MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE





| Policy: | Psoriatic Arthritis (PsA) | P&T DATE | 6/10/2025 |
|---------|-----------------------------------|----------------|--------------------------|
| CLASS: | Rheumatology/Immunology Disorders | REVIEW HISTORY | 6/24 6/23, 7/22, 5/21, |
| LOB: | MCL | | 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 |

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

Effective 1/1/2022, the Pharmacy Benefit is regulated by Medi-Cal Rx. Please visit https://medicalrx.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.

Any biosimilars pending litigations or not officially available in the US Market for consumer use is not an available treatment option or covered on the medical benefit. Biosimilars that are FDA approved and available in the US Market for consumer use will follow the reference brand name criteria as available per our PH05 - Prior Authorizations processes. Certain biosimilars may be subject to alternative criteria based on the preferences of Health Plan.

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 | Significant involvement in specific areas (e.g, face, |
| causing major impairment in quality of life | 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 | Impairment of physical or mental function and the |
| progressive disease | 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 5/2025)

| CPT Code | Generic Name (Brand Name) | Available Strengths | Pharmacy Benefit | Outpatient Medical Benefit (Restrictions) | |
|--------------------------------|--|--|---------------------|---|--|
| | Ora | al DMARDS | | | |
| | Cyclosporine, micronized | 25 mg, 100 mg capsule | Yes | No | |
| | Leflunomide (Arava) | 10 mg tablet | Yes | No | |
| J8610 (tablet) J9260 (vial) | Methotrexate | 2.5 mg tablet 10 mg/0.4mL, 7.5 mg/0.15 mL, and others auto-injector 25 mg/2ml and others vial | Yes | No | |
| | Sulfasalazine Tablet, DR Tablet | 500 mg tablet | Yes | No | |
| | | E4-Inhibitor | | | |
| | Apremilast (Otezla) | 30 mg tablet | Yes | No | |
| | * | Biologics | | | |
| J0139 | Adalimumab (Humira, Humira CF) | Pen-injector Kit, | Yes | No | |
| Q5143 | Adalimumab-adbm (Cyltezo) | Prefilled Syringe kit: | Yes | No | |
| Q5142 | Adalimumab-ryvk (Simlandi) | 20mg/0.2ml, | Yes | No | |
| Q5140 | Adalimumab-fkjp (Hulio) | 20mg/0.4ml, 40 | Yes | No | |
| Q5141 | Adalimumab-aaty (Yuflyma) Other Adalimumb biosimilars | mg/0.4ml, 40mg/0.8ml, 80 | Yes | No | |
| | Adalimumab (Amjevita) Adalimumab-afzb (Abrilada) Adalimumab-bwwd (Hadlima) Adalimumab-aqyh (Yusimry) Adalimumab-adaz (Hyrimoz) | mg/0.8 mL | Yes | No | |
| J1438 | | | 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 | | | Yes | Yes, for vials (PA) | |
| J0717 Certolizumab (Cimzia) | | 250mg IV vial 200mg pre-filled syringe, lyophilized solution | 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) | |

| J3247 (for IV only) | Secukinumab (Cosentyx) | 125mg/5ml IV vial 150mg/ml auto- injector and pre- filled syringe | Yes | Yes, for vials (PA) |
|------------------------|-----------------------------------|--|------|---------------------|
| J1628 | Guselkumab (Tremfya) | 100mg/mL auto- injector or pre-filled syringe | Yes | No |
| | Ixekizumab (Taltz) | 80mg/ml auto- injector or pre-filled syringe | Yes | No |
| J3357 | Ustekinumab (Stelara) | Subcutaneous solution, pre-filled | Yes | No |
| Q5137 | Ustekinumab-auub (Wezlana) | syringe: 45mg/0.5ml, | Yes* | No |
| Q9996 | Ustekinumab-ttwe (Pyzchiya) | | Yes | No |
| Q9998 | Ustekinumab-aekn (Selarsdi) | 90mg/ml | Yes | No |
| Q9999 | Ustekinumab-aauz (Otulfi) | | Yes | No |
| Q5100 | Ustekinumab-kfce (Yesintek) | | Yes | No |
| Q5099 | Ustekinumab-stba (Steqeyma) | | Yes | No |
| J2327 | Risankizumab (Skyrizi) | 150mg pre-filled syringe kit 150mg/mL auto- injector | Yes | No |
| | Tofacitinib (Xeljanz, Xeljanz XR) | IR: 5mg tablet XR: 10mg tablet | Yes | No |
| | Upadacitinib (Rinvoq) | 15mg tablet | Yes | No |

^{*}Only distributed through Optum PBM's Nuvaila biosimilar procurement business.54

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 Health Plan Pharmacy & Therapeutics (P&T) Advisory Committee. For agents that do not have established prior authorization criteria, Health Plan will make the determination based on Medical Necessity criteria as described in Health Plan Medical Review Guidelines (UM06).

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 lin | e—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. |
| Cosent | yx (secukinumab) IV |
| | Coverage Criteria: |
| | 1. Reserved for either |
| | (a) treatment failure/documented intolerance to Renflexis, Inflectra, Avsola, or Remicade OR |
| | (b) patients with clinically relevant skin involvement defined as either having body surface area >10% or negatively impacting quality of life (such as face or genital involvement) with 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. |
| | 2. Must be prescribed by a rheumatologist or dermatologist. |
| | Limits: None |
| | Required Information for Approval: Prescription history of Renflexis, Inflectra, Avsola, or |
| | Remicade OR documented clinically relevant skin involvement with clinic notes or prescription |
| | history indicating patient has tried at least 12 weeks of dose-optimized oral DMARD (Methotrexate, |
| | Cyclosporine Sulfasalazine and Leflunomide) |

CLINICAL JUSTIFICATION

Psoriatic Arthritis

2018 The American College of Rheumatology (ACR) and the National Psoriasis Foundation (NPF) Guideline for the Treatment of Psoriatic Arthritis³⁹

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).
 - o Switch to a TNFi monoclonal antibody over switching to an interleukin (IL)-17 biologic
 - o 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
 - o 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.
- o 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.
- O 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.
- o 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. It should be noted that the recommendation from the ACR/NPF guidelines to use TNF inhibitors as first-line therapy over OSM/DMARDs is a conditional recommendation due to low to very-low quality of evidence. They 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. Health Plan will continue to use oral small molecule drugs as first-line agents from a cost-effective standpoint. The 2018 ACR/NPF guidelines also use data that is more outdated than that of the new 2023 EULAR guidelines.

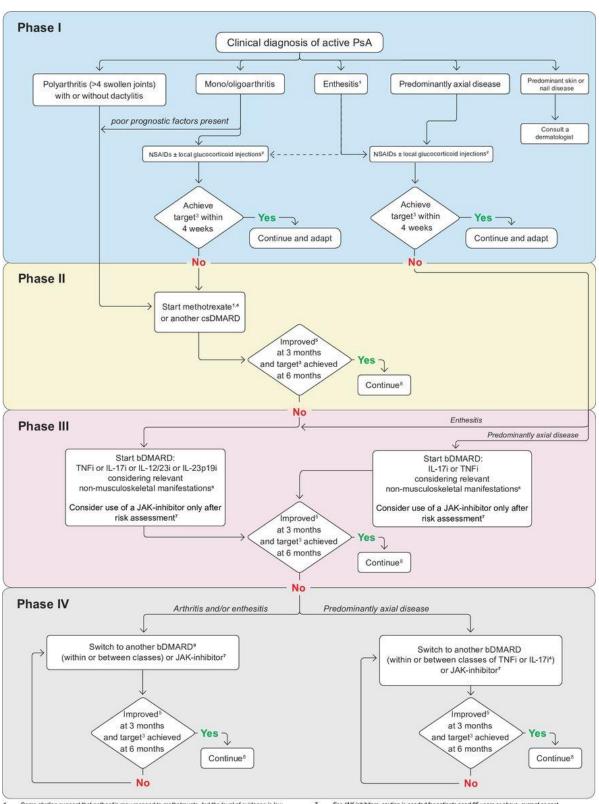
The 2023 EULAR PsA Guidelines⁴⁶ recommends the following:

Table 2
2023 updated EULAR recommendations for the pharmacological management of psoriatic arthritis

| | | Level of agreement, |
|---|--|---------------------|
| | Overarching principles | mean (SD) |
| 4 | Psoriatic arthritis is a heterogeneous and potentially severe disease, which may require multidisciplinary treatment. | 10.0 (0.1) |
| 3 | Treatment of psoriatic arthritis patients should aim at the best care and must be based on a shared decision between the patient and the rheumatologist, considering efficacy, safety, patient preferences and costs. | 9.7 (0.6) |
| | Rheumatologists are the specialists who should primarily care for the musculoskeletal manifestations of patients with psoriatic arthritis; in the presence of clinically relevant skin involvement, a rheumatologist and a dermatologist should collaborate in diagnosis and management. | 9.7 (0.5) |
| | The primary goal of treating patients with psoriatic arthritis is to maximise health-related quality of life, through control of symptoms, prevention of structural damage, normalisation of function and social participation; abrogation of inflammation is an important component to achieve these goals. | 9.9 (0.3) |
| | In managing patients with psoriatic arthritis, consideration should be given to each musculoskeletal manifestation and treatment decisions made accordingly. | 9.8 (0.4) |
| | When managing patients with psoriatic arthritis, non-musculoskeletal manifestations (particularly skin, eye and gastrointestinal tract) should be taken into account; comorbidities such as obesity, metabolic syndrome, cardiovascular disease or depression should also be considered. | 9.7 (0.7) |
| ì | The choice of treatment should take account of safety considerations regarding individual modes of action to optimise the benefit–risk profile. | 9.9 (0.4) |

| | 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 | 9.5 (1.0) |
| 2 | Non-steroidal anti-inflammatory drugs may be used to relieve musculoskeletal signs and symptoms ^a ; local injections of glucocorticoids may be considered as adjunctive therapy ^b . | 1b ^a , 3b ^b | A ^a , C ^b | 9.5 (0.7) |
| 3 | In patients with polyarthritis, or those with monoarthritis/oligoarthritis and poor prognostic factors (eg, structural damage, elevated acute phase reactants, dactylitis or nail involvement), a csDMARD should be initiated rapidly, with methotrexate preferred in those with clinically relevant skin involvement. | 1b, 4 ^a | B, C ^a | 9.3 (0.8) |
| 4 | In patients with peripheral arthritis and an inadequate response to at least one csDMARD, therapy with a bDMARD should be commenced. | 1 a | A | 9.5 (1.3) |
| 5 | In patients with peripheral arthritis and an inadequate response to at least one bDMARD, or when a bDMARD is not appropriate ⁸ , a JAKi may be considered, taking safety considerations* into account. | 1b, 4 ^a | B, D ^a | 9.1 (1.5) |
| 6 | In patients with mild disease and an inadequate response to at least one csDMARD, in whom neither a bDMARD nor a JAKi* is appropriate, a PDE4 inhibitor may be considered. | 1 b | В | 8.7 (1.1) |
| 7 | In patients with unequivocal enthesitis and an insufficient response to NSAIDs or local glucocorticoid injections, therapy with a bDMARD should be considered. | 1 b | В | 9.5 (0.9) |
| 8 | In patients with clinically relevant axial disease with an insufficient response to NSAIDs, therapy with an IL-17A inhibitor, a TNF inhibitor, an IL-17 A/F inhibitor or a JAKi* should be considered. | 1 b | В | 9.4 (1.3) |
| 9 | The choice of the mode of action should reflect non-musculoskeletal manifestations related to psoriatic arthritis; with clinically relevant skin involvement, preference should be given to an IL-17A or IL-17A/F or IL-23 or IL-12/23 inhibitor; with uveitis to an anti-TNF monoclonal antibody; and with IBD to an anti-TNF monoclonal antibody or an IL-23 inhibitor or IL-12/23 inhibitor or a JAKi*. | 1b | В | 9.6 (0.7) |
| 10 | In patients with an inadequate response or intolerance to a bDMARD or a JAKi, switching to another bDMARD or JAKi* should be considered ^a , including one switch within a class ^b . | 1b ^a , 4 ^b | С | 9.5 (0.7) |
| 11 | In patients in sustained remission, tapering of DMARDs may be considered. | 2b | В | 9.4 (1.2) |

- · 'Mild disease' is defined as oligoarticular or entheseal disease without poor prognostic factors and limited skin involvement.
- csDMARDs (conventional synthetic DMARDs) include methotrexate, sulfasalazine or leflunomide. bDMARDs (biologic DMARDs) here include TNF inhibitors (both original and biosimilars), drugs targeting the IL-17 and IL-12–23/IL-23-p19 pathways, and in the context of recommendation 10 also CTLA4 (cytotoxic T-lymphocyte—associated antigen 4) inhibition. JAKis (Januse kinase inhibitors) include tofacitinib and upadacitinib.
- . The superscript letters 'a' and 'b' are used to link a part of the recommendation to a level of evidence.
- The table shows the level of evidence, grade of recommendation and level of agreement among taskforce members (0-10 scale).
- *For JAKis, caution is needed for patients aged 65 years or above, those who are current or past long-time smokers, with a history of atherosclerotic
 cardiovascular disease or other cardiovascular risk factors or with other malignancy risk factors, and with known risk factors for venous
 thromboembolism.
- bDMARD, biological disease-modifying antirheumatic drug; csDMARD, conventional synthetic disease-modifying antirheumatic drug; CTLA4, cytotoxic
 T-lymphocyte—associated antigen 4; DMARDs, disease-modifying antirheumatic drugs; IBD, inflammatory bowel disease; IL, interleukin; JAKi, Janus kinase inhibitor; NSAIDs, non-steroidal anti-inflammatory drugs; PDE4, phosphodiesterase 4; TNF, tumour necrosis factor.



- Some studies suggest that enthesitis may respond to methotrexate, but the level of evidence is low. No glucocordicoids for axial disease.

 The larget is remission or low disease activity (especially with long standing disease) in accordance with the treat-to-target recommendations.

 Preferred in the presence of relevant skin involvement, however in case of concomitant inflammatory bowel disease or uverities. a TNF monoclonal antibody or (for IBD) IL-23 or 12/23 or JAK/i is recommended. Improvement means at least 50% reduction in disease activity.

 Attritis-indesitis: TNFi or IL-171 or IL-12/23 or IL-23p19; Skin: IL-171 or IL-12/23 or IL-23p19; Uveitis: anti-TNF monoclonal antibody, IBD. anti-TNF monoclonal antibody or IL-12/23 or IL-23p19; or JAK/; Consider using PDE-4i in mild disease of bDMARD and JAKi is inappropriate.

For JAK-inhibitors, caution is needed for patients aged 65 years or above, current or past long-time smokers, with a history of atheroscierotic cardiovascular disease or other cardiovascular risk factors or with other malignancy risk factors; with known risk factors for venous thromboembolis Consider tapering in sustained remission. Including abatacept.

Highlights

- The 2023 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, or those with monoarthritis/oligoarthritis and poor prognostic factors (eg, structural damage, elevated acute phase reactants, dactylitis or nail involvement), a csDMARD should be initiated rapidly, with methotrexate preferred in those with clinically relevant skin involvement.
- In patients with peripheral arthritis and an inadequate response to at least one csDMARD, therapy with a bDMARD should be commenced.
- In patients with peripheral arthritis and an inadequate response to at least one bDMARD, or when a bDMARD is not appropriate, a JAKi may be considered, taking safety considerations into account.
- 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.
- In patients with clinically relevant axial disease with an insufficient response to NSAIDs, therapy with an IL-17Ai, a TNFi, an IL-17 A/Fi or a JAKi should be considered.
- The choice of the mode of action should reflect non-musculoskeletal manifestations related to psoriatic arthritis; with clinically relevant skin involvement, preference should be given to an IL-17A or IL-17A/F or IL-23 or IL-12/23 inhibitor; with uveitis to an anti-TNF monoclonal antibody; and with IBD to an anti-TNF monoclonal antibody or an IL-23i or IL-12/23i or a JAKi.
- In patients with an inadequate response or intolerance to a bDMARD or a JAKi, switching to another bDMARD or JAKi should be considered, including one switch within a class.

The 2023 EULAR guidelines recommend 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. Therefore, our Health Plan criteria generally requires initiating therapy with oral DMARDs prior to biologics and allowing some exceptions upon review. Efficacy between biologics is analyzed and cost may vary due to differences in administration frequency (twice monthly vs. weekly vs. monthly, and so forth). The new guidelines also prefer biologics with different modes of action for patients with certain non-musculoskeletal manifestations. Therefore, Health Plan's order of preference of the biologic therapies are based on efficacy and costs.

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 | Avoid use | Not recommended |
| - | | | | | adjust | | |
| Cyclosporine | X* | X | Х* | monitor | monitor & dose | Avoid use | Not recommended |
| | | | | | adjust | | |
| Leflunomide | X | X | Х* | avoid use | avoid use | Contraindicated | Unknown |
| Mercaptopurine | X* | X* | X | monitor | monitor & dose | Avoid use | Unknown |
| • • | | | | | adjust | | |

| 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- | 2/2008 | Allen Shek, PharmD |
| | 08.doc | | |
| Updated Policy | HPA Suppression among Medium Potency Topical | 6/2008 | Allen Shek, PharmD |
| | Corticosteroids.doc | | |
| 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 | 2/2013 | Allen Shek, PharmD |
| | 2013-2-19.docx | | |
| Updated Policy | Psoriatic Arthritis & Ankylosing | 10/2014 | Jonathan Szkotak, PharmD |
| | Spondylitis.docx | | |
| Updated Policy | Class Review of Topical & Systemic Agents | 5/2015 | Jonathan Szkotak, PharmD |
| | Used for Skin Inflammation Disorders with | | |
| | an Emphasis on Psoriasis.docx | | |
| Updated Policy | HPSJ Coverage Policy - Rheum & immuno - | 9/2015 | Jonathan Szkotak, PharmD |
| | Psoriatic Arthritis 2015-05.docx | | |
| Updated Policy | Class Review- Biologics, Apremilast, and | 2/2016 | Johnathan Yeh, PharmD |
| | Tofacitinib in Inflammatory Joint, Skin, and Bowel | | |
| | Diseases.docx | | |
| Updated Policy | HPSJ Coverage Policy - Rheum & Immuno - | 2/2017 | Johnathan Yeh, PharmD |
| | Psoriatic Arthritis 2017-02.docx | | |
| Updated Policy | HPSJ Coverage Policy - Rheum & Immuno - | 02/2018 | Johnathan Yeh, PharmD |
| | Psoriatic Arthritis 2018-02.docx | | |

| Updated Policy | HPSJ Coverage Policy - Rheum & Immuno - | 05/2019 | Matthew Garrett, PharmD |
|----------------|---|---------|-------------------------|
| | Psoriatic Arthritis 2019-05.docx | | |
| Updated Policy | Psoriatic Arthritis 2020-05.docx | 05/2020 | Matthew Garrett, PharmD |
| Updated Policy | Psoriatic Arthritis.docx | 05/2021 | Matthew Garrett, PharmD |
| Updated Policy | Psoriatic Arthritis.docx | 07/2022 | Matthew Garrett, PharmD |
| Updated Policy | Psoriatic Arthritis.docx | 06/2023 | Matthew Garrett, PharmD |
| Updated Policy | Psoriatic Arthritis.docx | 06/2024 | Matthew Garrett, PharmD |
| Updated Policy | Psoriatic Arthritis.docx | 06/2025 | Matthew Garrett, PharmD |

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