ANKYLOSING SPONDYLITIS DRUGS

DRUG NAME: Adalimumab **Brand(s): Humira** **DOSAGE FORM/ STRENGTH: 40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection**
DRUG NAME: Certolizumab **Brand(s): Cimzia** **DOSAGE FORM/ STRENGTH: 200 mg/mL prefilled syringe**
DRUG NAME: Etanercept **Brand(s): Enbrel** **DOSAGE FORM/ STRENGTH: 25mg/vial and 50mg prefilled syringe for subcutaneous injection**
DRUG NAME: Golimumab **Brand(s): Simponi** **DOSAGE FORM/ STRENGTH: 50 mg/0.5 ml prefilled syringe and autoinjector**
DRUG NAME: Infliximab **Brand(s): Remicade** **DOSAGE FORM/ STRENGTH: 100mg/10mL intravenous infusion**
DRUG NAME: Secukinumab **Brand(s): Cosentyx** **DOSAGE FORM/ STRENGTH: 150 mg/mL prefilled syringe and 150 mg/mL prefilled pen**
Biosimilars on the formulary as Limited Use Benefits: *Effective February 25, 2016, Infliximab as Remicade for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis will only be considered for funding for existing EAP renewals. Infliximab as Inflectra can be considered through Limited Use*

Cont …

criteria on the Ontario Drug Benefit Formulary.

Effective July 31, 2017, etanercept as Enbrel tor the treatment of ankylosing spondylitis (AS) and rheumatoid arthritis (RA) will only be considered for funding for existing EAP renewals. Etanercept as Brenzys can be considered through Limited Use criteria on the Ontario Drug Benefit Formulary.

Effective December 21, 2017 etanercept as Erelzi tor the treatment of ankylosing spondylitis (AS), rheumatoid arthritis (RA), and polyarticular juvenile idiopathic arthritis (pJIA) will only be considered for funding for existing EAP renewals. Etanercept as Brenzys can be considered through Limited Use criteria on the Ontario Drug Benefit Formulary.

For the treatment of ankylosing spondylitis (AS) OR psoriatic spondylitis (PS) in patients who have severe active disease with:

- Age of disease onset 50 years of age or younger; **AND**
- Low back pain and stiffness for greater than 3 months that improves with exercise and not relieved by rest; **AND**
- 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**
- BASDAI score of ≥ 4 for at least 4 weeks while on standard therapy; **AND**

The information submitted with the request must include the following:

- A list of current concomitant medications related to the AS/PS, including pain medications (if relevant). Please include dosing regimens.
- Details of review of radiographic reports for severe active disease.
  - X-ray or CT scan report stating the presence of "SI joint fusion" or "SI joint erosion" OR
  - MRI report stating the presence of "inflammation" or "edema" of the SI joint
  - Actual radiographic reports must be submitted with the request. If the radiographic reports do not specify the above, the request will be reviewed by external medical experts.

Additional information that should be provided if applicable:

- Schober measurement and chest expansion measurement
- Evidence of restricted spinal mobility
- If the patient has AS/PS with predominantly peripheral joint involvement, additional information pertaining to trials of DMARDs must be provided, and these requests will be reviewed by external medical experts.

Duration of Approval: 1 year

Renewal will be considered for patients with objective evidence of at least a 50% reduction in BASDAI score or ≥ 2 absolute point reduction in BASDAI score. Please provide an update on concomitant medications for AS/PS and whether there has been a reduction in pain medication for AS/PS since initiating the biologic (if applicable).

For renewals beyond the second year, objective evidence of preservation of treatment effect must be provided.

The planned dosing regimen for the requested biologic should be provided. The recommended doses for the treatment of AS/PS

Duration of Approval: 1 year, Second and subsequent renewals: 2 years