MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	Psoriatic Arthritis (PsA)	**P&T DATE**	6/20/2023
CLASS:	Rheumatology/Immunology Disorders	**REVIEW HISTORY**	7/22, 5/21, 5/20, 5/19, 2/18, 2/17, 2/16, 5/15, 10/14, 2/13, 2/12, 11/12, 5/10, 2/08, 6/08, 2/07
LOB:	MCL		

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.

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medi-calrx.dhcs.ca.gov/home/ for portal access, formulary details, pharmacy network information, and updates to the pharmacy benefit.

All medical claims require that an NDC is also submitted with the claim. If a physician administered medication has a specific assigned CPT code, that code must be billed with the correlating NDC. If there is not a specific CPT code available for a physician administered medication, the use of unclassified CPT codes is appropriate when billed with the correlating NDC.

OVERVIEW

Psoriatic arthritis (PsA) is an inflammatory condition that usually involves small joints and skin. Individuals with PsA exhibit both arthritis and psoriasis (PsO) symptoms (i.e. joint pain/stiffness, joint swelling, psoriatic plaque development, and/or nail disfiguration). This review will examine the treatment guidelines of PsA, the currently available PsA drug products, and their coverage criteria.

Severe Psoriatic Arthritis*	Severe Psoriasis*
Erosive disease	Psoriasis area & Severity Index (PASI) ≥12
Elevated markers of inflammation (ESR, CRP)	Body surface area (BSA) ≥ 10
Long-term damage that interferes with function and causing major impairment in quality of life	Significant involvement in specific areas (e.g, face, hands or feet, nails intertriginous areas, scalp)
Many affected sites including dactylitis, enthesitis	Burden of the disease causing significant disability
Function-limiting PsA at a few sites, rapidly progressive disease	Impairment of physical or mental function and the designation of moderate-to-severe disease despite lower BSA

*The definition of severe PsA and psoriasis as the presence of 1 or more of the items listed. This is not a formal definition. Table adapted from the 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis.

The purpose of this coverage policy is to review the available agents (Table 1) and distinguish where the medications may be billed to. For agents listed for coverage under the medical benefit, this coverage is specific to outpatient coverage only (excludes emergency room and inpatient coverage).

Table 1. Available Psoriatic Arthritis Agents *(Current as of 4/2023)*

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
Oral DMARDS				
--	Cyclosporine, micronized	25 mg, 100 mg capsule	Yes	No
--	Leflunomide (Arava)	10 mg tablet	Yes	No
J8610 J9260	Methotrexate	2.5 mg tablet 25 mg/2ml vial	Yes	Yes (QL for vials)
--	Sulfasalazine Tablet, DR Tablet	500 mg tablet	Yes	No
PDE4-Inhibitor				
--	Apremilast (Otezla)	30 mg tablet	Yes	No

Biologics				
J0135	Adalimumab (Humira, Humira CF)	20mg/0.4ml, 40mg/0.8ml 40mg/0.4ml	Yes	No
--	Adalimumab (Amjevita)	40 mg/0.8 mL, 20 mg/0.4 mL	Yes	No
J1438	Etanercept (Enbrel)	25mg/ml, 50mg/ml	Yes	No
Q5103 Q5104	Infliximab-dyyb (Inflectra) Infliximab-abda (Renflexis)	100mg IV vial	Yes	Yes (PA)
J1745	Infliximab (Remicade)	100mg IV vial	Yes	Yes (PA)
Q5121	Infliximab-axxq (Avsola)	100mg IV vial	Yes	Yes (PA)
J0129	Abatacept (Orencia)	125mg/ml clickjet; 50mg/0.4mL, 87.5mg/0.7ml, 125mg/ml prefilled syringe; 250mg IV vial	Yes	Yes, for vials (PA)
J0717	Certolizumab (Cimzia)	200mg	Yes	Yes, for lyophilized solutions (PA)
J1602	Golimumab (Simponi)	50mg/4ml IV vial, 100mg/ml, 50mg/0.5ml auto-injector, 50mg/0.5ml 100mg/ml prefilled syringe	Yes	Yes, for vials (PA)
--	Secukinumab (Cosentyx)	150mg/ml	Yes	No
J1628	Guselkumab (Tremfya)	100mg/mL	Yes	No
--	Ixekizumab (Taltz)	80mg/ml	Yes	No
J3357	Ustekinumab (Stelara)	45mg/0.5ml, 90mg/ml	Yes	No
J2327	Risankizumab (Skyrizi)	150mg pre-filled syringe kit 150mg/mL auto-injector	Yes	No
--	Tofacitinib (Xeljanz, Xeljanz XR)	IR: 5mg, XR: 10mg	Yes	No
--	Upadacitinib (Rinvoq)	15mg	Yes	No

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for agents with medical benefit restrictions. This coverage criteria has been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, HPSJ will make the determination based on Medical Necessity criteria as described in HPSJ Medical Review Guidelines (UM06).

DMARDs

Methotrexate 25mg/ml Vial

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** Quantity limit 4 units of J9260 METHOTREXATE SODIUM, 50 MG per 28 days.
- ❒ **Required Information for Approval:** None

Biologics

1st line—Renflexis (infliximab-abda), Inflectra (infliximab-dyyb), Avsola (infliximab-axxq), Remicade (infliximab)

- ❒ **Coverage Criteria:** Reserved for treatment failure to 12 weeks of dose-optimized, oral DMARD therapy (Methotrexate 15-25mg/week, Cyclosporine, Sulfasalazine, and Leflunomide). If patient is unable to tolerate one oral DMARD, a second oral DMARD must be tried. Must be prescribed by a rheumatologist or dermatologist.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Clinic notes or prescription history indicating patient has tried at least 12 weeks of dose-optimized oral DMARD (Methotrexate, Cyclosporine, Sulfasalazine, and Leflunomide).

2nd line—Simponi (golimumab), Cimzia (certolizumab)

- ❒ **Coverage Criteria:** Reserved for treatment failure/documented intolerance to Renflexis, Inflectra, Avsola, or infliximab (Remicade). Must be prescribed by a rheumatologist or dermatologist.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Prescription history of Renflexis, Inflectra, Avsola, or infliximab (Remicade).

2nd line—Orencia (abatacept)

- ❒ **Coverage Criteria:** Reserved for treatment failure/documented intolerance to Renflexis, Inflectra, Avsola, or Remicade. Abatacept may be used instead of a TNF-inhibitor in patients with recurrent or serious infections. Must be prescribed by a rheumatologist or dermatologist.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Prescription history of Renflexis, Inflectra, Avsola, or Remicade OR documented history of recurrent or serious infections.

CLINICAL JUSTIFICATION

Psoriatic Arthritis

2018 The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) Guideline for the Treatment of Psoriatic Arthritis[39]

Highlights

- Most recommendations are conditional and applies to the majority of patients but may not be appropriate for all (shared decision-approach).
- Strong recommendations for patients with active PsA and concomitant active inflammatory bowel disease despite treatment with an oral small molecule (e.g. methotrexate)
    - Switch to a TNFi monoclonal antibody biologic over switching to a TNFi biologic soluble receptor biologic (i.e, etanercept).
    - Switch to a TNFi monoclonal antibody over switching to an interleukin (IL)-17 biologic
    - Switch to an IL-12/IL-23i biologic over switching to an IL-17i biologic.
- Other strong recommendations:
    - In adult patients with active PsA and frequent serious infections who are naïve to oral small molecule (OSM) and biologic drugs may start an oral small molecule over a TNFi biologic.
    - Smoking cessation over no smoking cessation.
- Conditional Recommendations
    - Treat-to-target approach for all patients with active PsA.

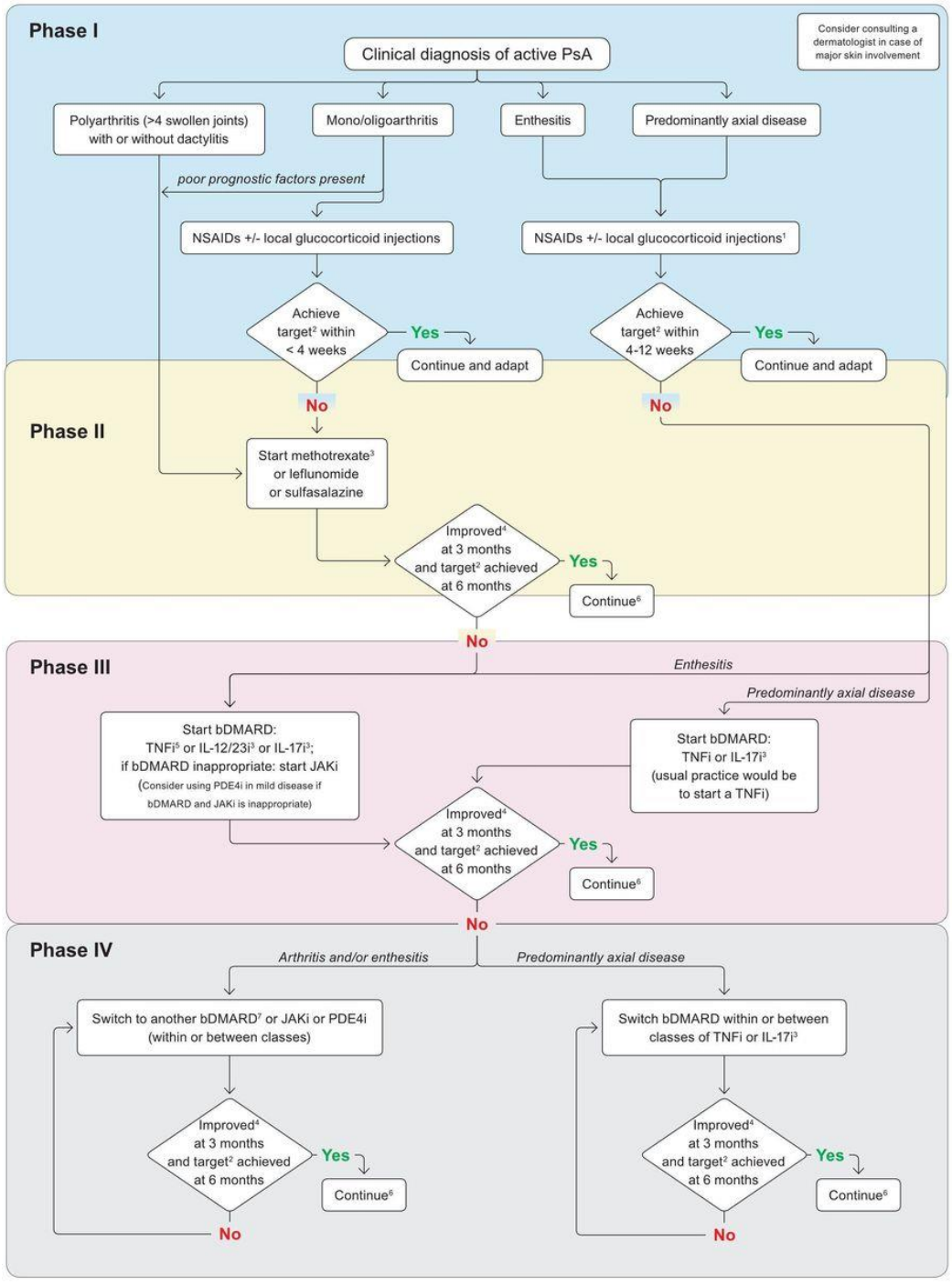
- For treatment naïve, active PsA patients- use TNFi biologics as first-line therapy over OSM/DMARDs.
- OSM drugs may be used instead of a TNFi biologic in patients without severe PsA and without severe psoriasis or in those who prefer an oral drug instead of parenteral therapy, or those with contraindications to TNFi treatment (congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease).
- For treatment-naïve patients with active PsA, the use of TNFi biologic or OSM is recommended over an interleukin-17.
- An IL-17i or IL-12/23i may be used instead of TNFi biologics with severe psoriasis or contraindications to TNF biologics.
- In patients with active PsA despite OSM therapy, switching to a TNFI, IL-17i, or an IL-12/23i biologic is recommended over switching to a different OSM. A different OSM may be used rather than a TNFi, IL17i, or IL-12/23i in patients who prefer an oral medication or those without evidence of severe PsA or severe psoriasis.
- In patients with active PsA despite TNFi treatment, switching to a different TNFi biologic monotherapy is recommended over switching to IL-12/23i biologic, IL-17i biologic, abatacept, or tofacitinib monotherapy or adding methotrexate to the current TNFi biologic. An IL-12/23i biologic, IL-17i biologic, abatacept, or tofacitinib may be used instead of a different TNFi biologic monotherapy in the case of a primary TNFi biologic failure or serious adverse event to a TNFi.
- An IL-17i or Il-12/23i biologic may be used instead of a different TNFi biologic, particularly in the presence of severe psoriasis. Abatacept may be used instead of a TNFi biologic in patients with recurrent or serious infections in the absence of severe psoriaisis.
- In treatment-naïve PsA patients with predominant enthesitis, a TNFi biologic is recommended over an OSM as a first-line option.

- The recommendation to use biologics as first-line treatment diverges from recommendations by the European League for Rheumatism (EULAR) for PsA where oral small molecules drugs are recommended as first-line agents for treatment-naïve patients. This was in part due to the lower cost of conventional oral small molecules agents. However, because the ACR/NPF guidelines note that this is a conditional recommendation due to low-to very-low quality evidence, HPSJ will continue to use oral small molecule drugs as first-line agents from a cost effective standpoint. HPSJ will take into consideration with the use of TNF-inhibitors as first line treatments in patients with predominant enthesitis or severe PsA.

The *2019 EULAR PsA Guidelines*[46] recommends the following:

	Recommendations	Level of evidence	Grade of recommendation	Level of agreement, mean (SD)
1	Treatment should be aimed at reaching the target of remission or, alternatively, low disease activity, by regular disease activity assessment and appropriate adjustment of therapy.	1b	A	9.4 (1.0)
2	Non-steroidal anti-inflammatory drugs may be used to relieve musculoskeletal signs and symptoms.	1b	A	9.6 (0.8)
3	Local injections of glucocorticoids should be considered as adjunctive therapy in psoriatic arthritis*; systemic glucocorticoids may be used with caution at the lowest effective dose†.	3b* 4†	C	9.5 (1.1)
4	In patients with polyarthritis, a csDMARD should be initiated* rapidly†, with methotrexate preferred in those with relevant skin involvement*.	1b* 5†	B	9.5 (0.8)
5	In patients with monoarthritis or oligoarthritis, particularly with poor prognostic factors such as structural damage, high erythrocyte sedimentation rate/C reactive protein, dactylitis or nail involvement, a csDMARD should be considered.	4	C	9.3 (1.0)
6	In patients with peripheral arthritis and an inadequate response to at least one csDMARD, therapy with a bDMARD should be commenced; when there is relevant skin involvement, an IL-17 inhibitor or IL-12/23 inhibitor may be preferred.	1b	B	9.4 (1.1)
7	In patients with peripheral arthritis and an inadequate response to at least one csDMARD and at least one bDMARD, or when a bDMARD is not appropriate, a JAK inhibitor may be considered.	1b	B	9.2 (1.3)
8	In patients with mild disease* and an inadequate response to at least one csDMARD†, in whom neither a bDMARD nor a JAK inhibitor is appropriate*, a PDE4 inhibitor may be considered.	5* 1b†	B	8.5 (1.9)
9	In patients with unequivocal enthesitis and insufficient response to NSAIDs or local glucocorticoid injections, therapy with a bDMARD should be considered.	1b	B	9.3 (0.9)
10	In patients with predominantly axial disease which is active and has insufficient response to NSAIDs, therapy with a bDMARD should be considered, which according to current practice is a TNF inhibitor; when there is relevant skin involvement, IL-17 inhibitor may be preferred.	1b	B	9.7 (0.6)
11	In patients who fail to respond adequately to, or are intolerant of a bDMARD, switching to another bDMARD or tsDMARD should be considered*, including one switch within a class†.	1b* 4†	C	9.5 (1.2)
12	In patients in sustained remission, cautious tapering of DMARDs may be considered.	4	C	9.5 (0.9)

The level of agreement was computed on a 0–10 scale.
csDMARDs include methotrexate, sulfasalazine or leflunomide; bDMARDs include here TNF inhibitors (both original and biosimilars) and drugs targeting the IL-17 and IL-12/23 pathways.
bDMARDs, biological disease-modifying antirheumatic drugs; csDMARDs, conventional synthetic disease-modifying antirheumatic drugs; DMARDs, disease-modifying antirheumatic drugs; EULAR, European League Against Rheumatism; IL, interleukin; JAK, Janus kinase; NSAIDs, non-steroidal anti-inflammatory drugs; PDE4, phosphodiesterase-4; TNF, tumour necrosis factor.



1. No glucocorticoids for axial disease.
2. The target is remission or low disease activity (especially with long standing disease) in accordance with the treat-to-target recommendations.
3. Preferred in the presence of relevant skin involvement, however in case of concomitant inflammatory bowel disease or uveitis, an anti-TNF antibody would be preferred.
4. Improvement means at least 50% reduction in disease activity.
5. As add-on to methotrexate.
6. Consider cautious tapering in sustained remission.
7. Including abatacept.
8. For definition of individual items see text.
   Phase I: recommendations 1, 2, 3, 4, 5;
   Phase II: recommendations 1, 3, 4, 5, 12;
   Phase III: recommendations 6, 8, 9, 10, 12;
   Phase IV: recommendations 7, 11,12

Highlights

- The 2019 EULAR Guidelines recommend a "treat-to-target" approach for PsA.
    - Patients with active disease should be monitored every 3 months and treatment should be adjusted when appropriate. The TICOPA trial demonstrated patients who had treatment escalation from DMARD therapy to biologics had better therapeutic outcomes when they were monitored and the treatment regimen was adjusted more vigorously.[3]
- In patients with polyarthritis, a csDMARD (methotrexate, sulfasalazine, or leflunomide) should be considered first, with methotrexate preferred in those with relevant skin involvement.[4]
- Patients with monoarthritis or oligoarthritis, particularly with poor prognostic factors such as structural damage, high erythrocyte sedimentation rate/C reactive protein, dactylitis or nail involvement, a csDMARD should be considered.
- Patients with peripheral arthritis and an inadequate response to at least one csDMARD, can consider therapy with a bDMARD (TNF, IL-12/23, or IL-17 inhibitor). When there is relevant skin involvement, an IL-17 inhibitor or IL-12/23 inhibitor may be preferred.
- Patients with peripheral arthritis and an inadequate response to at least one csDMARD and at least one bDMARD, or when a bDMARD is not appropriate, a JAK inhibitor may be considered.
- In patients with mild disease and an inadequate response to at least one csDMARD, in whom neither a bDMARD nor a JAK inhibitor is appropriate, a PDE4 inhibitor may be considered.
- Patients with predominantly axial disease that is active and has insufficient response to NSAIDs, biologics should be considered, which according to current practice is a TNF inhibitor. When there is relevant skin involvement an IL-17 inhibitor may be preferred.

The 2019 EULAR guidelines recommends for patients with polyarthritis that a csDMARD (methotrexate, sulfasalazine, or leflunomide) is initiated first. Only in patients with an inadequate response to at least one csDMARD do they recommend therapy with a bDMARD instead. On the other hand, the 2018 ACR guidelines recommend TNF inhibitors as first line, followed by IL-17 inhibitors and then IL-12/23 inhibitors. However, the 2018 ACR guidelines do recommend csDMARD's as first line therapy like the EULAR guidelines in specific instances. These instances include if the patient does not have severe PsA, does not have severe psoriasis, prefers oral therapy, has concern over starting a biologic as the first therapy, or has contraindications to TNFi biologics. Therefore, our HPSJ criteria generally requires initiating therapy with oral DMARDs prior to biologics and allowing some exceptions upon review. Efficacy between biologics does 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.

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
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
**limited evidence*							

Special Populations

Pregnancy

Guidelines for pregnancy, as stated by the Canadian guidelines and the American National Psoriasis Foundation, indicate that 1st line therapy includes low- to moderate potency corticosteroids, 2nd line therapy includes narrow ban UVB, and 3rd line therapy, only to be used if benefits outweigh risks, includes cyclosporine or TNF inhibitors.[20-21] Other DMARDS deemed safe include sulfasalazine and azathioprine, and possibly leflunomide.[22] Azathioprine has a risk for premature births and, although limited animal data contraindicates its use, leflunomide has an apparently low human teratogenicity risk. Cyclosporine and sulfasalazine seem to be the safest or most preferred DMARD agents.[22]

Elevated LFTs

Specific guidelines for patients who have elevated LFTs are not available, but the American Academy of Dermatology guidelines do have suggestions for LFT monitoring and some recommendations on protocol if LFTs are elevated to a certain level. For methotrexate, if elevation exceeds 2x normal levels, LFT monitoring must be checked more frequently; if elevation exceeds 3x normal levels, consider dose reduction (administer 75% of dose); if elevation exceeds 5x normal, discontinuation of the medication is recommended. No other drugs have specific guidelines for LFT levels.[23] The 2008 ACR guidelines state that leflunomide, methotrexate, and sulfasalazine should not be started nor resumed if liver transaminases were >2x the upper normal limit. Despite this, there are no recommendations on discontinuation.[24] A paper regarding expert opinion on the treatment of psoriasis in special circumstances speaks to the use of biologics in the setting of fatty liver disease. The panel considered etanercept and ustekizumab to be the best options for use in a patient with fatty liver disease.[25]

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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	HPA Suppression among Medium Potency Topical Corticosteroids.doc	6/2008	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	Calcipotriene.docx	11/2012	Allen Shek, PharmD
Updated Policy	Biologic Response Modifiers for Psoriasis 2013-2-19.docx	2/2013	Allen Shek, PharmD
Updated Policy	Psoriatic Arthritis & Ankylosing Spondylitis.docx	10/2014	Jonathan Szkotak, PharmD
Updated Policy	Class Review of Topical & Systemic Agents Used for Skin Inflammation Disorders with an Emphasis on Psoriasis.docx	5/2015	Jonathan Szkotak, PharmD
Updated Policy	HPSJ Coverage Policy – Rheum & immuno – Psoriatic 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	HPSJ Coverage Policy - Rheum & Immuno - Psoriatic Arthritis 2017-02.docx	2/2017	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Rheum & Immuno - Psoriatic Arthritis 2018-02.docx	02/2018	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Rheum & Immuno - Psoriatic Arthritis 2019-05.docx	05/2019	Matthew Garrett, Pharm D
Updated Policy	Psoriatic Arthritis 2020-05.docx	05/2020	Matthew Garrett, Pharm D
Updated Policy	Psoriatic Arthritis.docx	05/2021	Matthew Garrett, Pharm D
Updated Policy	Psoriatic Arthritis.docx	07/2022	Matthew Garrett, Pharm D
Updated Policy	Psoriatic Arthritis.docx	06/2023	Matthew Garrett, Pharm D

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