## ANKYLOSING SPONDYLITIS DRUGS

<table>
<thead>
<tr>
<th>DRUG NAME</th>
<th>BRANDS REIMBURSED</th>
<th>DOSAGE FORM/STRENGTH</th>
<th>REIMBURSEMENT CRITERIA</th>
<th>STANDARD APPROVAL DURATION</th>
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| Adalimumab| Humira            | 40mg/0.8mL prefilled syringe and 40mg/0.8mL prefilled pen for subcutaneous injection | For the treatment of ankylosing spondylitis (AS) OR psoriatic spondylitis (PS) in patients who have severe active disease with:  
  - Age of disease onset ≤ 50; **AND**  
  - Low back pain and stiffness for > 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** | Initial: 1 year |
| Etanercept| Enbrel            | 25mg/vial and 50mg prefilled syringe for subcutaneous injection | 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... | |
**Infliximab (Remicade)**

*100mg/10mL intravenous infusion*

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.

**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 are as follows:
1. Adalimumab 40mg every other week.
2. Etanercept 25mg twice weekly or 50mg once weekly
3. Golimumab 50 mg once a month
4. Infliximab 3-5mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of up to 5mg/kg/dose every 6 to 8 weeks.

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<thead>
<tr>
<th>First renewal: 1 year</th>
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<td>Second and subsequent renewals: 2 years</td>
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