

# PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	TOPICAL RETINOIDS
BRAND NAME* (generic)	<p>ALTRENO (tretinoin)</p> <p>ATRALIN (tretinoin)</p> <p>AVITA (tretinoin)</p> <p>RETIN-A (tretinoin)</p> <p>RETIN-A MICRO (tretinoin)</p> <p>TWYNEO (tretinoin/benzoyl peroxide)</p> <p>VELTIN (clindamycin/tretinoin)</p> <p>ZIANA (clindamycin/tretinoin)</p>
<p><b>Status: CVS Caremark Criteria</b>  <b>Type: Initial Prior Authorization</b></p>	
<p><b>Ref # 355-A</b>  <b>Ref # 237-A</b></p>	

\* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.

## FDA-APPROVED INDICATIONS

### Atralin, Avita, Retin-A, Retin-A Micro

Atralin, Avita, Retin-A, and Retin-A Micro are indicated for topical application in the treatment of acne vulgaris.

### Altreno (tretinoin) lotion 0.05%, Twynéo

Altreno (tretinoin) lotion 0.05% and Twynéo are indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

### Veltin, Ziana

Veltin and Ziana are indicated for the topical treatment of acne vulgaris in patients 12 years and older.

## Compendial Uses

Keratosis follicularis (Darier's disease, Darier-White disease) <sup>12,15-17</sup>

Tretinoins (Topical) PA 355-A, 237-A 08-2021

©2021 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Caremark.

## **COVERAGE CRITERIA**

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of acne vulgaris

**OR**

- The patient has a diagnosis of keratosis follicularis (Darier's disease, Darier-White disease)

## **RATIONALE**

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Altreno, Atralin, Avita, Retin-A, Retin-A Micro, Twynéo, Veltin, and Ziana are indicated for the topical treatment of acne vulgaris.<sup>1-4,7-13</sup> The criteria does not provide for coverage of cosmetic uses for tretinoin drugs.

The American Academy of Dermatology (AAD) guidelines state that the topical therapy of acne vulgaris includes the usage of agents that are available over the counter or via prescription. Therapy choice may be influenced by age of the patient, site of involvement, extent and severity of disease, and patient preference. Topical therapies may be used as monotherapy, in combination with other topical agents or in combination with oral agents in both initial control and maintenance. Commonly used topical acne therapies include benzoyl peroxide, salicylic acid, antibiotics, combination antibiotics with benzoyl peroxide, retinoids, retinoid with benzoyl peroxide, retinoid with antibiotic, azelaic acid, and sulfone agents. A topical retinoid alone is a first-line treatment option for mild acne vulgaris. Topical retinoids are also considered to be a first-line treatment option for mild, moderate or severe acne vulgaris when used as combination therapy with benzoyl peroxide, oral antibiotics, and/or topical antibiotics. Topical retinoids are important in addressing the development and maintenance of acne and are recommended as monotherapy in primarily comedonal acne, or in combination with topical or oral antimicrobials in patients with mixed or primarily inflammatory acne lesions. Using multiple topical agents that affect different aspects of acne pathogenesis can be useful; combination therapy should be used in the majority of patients with acne.<sup>14</sup>

Per AAD guidelines, topical adapalene, tretinoin, and benzoyl peroxide can be safely used in the management of preadolescent acne in children. Current data show that retinoids in younger patients are effective and are not associated with increased irritation or risk.<sup>14</sup>

Topical tretinoin has been used for the treatment of keratosis follicularis.<sup>12</sup> Keratosis follicularis (also known as Darier White Disease or Darier's Disease) is a rare, genetic skin condition characterized by wart-like blemishes on the body. The treatment of keratosis follicularis is directed toward the specific symptoms that are apparent in each individual. Basic measures to manage this condition include using sunscreen, wearing cool cotton clothing, and avoiding hot environments. Medicinal treatment options include emollients, topical antibacterial soaps, antibiotics, antifungals, salicylic acid, retinoids (tretinoin, isotretinoin, adapalene, tazarotene), and corticosteroids. Moisturizers with urea or lactic acid can help reduce scaling and thickening of the lesions, low to medium potency topical steroids are sometimes useful for reducing inflammation, and when bacterial growth is suspected, use of antiseptics, astringents, or antibiotics may be necessary. Intermittent usage of topical antifungals and antibiotics can prevent microorganism colonization and reduce bad odor. Because bacterial infections can trigger the disease, if necessary, systemic antibiotics can be used. Topical retinoids are another treatment option for keratosis follicularis, as they may reduce hyperkeratosis (scaly thickening of the skin) within three months.<sup>15-17</sup>

Renova and Refissa are indicated as adjunctive agents for use in the mitigation of fine facial wrinkles in patients who use comprehensive skin care and sunlight avoidance programs.<sup>5-6</sup> Since the treatment of these indications is considered cosmetic, these two tretinoin products are not included in the criteria.

## **REFERENCES**

1. Altreno [package insert]. Bridgewater, NJ: Bausch Health US, LLC; March 2020.
2. Atralin [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2016.
3. Avita Cream [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; June 2018.
4. Avita Gel [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; January 2018.
5. Refissa [package insert]. Irvine, CA: ZO Skin Health, Inc.; April 2020.

6. Renova [package insert]. Bridgewater, NJ: Bausch Health US, LLC; September 2019.
7. Retin-A [package insert]. Bridgewater, NJ: Bausch Health US, LLC; September 2019.
8. Retin-A Micro [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; October 2017.
9. Twyneo [package insert]. Whippany, NJ: Sol-Gel Technologies Inc.; July 2021.
10. Veltin [package insert]. Exton, PA: Almirall, LLC; June 2019.
11. Ziana [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.
12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed July 13, 2021.
13. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed July 13, 2021.
14. Zaenglein A, Pathy A, Schlosser B, et al. Guidelines of Care for the Management of Acne Vulgaris. *J Am Acad Dermatol*. 2016; 74(5):945-973.
15. Darier disease. Office of Rare Disease Research. <https://rarediseases.info.nih.gov/gard/6243/darier-disease/resources/8>. Accessed July 13, 2021.
16. Keratosis Follicularis National Organization for Rare Disorders. <https://rarediseases.org/rare-diseases/keratosis-follicularis/>. Accessed July 13, 2021.
17. Engin B, Kutlubay Z, Erkan E, et al. Darier Disease: A Fold (Intertriginous) Dermatitis. *Clin. Dermatol*. 2015;33(4):448-451.

Written by: UM Development (GP)

Date Written: 08/1997

Revised: (LS) 12/1998; (MG) 12/2002, 12/2003; (TM) 11/2004; (NB) 09/2005, 05/2006 (Added Tretin-X), 09/2006; (CT) 11/2006 (Added Ziana); (AM) 08/2007; (MS) 08/2008; (AM) 09/2008; (SE) 09/2009; (CY) 08/2010; (MS) 08/2011, 08/2012, 10/2012 (extended duration), 06/2013, 06/2014; (RP) 06/2015, (SF) 06/2016 (no clinical changes); (RP) 06/2017 (no clinical changes), 06/2018 (no clinical changes), 08/2018 (Added Altreno), 06/2019 (separated diagnoses questions; combined 237-A [removed MDC designation and applied compendial use to 237-A]); (JK) 07/2020 removed Tretin-X); (CJH) 07/2021 (added Twyneo), 07/2021 (no clinical changes)

Reviewed: CRC: 01/2004; Medical Affairs (MM) 10/2004, 09/2005, 11/2006; (WF) 08/2007, 08/2008, 09/2008, 09/2009; (KP) 09/2010, 08/2011, 08/2012; (LS) 06/2013; (DC) 06/2014, 06/2015, 09/2018, 06/2019; (CHART) 07/30/2020, 08/05/2021  
External Review: 02/2004, 12/2004, 12/2005, 12/2006, 02/2008, 04/2009, 12/2009, 02/2011, 02/2012, 12/2012, 10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 10/2019, 10/2020, 10/2021

### **CRITERIA FOR APPROVAL**

- |   |   |     |    |
|---|---|-----|----|
| 1 | Does the patient have a diagnosis of acne vulgaris?<br>[If yes, then no further questions.]           | Yes | No |
| 2 | Does the patient have a diagnosis of keratosis follicularis (Darier's disease, Darier-White disease)? | Yes | No |

### **Mapping Instructions (355-A)**

	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 36 Months	Go to 2	
2.	Approve, 36 Months	Deny	<p>You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions:</p> <ul style="list-style-type: none"> <li>- Acne vulgaris</li> <li>- Keratosis follicularis (Darier's disease, Darier-White disease)</li> </ul> <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis]</p>

Mapping Instructions (237-A)			
	Yes	No	DENIAL REASONS – DO NOT USE FOR MEDICARE PART D
1.	Approve, 12 Months	Go to 2	
2.	Approve, 12 Months	Deny	<p>You do not meet the requirements of your plan.  Your plan covers this drug when you have any of these conditions:</p> <ul style="list-style-type: none"> <li>- Acne vulgaris</li> <li>- Keratosis follicularis (Darier's disease, Darier-White disease)</li> </ul> <p>Your request has been denied based on the information we have.</p> <p>[Short Description: No approvable diagnosis]</p>