

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY	Other Skin Disorders	P&T DATE:	6/18/2024
THERAPEUTIC CLASS	Dermatology	REVIEW HISTORY (MONTH/YEAR)	6/23, 12/22, 12/21, 12/20, 12/19, 12/18, 5/17, 9/15, 5/15, 11/14, 9/11, 5/09
LOB AFFECTED	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/MVHP 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.¹ 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.²

CHRONIC IDIOPATHIC URTICARIA¹²

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 SUPPURATIVA¹³

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)
--	Gentamicin <i>Cream, Ointment</i>	0.1%	Yes	No
--	Bacitracin Zinc <i>Ointment, Packet</i>	500 Unit/Gm	Yes	No
--	Mupirocin (Bactroban) <i>Cream, Ointment</i>	2%	Yes	No
--	Neomycin/Bacitra/Polymyx (Triple Antibiotic) <i>Ointment</i>	3.5mg-400 U- 5,000 U/Gm	Yes	No
--	Neomycin/Bacitracin/Pmyx/ Pramox (Neosporin Plus) <i>Ointment, Cream</i>	3.5mg-500 U- 10,000 U/Gm	Yes	No
--	Bacitracin/Polymyxin/Pramx (Neosporin Plus) <i>Cream</i>	3.5mg-10,000 U/Gm-0.5%	Yes	No
--	Ozenoxacin (Xepi) <i>Cream</i>	1%	Yes	No
--	Calamine <i>Lotion</i>	-	Yes	No
--	Calamine/Zinc Oxide <i>Lotion</i>	-	Yes	No
--	Silver Sulfadiazine (SSD) <i>Cream</i>	1%	Yes	No
--	Lidocaine-Prilocaine <i>Cream</i>	2.5%-2.5%	Yes	No
--	Medihoney <i>Paste</i>	-	Yes	No
--	Collagenase (Santyl) <i>Ointment</i>	250 U/Gm	Yes	No
--	Cadexomer Iodine (Iodosorb) <i>Gel</i>	-	Yes	No
--	Becaplermin (Regranex) <i>Gel</i>	0.01%	Yes	No
Q4100	Skin Substitute not Otherwise Specified	-	No	Yes (PA)
Q4101	Apligraf	-	No	Yes (PA)
Q4102	Oasis Wound Matrix	-	No	Yes (PA)
Q4103	Oasis Burn Matrix	-	No	Yes (PA)
Q4104	Integra Bilayer Matrix Wound Dressing	-	No	Yes (PA)
Q4105	Integra Dermal Regeneration Template	-	No	Yes (PA)
Q4106	Dermagraft	-	No	Yes (PA)
Q4107	Graftjacket	-	No	Yes (PA)
Q4116	Alloderm	-	No	Yes (PA)
Q4117	Hyalomatrix	-	No	Yes (PA)
Q4121	TheraSkin	-	No	Yes (PA)
Q4122	Dermacell	-	No	Yes (PA)
Q4124	Oasis Ultra Tri-Layer Wound Matrix	-	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)
ATOPIC DERMATITIS				
--	Crisaborole (Eucrisa) Ointment	2%	Yes	No
--	Dupilumab (Dupixent) Solution Prefilled Syringe	300 mg/2 mL (2 mL)	Yes	No
CHRONIC IDIOPATHIC URTICARIA				
J2357	Omalizumab (Xolair) Solution Prefilled Syringe	150 mg/mL (1 mL)	Yes	No
HIDRADENITIS SUPPURATIVA				
J0135	Adalimumab (Humira) Prefilled Syringe and Pen-injector Kit	40mg/0.8ml	Yes	No
--	Secukinumab (Cosentyx) Prefilled Syringe	150mg/mL (300 mg dose)	Yes	No

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

WOUND CARE

Agents listed in Table 1 on the Medical Benefit

CPT Codes: Q4100 to Q4107, Q4116, Q4117, Q4121, Q4122, Q4124, Q4128, Q4130, Q4132, Q4133, Q4151, Q4168, Q4182, Q4186, Q4187

- ☐ **Coverage Criteria:** Prior authorization required. Medical necessity criteria applies.
- ☐ **Limits:** None
- ☐ **Required Information for Approval:** Chart notes documenting the medical necessity of the wound care agent as well as measurements of the wound to be addressed.

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.

REFERENCES

1. Silverberg JI, Hanifin JM. Adult eczema prevalence and associations with asthma and other health and demographic factors: A US population-based study. *J Allergy Clin Immunol*. 2013 Oct 3. doi:pii: S0091-6749(13)01366-3. 10.1016/j.jaci.2013.08.031.
2. Boguniewicz M, Leung DY. Atopic dermatitis: a disease of altered skin barrier and immune dysregulation. *Immunol Rev* 2011; 242:233.
3. Kakita L. Tazarotene versus tretinoin or adapalene in the treatment of acne vulgaris. *American Academy of Dermatology*. 2000; 43:S51-4. doi: <http://dx.doi.org/10.1067/mdj.2000.108322>.
4. Ozolins M, Eady EA, Avery AJ, et al. Comparison of five antimicrobial regimens for treatment of mild to moderate inflammatory facial acne vulgaris in the community: randomized controlled trial. *Lancet*. 2004; 364:2188-95.
5. Koo EB, Petersen TD, and Kimball AB. Meta-analysis comparing efficacy of antibiotics versus oral contraceptives in acne vulgaris. *American Academy of Dermatology*. 2014. 3(51)450-458. doi: <http://dx.doi.org/10.1016/j.jaad.2014.03.051>.
6. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. *J Am Acad Dermatol* 2014; 71:116.
7. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol*. 2014;71(2):327-49.
8. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 5. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. *J Am Acad Dermatol*. 2010;62(1):114-35.
9. Jang IG, Yang JK, Lee HJ, Yi JY, Kim HO, Kim CW, et al. Clinical improvement and immunohistochemical findings in severe atopic dermatitis treated with interferon gamma. *J Am Acad Dermatol*. 2000;42:1033-40.
10. Dupixent (dupilimumab) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc; 2020.
11. Matterne U, Böhmer MM, Weisshaar E, et al. Oral H1 antihistamines as 'add-on' therapy to topical treatment for eczema. *Cochrane Database Syst Rev* 2019; 1:CD012167. <https://pubmed.ncbi.nlm.nih.gov/30666626/>.
12. Bernstein, David I, et al. The Diagnosis and Management of Acute and Chronic Urticaria: 2014 update. *Journal of Allergy and Clinical Immunol*. 2014;133(5):1270-1277.
13. Alikhan, Ali, et al. North American clinical management guidelines for hidradenitis suppurativa: A publication from the United States and Canadian Hidradenitis Suppurativa Foundations. *J Am Acad Dermatol*. 2019;81(1):91-101.

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
Review of Policy	Other Skin Disorders	06/2024	Matthew Garrett, PharmD

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