Brenzys (etanercept) Frequently Asked Questions

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

Effective July 31, 2017, Brenzys (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) and ankylosing spondylitis (AS).

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

Reason For Use (RFU) Code and Clinical Criteria

A. Rheumatoid Arthritis (Code 499)

For the treatment 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 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 physician with expertise in rheumatology.

The recommended dosing regimen is 50mg sc per week.

LU Authorization Period: 1 year

B. Ankylosing Spondylitis (Code 498)

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 less than or equal to 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 physician with expertise in rheumatology.

The recommended dosing regimen is 50mg sc per week.

LU Authorization Period: 1 year

3. What is difference between Brenzys (etanercept) and Enbrel (etanercept)?

Brenzys and Enbrel are both etanercept products. Etanercept is an anti-inflammatory medicine that belongs to the class of drugs called biological response modifiers. Brenzys is approved by Health Canada as a subsequent entry biologic (SEB) to Enbrel. Brenzys and Enbrel are manufactured and marketed by different companies.

Please refer to Health Canada's website for further details on SEBs.

4. Are patients with existing Exceptional Access Program (EAP) approval for Enbrel (etanercept) required to switch to Brenzys (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 Brenzys (etanercept) will apply to both new and existing patients with severe RA and AS.

Claims for Brenzys (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 or ankylosing spondylitis?

The ministry will no longer accept new requests for Enbrel (etanercept) under the EAP for the treatment of rheumatoid arthritis or ankylosing spondylitis. EAP requests 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 Brenzys (etanercept), or are intolerant to Brenzys (etanercept)?

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

7. Is Brenzys (etanercept) currently funded for indications other than rheumatoid arthritis and ankylosing spondylitis??

Effective July 31, 2017 Brenzys (etanercept) will be listed on the ODB Formulary as a Limited Use (LU) benefit for the following indications: rheumatoid arthritis and ankylosing spondylitis. At this time, there is no reimbursement for Brenzys (etanercept) for any other indications either as an LU benefit or through the Exceptional Access Program.

8. How should pharmacies submit claims for Brenzys (etanercept)?

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

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