Initial Approval Date: July 10, 2019

**CRITERIA FOR PRIOR AUTHORIZATION**

Ankylosing Spondylitis Agents

**BILLING CODE TYPE** For drug coverage and provider type information, see the KMAP Reference Codes webpage.

**MANUAL GUIDELINES** Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in table 1 below.

Etanercept (Enbrel®, Erelzi™, Eticovo™)
Infliximab (Remicade®, Inflectra®, Ixifi™, Renflexis®)
Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™)
Certolizumab (Cimzia®)
Golimumab (Simponi®)
Secukinumab (Cosentyx®)

**GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION:** (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a rheumatologist.[2]
- Patient must have had an adequate trial (at least 14 consecutive days) of at least two chemically unique conventional therapies or contraindication to all conventional therapies listed in Table 2.[1,2]
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of one of the following criteria:
    - Patient has high disease activity defined as one of the following:[2]
        - Ankylosing Spondylitis Disease Activity Score (ASDAS) score ≥ 2.1.
        - Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score ≥ 4.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits for Ankylosing Spondylitis (AS) Agents.[3-9]

| Medication | Indication(s) | Age | Dosing Limits |
|---|---|---|---|
| **Interleukin-17a Inhibitors** | | | |
| Secukinumab (Cosentyx™) | Active AS | ≥ 18 years | 150 mg SC once weekly at weeks 0, 1, 2, 3, and 4, then every 4 weeks. |
| **Tumor Necrosis Factor-Alpha (TNF-α) Blockers** | | | |
| Adalimumab (Humira®, Amjevita™, Cyltezo™, Hyrimoz™) | Active AS | ≥ 18 years | 40 mg SC every other week. |
| Certolizumab (Cimzia®) | Active AS | ≥ 18 years | 400 mg initially SC at week 0, 2, and 4 followed by 200 mg every other week or 400 mg every 4 weeks. |
| Etanercept (Enbrel®, Erelzi™, Eticovo®) | Active AS | ≥ 18 years | 50 mg SC once weekly. |
| Golimumab (Simponi®) | Active AS | ≥ 18 years | 50 mg SC once monthly. |
| Golimumab (Simponi Aria®) | Active AS | ≥ 18 years | 2 mg/kg IV at 0 and 4 weeks, then every 8 weeks. |
| Infliximab (Remicade®, Renflexis™, Inflectra®, Ixifi™) | Active AS | ≥ 18 years | 5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks. |

SC: subcutaneous. IV: intravenous

**LENGTH OF APPROVAL (INITIAL):** 12 months

**CRITERIA FOR RENEWAL PRIOR AUTHORIZATION:** (must meet all of the following)

- Prescriber must provide at least one of the following response measure(s):
  - ASDAS score reduction of ≥ 1.1 compared to previous assessment (not compared to baseline).[2]
  - Patient is in remission defined as ASDAS score < 2.1.[2]
  - BASDAI score reduction of ≥ 2 compared to previous assessment (not compared to baseline).[2]
  - Patient is in remission defined as BASDAI score < 4.0.[2]
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

**LENGTH OF APPROVAL (RENEWAL):** 12 months

**FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:**

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

**LENGTH OF APPROVAL (INITIAL AND RENEWAL):** 12 months

Table 2. List of conventional therapy in the treatment of AS

| Oral Ankylosing Spondylitis Therapy | |
|---|---|
| **Generic Name** | **Brand Name** |
| Celecoxib | Celebrex |
| Diclofenac | Cambia, Cataflam, Voltaren oral, Zipsor, Zorvolex |
| Diflunisal | Dolobid |
| Etodolac | Lodine |
| Fenoprofen | Fenortho, Nalfon, ProFeno |
| Flurbiprofen | Ansaid |
| Ibuprofen | Motrin, Advil |
| Indomethacin | Indocin, Tivorbex |
| Ketoprofen | Actron, Nexcede, Orudis, Oruvail |
| Meclofenamate | Meclomen |
| Mefenamic acid | Ponstel |
| Meloxicam | Mobic, Qmiiz, Vivlodex |
| Nabumetone | Relafen |
| Naproxen | Aleve, Anaprox DS, Naprelan, Naprosyn |
| Oxaprozin | Daypro |
| Piroxicam | Feldene |
| Salsalate | Disalcid |
| Sulindac | Clinoril |
| Tolmetin | Tolectin |

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

| Biologic Agents/Janus Kinase Inhibitors | | |
|---|---|---|
| Actemra® (tocilizumab) | Humira® (adalimumab) | Rituxan® (rituximab) |
| Amevive® (alefacept) | Hyrimoz™ (adalimumab-adaz) | Siliq® (brodalumab) |
| Amjevita™ (adalimumab-atto) | Ilaris® (canakinumab) | Simponi® (golimumab) |
| Cimzia® (certolizumab) | Ilumya™ (tildrakizumab-asmn) | Simponi Aria (golimumab) |
| Cinqair® (reslizumab) | Inflectra® (infliximab-dyyb) | Skyrizi™ (Risankizumab) |
| Cosentyx® (secukinumab) | Ixifi™ (infliximab-qbtx) | Stelara® (ustekinumab) |
| Cyltezo™ (adalimumab-adbm) | Kevzara® (sarilumab) | Taltz® (ixekizumab) |
| Dupixent® (benralizumab) | Kineret® (anakinra) | Tremfya® (guselkumab) |
| Enbrel® (etanercept) | Nucala® (mepolizumab) | Tysabri® (natalizumab) |
| Entyvio® (vedolizumab) | Olumiant® (baricitinib) | Xeljanz® (tofacitinib) |
| Erelzi™ (etanercept-szzs) | Orencia® (abatacept) | Xeljanz XR® (tofacitinib) |
| Eticovo® (etanercept-ykro) | Remicade® (infliximab) | Xolair® (omalizumab) |
| Fasenra™ (benralizumab) | Renflexis® (infliximab-abda) | |

References


1. American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network 2015 Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol 2016; 68 (2):282-98. Also available at https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Axial-Spondyloarthritis . Accessed 6/4/19.
2. 2016 update of the ASAS-EULAR management recommendations for axial spondyloarthritis. Ann Rheum Dis 2017; 76:978-91. Available at https://ard.bmj.com/content/76/6/978 . Accessed 6/4/19.
3. Enbrel (etanercept) [package insert]. Thousand Oaks, CA: Immunex Corp., Amgen; Nov 2017.
4. Remicade (infliximab) [package insert]. Horsham, PA: Janssen Biotech, Inc; Jun 2018.
5. Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc.; Dec 2018.
6. Cimzia (certolizumab) [package insert]. Smyrna, GA: UCB, Inc.; Mar 2019.
7. Simponi (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; May 2018.
8. Simponi Aria (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; Feb 2018.
9. Cosentyx (Secukinumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; Jan 2018.


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DRUG UTILIZATION REVIEW COMMITTEE CHAIR

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DATE

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PHARMACY PROGRAM MANAGER
DIVISION OF HEALTH CARE FINANCE
KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT

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DATE