DRAFT PA Criteria

Initial Approval Date: July 10, 2019
Revised Dates: January 19, 2022
October 9, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Adult Rheumatoid Arthritis 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.

Abatacept (Orencia®)
Adalimumab (Humira®~~, Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™)~~
Anakinra (Kineret®)
Baricitinib (Olumiant®)
Certolizumab (Cimzia®)
Etanercept (Enbrel®~~, Erelzi™, Eticovo™~~)
Golimumab (Simponi®, Simponi Aria®)
Infliximab (Remicade®, Avsola®, Inflectra®, ~~Ixifi™,~~ Renflexis®)
Rituximab (Rituxan®, Ruxience®, Truxima®)
Sarilumab (Kevzara®)
Tocilizumab (Actemra®)
Tofacitinib (Xeljanz®)
Upadacitinib (Rinvoq®™)

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~~3
- Patient must have had an adequate trial (at least 90 consecutive days) of or contraindication to methotrexate. If the patient has a contraindication to methotrexate, the patient must have an adequate trial of at least one other conventional therapy or contraindication to all conventional therapies listed in Table 2.~~1,2~~,3
- For baricitinib, tofacitinib, and upadacitinib, patient must have had an adequate trial (at least 6-8 weeks) of at least one or contraindication to all Tumor Necrosis Factor (TNF) blocker listed in Table 1.[15-17,23]
- 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:
    - Patient has active moderate to severe rheumatoid arthritis disease activity, as defined by:[1,2]
        - Patient Activity Scale (PAS) or PAS-II score > 3.7
        - Routine Assessment of Patient Index Data (RAPID3) score > 2.0
        - Clinical Disease Activity Index (CDAI) > 10
        - Disease Activity Score (DAS28) score > 3.2
        - Simplified Disease Activity Index (SDAI) score > 11.0
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Adult Rheumatoid Arthritis (RA) Agents.[3-24][1-22]

Medication	Indication(s)	Age	Dosing Limits
Anti-CD 20			
Rituximab (Rituxan®, Ruxience®, Truxima®)*	Moderate to Severe active RA	≥ 18 years	1000 mg IV at weeks 0 and 2 per every 24 week cycle.
Interleukin-1 Inhibitors			
Anakinra (Kineret ®)	Moderate to Severe active RA	≥ 18 years	100 mg SC once daily.
Interleukin-6 Inhibitors			
Sarilumab (Kevzara®	Moderate to Severe active RA	≥ 18 years	200 mg SC once every 2 weeks.
Tocilizumab (Actemra®)	Moderate to Severe active RA	≥ 18 years	IV: 8 mg/kg every 4 weeks up to a maximum of 800 mg. SC: < 100 kg: 162 mg once every 2 weeks initially, followed by an increase to weekly based on clinical response. ≥ 100 kg: 162 mg once every week.
Janus Kinase Inhibitors			
Baricitinib (Olumiant®)	Moderate to Severe active RA	≥ 18 years	2 mg orally once daily.
Tofacitinib (Xeljanz®)	Moderate to Severe active RA	≥ 18 years	5 mg orally twice daily.
Tofacitinib (Xeljanz XR®)	Moderate to Severe active RA	≥ 18 years	11 mg orally once daily.
Upadacitinib (Rinvoq®™)	Moderate to Severe active RA	≥ 18 years	15 mg orally once daily.
Selective T-Cell Costimulation Blockers			
Abatacept (Orencia®)	Moderate to Severe active RA	≥ 18 years	IV: at 0, 2 and 4 weeks, then every 4 weeks thereafter < 60 kg: 500 mg. 60-100 kg: 750 mg > 100 kg: 1,000 mg SC: 125 mg once every week.
Tumor Necrosis Factor-Alpha (TNF-α) Blockers			
Adalimumab (Humira®, ~~Amjevita™, Cyltezo™, Hyrimoz™, Hadlima™~~)**	Moderate to Severe active RA	≥ 18 years	40 mg SC every week or 80mg every other week.
Certolizumab (Cimzia®)	Moderate to Severe active RA	≥ 18 years	400 mg initially SC at weeks 0, 2, and 4 followed by 200 mg every other week or 400 mg every 4 weeks.
Etanercept (Enbrel®, ~~Erelzi™, Eticovo™~~)**	Moderate to Severe active RA	≥ 18 years	50 mg SC once weekly.
Golimumab (Simponi®)	Moderate to Severe active RA	≥ 18 years	50 mg SC once ~~monhtly~~monthly.
Golimumab (Simponi Aria®)	Moderate to Severe active RA	≥ 18 years	2 mg/kg IV at weeks 0, 4, then every 8 weeks thereafter

Infliximab (Remicade®, Renflexis™, Inflectra®, ~~Ixifi™~~, Avsola®)**	Moderate to Severe active RA	≥ 18 years	3 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks.

SC: subcutaneous. IV: intravenous. *~~Truxima® and Ruxience™ are~~Riabni™ is a rituximab biosimilar~~s~~, but ~~are~~ is 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):
  - Low disease activity or remission.[1,2]
    - PAS or PAS-II score ≤ 3.7
    - RAPID3 score ≤ 2.0
    - CDAI score ≤ 10.0
    - DAS28 score ≤ 3.2
    - SDAI score ≤ 11.0
- Must not exceed dosing limits listed in Table 1.
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 3. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating 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 RA.[1]

Non-Biologic DMARDs	
Generic Name	**Brand Name**
Hydroxychloroquine	Plaquenil®
Leflunomide	Arava®
Methotrexate	Trexall®, Rheumatrex®, Otrexup®, Rasuvo®
Sulfasalazine	Azulfidine®

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

Immunomodulating Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Ilumya™ (tildrakizumab-asmn)	Siliq® (brodalumab)
Adbry™ (tralokinumab)	Kevzara® (sarilumab)	Simponi® (golimumab)
Benlysta® (belimumab)	Kineret® (anakinra)	Simponi Aria (golimumab)
Cimzia® (certolizumab)	Nucala® (mepolizumab)	Skyrizi™ (risankizumab-rzaa)
Cinqair® (reslizumab)	Olumiant® (baricitinib)	Stelara® (ustekinumab)
Cosentyx® (secukinumab)	Opzelura™ (ruxolitinib)	Taltz® (ixekizumab)
Dupixent® (dupilumab)	Orencia® (abatacept)	Tezspire™ (tezepelumab-ekko)
Enbrel® (etanercept) & biosimilars (Erelzi™, Eticovo®)	Remicade® (infliximab) & biosimilars (Avsola™, Inflectra®, Ixifi™, Renflexis®)	Tremfya® (guselkumab)
Entyvio® (vedolizumab)	Rinvoq™ (upadacitinib)	Tysabri® (natalizumab)

Fasenra™ (benralizumab)	Rituxan® (rituximab) & biosimilars (Riabni™, Ruxience™, Truxima®)	Xeljanz® (tofacitinib)
Humira® (adalimumab) & biosimilars (Abrilada™, Amjevita™, Cyltezo™, Hulio™, Hyrimoz™, Yusimry™)	Rituxan Hycela™ (rituximab/hyaluronidase)	Xeljanz XR® (tofacitinib)
Ilaris® (canakinumab)	Saphnelo™ (anifrolumab)	Xolair® (omalizumab)
		~~Amevive® (alefacept)~~

Notes:

Humira (adalimumab)	There are 7 FDA-approved biosimilars (Abrilada, Amjevita, Cyltezo, Hadlima, Hulio, Hyrimoz, Yusimry). None of these products are expected to be marketed until 2023. Cyltezo became an interchangeable product on 10/15/21.
Enbrel (etanercept)	There are 2 FDA-approved biosimilars (Erelzi, Eticovo). None of these biosimilars are currently marketed.
Remicade (infliximab)	Out of 4 FDA-approved biosimilars, Ixifi is the only biosimilar that is not currently marketed.
Rinvoq®™ (upadacitinib)	May be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). Use in combination with biologic DMARDs or potent immunosuppressants (eg, azathioprine, cyclosporine) is not recommended.
JAK inhibitors	The FDA now requires boxed warnings for JAK inhibitors used to treat inflammatory conditions (Xeljanz, Olumiant, Rinvoq, Opzelura). As of 9/1/2021, the latest announcement requires information about the risk of major adverse cardiovascular events (MACE). [15-17]

References

1. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research 2021; 73(7):924-939. Available at https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Rheumatoid-Arthritis. Accessed 9/1/21.
~~1.~~2. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016; 68(1):1-26. https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Rheumatoid-Arthritis . Accessed 5/30/19.
~~2.~~3. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2016 update. Ann Rheum Dis 2017; 76:960-77. Available at https://www.eular.org/recommendations_management.cfm . Accessed 6/11/19.
~~3.~~4. Enbrel (etanercept) [package insert]. Thousand Oaks, CA: Immunex Corp., Amgen; ~~Nov 2017~~Aug 2020.
~~4.~~5. Remicade (infliximab) [package insert]. Horsham, PA: Janssen Biotech, Inc; ~~Jun 2018~~Oct 2021.
~~5.~~6. Humira (adalimumab) [package insert]. North Chicago, IL: AbbVie Inc.; ~~Dec 2018~~Feb 2021.
~~6.~~7. Cimzia (certolizumab) [package insert]. Smyrna, GA: UCB, Inc.; ~~Mar~~ Sep 2019.
~~7.~~8. Simponi (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; ~~May 2018~~Sep 2019.
~~8.~~9. Simponi Aria (golimumab) [package insert]. Horsham, PA: Janssen Biotech, Inc.; Feb ~~2018~~2021.
~~9.~~10. Kineret (anakinra) [package insert]. Stockholm, Sweden: Swedish Orphan Biovitrum AB; ~~Jun 2018~~Dec 2020.
~~10.~~11. Orencia (abatacept) [package insert]. Princeton, NJ: Bristol-Myers Sq uibb ~~Compant~~Company; Mar 2019.
~~11.~~12. Rituxan (rituximab) [package insert]. South San Francisco, CA: Genentech, Inc..; ~~Jan 2019~~Dec 2021.
~~12.~~13. Actemra (tocilizumab) [package insert]. South San Francisco, CA: Genentech, Inc..; ~~Apr 2019~~Mar 2021.
~~13.~~14. Kevzara (sarilumab) [package insert]. Bridgewater, NJ: Sanofi-Aventis US LLC; Apr 2018.

~~14.~~15. Xeljanz (~~tafacitinib~~tofacitinib) [package insert]. New York, NY: Pfizer Labs; ~~Oct 2018~~Dec 2021.
~~15.~~16. Olumiant (baricitinib) [package insert]. Indianapolis, IN: Lilly USA; ~~May 2018~~ Dec 2021.
~~16.~~17. Rinvoq (upadacitinib) [prescribing information]. North Chicago, IL: AbbVie Inc; ~~August 2019~~ Dec 2021.
~~17. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; March 2018.~~
~~18. Cyltezo (adalimumab- adbm) [prescribing information]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals Inc: August 2017.~~
~~19. Hadlima (adalimumab-bwwd) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; July 2019.~~
~~20. Erelzi (etanercept) [prescribing information]. Princeton, NJ: Sandoz Inc; January 2018.~~
~~21. Eticovo (etanercept) [prescribing information]. Republic of Korea: Samsung Bioepis Co., Ltd. Apr 2018.~~
~~22.~~18. Inflectra (infliximab-dyyb) [prescribing information]. New York, NY: Pfizer; ~~September 2016~~June 2021.
~~23.~~19. Renflexis (infliximab-abda) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; June 2019.
20. ~~Ixifi (infliximab-qbtx) [prescribing information]. New York, NY: Pfizer; December 2017.~~Ruxience (rituximab-pvvr) [prescribing information]. New York, NY: Pfizer; November 2021.
21. Truxima (rituximab-abbs) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc; May 2020.
22. Avsola (infliximab-axxq) [prescribing information]. Thousand Oaks, CA: Amgen, Inc; Sep 2021.
~~24.~~23. U.S. Food and Drug Administration. FDA requires warnings about increased risk of serious heart-related events, cancer, blood clots and death for JAK inhibitors that treat certain chronic inflammatory conditions, September 1, 2021. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-warnings-about-increased-risk-serious-heart-related-events-cancer-blood-clots-and-death. Accessed on 12/15/2021.

~~Drug Utilization Review Committee Chair~~

~~Pharmacy Program Manager~~
~~Division of Health Care Finance~~
~~Kansas Department of Health and Environment~~

~~Date~~

~~Date~~