

**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.

- Adalimumab (Humira<sup>®</sup>, [Amjevita™](#), [Cyltezo<sup>®</sup>](#), [Hyrimoz™](#))
- Certolizumab (Cimzia<sup>®</sup>)
- Etanercept (Enbrel<sup>®</sup>, [Erelzi™](#), [Eticovo<sup>®</sup>](#))
- Golimumab (Simponi<sup>®</sup>, [Simponi Aria<sup>®</sup>](#))
- Infliximab (Remicade<sup>®</sup>, [Avsola<sup>®</sup>](#), Inflectra<sup>®</sup>, [Ixifi™](#), Renflexis<sup>®</sup>)
- Ixekizumab (Taltz<sup>®</sup>)
- Secukinumab (Cosentyx<sup>®</sup>)
- [Tofacitinib \(Xeljanz<sup>®</sup>, Xeljanz<sup>®</sup> XR\)](#)

**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.<sup>2</sup>
- 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.<sup>1,2</sup>
- [For tofacitinib, patient must have had an adequate trial \(at least 12 weeks\) of at least one or contraindication to all Tumor Necrosis Factor \(TNF\) blockers listed in Table 1.](#)<sup>1,11</sup>
- For all agents listed, the preferred PDL drug, [if applicable](#), 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:<sup>2</sup>
    - Ankylosing Spondylitis Disease Activity Score (ASDAS) score  $\geq$  2.1.
    - Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score  $\geq$  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.<sup>3-14</sup>

Medication	Indication(s)	Age	Dosing Limits
<b>Interleukin-17a Inhibitors</b>			
Ixekizumab (Taltz <sup>®</sup> )	Active AS	$\geq$ 18 years	160 mg SC initially, then 80 mg SC every 4 weeks.
Secukinumab (Cosentyx <sup>®</sup> )	Active AS	$\geq$ 18 years	150 mg SC once weekly at weeks 0, 1, 2, 3, and 4, then every 4 weeks.
<b>Janus Kinase Inhibitors</b>			
<a href="#">Tofacitinib (Xeljanz<sup>®</sup>)</a>	<a href="#">Active AS</a>	<a href="#">≥ 18 years</a>	<a href="#">5 mg orally twice daily.</a>
<a href="#">Tofacitinib (Xeljanz<sup>®</sup> XR)</a>	<a href="#">Active AS</a>	<a href="#">≥ 18 years</a>	<a href="#">11 mg orally daily.</a>
<b>Tumor Necrosis Factor-Alpha (TNF-α) Blockers</b>			

**APPROVED-DRAFT PA Criteria**

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®), Avsola®, Inflectra®, Renflexis®, Inflectra®, Ixifi™)**	Active AS	≥ 18 years	5 mg/kg IV at 0, 2, and 6 weeks, then every <u>6-8</u> weeks.

SC: subcutaneous. IV: intravenous. \*Inflectra® and Ixifi™ are infliximab biosimilars, but are currently not indicated for RA. \*\*Biosimilars to these products are FDA-approved, but some are not currently marketed.

**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).<sup>2</sup>
  - Patient is in remission defined as ASDAS score < 2.1.<sup>2</sup>
  - BASDAI score reduction of ≥ 2 compared to previous assessment (not compared to baseline).<sup>2</sup>
  - Patient is in remission defined as BASDAI score < 4.0.<sup>2</sup>
- 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-szsz)	Orencia® (abatacept)	Xeljanz XR® (tofacitinib)
Eticovo® (etanercept-ykro)	Remicade® (infliximab)	Xolair® (omalizumab)
Fasenra™ (benralizumab)	Renflexis® (infliximab-abda)	

References

1. [2019 Update of the 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.* 2019;71(10):1599-1613. ~~Arthritis Rheumatol 2016; 68 (2):282-98.~~ Also available at <https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Axial-Spondyloarthritis> . Accessed ~~36/164/2219~~.
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 Inc.~~; ~~Nov 2017~~ April 2021.
4. Remicade (infliximab) [package insert]. Horsham, PA: Janssen Biotech, Inc; ~~Jun 2018~~ October 2021.
5. Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc.; ~~Dec 2018~~ February 2021.
6. Cimzia (certolizumab) [package insert]. Smyrna, GA: UCB, Inc.; ~~Mar~~ September 2019.
7. Simponi (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; ~~May 2018~~ September 2019.
8. Simponi Aria (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; ~~Feb 2018~~ February 2021.
9. Cosentyx (Secukinumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; ~~Jan 2018~~ December 2021.
10. Taltz (ixekizumab) [package insert]. Indianapolis, IN: Eli Lilly and Company; ~~March~~ November 2021.
11. Xeljanz/Xeljanz XR (tofacitinib) [package insert]. New York, NY: Pfizer; January 2022.
12. Inflectra (infliximab-dyyb) [package insert]. New York, NY: Pfizer; March 2022.
13. Renflexis (infliximab-abda) [package insert]. Jersey City, NJ: Organon & Co.; January 2022.
- 10.14. Avsola (infliximab-axxq) [package insert]. Thousand Oaks, CA: Amgen, Inc; Sept 2021.

