MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY	Psoriasis (PsO)	**P & T DATE**	06/20/2023
THERAPEUTIC CLASS	Dermatology	**REVIEW HISTORY**	09/21, 09/20, 02/07, 02/08, 06/08, 05/10, 11/12, 02/13, 10/14, 05/15, 11/15, 02/16, 02/17, 02/18, 05/19, 05/20
LOB AFFECTED	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

Psoriasis (PsO) is an autoimmune, inflammatory skin disorder that disease that fluctuates between disease remission and relapse. The economic burden of psoriasis and psoriatic arthritis is significant. In 2004, the annual direct and indirect costs of psoriasis was reported to be $1.4 billion.[1] However, in 2013, it was estimated that the annual direct and indirect cost of psoriasis in the United States had increased to $112-$135 billion.[2] This review will examine the treatment guidelines of PsO, the currently available PsO drug products, and their coverage criteria.

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 Psoriasis Agents *(Current as of 2/2023)*

Topical Agents				
CPT Code	**Generic Name (Brand Name)**	**Available Strengths**	**Pharmacy Benefit**	**Outpatient Medical Benefit (Restrictions)**
Topical Corticosteroids (TCS)				
--	Betamethasone Diprop (Augmented) Cream, Oint, Lotion	0.05%	Yes	No
--	Betamethasone Diprop Lotion	0.05%	Yes	No
--	Betamethasone Valerate Cream, Lotion, Oint	0.1%	Yes	No
--	Clobetasol Propionate Cream, Oint, Solution	0.05%	Yes	No
--	Clobetasol Propionate Shampoo, Gel	0.05%	Yes	No
--	Clobetasol Propionate Emollient	0.05%	Yes	No
--	Desonide Oint, Cream, Lotion	0.05%	Yes	No
--	Fluocinolone Acetonide Lotion, Oil	0.01%, 0.025%	Yes	No
--	Fluocinolone Acetonide Cream, Oint	0.025%	Yes	No
--	Fluocinolone Acetonide Solution, Oil	0.01%	Yes	No

--	Fluocinonide, Fluocinonide-Emollient Gel, Oint, Cream	0.05%	Yes	No
--	Fluocinonide Solution	0.05%	Yes	No
--	Fluticasone Propionate	0.05%	Yes	No
--	Halobetasol Propionate Cream, Oint	0.05%	Yes	No
--	Hydrocortisone Cream, Oint, Lotion	0.5%, 1%, 2.5%	Yes	No
--	Mometasone Furoate Cream*, Oint	0.1%	Yes	No
--	Triamcinolone Acetonide Cream, Ointment, Lotion	0.025%, 0.05%, 0.1%	Yes	No
Topical Calcineurin Inhibitors (TCI)				
--	Pimecrolimus (Elidel) Cream	1%	Yes	No
--	Tacrolimus (Protopic) Oint	0.03%, 0,1%	Yes	No
Miscellaneous				
--	Anthralin (Dritho-Creme) Cream	1%	Yes	No
--	Calcipotriene (Dovonex) Cream, Oint, Solu	0.005%	Yes	No
--	Calcipotriene/ Betamethasone (Taclonex) Cream, Topical Suspension	0.005%-0.064%	Yes	No
--	Tazarotene (Tazorac) Cream, Gel	0.05%, 0.1%	Yes	No
--	Tapinarof (Vtama) Cream	1%	Yes	No

Systemic Agents

CPT Code	Drug	Available Strengths	Pharmacy Benefit	Medical Benefit
Oral Retinoid				
--	Acitretin (Soriatane)	10mg, 25mg	Yes	No
DMARDs				
--	Cyclosporine, micronized	25mg, 100mg	Yes	No
J9260	Methotrexate tablet, vial	2.5mg; 25mg/2ml	Yes, for tablets	Yes, for vials (QL)
PDE-4 Inhibitor				
--	Apremilast (Otezla)	30mg	Yes	No
Biologics				
J0135	Adalimumab (Humira, Humira CF)	20mg/0.4ml, 40mg/0.8ml, 40mg/0.4ml	Yes	No
--	Adalimumab-atto (Amjevita)	20mg/0.4ml, 40mg/0.8ml	Yes	No
J1438	Etanercept (Enbrel)	25mg/ml, 50mg/ml	Yes	No
Q5103	Infliximab-dyyb (Inflectra)	100mg IV vial	Yes	Yes (PA)
Q5104	Infliximab-abda (Renflexis)			
J1745	Infliximab (Remicade)			
Q5121	Infliximab-axxq (Avsola)			
--	Brodalumab (Siliq)	210mg/1.5ml	Yes	No
J1628	Guselkumab (Tremfya, Tremfya One-Press)	100mg/ml	Yes	No
--	Secukinumab (Cosentyx)	150mg/ml	Yes	No
--	Ixekizumab (Taltz)	80 mg/ml	Yes	No
J3245	Tildrakizumab (Ilumya)	100mg/ml	Yes	Yes (PA)
J3357	Ustekinumab (Stelara)	45mg/0.5ml, 90mg/ml	Yes	No

J0717	Certolizumab (Cimzia)	200mg/ml	Yes, for prefilled syringe	Yes, for lyophilized powder (PA)
J2327	Risankizumab (Skyrizi)	150mg/ml	Yes	No
--	Spesolimab (Spevigo)	450mg/7.5ml	Yes	Yes (PA)
--	Deucravacitinib (Sotyktu)	6mg	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:** Auth is not required office based. Auth is required facility based.
- ❒ **Limits:** 4 units of J9260 METHOTREXATE SODIUM, 50 MG per 28 days
- ❒ **Required Information for Approval:** N/A
- ❒ **Other Notes:** N/A

Biologics

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

- ❒ **Coverage Criteria:** Reserved for treatment failure to 12 weeks of dose-optimized, oral DMARD therapy (Methotrexate 15-25mg/week, Cyclosporine, and Acitretin). If patient is unable to tolerate one oral DMARD, a second oral DMARD must be tried. Must be prescribed by a 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, Acitretin, etc).
- ❒ **Other Notes:** None

2nd line—Tildrakizumab (Ilumya)

- ❒ **Coverage Criteria:** Reserved for treatment failure/documented intolerance to Adalimumab, Etanercept, or Infliximab. Must be prescribed by dermatologist.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Prescription history of Adalimumab, Etanercept, or Infliximab.
  Other Notes: N/A

3rd line—Certolizumab (Cimzia):

- ❒ **Coverage Criteria:** Reserved for [1] treatment failure/documented intolerance to A) Adalimumab, Etanercept, or Infliximab and B) Secukinumab, Guselkumab, Brodalumab, Tildrakizumab, or Ixekizumab OR [2] women that are currently pregnant or breastfeeding. Must be prescribed by a dermatologist.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Prescription history of Adalimumab, Etanercept, or Infliximab and Secukinumab, Guselkumab, Brodalumab, Tildrakizumab, or Ixekizumab OR pregnancy/breastfeeding status.
- ❒ **Other Notes:** N/A

Spesolimab-sbzo (Spevigo):

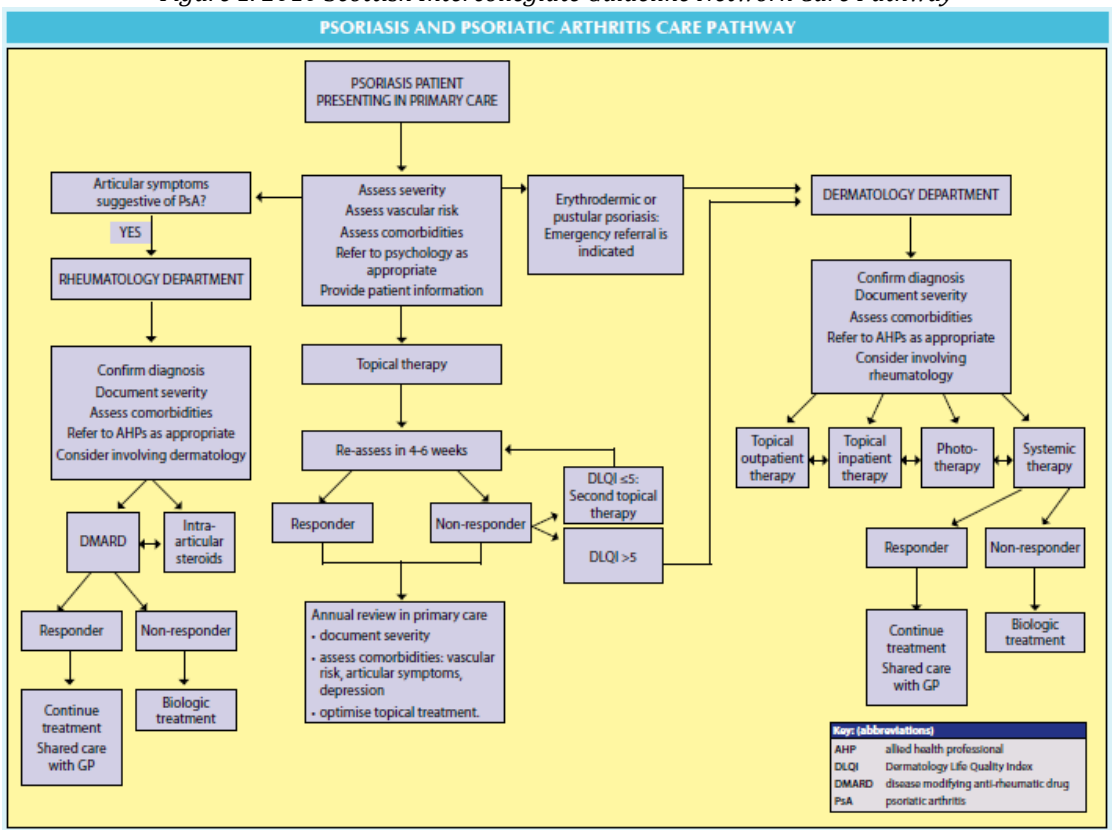
- ❒ **Coverage Criteria:** Spevigo is reserved for the following criteria: [1] Treatment of moderate to severe acute flare of generalized pustular psoriasis (defined as a GPPGA total score of ≥3, new or worsening pustules, a GPPGA pustulation subscore of ≥2, and ≥5% of body-surface area with erythema and the presence of pustules) AND [2] The diagnosis of generalized pustular psoriasis must be confirmed by the presence of primary, sterile, macroscopically visible pustules on non-acral skin and pustulation must not be restricted to psoriatic plaques (i.e. occurs outside of psoriatic plaques). Must be prescribed by a dermatologist.
- ❒ **Limits:** Two 900mg doses per month if needed for acute flare.
- ❒ **Required Information for Approval:** N/A
- ❒ **Other Notes:** Other systemic and topical treatments for generalized pustular psoriasis should be discontinued prior to and during Spevigo use.

⌖ CLINICAL JUSTIFICATION

The treatment goal for patients with PsO is to minimize disease activity by regularly monitoring regimen. The *2008 American Academy of Dermatology PsO*[3-6] *Guidelines* and 2010 *Scottish Intercollegiate Guideline Network*[7] recommends the following:

Limited Disease
• Topical corticosteroids are the mainstay of therapy. • For patients requiring long-term TCS therapy, may want to consider "Pulse therapy" or adding on corticosteroid-sparing agents (tacrolimus, pimecrolimus, calcipotriene, tazarotene). • Tacrolimus and pimecrolimus are not as effective as other topical therapies unless used on intertriginous areas or areas where skin is occluded.
Extensive Disease
• Oral DMARDs and phototherapy are first-line treatment therapies. • TNF inhibitor biologics should be considered in patients who have failed 1 or more dose-optimized DMARD therapy for 3-6 months. • Consider combination therapy (topical + phototherapy OR topical/phototherapy + DMARD/TNF) for improved effectiveness.

Figure 1. 2010 Scottish Intercollegiate Guideline Network Care Pathway



The extent and staging of psoriasis drives the type of treatment. According to the 2008 American Academy of Dermatology guidelines, treatment with topical treatments are appropriate for patients with mild or localized psoriasis.[3] Patients with more extensive disease may require phototherapy and/or systemic agents. The National Psoriasis Foundation supports phototherapy as first-line therapy for treatment of psoriatic lesions.[8] Methotrexate, cyclosporine, and acitretin are all effective, first-line systemic agents for treatment of extensive psoriasis or psoriasis with inadequate response to topical therapies. It is important to note that not all patients with limited skin disease should be treated with systemic therapy even if treatment with topical therapy is inadequate; the risk-to-benefit ratio should be evaluated. In most cases, the patient may likely benefit first with a trial of phototherapy in combination with topical corticosteroids. Patients with severe, refractory psoriasis (treatment failure to 1 or more DMARD) may be a candidate for biologic therapy. 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.

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 2: Commonly used oral agents in chronic inflammatory diseases

Oral Agent	Joint	Skin	GI	liver damage	kidney damage	Pregnancy	Breastfeeding
Acitretin		X		avoid use	avoid use	Contraindicated	Contraindicated; wait at least 3 years after tx
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
Mycophenolate		X*	X*	monitor	monitor & dose adjust	Avoid use	Avoid during and 6 wks after tx
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.[27-28] Other DMARDS deemed safe include sulfasalazine and azathioprine, and possibly leflunomide.[29] 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.[29]

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.[30] 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.[31] 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.[32]

Additional Information

NICE guidelines state a 3-month trial for methotrexate and cyclosporine, and 4 months for acitretin should be done before assessing treatment response.[33]

A review article regarding calcineurin inhibitors states that tacrolimus and pimecrolimus have demonstrated efficacy for use on thin or sensitive skin areas, such as the face or genitals, although no studies regarding the comparative efficacy of the two agents exist. One study suggests that these agents are not as potent efficacy wise compared to corticosteroids (study was comparing pimecrolimus to topical steroids).[36] Regarding the safety tolerability of these calcineurin inhibitors, two studies found no difference between pimecrolimus or tacrolimus when compared to placebo in the setting of facial or intertriginous psoriasis.[37-38] There is no information on utilizing both calcineurin inhibitors in combination. Furthermore, high-potency steroids should be avoided when used on thin or sensitive skin areas, including the face and genitals, but calcineurin inhibitors can be used in cases involving the face or other sensitive skin areas. If necessary, the 2009 Canadian guidelines do suggest that a short course of moderate potency topical steroid can be used in combination with calcineurin inhibitors as well.[39] In addition the NICE 2012 and NHS 2016 guidelines for psoriasis also recommend a short course of mild to moderate potency corticosteroid for facial psoriasis in children and adolescents.[33,40]

The American Academy of Dermatology guidelines mention that it is rational to use different vehicles of the same agent at different times of the day (morning vs evening) and also mention that different vehicles have different indications for certain areas of the body.[41] Nothing specific was mentioned on using the same agent with different vehicles at the exact same time or application, but with the previous statements, it is rational to use multiple vehicles at the same time. Also, caution not to use over the recommended maximum daily or weekly amount if using a high-potency steroid such as clobetasol.

High-potency steroids such as clobetasol have an upper bound of 50g/week over 2-4 weeks as stated by the American Academy of Dermatology guidelines.[41] Of note, there is some evidence that HPA axis suppression can occur in doses as low as 2g/day for 2 or more weeks.[44] For this reason, proper selection of patients and conservative use is important when prescribing high-potency steroids. Table 3 provides guidance for standard amounts of topical needed, in grams and based on BSA, in adults and children. Some factors that predispose HPA axis include chronic use, use on sensitive or permeable skin, application to a large area of skin, occlusion, poor skin integrity, young age and liver failure. The American Academy of Dermatology does state that in practice longer durations of use over 4 weeks is possible, but proper supervision is needed to avoid side effects. The guidelines further state that consideration should be put into reducing dose once clinical improvement occurs, intermittent use, or combination therapy with non-steroidal agents.

Table 3. Fingertip Unit Guide for Adults and Children[41, 45]

Adults

Area to Be Treated	No. of FTU (Fingertip Units)	Approx. Dose (Gm)*	Approx. BSA (%)
Scalp	3	1.5	6
Face and neck	2.5	1.25	5
One hand (front and back) and fingers	1	0.5	2
One entire arm including entire hand	4	2	8
Elbows	1	0.5	2
Both soles	1.5	0.75	3
One foot (dorsal and sole) including toes	1.5	0.75	3
One entire leg including entire foot	8	4	16
Buttocks	4	2	8
Knees	1	0.5	2
Trunk (anterior)	8	4	16
Trunk (posterior)	8	4	16
Genitalia	0.5	0.25	1

*1 FTU = 500mg

Children^

Age	Face & Neck	Arm & Hand	Leg & Foot	Trunk (Anterior)	Trunk (Posterior) and Buttocks
3-6 Months	1	1	1.5	1	1.5
1-2 Years	1.5	1.5	2	2	3
3-5 Years	1.5	2	3	3	3.5
6-10 Years	2	2.5	4.5	3.5	5

^All values are FTU

The application of steroids to open wounds should theoretically increase the risk of HPA axis suppression and other systemic side effects. Nonetheless, there is data that suggests applying corticosteroids to chronic wounds does help improve the healing process. In these cases, usually only low-dose topical steroids are used.[42-43]

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REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Psoriasis - biologicals 2-20-07.docx	02/2007	Allen Shek, PharmD
Updated Policy	Biological Response Modifiers Review 2-19-08.docx	02/2008	Allen Shek, PharmD
Updated Policy	HPA Suppression among Medium Potency Topical Corticosteroids.docx	06/2008	Allen Shek, PharmD
Updated Policy	Biologic Response Modifiers 2010 final.docx	05/2010	Allen Shek, PharmD
Updated Policy	Calcipotriene.docx	11/2012	Allen Shek, PharmD
Updated Policy	Biologic Response Modifiers for Psoriasis 2013-2-19.docx	02/2013	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	05/2015	Jonathan Szkotak, PharmD
Updated Policy	HPSJ Coverage Policy - Dermatology – Psoriasis 2015-05.docx	05/2015	Jonathan Szkotak, PharmD, BCACP

Updated Policy	Coverage Policy Update – Dermatology – Psoriasis & Psoriatic Arthritis 2015-11.docx	11/2015	Johnathan Yeh, PharmD
Updated Policy	Class Review- Biologics, Apremilast, and Tofacitinib in Inflammatory Joint, Skin, and Bowel Diseases.docx	02/2016	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Dermatology – Psoriasis 2017-02.docx	02/2017	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Dermatology – Psoriasis 2018-02.docx	02/2018	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy - Dermatology – Psoriasis 2019-05.docx	05/2019	Matthew Garrett, PharmD
Updated Policy	Psoriasis.docx	05/2020	Matthew Garrett, PharmD
Updated Policy	Psoriasis.docx	09/2020	Matthew Garrett, PharmD
Updated Policy	Psoriasis.docx	09/2021	Matthew Garrett, PharmD
Updated Policy	Psoriasis.docx	11/2022	Matthew Garrett, PharmD
Updated Policy	Psoriasis.docx	06/2023	Matthew Garrett, PharmD

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