

MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE



POLICY	Acne	P+T DATE	12/11/2018
THERAPEUTIC CLASS	Dermatology	REVIEW HISTORY	5/17, 5/15, 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 Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Acne vulgaris is a common disease in adolescents with a reported prevalence of 70-87%. This disease state is a cause for concern due to the psychosocial impact among patients especially adolescents. There are multiple drug combinations with different mechanisms to treat acne vulgaris, but this depends on the severity of acne: mild, moderate, or severe. This review will examine the treatment guidelines of acne vulgaris and the currently available acne drug products and their coverage criteria.

Table 1: Available Acne Agents (Current as of 12/2018)

Topical Agents					
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Average Cost per 30 days	Notes
Single Agents	Benzoyl Peroxide <i>Bar, Cleanser, Cream, Gel, Lotion, Wash</i>	5%, 10%	--	\$6.90	
		4%, 6%	NF	--	
	Sulfacetamide/Sulfur <i>Cleanser</i>	-	FL	\$145.89	Limit 1 fill per month.
	Clindamycin Phosphate <i>Gel, Lotion, Solution</i>	1%	--	\$53.74	
	Erythromycin Base/Ethanol <i>Gel, Solution, Swab</i>	2%	--	\$70.81	
	Tretinoin <i>Cream, Gel</i>	0.01%, 0.025%, 0.05%, 0.1%	AL	\$116.90	Restricted to use by patients <35yo. Tretinoin 0.05% Gel is non-formulary.
	Adapalene <i>Cream, Gel, Lotion</i>	0.1%, 0.3%	AL	\$169.99	Restricted to use by patients <35yo. Differin 0.1% Gel (OTC) is formulary.
	Tazarotene (Tazorac) <i>Cream, Gel</i>	0.05%, 0.1%	PA; QL	\$308.88	Reserved for treatment failure to Tretinoin + BPO AND Adapalene + BPO. Limit 30gm per month.
Dapsone (Aczone) <i>Gel</i>	5%	PA; QL	\$393.63	Reserved for treatment failure to Tretinoin/Adapalene + Clindamycin/Erythromycin + BPO. Limit 30gm per month.	
Combination Agents	All combination acne products <i>(BenzaClin, Benzamycin, Epiduo, etc)</i>		NF	-	Use agents separately.
Systemic Agents					
Therapeutic Class	Generic Name (Brand Name)	Available Strengths	Formulary Limits	Average Cost per 30 days	Notes
Oral Tetracyclines	Doxycycline Monohydrate <i>Capsule, Tablet</i>	50mg, 100mg	-	\$23.68	Doxycycline Hyclate is non-formulary.
	Minocycline <i>Capsule</i>	50mg, 75mg, 100mg	-	\$14.88	
	Tetracycline <i>Capsule</i>	20mg, 500mg	NF	-	

Oral Retinoids	Isotretinoin (Claravis, Amnesteem, Myorisan, Zenatane)	10mg, 20mg, 40mg,	PA	\$642.89	Reserved for treatment failure to 2 conventional treatments: BPO, topical retinoids, topical/oral antibiotics. Approved up to 6 months at a time.
	Isotretinoin (Absorica)	10mg, 20mg, 40mg	NF	-	
AL = Age Limit; NF = Non-Formulary; PA = Prior Authorization Required; QL = Quantity Limit; ST = Step Therapy					

⊕ EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Topical Retinoids

Tretinoin (Retin-A); Adapalene (Differin)

- Coverage Criteria:** Tretinoin and Adapalene are restricted to patients under the age of 35 OR for patients 35 and older who have a diagnosis of moderate acne as evidenced by documentation of clinical evaluation by provider with treatment failure to topical Clindamycin/Erythromycin with Benzoyl Peroxide OR prescribed by a dermatologist.
- Limits:** None
- Required Information for Approval:** (Non-dermatologist prescribers) Clinic notes documenting diagnosis of moderate-severe acne with treatment failure to topical antibiotics and benzoyl peroxide; prescription history of topical/systemic antibiotics and benzoyl peroxide.
- Other Notes:** Adapalene 0.1% Gel (OTC) is formulary preferred.
- Non-Formulary:**
 - Retin-A Micro (tretinoin microspheres)
 - Renova (tretinoin – wrinkles)
 - Adapalene 0.1% Gel (Rx version)
 - Tretinoin 0.05% Gel

Tazarotene

Tazarotene (Tazorac)

- Coverage Criteria:** Tazarotene is reserved for use by Dermatologists or for patients with documented treatment failure/intolerance to Tretinoin AND Adapalene in combination with Benzoyl Peroxide.
- Limits:** 30gm per month.
- Required Information for Approval:** Prescription history of Tretinoin, Adapalene, and Benzoyl Peroxide.
- Other Notes:** None

Oral Retinoids

Isotretinoin (Amnesteem, Claravis, Myorisan, Zenatane)

- Coverage Criteria:** Isotretinoin is step therapy to failing 2 of the following conventional acne agents: benzoyl peroxide, topical retinoids, topical antibiotics, OR oral antibiotics.
- Limits:** Approval for 6 months at a time; renewal required after 6 months.
- Required Information for Approval:** Prescription history of previous antibiotics, topical retinoids/antibiotics, or benzoyl peroxide.
- Non-Formulary:** Absorica

Oral Antibiotics

Doxycycline Monohydrate, Minocycline, Tetracycline, Erythromycin, Azithromycin, Clindamycin, Trimethoprim, Amoxicillin*

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A
- Non-Formulary:**
 - *Tetracycline is non-formulary.*
 - *Doxycycline Hyclate is non-formulary.*

Topical Antibiotics

Clindamycin, Erythromycin

- Coverage Criteria:** None
- Limits:** None
- Required Information for Approval:** N/A

Dapsone (Aczone)

- Coverage Criteria:** Dapsone is reserved for patients with documented treatment failure/intolerance to Tretinoin/Adapalene AND topical Clindamycin/Erythromycin AND Benzoyl Peroxide.
- Limits:** 30gm per month.
- Required Information for Approval:** Prescription history of [1] Tretinoin or Adapalene [2] topical Clindamycin or Erythromycin AND [3] Benzoyl Peroxide.

OTC & Other Products

*Benzoyl Peroxide 5%, 10%; Salicylic Acid, Sulfacetamide-Sulfur**

- Coverage Criteria:** None
- Limits:** Sulfacetamide-Sulfur products are limited to 1 fill per month.
- Required Information for Approval:** N/A
- Non-Formulary:**
 - Benzoyl Peroxide 4%, 6% formulations are non-formulary.

CLINICAL JUSTIFICATION

The effectiveness of topical antibiotics, retinoids, and benzoyl peroxide for acne treatment has been well established. For mild acne, the *2016 Journal of American Academy of Dermatology* and *2013 Pediatrics Journal* recommend over-the-counter products (benzoyl peroxide, salicylic acid, sulfur agents) as first-line agents with or without topical antibiotics or retinoids. Moderate acne usually requires a combination of topical therapies (topical antibiotics, topical retinoids, and over-the-counter agents). Tazarotene is clinically comparable to topical tretinoin and adapalene with adapalene being more tolerable than tretinoin.² Long-term use of oral tetracyclines antibiotics (minocycline and doxycycline) may be useful for prevention of acne flares. Monotherapy with oral antibiotics has a similar efficacy to benzoyl peroxide in combination with topical antibiotics.³ Severe acne or cystic acne requires 5 to 6 months of systemic treatment with oral retinoids, often used in combination with topical therapies. For patients' with hormonal-induced acne, oral contraceptives may be used as adjunctive/monotherapies therapies. While only 3 contraceptives have a labeled indication for acne management, all oral contraceptives may be used for acne treatment.⁴ Topical combination products, while formulated for convenience, are significantly less cost-effective. Consequently, combination products are non-formulary.

REFERENCES

1. Eichenfield LF, Krakowski AC, Piggott C, et al. Evidence-based recommendations for the diagnosis and treatment of pediatric acne. *Pediatrics*. 2013; 131(3): S163-86. doi: 10.1542/peds.2013.0490B.
2. 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>.
3. 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.
4. 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>.
5. Zaenglein AL, Pathy AL, Schlosser BJ, Alikhan A, Baldwin HE, Berson DS, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016 Feb 15.

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
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 – Acne 2017-5.docx	5/2017	Johnathan Yeh, PharmD
Updated Policy	HPSJ Coverage Policy – Dermatology – Acne 2018-12.docx	12/2018	Matthew Garrett, PharmD

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