

# MEDICATION COVERAGE POLICY

## PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

<b>POLICY</b>	Other Skin Disorders	<b>P&amp;T DATE:</b>	6/20/2023
<b>THERAPEUTIC CLASS</b>	Dermatology	<b>REVIEW HISTORY</b> (MONTH/YEAR)	12/22, 12/21, 12/20, 12/19,
<b>LOB AFFECTED</b>	Medi-Cal		12/18, 5/17, 9/15, 5/15, 11/14, 9/11, 5/09

*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

### WOUND CARE

Wound care can be difficult to manage since wound type, size, location, ease of application, and other factors are all considerations that affect the wound care agent selected. Depending on the type of wounds, it may take anywhere from days to months for wounds to heal so the therapeutic benefits of some of these agents is not always immediately apparent. This review will examine the standards of practice for wound care management and the available formulary wound care products and their coverage criteria.

### ATOPIC DERMATITIS

Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with skin barrier dysfunction, immune dysregulation, and itchiness. AD affects approximately 3% of adults in the United States.<sup>1</sup> It is hypothesized that an abnormality in the filaggrin gene causes dysfunctional skin proteins to be synthesized, resulting in poorly hydrated skin and altered barrier function. The abnormal immune response occurs due to abnormal Th2 immune cells that release cytokines (including IL-4 and IL-13) which propagate inflammation. Patients can experience dry, scaly, itchy skin. Other symptoms include pain, sweating, bleeding, oozing, cracking, flaking and a heat sensation. Complications of AD include skin thickening and skin fissures due to chronic scratching. Patients with AD are also predisposed to infectious disease of the skin by bacteria and viruses. They also experience a reduced quality of life due to disrupted sleep, and reduced social and mental health.<sup>2</sup>

### CHRONIC IDIOPATHIC URTICARIA<sup>12</sup>

Chronic idiopathic urticaria (CU) is defined as urticaria that has been continuously or intermittently present for at least a 6 week duration. The incidence of CU is estimated at 1.4% per year with a prevalence estimated to range from 0.5% to 5%. Signs and symptoms associated with CU/angioedema can include organs other than the skin. The patient may experience wheezing, coughs, vomiting, diarrhea, dizziness, loss of consciousness, changes in blood pressure or heart rate, and anaphylaxis.

### HIDRADENITIS SUPPURATIVA<sup>13</sup>

Hidradenitis Suppurativa (HS) is a debilitating disease that causes abscesses and scarring on the skin. It has an unknown cause but typically presents itself near hair follicles at locations such as the bottom, armpits, groin, and breasts. The treatment guidelines currently available by the American Academy of Dermatology emphasize that following the guidelines do not guarantee successful treatment and that the care of a patient with HS is ultimately determined by the provider and patient.

The purpose of this coverage policy is to review the available agents (Tables 1 and 2) 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 Wound Care Agents**

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
--	<b>Gentamicin</b> <i>Cream, Ointment</i>	0.1%	Yes	No
--	<b>Bacitracin Zinc</b> <i>Ointment, Packet</i>	500 Unit/Gm	Yes	No
--	<b>Mupirocin (Bactroban)</b> <i>Cream, Ointment</i>	2%	Yes	No
--	<b>Neomycin/Bacitra/Polymyx (Triple Antibiotic)</b> <i>Ointment</i>	3.5mg-400 U-5,000 U/Gm	Yes	No
--	<b>Neomycin/Bacitracin/Pmyx/ Pramox (Neosporin Plus)</b> <i>Ointment, Cream</i>	3.5mg-500 U-10,000 U/Gm	Yes	No
--	<b>Bacitracin/Polymyxin/Pramx (Neosporin Plus)</b> <i>Cream</i>	3.5mg-10,000 U/Gm-0.5%	Yes	No
--	<b>Ozenoxacin (Xepi)</b> <i>Cream</i>	1%	Yes	No
--	<b>Calamine</b> <i>Lotion</i>	-	Yes	No
--	<b>Calamine/Zinc Oxide</b> <i>Lotion</i>	-	Yes	No
--	<b>Silver Sulfadiazine (SSD)</b> <i>Cream</i>	1%	Yes	No
--	<b>Lidocaine-Prilocaine</b> <i>Cream</i>	2.5%-2.5%	Yes	No
--	<b>Medihoney</b> <i>Paste</i>	-	Yes	No
--	<b>Collagenase (Santyl)</b> <i>Ointment</i>	250 U/Gm	Yes	No
--	<b>Cadexomer Iodine (Iodosorb)</b> <i>Gel</i>	-	Yes	No
--	<b>Becaplermin (Regranex)</b> <i>Gel</i>	0.01%	Yes	No
Q4100	<b>Skin Substitute not Otherwise Specified</b>	-	No	Yes (PA)
Q4101	<b>Apligraf</b>	-	No	Yes (PA)
Q4102	<b>Oasis Wound Matrix</b>	-	No	Yes (PA)
Q4103	<b>Oasis Burn Matrix</b>	-	No	Yes (PA)
Q4104	<b>Integra Bilayer Matrix Wound Dressing</b>	-	No	Yes (PA)
Q4105	<b>Integra Dermal Regeneration Template</b>	-	No	Yes (PA)
Q4106	<b>Dermagraft</b>	-	No	Yes (PA)
Q4107	<b>Graftjacket</b>	-	No	Yes (PA)
Q4116	<b>Alloderm</b>	-	No	Yes (PA)
Q4117	<b>Hyalomatrix</b>	-	No	Yes (PA)
Q4121	<b>TheraSkin</b>	-	No	Yes (PA)
Q4122	<b>Dermacell</b>	-	No	Yes (PA)
Q4124	<b>Oasis Ultra Tri-Layer Wound Matrix</b>	-	No	Yes (PA)

Q4128	FlexHD, AllopatchHD, or Matrix HD	-	No	Yes (PA)
Q4130	Strattice TM	-	No	Yes (PA)
Q4132	Grafix Core and Grafixpl Core	-	No	Yes (PA)
Q4133	Grafix Prime	-	No	Yes (PA)
Q4151	Amnioband or guardian	-	No	Yes (PA)
Q4168	Ambioband, 1 mg	-	No	Yes (PA)
Q4182	Transcyte	-	No	Yes (PA)
Q4186	Epifix	-	No	Yes (PA)
Q4187	Epicord	-	No	Yes (PA)

PA = Prior Authorization

**Table 2: Available Other Skin Disorders Agents**

CPT Code	Generic Name (Brand Name)	Available Strengths	Pharmacy Benefit	Outpatient Medical Benefit (Restrictions)
<b>ATOPIC DERMATITIS</b>				
--	<b>Crisaborole (Eucrisa)</b> <i>Ointment</i>	2%	Yes	No
--	<b>Dupilumab (Dupixent)</b> <i>Solution Prefilled Syringe</i>	300 mg/2 mL (2 mL)	Yes	Yes (PA)
<b>CHRONIC IDIOPATHIC URTICARIA</b>				
J2357	<b>Omalizumab (Xolair)</b> <i>Solution Prefilled Syringe</i>	150 mg/mL (1 mL)	Yes	Yes (PA)
<b>HIDRADENITIS SUPPURATIVA</b>				
J0135	<b>Adalimumab (Humira)</b> <i>Prefilled Syringe and Pen-injector Kit</i>	40mg/0.8ml	Yes	Yes (PA)

PA = Prior Authorization

## **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).

### **ATOPIC DERMATITIS**

#### **Interleukin-4 Receptor Antagonists**

##### ***Dupilumab (Dupixent)***

- Coverage Criteria:** Prior authorization required. Reserved for patients 6 years of age or older with confirmed diagnosis by a dermatologist, allergist, or immunologist of chronic moderate to severe atopic dermatitis that has failed treatment, shown intolerance, or has contraindication to one or more medium to super-high potency topical corticosteroid AND Tacrolimus (Protopic) AND an adequate trial of one of the following [1] phototherapy/photo-chemotherapy OR [2] oral systemic therapy (e.g. azathioprine, methotrexate, mycophenolate) within the past 365 days. Documentation of allergy testing (e.g. skin, in vitro) is also required.
- Limits:** Restricted to specialty pharmacy. Must be prescribed by dermatologist, allergist, or immunologist.
- Required Information for Approval:** Clinic notes documenting diagnosis of chronic moderate to severe atopic dermatitis by a dermatologist, allergist, or immunologist. Documentation of allergy testing. Prescription history of [1] one or more medium to super-high potency topical corticosteroids, [2] tacrolimus (Protopic), and [3] an adequate trial of one of the following:

phototherapy/photo-chemotherapy OR oral systemic therapy (e.g. azathioprine, methotrexate, mycophenolate).

- ❑ **Other Notes:** For sensitive areas of the skin (e.g., face, neck, and other skin folds) lowest to lower-medium potency topical corticosteroids may be used.

## CHRONIC IDIOPATHIC URTICARIA

### Anti-IgE Antibody

#### *Omalizumab (Xolair)*

- ❑ **Coverage Criteria:** Reserved for patients who must have urticaria for most days of the week for longer than a duration of six weeks. Must have tried and failed monotherapy with a second generation non-sedating antihistamine up to four-fold the standard daily dose for at least 1 to 4 weeks.
- ❑ **Limits:** None
- ❑ **Required Information for Approval:** Clinic notes documenting diagnosis of chronic idiopathic urticaria. Prescription history of second generation non-sedating antihistamine.
- ❑ **Other Notes:** Initial approval is for 6 months. Based on clinic notes, patient must have documented therapeutic response in the form of improved symptomology for continuing approval. If symptoms are not improved, recommend discontinuation.

## HIDRADENITIS SUPPURATIVA

### Tumor Necrosis Factor-Inhibitor

#### *Adalimumab (Humira)*

- ❑ **Coverage Criteria:** Reserved for patients at least 12 years of age with documented diagnosis of moderate to severe hidradenitis suppurativa for at least one year.
- ❑ **Limits:** Restricted to specialty pharmacy. Must be prescribed by dermatologist.
- ❑ **Required Information for Approval:** Documented diagnosis of moderate to severe hidradenitis suppurativa for at least one year.

## **CLINICAL JUSTIFICATION**

### **WOUND CARE**

Hydrocolloids are a popular class among wound care agents because they can both maintain moisture as well as absorb excess fluids. However, hydrocolloids are associated with higher costs compared to other wound care agents, and due to their occlusive nature, there is higher risk of wound infections and hypergranulation.

Medihoney® Paste is used for mild-moderate exudative wounds; it has advantages over traditional hydrocolloids in that it is less costly and approved for chronic use. In addition, its formulation is less viscous, allowing the paste to reach tunneled or irregular wounds. Likewise, cadexomer iodine is another alternative to traditional hydrocolloids. Its gel-like medium and co-formulation with iodine makes it useful for highly exudative or infected wounds. The iodine component is a potential safety concern and warrants a limitation on the duration of use to 90 days as recommended by the manufacturer.

Collagenase ointment is an alternative to surgical/mechanical debridement for the management of chronic dermal ulcers (pressure, diabetic, and venous leg ulcers) and severe burns. Through various, small studies, collagenase was shown to improve wound healing as compared to standard wound dressings, and when used in addition to surgical debridement, collagenase ointment showed a reduction ulcer size. Topical debridement provides minimal pain and can be used at home by the patient or caregiver. Also, collagenase ointment does not have a maximum duration of use because of its mild debriding properties. Collagenase ointment is slow-acting and may take weeks to achieve complete debridement.

### **ATOPIC DERMATITIS**

Topical agents are the mainstay of treatment in mild, moderate, and severe cases of AD. In more severe, topical agents are used in conjunction with phototherapy or systemic therapy. Topical agents used in AD treatment include moisturizers, topical corticosteroids, and topical calcineurin inhibitors.<sup>6</sup> Topical corticosteroids are the mainstay of topical anti-inflammatory treatment, and are initiated after failure of good skin care and regular use of moisturizers. Topical corticosteroids should be applied twice daily for 2-4 weeks for acute flares of AD. Topical corticosteroids may be used as maintenance therapy in patients who experience frequent, repeat outbreaks. Topical corticosteroids are applied once or twice weekly in maintenance therapy. Topical calcineurin inhibitors are used second line and may be combined with topical corticosteroids. Studies show mixed results on the efficacy of topical calcineurin inhibitors with topical corticosteroids. Tacrolimus is indicated for moderate-to-severe AD and pimecrolimus is indicated for mild-to-moderate AD.

In patients with more severe disease that is not controlled with optimal topical therapy, phototherapy is recommended. Phototherapy with UVB, BB-UVB, UVA, and PUVA has been shown to be beneficial for both acute and chronic disease.<sup>7</sup> Results from phototherapy are typically seen anywhere from 15-25 treatments over 2-4 weeks.<sup>8</sup>

Systemic therapy is recommended when optimized topical regimens and/or phototherapy do not adequately control the disease. Options for systemic therapy include calcineurin inhibitors, methotrexate, mycophenolate, and azathioprine. Among systemic agents for AD, these drugs have been widely used and have shown the most efficacy. Interferon gamma is moderately and variably effective, but may also be considered in patients where other oral therapies are not an option.<sup>9</sup> Systemic steroids should be avoided unless used for an acute exacerbation because prolonged use can lead to many side effects. Leukotriene inhibitors have limited data supporting use. Insufficient data exists to recommend optimal dosing, duration of therapy and precise monitoring protocols for any systemic agent. Currently, there are no recommendations for the use of biologics in AD. The comparative efficacy of phototherapy and systemic therapy is unknown due to inconsistency between studies regarding methods.<sup>7</sup>

## ☒ REFERENCES

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## REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Contraceptives May09_JHP01 5-11-09.doc	5/2009	Allen Shek, PharmD
Updated Policy	OC Class Review 9-20-11.docx	9/2011	Allen Shek, PharmD
Updated Policy	Formulary Realignment PT 9-18-12.xls	9/2012	Allen Shek, PharmD
Creation of Policy	Wound Care Agents 2014-11-18.docx	11/2014	Jonathan Szkotak, PharmD
Updated Policy	Wound Care Coverage Policy.docx	05/2015	Jonathan Szkotak, PharmD, BCACP
Updated Policy	Acne Class Review.docx	5/2015	Jonathan Szkotak, PharmD
Updated Policy	HPSJ Coverage Policy – Dermatology – Acne 2015-5.docx	5/2015	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Dermatology – Wound Care 2015-05.docx	09/2015	Jonathan Szkotak, PharmD, BCACP
Updated Policy	HPSJ Coverage Policy – Dermatology – Wound Care 2017-05.docx	5/2017	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Dermatology – Acne 2017-5.docx	5/2017	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Dermatology – Wound Care 2018-12.docx	12/2018	Matthew Garrett, PharmD
Updated Policy	HPSJ Coverage Policy – Dermatology – Acne 2018-12.docx	12/2018	Matthew Garrett, PharmD
Updated Policy	HPSJ Coverage Policy – Dermatology – Other Skin Disorders 2019-12.docx	12/2019	Matthew Garrett, PharmD
Updated Policy	HPSJ Coverage Policy – Dermatology – Other Skin Disorders 2020-12.docx	12/2020	Matthew Garrett, PharmD

Review of Policy	Other Skin Disorders	12/2021	Matthew Garrett, PharmD
Updated Policy	Other Skin Disorders	12/2022	Matthew Garrett, PharmD
Review of Policy	Other Skin Disorders	06/2023	Matthew Garrett, PharmD

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