PRIOR AUTHORIZATION CRITERIA

DRUG CLASS*	**RETINOIDS (ALL TOPICAL)**
BRAND NAME (generic)	
	ALTRENO (tretinoin)
	ATRALIN (tretinoin)
	AVITA (tretinoin)
	RETIN-A (tretinoin)
	RETIN-A MICRO (tretinoin)
	TRETIN-X (tretinoin)
	VELTIN (clindamycin/tretinoin)
	ZIANA (clindamycin/tretinoin)

Status: CVS Caremark Criteria ***Ref # 237-A***
Type: Initial Prior Authorization ***Ref # 355-A***

** 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, Tretin-X are indicated for topical application in the treatment of acne vulgaris. The safety and efficacy of these products in the treatment of other disorders have not been established.
Veltin and Ziana are indicated for the topical treatment of acne vulgaris in patients 12 years or older.
Altreno (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Compendial Use
Keratosis follicularis (Darier's disease, Darier-White disease) [12, 15, 16]

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:
- The patient has the diagnosis of acne vulgaris or 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. Tretinoins are indicated for the topical treatment of acne vulgaris. The safety and efficacy of these products in the treatment of other disorders have not been established. The criteria do not provide for cosmetic uses of these drugs.

The American Academy of Dermatology 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. 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. 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.[14]

Topical tretinoin has been used for the treatment of keratosis follicularis.[12] 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, application of antiseptics can be helpful. Topical retinoids also may reduce hyperkeratosis within three months.[15, 16]

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.[5-6] Since the treatment of these indications is considered cosmetic, these two tretinoin products are not included in the criteria.

REFERENCES

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3. Avita Cream [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc; January 2018.
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6. Renova [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.
7. Retin-A [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; June 2018.
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11. Ziana [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.
12. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed June 2019.
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14. Zaenglein A, Pathy A, Schlosser B, et al. Guidelines of Care for Acne Vulgaris Management. *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 June 2019.
16. Keratosis Follicularis National Organization for Rare Disorders. https://rarediseases.org/rare-diseases/keratosis-follicularis/. Accessed June 2019.

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])

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
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

CRITERIA FOR APPROVAL

1.	Does the patient have the diagnosis of acne vulgaris? [If yes, then no further questions.]	Yes	No
2.	Does the patient have the 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	You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions: - Acne vulgaris - Keratosis follicularis (Darier's disease, Darier-White disease) Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]

Guidelines for Approval (237-A)			
Duration of Approval 12 Months			
Set 1		**Set 2**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	2	1

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	You do not meet the requirements of your plan. Your plan covers this drug when you have any of these conditions: - Acne vulgaris - Keratosis follicularis (Darier's disease, Darier-White disease) Your request has been denied based on the information we have. [Short Description: No approvable diagnosis.]