

# Retinoids (topical) Prior Authorization Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
02-01-2025

**Date of Origin**

## FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Adapalene Gel* Pads Solution	Topical treatment of acne vulgaris	*generic available	3,12,13
Aklief® (trifarotene) Cream	Topical treatment of acne vulgaris in patients 9 years of age and older		19
Altreno® (tretinoin) Lotion	Topical treatment of acne vulgaris in patients 9 years of age and older		11
Arazlo® (tazarotene) Lotion	Topical treatment of acne vulgaris in patients 9 years of age and older		20
Atralin® (tretinoin) Gel*	Topical treatment of acne vulgaris	*generic available	1
CABTREO™ (adapalene/be nzoyl peroxide/clind amycin) Gel	Topical treatment of acne vulgaris in adult and pediatric patients 12 years of age and older		28
Differin® (adapalene)	<u>Cream (0.1%):</u> Topical treatment of acne vulgaris	*generic available	2,10,15

Agent(s)	FDA Indication(s)	Notes	Ref#
Cream*	<u>Gel (0.3%) and Lotion (0.1%):</u>		
Gel*	Topical treatment of acne vulgaris in patients 12 years of age and older		
Lotion			
Epiduo® Forte	Topical treatment of acne vulgaris in adults and pediatric patients 12 years of age and older	*generic available	26
(adapalene/benzoyl peroxide)			
Gel*			
Epiduo®	Topical treatment of acne vulgaris in patients 9 years of age or older	*generic available	25
(adapalene/benzoyl peroxide)			
Gel*			
Fabior®, Tazarotene	Topical treatment of acne vulgaris in patients 12 years of age or older		14
Foam			
Retin-A®	Topical application in the treatment of acne vulgaris	*generic available	4
(tretinoin)			
Cream*			
Gel*			
Retin-A Micro®	Topical application in the treatment of acne vulgaris	*generic available	5
(tretinoin)			
Gel microspheres*			
Tazorac®	<u>Cream (0.1%):</u>	*generic available	8,9
(tazarotene)	Topical treatment of plaque psoriasis		
Cream*	Topical treatment of acne vulgaris		
Gel*	<u>Gel:</u> <ul style="list-style-type: none"> <li>0.05% and 0.1% gel are indicated for the topical treatment of patients with plaque psoriasis of up to 20% body surface area involvement</li> <li>0.1% gel is indicated for the topical treatment of mild to moderate severity facial acne vulgaris</li> </ul> <p>Limitations of Use:</p>		

Agent(s)	FDA Indication(s)	Notes	Ref#
	<ul style="list-style-type: none"> <li>The safety of Tazorac Gel use on more than 20% body surface area has not been established</li> </ul>		
Twynéo® (tretinoin/benzoyl peroxide)  Cream	Topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older		24

See package insert for FDA prescribing information: <https://dailymed.nlm.nih.gov/dailymed/index.cfm>

## CLINICAL RATIONALE

Acne	<p>Acne vulgaris is a common, chronic, inflammatory skin disorder of the pilosebaceous unit. Signs and symptoms include comedones, papules, pustules, or nodules on the face, but may also affect the upper arms, trunk, and back. Acne vulgaris most commonly occurs in adolescents, but it can affect most age groups and can persist into adulthood.(17,18) Topical therapies are the mainstay of acne treatment, and are used alone or in combination with other topical or oral agents. Using a combination of multiple mechanisms of action of topical therapies is recommended as multimodal therapy to optimize efficacy and reduce the risk of antibiotic resistance. Systemic oral antibiotics are typically used to treat moderate to severe acne. (17)</p> <p>Topical retinoids are vitamin A derivatives and are strongly recommended for the treatment of acne by the American Academy of Dermatology (AAD). Topical retinoid agents include tretinoin, adapalene, tazarotene, and trifarotene. Only modest differences in activity, tolerability, and efficacy have been noted between the different retinoids, and comparative effectiveness data does not suggest superiority of one topical retinoid against another.(17)</p> <p>BP is strongly recommended by the AAD for the treatment of acne. BP is a topical antimicrobial agent and is available over-the-counter. BP use is limited by concentration and formulation dependent side effects, including burning, stinging, dryness, erythema, and irritation. (17)</p> <p>Topical antibiotics are strongly recommended by the AAD for the treatment of acne and have both antibacterial and anti-inflammatory effects. Treatment options include erythromycin, clindamycin, minocycline, and dapsone. Topical antibiotic monotherapy is not recommended due to the risk of antibiotic resistance, and they should be used in combination with BP and/or a topical retinoid. There is a lack of evidence to suggest superiority of one topical antibiotic against another.(17)</p> <p>Fixed dose combination products of topical antibiotics, topical retinoids, and/or BP are strongly recommended by the AAD. Fixed dose combination products assist in treatment regimen adherence and may be less expensive than their individual components separately. When using a combination topical retinoid/antibiotic agent, it is recommended to use concomitant BP to prevent antibiotic resistance. Insufficient evidence is available to recommend topical BP, retinoids, antibiotics, or their combinations over one another.(17)</p> <p>Clascoterone (Winlevi) is a topical antiandrogen agent. It is conditionally recommended for the treatment of acne by the AAD due to treatment access and cost, despite a high certainty of benefits over risks. Azelaic acid is a topical comedolytic, antibacterial, and anti-inflammatory agent and is also conditionally recommended for the treatment of acne by the AAD. Azelaic acid may be beneficial for patients with sensitive skin or dyspigmentation due to its lightening effects. Insufficient evidence is</p>
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	available to develop a recommendation on the use of topical sodium sulfacetamide for acne even though it is used in practice.(17)
Additional Information	The age limit of 40 years or older as the edit parameter has been based on analysis of National Ambulatory Medical Care Survey (NAMCS) data (1990-1994)(21) and (1990-2004).(22) In the initial analysis, acne-related treatment with tretinoin was equal to non-acne conditions around 44 years of age.(21) The second analysis confirmed that there was a “minute probability” of non-acne-related use of topical retinoids in the population aged 40 years and younger.(22) The authors of the NAMCS data evaluations suggest a minimum age of 40 years as a cut-off to determine coverage of retinoid agents for acne.(21,22) These analyses were consistent with a study of the prevalence of acne in adults in the United Kingdom (UK). Data from the UK study indicated the prevalence of acne did not substantially decline between the ages of 24 and 44 years of life but fell significantly after 45 years of age.(23)
Safety	<p>Adapalene is contraindicated for use in individuals who are hypersensitive to adapalene or any of the components in the vehicle.(3,12,13)</p> <p>Aklief has no FDA labeled contraindications for use.(19)</p> <p>Altreno has no FDA labeled contraindications for use.(11)</p> <p>Arazlo is contraindicated in pregnancy.(20)</p> <p>Atralin has no FDA labeled contraindications for use.(1)</p> <p>CABTREO is contraindicated in the following:(28)</p> <ul style="list-style-type: none"> <li>• Individuals with known hypersensitivity to clindamycin, adapalene, benzoyl peroxide, any components of the formulation, or lincomycin</li> <li>• History of regional enteritis, ulcerative colitis, or antibiotic-associated colitis</li> </ul> <p>Differin is contraindicated for use in individuals who have known hypersensitivity to adapalene or any of the components in the vehicle.(2,10,15)</p> <p>Epiduo has no FDA labeled contraindications for use.(25)</p> <p>Epiduo Forte is contraindicated in patients with a history of hypersensitivity reactions to benzoyl peroxide or any components of the formulation in Epiduo Forte.(26)</p> <p>Fabior is contraindicated in pregnancy.(14)</p> <p>Retin-A is contraindicated for use in individuals who have hypersensitivity to any of the ingredients.(4)</p> <p>Retin-A Micro has no FDA labeled contraindications for use.(5)</p> <p>Tazorac is contraindicated in the following:(8,9)</p> <ul style="list-style-type: none"> <li>• Pregnancy</li> <li>• Individuals who have a known hypersensitivity to any of its components</li> </ul> <p>Twynéo is contraindicated in patients with a history of hypersensitivity reaction to benzoyl peroxide or any components of Twynéo.(24)</p>

## REFERENCES

Number	Reference
1	Atralin prescribing information. Bausch Health US, LLC. February 2024.
2	Differin Gel 0.3% prescribing information. Galderma Laboratories, L.P. December 2023.
3	Adapalene 0.1% gel prescribing information. PruGen, Inc. January 2018.
4	Retin-A prescribing information. Bausch Health US, LLC. May 2024.
5	Retin-A Micro prescribing information. Bausch Health US, LLC. April 2024.
6	Reference no longer used.
7	Reference no longer used.
8	Tazorac Gel prescribing information. Almirall, LLC. February 2020.
9	Tazorac Cream prescribing information. Almirall, LLC. December 2022.
10	Differin Cream prescribing information. Galderma Laboratories, L.P. October 2022.
11	Altreno lotion prescribing information. Bausch Health US, LLC. March 2020.
12	Adapalene 0.1% solution prescribing information. Rochester Pharmaceuticals. October 2023.
13	Adapalene 0.1% swab prescribing information. Rochester Pharmaceuticals. October 2023.
14	Fabior prescribing information. Mayne Pharma. May 2024.
15	Differin Lotion 0.1% prescribing information. Galderma Laboratories, LP. April 2023.
16	Reference no longer used.
17	Reynolds RV, Yeung H, Cheng CE, et al. Guidelines of care for the management of acne vulgaris. <i>Journal of the American Academy of Dermatology</i> . 2024;90(5):1006.e1-1006.e30. doi:10.1016/j.jaad.2023.12.017
18	Sutaria AH, Masood S, Saleh HM, Schlessinger J. Acne vulgaris. StatPearls - NCBI Bookshelf. Published August 17, 2023. <a href="https://www.ncbi.nlm.nih.gov/books/NBK459173/">https://www.ncbi.nlm.nih.gov/books/NBK459173/</a>
19	Aklief prescribing information. Galderma Laboratories, L.P. October 2023.
20	Arazlo prescribing information. Bausch Health US, Inc. September 2023.
21	McConnel RC, Fleisher AB, Williford PM, Feldman SR. Most topical tretinoin treatment is for acne vulgaris through the age of 44 years: An analysis of the National Ambulatory Medical Care Survey, 1990-1994. <i>J Am Acad Dermatol</i> . 1998;38:221-226.
22	Balkrishnan R, Bhosle MJ, Camacho F, Fleischer Jr AB, Feldman SR. Prescribing patterns for topical retinoids: Analyses of 15 years of data from the National Ambulatory Medical Care Survey. <i>J Dermatol Treat</i> . 2010;21:193-200.
23	Goulden V, Stables GI, Cunliffe WJ. Prevalence of acne in adults. <i>J Am Acad Dermatol</i> . 1999;41(4):577-580.
24	Twynéo prescribing information. Galderma Laboratories L.P. July 2023.
25	Epiduo prescribing information. Galderma Laboratories, L.P. February 2018.
26	Epiduo Forte prescribing information. Galderma Laboratories, L.P. April 2022.
27	Reference no longer used.
28	CABTREO prescribing information. Bausch Health US, LLC. November 2023.

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Differin	adapalene cream	0.1 %	M ; N ; O ; Y	O ; Y	Greater than or equal to 40 years	

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Adapalene treatment ; Cvs adapalene ; Differin	adapalene gel	0.1 % ; 0.3 %	M ; N ; O ; Y	O ; Y	Greater than or equal to 40 years	
Differin	adapalene lotion	0.1 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	
	Adapalene Pads 0.1%	0.1 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	
	Adapalene Soln 0.1%	0.1 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	
Epiduo ; Epiduo forte	adapalene-benzoyl peroxide gel	0.1-2.5 % ; 0.3-2.5 %	M ; N ; O ; Y	O ; Y	Greater than or equal to 40 years	
Cabtreo	adapalene-benzoyl peroxide-clindamycin gel	0.15-3.1-1.2 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	
Fabior	tazarotene (acne) foam	0.1 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	
Arazlo	tazarotene (acne) lotion	0.045 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	
Tazorac	Tazarotene Cream 0.1%	0.1 %	M ; N ; O ; Y	O ; Y	Greater than or equal to 40 years	
Tazorac	tazarotene gel	0.05 % ; 0.1 %	M ; N ; O ; Y	O ; Y	Greater than or equal to 40 years	
Avita ; Retin-a	tretinoin cream	0.025 % ; 0.05 % ; 0.1 %	M ; N ; O ; Y	O ; Y	Greater than or equal to 40 years	
Atralin ; Avita ; Retin-a	tretinoin gel	0.01 % ; 0.025 % ; 0.05 %	M ; N ; O ; Y	O ; Y	Greater than or equal to 40 years	
Altreno	tretinoin lotion	0.05 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	
Retin-a micro ; Retin-a micro pump	tretinoin microsphere gel	0.04 % ; 0.06 % ; 0.08 % ; 0.1 %	M ; N ; O ; Y	N ; O ; Y	Greater than or equal to 40 years	
Twynéo	tretinoin-benzoyl peroxide cream	0.1-3 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	
Aklief	trifarotene cream	0.005 %	M ; N ; O ; Y	N	Greater than or equal to 40 years	

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Adapalene Pads 0.1%	0.1 %	Commercial ; HIM ; ResultsRx
	Adapalene Soln 0.1%	0.1 %	Commercial ; HIM ; ResultsRx
Adapalene treatment ; Cvs adapalene ; Differin	adapalene gel	0.1 % ; 0.3 %	Commercial ; HIM ; ResultsRx
Aklief	trifarotene cream	0.005 %	Commercial ; HIM ; ResultsRx
Altreno	tretinoin lotion	0.05 %	Commercial ; HIM ; ResultsRx
Arazlo	tazarotene (acne) lotion	0.045 %	Commercial ; HIM ; ResultsRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Atralin ; Avita ; Retin-a	tretinoin gel	0.01 % ; 0.025 % ; 0.05 %	Commercial ; HIM ; ResultsRx
Avita ; Retin-a	tretinoin cream	0.025 % ; 0.05 % ; 0.1 %	Commercial ; HIM ; ResultsRx
Cabtreo	adapalene-benzoyl peroxide-clindamycin gel	0.15-3.1-1.2 %	Commercial ; HIM ; ResultsRx
Differin	adapalene cream	0.1 %	Commercial ; HIM ; ResultsRx
Differin	adapalene lotion	0.1 %	Commercial ; HIM ; ResultsRx
Epiduo ; Epiduo forte	adapalene-benzoyl peroxide gel	0.1-2.5 % ; 0.3-2.5 %	Commercial ; HIM ; ResultsRx
Fabior	tazarotene (acne) foam	0.1 %	Commercial ; HIM ; ResultsRx
Retin-a micro ; Retin-a micro pump	tretinoin microsphere gel	0.04 % ; 0.06 % ; 0.08 % ; 0.1 %	Commercial ; HIM ; ResultsRx
Tazorac	Tazarotene Cream 0.1%	0.1 %	Commercial ; HIM ; ResultsRx
Tazorac	tazarotene gel	0.05 % ; 0.1 %	Commercial ; HIM ; ResultsRx
Twynéo	tretinoin-benzoyl peroxide cream	0.1-3 %	Commercial ; HIM ; ResultsRx

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
Brand Retinoids	<p><b>Brand Retinoid Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>The patient is 40 years of age or over <b>AND</b></li> <li>The patient is not using the requested agent for treatment of wrinkles, stretch marks, age spots, or skin lightening <b>AND</b></li> <li>ONE of the following: <ul style="list-style-type: none"> <li>A.The patient has tried and had an inadequate response to a generic topical retinoid <b>OR</b></li> <li>B.The patient has an intolerance or hypersensitivity to a generic topical retinoid <b>OR</b></li> <li>C.The patient has an FDA labeled contraindication to ALL generic topical retinoids</li> </ul> </li> </ol> <p><b>Length of Approval:</b> 12 months</p>
Generic Retinoids	<p><b>Generic Retinoid Agent(s)</b> will be approved when BOTH of the following are met:</p> <ol style="list-style-type: none"> <li>The patient is 40 years of age or over <b>AND</b></li> <li>The patient is not using the requested agent for treatment of wrinkles, stretch marks, age spots, or skin lightening</li> </ol> <p><b>Length of Approval:</b> 12 months</p>

