MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

POLICY:	Rheumatoid Arthritis (RA)	**P&T DATE:**	9/15/2020
CLASS:	Rheumatology/Anti-inflammatory Disorders	**REVIEW HISTORY** (*month/year*)	05/19, 02/18, 02/17, 2/16, 5/15, 10/14, 2/13, 2/12, 5/10, 2/08, 2/07
LOB:	Medi-Cal		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Rheumatoid Arthritis (RA) is an inflammatory condition that usually involves small joints and estimated to affect 1.3 million individuals in the U.S. with 75% of patients suffering from RA being female.[1] Early manifestations of RA include joint pain, stiffness, and swelling. Progression of RA will lead to permanent joint damage and deformity. This review will examine the treatment guidelines of RA, the currently available RA drug products, and their coverage criteria.

Available Rheumatoid Arthritis Agents *(Current as of 01/2019)*

Formulary Agents					
Therapeutic Class	**Generic Name (Brand Name)**	**Available Strengths**	**Fml Limits**	**Cost/ Month***	**Notes**
Oral DMARDs	Azathioprine (Imuran)	50mg, 75mg, 100mg	-	$24.94	
	Cyclosporine, micronized	25mg, 100mg Capsule	-	$196.83	Regular cyclosporine is non-formulary.
	Leflunomide (Arava)	10mg Tablet	-	$81.52	
	Methotrexate Tablet, Vial	2.5mg; 25mg/2ml	-	$35.94	
	Sulfasalazine Tablet, DR Tablet	500mg	-	$23.06	
Tumor Necrosis Factor Inhibitor	Adalimumab (Humira)	20mg/0.4ml, 40mg/0.8ml	PA; PL; SP	$6,208.92	Reserved for treatment failure to one oral DMARD for 3 months.
	Etanercept (Enbrel)	50mg/ml, 25mg/ml,	PA; PL; SP	$6,335.60	Reserved for treatment failure to one oral DMARD for 3 months.
	Infliximab-dyyb (Inflectra) Infliximab-abda (Renflexis)	100mg IV vial	PA; PL; SP	$1,531.26 $1,219.12	Reserved for treatment failure to one oral DMARD for 3 months.
	Infliximab (Remicade)	100mg IV vial	NF	$8,858.05	Non-Formulary
	Golimumab (Simponi)	50mg/0.5ml, 100mg/ml	PA; PL; SP	$5,770.82	Reserved for treatment failure to either Adalimumab, Etanercept, Infliximab, Sarilumab, or Abatacept
	Golimumab (Simponi Aria)	50mg/4ml IV vial	NF	--	Non-Formulary
	Certolizumab (Cimzia)	200mg/ml	PA; PL; SP	$10,385.84	Reserved for treatment failure to either Adalimumab, Etanercept, Infliximab, Sarilumab, or Abatacept
Other Therapies	Sarilumab (Kevzara)	150mg/1.14ml; 200mg/1.14ml	PA; PL; SP	$3,498.18	Reserved for treatment failure to one oral DMARD for 3 months.
	Abatacept (Orencia)	125mg/ml; 250mg IV vial	PA; PL; SP	$5,254.68	Reserved for treatment failure to one oral DMARD for 3 months.
	Rituximab (Rituxan)	10mg/ml IV vial	PA; PL; SP	$1,879.03	Reserved for treatment failure to either Adalimumab, Etanercept, Infliximab, Sarilumab, or Abatacept

	Tocilizumab (Actemra)	162mg/0.9ml; 80mg/4ml IV vial, 200mg/10ml IV vial, 400mg/20ml IV vial	PA; PL; SP	$2,363.32-$4,726.64	Reserved for treatment failure to either Adalimumab, Etanercept, Infliximab, Sarilumab, or Abatacept
	Baricitinib (Olumiant)	2mg	PA;PL;SP; QL	$2,564.10	Reserved for treatment failure to one oral DMARD for 3 months.
	Tofacitinib (Xeljanz)	5mg, 11mg	PA;PL; SP;QL	$5,376.60	Reserved for treatment failure to Baricitinib
	Upadacitinib (Rinvoq)	15mg	PA;PL;SP; QL	$5,899.80	Reserved for treatment failure to Baricitinib
	Anakinra (Kineret)	100mg/0.67ml	NF	--	Non-Formulary

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Oral DMARDs

Azathioprine, Cyclosporine (Modified), Hydroxychloroquine, Leflunomide, Methotrexate 25mg/ml Vial, Methotrexate Tablets, Sulfasalazine IR/DR Tablets

- ❒ **Coverage Criteria:** None.
- ❒ **Limits:** None.
- ❒ **Required Information for Approval:** None.
- ❒ **Non-Formulary*:*** Otrexup, Rasuvo, Cyclosporine (Regular)

Biologics

1st line—Adalimumab (Humira), Etanercept (Enbrel), Infliximab, Sarilumab (Kevzara), Abatacept (Orencia), Baricitinib (Olumiant)

- ❒ **Coverage Criteria:** Reserved for treatment failure to 12 weeks of dose-optimized, oral DMARD therapy (Methotrexate 15-25mg/week, Leflunomide, Hydroxychloroquine, Sulfasalazine, Azathioprine). If patient is unable to tolerate one oral DMARD, a second oral DMARD must be tried.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Prescription history showing at least 3 month trial of one oral DMARD.
- ❒ **Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy. Must be initiated by a rheumatologist.

2nd line—Certolizumab (Cimzia), Golimumab (Simponi), Tocilizumab (Actemra), Rituximab (Rituxan)

- ❒ **Coverage Criteria:** Reserved for treatment of rheumatoid arthritis with treatment failure to Adalimumab, Etanercept, Infliximab, Sarilumab, or Abatacept. Restricted to specialty pharmacy. Must be prescribed by a rheumatologist.
- ❒ **Limits:** 30 tablets per 30 days
- ❒ **Required Information for Approval:** Prescription history showing at least 3 month trial of one first line agent (Adalimumab, Etanercept, Infliximab, Sarilumab, or Abatacept).

- ❒ **Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy. Must be initiated by a rheumatologist. Must not have a previous history of thrombosis.

2nd line—Tofacitinib (Xeljanz), Upadacitinib (Rinvoq)

- ❒ **Coverage Criteria:** Reserved for treatment of rheumatoid arthritis with treatment failure or contraindication to Baricitinib. Restricted to specialty pharmacy.
- ❒ **Limits:**
  - Xeljanz 5mg tablets: Limited to 60 tablets per 30 days.
  - Xeljanz XR 11mg tablets: Limited to 30 tablets per 30 days.
- ❒ **Required Information for Approval:** Prescription history or medical authorization history showing at least 3 month trial of Baricitinib.
- ❒ **Other Notes:** Medication is to be dispensed by HPSJ's designated specialty pharmacy. Must be initiated by a rheumatologist.

⌖ CLINICAL JUSTIFICATION

The *2015 American College of Rheumatology (ACR) Guidelines*[2] recommends the following:

Treat-to-Target Approach

The 2015 ACR guidelines strongly emphasize the "treat to target" approach—that is, adjust a patient's therapeutic regimen as necessary to achieve a specific goal rather than treating without a measureable goal. Treatment goal is usually to achieve remission or low disease activity. The ACR approves 6 different assessment tools *(see Figure 1 below)* that objectively calculates patient's disease activity. Evidence suggests patients on RA therapies benefit the most when providers practice the "treat to target" approach.

Figure 1: ACR recommended Instruments to measure RA disease activity

Instrument (reference)	Thresholds of disease activity
Patient Activity Scale (PAS) or PASII (range 0–10) (149)	Remission: 0–0.25 Low activity: >0.25–3.7 Moderate activity: >3.7 to <8.0 High activity: ≥8.0
Routine Assessment of Patient Index Data 3 (RAPID3) (range 0–10) (155)	Remission: 0–1.0 Low activity: >1.0–2.0 Moderate activity: >2.0–4.0 High activity: >4.0–10
Clinical Disease Activity Index (CDAI) (range 0–76.0) (156)	Remission: ≤2.8 Low activity: >2.8–10.0 Moderate activity: >10.0–22.0 High activity: >22
Disease Activity Score (DAS) 28 erythrocyte sedimentation rate (ESR) (range 0–9.4) (157)	Remission: <2.6 Low activity: ≥2.6 to <3.2 Moderate activity: ≥3.2 to ≤5.1 High activity: >5.1
Simplified Disease Activity Index (SDAI) (range 0–86.0) (158)	Remission: ≤3.3 Low activity: >3.3 to ≤11.0 Moderate activity: >11.0 to ≤26 High activity: >26

* These 6 measures were endorsed by the American College of Rheumatology in 2012 (16). Other measures are now available to clinicians, but they were not included in this guideline because it was beyond the scope of this review. Adapted from ref. 16.

Early RA Patients

Low Disease Activity

- DMARD monotherapy (MTX preferred) over double or triple DMARD therapy as initial first-line therapy.
  - Other conventional DMARDs include hydroxychloroquine, leflunomide, sulfasalazine.

Moderate-High Disease Activity (despite DMARD use)

- Combination DMARD therapy OR biologic + MTX is recommended.
  - Biologics should be used in combination with MTX whenever possible due superior efficacy.
- Patients with moderate or high disease activity despite treatment with DMARD or biologic therapies, consider adding low-dose corticosteroids (≤10 mg/day of prednisone or equivalent dose of another corticosteroid).
  - Low-dose corticosteroids may act as a bridging agent until the benefits of DMARDs are observed.

- Patients experiencing a flare, consider a short-term course (<3 months) of low dose corticosteroid

Established RA Patients

Low Disease Activity

- MTX is the preferred initial therapy.
- DMARD monotherapy is preferred over combination DMARD therapy.
- DMARD monotherapy is recommended over Tofacitinib.

Moderate-High Disease Activity (despite DMARD use)

- Combination DMARD therapy OR biologic + MTX is recommended.
    - Biologics should be used in combination with MTX whenever possible due superior efficacy.
- If disease activity is moderate to high despite currently on a biologic (without DMARD), consider adding one or two DMARDs to biologic therapy.
    - If patient failed TNF biologic, consider switching to another TNF biologic or to a non-TNF biologic. However, if patient has failed 2 or more TNF-biologics, consider switching to a non-TNF biologic (and vice versa).
    - TNF biologics and non-TNF biologics are recommended over Tofacitinib.

RA in special populations

Congestive Heart Failure (CHF) NHYA Class III or IV

- Combination DMARD therapy, non-TNF biologic, or Tofacitinib recommended over TNF biologics.

Hepatitis B

- Patients with active Hep B infection who are currently receiving antiviral treatment or patients with natural immunity (HB core antibody and HB antibody positive), the guidelines strongly recommend proceeding with standard RA treatment (includes TNF biologic therapies).
    - "Active infection" = Hep B surface antigen positive for >6 months)
- Patients with chronic Hep B infection currently NOT receiving treatment, the guidelines recommend treating the infection first before initiating immunosuppressive therapy.

Hepatitis C

- Patients with chronic Hepatitis C treatment, currently received or have received antiviral treatment, guidelines conditionally recommend proceeding with standard RA treatment.
- Patients with chronic Hepatitis C treatment, currently not receiving antiviral treatment, recommend using DMARD therapy over TNF biologics.

Cancer

- *Skin Cancer (melanoma or non-melanoma)*—DMARD therapy preferred over biologics or Tofacitinib.
- *Lymphoproliferative Disorders*—Rituximab is preferred. Recommend combination DMARD therapy, Abatacept, or Tocilizumab over TNF biologics.
- *Solid Organ Cancers*—conditionally recommend proceeding with standard RA treatment.

Serious Infections

- Patients with established RA with moderate or high disease activity with history of serious infections, guidelines conditionally recommend using combination DMARD therapy or Abatacept over TNF biologics.

The 2015 ACR Guidelines and 2016 EULAR guidelines recommend initiating 3-month DMARD monotherapy (Methotrexate or Leflunomide) for patients with low disease activity without poor prognosis. Poor prognosis is defined as: presence of 1 or more of the following features: functional limitation (e.g., HAQ DI or similar valid tools), extraarticular disease (e.g., presence of rheumatoid nodules, RA vasculitis, Felty's syndrome), positive rheumatoid factor, or bony erosions by radiograph. For patients not responding to monotherapy, the guidelines recommend adding another or switching to a non-methotrexate DMARD. Patients still not responding may need to add or switch to a TNF inhibitor.

For patients with moderate/severe disease activity or patients with low disease activity but poor prognosis, initiate 3-month trial of Methotrexate or consider combinational (dual or triple) DMARD therapy. Unresponsive patients may require adding a biologic therapy. Most biologics require 3 months to observe therapeutic benefits. However, certain biologics (Abatacept, Rituximab, Ustekinumab), require 6 months or longer before the full benefits are seen. The efficacy between biologics do not differ significantly but the cost

may vary due to differences in administration frequency (twice monthly vs. weekly vs. monthly, and so forth). Therefore, HPSJ's order of preference of the biologic therapies are based on the cost-benefit ratio where the first-line biologics are agents associated with the lowest cost-benefit ratio.

Xeljanz had similar efficacy rates to Humira in the ORAL Standard trial where Humira was an active control group, but no formal non-inferiority analysis was performed.[3] Further head-on trials are needed in order to determine the role of Xeljanz. For this reason, the 2015 ACR guidelines recommend Xeljanz as last line therapy if patients have an insufficient response to TNF inhibitors.

Role of oral agents (DMARDs and immunosuppressants)

Oral DMARDs are commonly used as first-line therapies in many mild-moderate inflammatory disorders with a few exceptions (e.g. Ankylosing Spondylitis). For most patients, treatment with oral agents may be sufficient for their condition. Generally, 12 weeks of continuous DMARD therapy is considered to be an adequate trial—assuming the drug is adequately dosed. In patients with liver and/or renal impairment, DMARDs are not necessarily excluded right away. In most cases, DMARDs can be safely used as long as there is regular monitoring of labs and side effects and the dosing is adjusted accordingly.

Table 1: Commonly used oral agents in chronic inflammatory diseases

Oral Agent	Joint	Skin	GI	liver damage	kidney damage	Pregnancy	Breastfeeding
Azathioprine	X	X*	X	monitor	monitor & dose adjust	Avoid use	Not recommended
Cyclosporine	X*	X	X*	monitor	monitor & dose adjust	Avoid use	Not recommended
Hydroxychloroquine	X		X*	monitor	monitor	Generally safe	Generally safe
Leflunomide	X	X	X*	avoid use	avoid use	Contraindicated	Unknown
Mercaptopurine	X*	X*	X	monitor	monitor & dose adjust	Avoid use	Unknown
Methotrexate	X	X	X	avoid use	monitor & dose adjust	Contraindicated	Contraindicated
Sulfasalazine	X	X*	X	monitor	monitor	Generally safe	Generally safe

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⌖ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Psoriasis - biologicals 2-20-07.doc	2/2007	Allen Shek, PharmD
Updated Policy	Biological Response Modifiers Review 2-19-08.doc	2/2008	Allen Shek, PharmD
Updated Policy	Biologic Response Modifiers 2010 final.docx	5/2010	Allen Shek, PharmD
Updated Policy	TNF MUE summary 2-21-2012.docx	2/2012	Allen Shek, PharmD
Updated Policy	Xeljanz Monograph 2013-02-13.docx	2/2013	Allen Shek, PharmD
Updated Policy	Psoriatic Arthritis & Ankylosing Spondylitis.docx	10/2014	Jonathan Szkotak, PharmD
Updated Policy	HPSJ Coverage Policy - Rheum & Immuno - Rheumatoid Arthritis 2015-05.docx	9/2015	Jonathan Szkotak, PharmD
Updated Policy	Class Review- Biologics, Apremilast, and Tofacitinib in Inflammatory Joint, Skin, and Bowel Diseases.docx	2/2016	Johnathan Yeh, PharmD
Updated Policy	Class Review- Biologics, Apremilast, and Tofacitinib in Inflammatory Joint, Skin, and Bowel Diseases.docx	02/2017	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Rheum & Immuno - Rheumatoid Arthritis 2018-02.docx	02/2018	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Rheum & Immuno - Rheumatoid Arthritis 2019-05.docx	05/2019	Matthew Garrett, PharmD
Updated Policy	HPSJ Coverage Policy - Rheum & Immuno - Rheumatoid Arthritis 2020-09.docx	09/2020	Matthew Garrett, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy.