

## Erelzi (etanercept) Frequently Asked Questions

### 1. What is the funding status of Erelzi (etanercept)?

Effective **December 21, 2017**, Erelzi (etanercept) will be added to the Ontario Drug Benefit (ODB) Formulary as a Limited Use (LU) benefit for the treatment of severe rheumatoid arthritis (RA), ankylosing spondylitis (AS) and polyarticular juvenile idiopathic arthritis (pJIA).

### 2. What are the Limited Use Criteria for Erelzi (etanercept)?

#### Reason For Use (RFU) Code and Clinical Criteria

##### A. Rheumatoid Arthritis (Code 512)

For the treatment of RA in patients who have severe active disease (greater than or equal to 5 swollen joints and rheumatoid factor positive and/or, anti-CCP positive, and/or radiographic evidence of rheumatoid arthritis) and have experienced failure, intolerance, or have a contraindication to adequate trials of disease-modifying anti-rheumatic drugs (DMARDs) treatment regimens, such as one of the following combinations of treatments:

- A. i) Methotrexate (20mg/week) for at least 3 months, AND
  - ii) leflunomide (20mg/day) for at least 3 months, in addition to
  - iii) an adequate trial of at least one combination of DMARDs for 3 months; OR
  
- B. i) Methotrexate (20mg/week) for at least 3 months, AND
  - ii) leflunomide (20mg/day) in combination with methotrexate for at least 3 months; OR
  
- C. i) Methotrexate (20mg/week), sulfasalazine (2g/day) and hydroxychloroquine (400mg/day) for at least 3 months. (Hydroxychloroquine is based by weight up to 400mg per day.)

Maintenance/Renewal: After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year.

For renewals beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

The recommended dosing regimen is 50mg per week or 25mg twice weekly.

LU Authorization Period: 1 year

**B. Ankylosing Spondylitis (Code 513)**

For the treatment of AS in patients who have severe active disease confirmed by radiographic evidence (see note below) with:

- I. Age of disease onset equal to or younger than 50; AND
- II. Low back pain and stiffness for greater than 3 months that improves with exercise and not relieved by rest; AND
- III. Failure to respond to or documented intolerance to adequate trials of 2 non-steroidal anti-inflammatory drugs (NSAIDs) for at least 4 weeks each; AND
- IV. Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of greater than or equal to 4 for at least 4 weeks while on standard therapy.

Note: Radiographic evidence demonstrating the presence of "SI joint fusion" or "SI joint erosion" on X-ray or CT scan, or MRI demonstrating the presence of "inflammation" or "edema" of the SI joint.

Maintenance/Renewal: After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 50 percent reduction in BASDAI score or greater than or equal to 2 absolute point reduction in BASDAI score. For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

The recommended dosing regimen is 50mg per week or 25mg twice weekly.

LU Authorization Period: 1 year

### **C. Polyarticular Juvenile Idiopathic Arthritis (Code 514)**

For the treatment of polyarticular juvenile idiopathic arthritis in patients who have active disease (greater than or equal to 3 swollen joints and greater than or equal to 5 active joints) despite a trial of optimal doses of subcutaneously administered methotrexate (i.e. 15 mg/m<sup>2</sup> per week) for at least 3 months. If the patient is unable to tolerate or has a contraindication to subcutaneous methotrexate, the nature of the intolerance or contraindication should be documented.

Maintenance/Renewal: After 12 months of treatment, maintenance therapy is funded for patients with objective evidence of at least a 20 percent reduction in swollen joint count and a minimum of improvement in 2 swollen joints over the previous year. For funding beyond the second year, the patient must demonstrate objective evidence of preservation of treatment effect.

Therapy must be prescribed by a rheumatologist or a prescriber with expertise in rheumatology.

The recommended dosing regimen for pediatric patients ages 4 to 17 years with active pJIA is 0.8mg/kg per week (up to a maximum of 50 mg per week).

LU Authorization Period: 1 year

### **3. What is difference between Erelzi (etanercept) and Enbrel (etanercept)?**

Erelzi and Enbrel are both etanercept products. Etanercept is an anti-inflammatory medicine that belongs to the class of drugs called biological response modifiers. Erelzi is approved by Health Canada as a biosimilar to Enbrel. Erelzi and Enbrel are manufactured and marketed by different companies.

Please refer to Health Canada's website for further details on [biosimilars](#).

### **4. Are patients with existing Exceptional Access Program (EAP) approval for Enbrel (etanercept) required to switch to Erelzi (etanercept)?**

No. Patients who have an existing Exceptional Access Program (EAP) approval for Enbrel (etanercept) can continue to receive Enbrel (etanercept) for the duration of the EAP approval period. The ministry will also consider EAP renewal requests for Enbrel (etanercept) for patients with existing EAP approvals.

The LU criteria for Erelzi (etanercept) will apply to both new and existing patients with severe RA, AS and pJIA.

Claims for Erelzi (etanercept) will be reimbursed under the ODB program when prescribed in accordance with the LU criteria and accompanied by a valid, fully completed prescription with the appropriate LU documentation (RFU code).

**5. Will the ministry consider new requests for Enbrel (etanercept) reimbursement under the Exceptional Access Program, for the treatment of rheumatoid arthritis, ankylosing spondylitis or polyarticular juvenile idiopathic arthritis?**

The ministry has not accepted new requests for Enbrel (etanercept) under the EAP for the treatment of rheumatoid arthritis and ankylosing spondylitis since July 31, 2017. The ministry will no longer accept new requests for Enbrel for the treatment of polyarticular juvenile idiopathic arthritis once Erelzi is available on the Formulary.

The funding of only biosimilar etanercept products for new requests for patients starting on etanercept is intended to be applied to all three conditions noted above. This includes requests from prescribers granted Temporary Facilitated Access (Rheumatology) starting January 1, 2018 for the children and youth aged 24 years and under who are initiating treatment for pJIA with etanercept following the public funding of Erelzi.

EAP requests for Enbrel for other indications may be considered.

**6. Will the ministry consider requests for Enbrel reimbursement under the Exceptional Access Program for patients who do not respond to Erelzi (etanercept), or are intolerant to Erelzi (etanercept)?**

The ministry will not consider requests for Enbrel (etanercept) reimbursement for patients who do not respond to Erelzi (etanercept), or are intolerant to Erelzi (etanercept) under any program. The physician may wish to consider other therapeutic options.

**7. Is Erelzi (etanercept) currently funded for indications other than rheumatoid arthritis, ankylosing spondylitis and polyarticular juvenile idiopathic arthritis?**

Effective [enter December 2017 Formulary effective date] Erelzi (etanercept) will be listed on the ODB Formulary as a Limited Use (LU) benefit for the following indications: rheumatoid arthritis, ankylosing spondylitis and polyarticular juvenile idiopathic arthritis. At this time, there is no reimbursement for Erelzi (etanercept) for any other indications either as an LU benefit or through the Exceptional Access Program.

**8. How should pharmacies submit claims for Erelzi (etanercept)? Are Erelzi and Brenzys “interchangeable”?**

Pharmacies should be submitting claims using the drug identification number (DIN) of the product and the appropriate reason for use code.

Erelzi and Brenzys are both etanercept products that are approved by Health Canada as biosimilars to Enbrel. However, the two products are not “interchangeable” – i.e., pharmacists do not have the ability to change a patient from one drug to the other drug without the intervention of the doctor who wrote the prescription.

**Additional Information:**

**For pharmacies:**

Please call ODB Pharmacy Help Desk at: 1-800-668-6641

**For all other Health Care Providers and the Public:**

Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282