in patients refractory to or with contraindications to an adequate course of corticosteroids and other immunosuppressive therapy.<br>Clinical response should be assessed after the induction regimen. Ongoing coverage of maintenance therapy will only be provided for responders, and for doses not exceeding 40mg every two weeks.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Ulcerative Colitis** | For the treatment of ulcerative colitis in patients unresponsive to high dose steroids.<br>Initial clinical response should be assessed after three months of therapy. Ongoing coverage will only be provided for those who respond to therapy.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Hidradenitis suppurativa** | For the treatment of patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy (including systemic antibiotics) and who have met the following:<br>o A total abscess and nodule count of 3 or greater;<br>o Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III;<br>o An inadequate response to a 90 day trial of oral antibiotics;<br>o Prescribed by a specialist with expertise in the management of patients with HS.<br>**Note:** Treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment. |

**adalimumab, pre-filled syringe, 20mg/0.2mL (Humira-ABV)**

**Effective June 1, 2021, all listed Humira indications have a biosimilar adalimumab option. As such, new patients (i.e., patients without previous EDS approval for Humira) will be eligible only for a listed biosimilar formulation of adalimumab.**

For pediatric patients requiring a 20mg dose of adalimumab for the treatment of the following indications. Please note: once patients escalate to a dose greater than 20mg of adalimumab, they will only be eligible for coverage of the 40mg/0.8mL strength.

| Indication | Criteria |
|---|---|
| **Juvenile idiopathic arthritis** | For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have inadequate response to one or more non-biologic, disease-modifying anti-rheumatic drugs (DMARDs).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Crohn's disease** | For the treatment of moderate to severely active Crohn's disease in patients refractory to or with contraindications to an adequate course of corticosteroids and other immunosuppressive therapy. |

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| | Clinical response should be assessed after the induction regimen. Ongoing coverage of maintenance therapy will only be provided for responders, and for doses not exceeding 20mg every two weeks.<br>**Note:** This product should be used in consultation with a specialist in this area. |

**anakinra, subcutaneous injection (pre-filled syringe), 100mg/0.67mL (Kineret-BIO)**

| Indication | Criteria |
|---|---|
| Rheumatoid arthritis | For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.<br><br>Coverage will not be provided when used in combination with tumor necrosis factor inhibitors.<br><br>**Note:** This product should be used in consultation with a specialist in this area. |

**brodalumab, pre-filled syringe, 210mg/1.5mL (Siliq-VAE)**

| Indication | Criteria |
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| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to, methotrexate OR cyclosporine AND have failed, are intolerant to, or are unable to access phototherapy.<br>*Coverage will be approved initially for the induction phase of up to 16 weeks*.<br>*Coverage can be renewed in patients who have responded to therapy.*<br>**Note:** This product should be used in consultation with a specialist in this area. |

**certolizumab pegol, solution for injection, 200mg/mL pre-filled syringe; 200mg/mL autoinjector (Cimzia-UCB)**

| Indication | Criteria |
|---|---|
| **Rheumatoid arthritis** | For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Psoriatic arthritis** | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Ankylosing Spondylitis** | For the treatment of ankylosing spondylitis (AS) according to the following criteria:<br>**Initial Application (for a 12-week medication trial):**<br>o For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at |

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| | maximum tolerated or recommended doses for four weeks without symptom control;<br>AND<br>o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.<br><br>**Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):**<br>o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.<br><br>**Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):**<br>o The 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.<br>**Notes:**<br>o Requests for coverage for this indication must be made by a rheumatologist.<br>o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website. |

**etanercept, powder for injection (vial), 25mg/vial; pre-filled syringe /autoinjector, 50mg/mL (Enbrel-AMG)**

**Effective March 1, 2021, all listed Enbrel indications have a biosimilar etanercept option. As such, new patients (i.e., patients without previous EDS approval for Enbrel) will be eligible only for a listed biosimilar formulation of etanercept.**

| Indication | Criteria |
|---|---|
| **Rheumatoid arthritis** | For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Psoriatic arthritis** | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Juvenile idiopathic arthritis** | For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have inadequate response to one or more non-biologic, disease-modifying anti-rheumatic drugs (DMARDs).<br>**Note:** This product should be used in consultation with a specialist in this area. |

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| **Ankylosing spondylitis** | For the treatment of ankylosing spondylitis (AS) according to the following criteria:<br><br>**Initial Application (for a 12-week medication trial):**<br>o For patients who have 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;<br>AND<br>o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.<br><br>**Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):**<br>o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.<br>**Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):**<br>o The 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.<br>**Notes:**<br>o Requests for coverage for this indication must be made by a rheumatologist.<br>o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website. |
| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br>*Coverage will be approved initially for the induction phase of up to 16 weeks*.<br>*Coverage can be renewed in patients who have responded to therapy.*<br>**Note:** This product should be used in consultation with a specialist in this area. |

**etanercept**

Effective March 1, 2021, new patients (i.e., patients **without** previous EDS approval for Enbrel) will only be eligible for one of the listed biosimilar formulations of etanercept.

**Brenzys, etanercept, subcutaneous injection, pre-filled syringe/pre-filled autoinjector, 50mg/mL (Brenzys-MRK)**

**Erelzi, etanercept, subcutaneous injection, pre-filled syringe, 25mg/0.5mL, 50mg/mL; pre-filled autoinjector 50mg/mL (Erelzi-SDZ)**

Note: These products are not interchangeable. When requesting coverage, please state which specific etanercept product is being prescribed to avoid administrative and assessment delays.

| Indication | Criteria |
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| **Rheumatoid arthritis** | For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Psoriatic arthritis** | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Juvenile idiopathic arthritis** | For the treatment of juvenile idiopathic arthritis in patients who are intolerant to, or have inadequate response to one or more non-biologic, disease-modifying anti-rheumatic drugs (DMARDs).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Ankylosing spondylitis** | For the treatment of ankylosing spondylitis (AS) according to the following criteria:<br><br>**Initial Application (for a 12-week medication trial):**<br>o For patients who have 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;<br>AND<br>o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.<br><br>**Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):**<br>o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.<br>**Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):**<br>o The 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.<br>**Notes:**<br>o Requests for coverage for this indication must be made by a rheumatologist.<br>o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website. |
| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br>*Coverage will be approved initially for the induction phase of up to 16 weeks*. |

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| | *Coverage can be renewed in patients who have responded to therapy.*<br>**Note:** This product should be used in consultation with a specialist in this area. |

**infliximab**
**Avsola, infliximab, powder for solution, 100mg/vial (Avsola-AMG)**
**Inflectra, infliximab, powder for solution, 100mg/vial (Inflectra-HOS)**
**Remicade, infliximab, injection (mg),100mg/vial (Remicade-JAN)**
**Renflexis, infliximab, injection (mg),100mg/vial (Renflexis-MRK)**

Note: These products are not interchangeable. When requesting coverage, please state which specific infliximab product is being prescribed to avoid administrative and assessment delays.

| Indication | Criteria |
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| **Rheumatoid arthritis** | For the treatment of active rheumatoid arthritis in patients who have failed, or are intolerant to, methotrexate and leflunomide.<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br>*Coverage will be approved initially for the induction phase of up to 16 weeks*.<br>*Coverage can be renewed in patients who have responded to therapy.*<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Psoriatic arthritis** | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Ankylosing Spondylitis** | For the treatment of ankylosing spondylitis (AS) according to the following criteria:<br><br>**Initial Application (for a 12-week medication trial):**<br>o For patients who have 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;<br>AND<br>o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.<br><br>**Second Application (following the initial 12-week approval, requests will be considered for a one-year approval timeframe):**<br>o Adequate response to treatment assessed at 12 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS. |

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| | **Subsequent Annual Renewal Applications (beyond the first 15 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):**<br>o The 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.<br>**Notes:**<br>o Requests for coverage for this indication must be made by a rheumatologist.<br>o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website. |
| **Crohn's Disease** | For the treatment of moderate to severely active Crohn's disease in patients refractory to, or with contraindications to, an adequate course of corticosteroids and other immunosuppressive therapy.<br><br>Clinical response should be assessed after the induction regimen.<br>*Ongoing coverage of maintenance therapy will only be provided for responders.*<br><br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Fistulizing Crohn's Disease** | For the treatment of patients with fistulizing Crohn's Disease including but not limited to, symptomatic enterocutaneous or perineal fistulae, enterovaginal fistulae or enterovesical fistulae.<br><br>Clinical response should be assessed after the induction regimen.<br>*Ongoing coverage of maintenance therapy will only be provided for those who respond to treatment.*<br><br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Ulcerative Colitis** | For the treatment of ulcerative colitis in patients unresponsive to high dose steroids.<br><br>Initial clinical response should be assessed after the induction regimen.<br>*Ongoing coverage will only be provided for those who respond to therapy.*<br>Note: This product should be used in consultation with a specialist in this area. |

**ixekizumab, subcutaneous injection, 80mg/mL pre-filled autoinjector; 80mg/mL pre-filled syringe (Taltz-LIL)**

| Indication | Criteria |
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| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br><br>Coverage will be approved initially for the induction phase of up to 12 weeks. |

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| | Coverage can be renewed in patients who have responded to therapy.<br><br>Note: This product should be used in consultation with a specialist in this area. |
| **Psoriatic Arthritis** | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |

**risankizumab, pre-filled syringe, 75mg/0.83mL (Skyrizi-ABV)**

| Indication | Criteria |
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| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br><br>Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy.<br><br>Note: This product should be used in consultation with a specialist in this area. |

**secukinumab, subcutaneous solution, 150mg/1.0mL (Cosentyx-NVR)**

| Indication | Criteria |
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| **Plaque Psoriasis** | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br><br>Coverage will be approved initially for the induction phase of up to 12 weeks. Coverage can be renewed in patients who have responded to therapy.<br><br>Note: This product should be used in consultation with a specialist in this area.<br><br>Coverage may be approved as follows: initial dosing of 300mg doses at weeks 0, 1, 2 and 3, followed by monthly maintenance dosing of 300mg doses starting at week 4. |
| **Psoriatic Arthritis** | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic, disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Ankylosing Spondylitis** | For the treatment of ankylosing spondylitis (AS) according to the following criteria:<br><br>**Initial Application (for a 16-week medication trial):**<br>o For patients who have already been treated conventionally with two or more non-steroidal anti-inflammatory drugs (NSAIDs) taken sequentially at |

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| | maximum tolerated or recommended doses for four weeks without symptom control;<br>AND<br>o Satisfy New York diagnostic criteria: a score ≥ 4 on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) AND a score of ≥ 4 cm on the 0-10cm spinal pain visual analogue scale (VAS) on two occasions at least 12 weeks apart without any change of treatment.<br><br>**Second Application (following the initial 16-week approval, requests will be considered for a one-year approval timeframe):**<br>o Adequate response to treatment assessed at 16 weeks defined as at least 50% reduction in pre-treatment baseline BASDAI score OR by ≥ 2 units AND a reduction of ≥ 2cm in the spinal pain VAS.<br><br>**Subsequent Annual Renewal Applications (beyond the first 16 months, requests are to be submitted annually for consideration of ongoing approval on a yearly basis):**<br>o The 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.<br>**Notes:**<br>o Requests for coverage for this indication must be made by a rheumatologist.<br>o Applications for this indication must be submitted on the designated EDS Application – Ankylosing Spondylitis Drugs form found on the Formulary website. |

**ustekinumab, solution for injection, 45mg/0.5mL, 90mg/1.0ml, 5mg/mL (130mg/26mL) (Stelara-JAN)**

| Indication | Criteria |
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| **Plaque Psoriasis** (solution for injection, 45mg/0.5mL, 90mg/1.0ml only) | For the treatment of adult patients with severe debilitating plaque psoriasis who have failed, or are intolerant to methotrexate OR cyclosporine AND have failed, are intolerant to, or unable to access phototherapy.<br><br>Coverage will be approved initially for the induction phase of up to 16 weeks. Coverage can be renewed in patients who have responded to therapy.<br><br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Psoriatic arthritis** (solution for injection, 45mg/0.5mL, 90mg/1.0ml only) | For the treatment of psoriatic arthritis in patients who have failed, or are intolerant to, methotrexate and one other non-biologic disease-modifying anti-rheumatic drug (DMARD).<br>**Note:** This product should be used in consultation with a specialist in this area. |
| **Crohn's Disease** (solution for infusion, 5mg/mL (130mg/26mL), solution for injection, 90mg/1.0ml only) | For treatment of adult patients with moderate to severely active Crohn's disease (CD) who have had an inadequate response to, loss of response to, or were intolerant to either immunomodulators or one or more tumor necrosis factor-alpha antagonists, or have had an inadequate response to, intolerance to or demonstrated dependence on corticosteroids. |

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| | Clinical response should be assessed in the eight weeks following the single intravenous (IV) induction dose. Ongoing coverage of the maintenance subcutaneous injections will only be provided for those who respond to treatment.<br><br>**Note:** This product should be used in consultation with a specialist in this area. |

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