

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	ISOTRETINOINS (ALL ORAL)
BRAND NAME (generic)	
	ABSORICA (isotretinoin)
	AMNESTEEM (isotretinoin)
	CLARAVIS (isotretinoin)
	MYORISAN (isotretinoin)
	SOTRET (isotretinoin)
	ZENATANE (isotretinoin)
Status: CVS Caremark Criteria	
Type: Initial Prior Authorization	

POLICY

FDA-APPROVED INDICATIONS

Isotretinoin is indicated for the treatment of severe recalcitrant nodular acne. Nodules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhagic. "Severe," by definition, means "many" as opposed to "few or several" nodules. Because of significant adverse effects associated with its use, isotretinoin should be reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics. In addition, isotretinoin is indicated only for those female patients who are not pregnant, because isotretinoin can cause severe birth defects.

A single course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course, because experience has shown that patients may continue to improve while off isotretinoin. The optimal interval before retreatment has not been defined for patients who have not completed skeletal growth.

Compendial Uses

Acne – refractory⁸

Cutaneous T-cell Lymphoma (CTCL) (e.g., mycosis fungoides, Sézary syndrome)⁷

Keratosis follicularis (Darier Disease) – severe⁸

Lamellar ichthyosis – severe skin involvement⁷

Neuroblastoma⁸

Pityriasis rubra pilaris⁷

Rosacea – severe refractory⁸

Squamous Cell Cancers – to reduce the development of precancers and skin cancers in high risk patients⁸

Transient acantholytic dermatosis (Grover's Disease) – severe⁸

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 (severe recalcitrant nodular or refractory) OR severe refractory rosacea AND
 - The patient has tried and had inadequate treatment responses to any topical acne product AND an oral antibiotic
- AND**
- Treatment will be limited to 40 weeks (2 courses) or less AND with at least 8 weeks between each course

OR

- The patient has any of the following diagnoses: A) neuroblastoma, B) cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides, Sézary syndrome), C) is at high risk for developing skin cancer (squamous cell cancers), D) transient acantholytic dermatosis (Grover's Disease), E) keratosis follicularis (Darier Disease), F) lamellar ichthyosis, G) pityriasis rubra pilaris

REFERENCES

1. Absorica [package insert]. Jacksonville, FL: Ranbaxy Laboratories Inc.; September 2015.
2. Amnesteem [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; March 2015.
3. Claravis [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; April 2016.
4. Myorisan [package insert]. Marietta, GA: VersaPharm Incorporated; September 2015.
5. Sotret [package insert]. Jacksonville, FL: Ranbaxy Laboratories Inc.; June 2012.
6. Zenatane [package insert]. Bachupally, India: Dr. Reddy's Laboratories Limited; June 2015.
7. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed June 2017.
8. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed June 2017.
9. Questions and Answers about Acne. National Institute of Arthritis and Musculoskeletal and Skin Diseases. http://www.niams.nih.gov/Health_Info/Acne/#acne_g. Accessed June 2017.
10. Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. *J Am Acad Dermatol*. 2016;74:945-73.
11. Questions and Answers about Rosacea. National Institute of Arthritis and Musculoskeletal and Skin Diseases. http://www.niams.nih.gov/Health_Info/Rosacea/default.asp#6. Accessed June 2017.
12. Granulomatous Rosacea. <http://rarediseases.info.nih.gov/gard/6548/granulomatous-rosacea/case/26122/case-questions>. Accessed June 2017.
13. Neuroblastoma Treatment. National Cancer Institute at the National Institute of Health. http://www.cancer.gov/types/neuroblastoma/hp/neuroblastoma-treatment-pdq/#link/_661. Accessed June 2017.

14. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Squamous Cell Skin Cancer. Version 1.2016. NCCN Guidelines
http://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf. Accessed June 2017.
15. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Non-Hodgkin's Lymphomas. Version 3.2016. Available at: www.nccn.org. Accessed June 2017.
16. National Comprehensive Cancer Network. NCCN Drugs & Biologics Compendium.
https://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed June 2017.
17. Office of Rare Disease Research. NIH National Center for Advancing Translational Sciences. Transient acantholytic dermatosis. <https://rarediseases.info.nih.gov/gard/6551/transient-acantholytic-dermatosis/resources/8#2884>. Accessed June 2017.
18. National Organization for Rare Disorders, Inc. Grover's Disease. <https://rarediseases.org/rare-diseases/grover-disease>. Accessed June 2017.
19. American Osteopathic College of Dermatology. Grover's Disease.
<http://www.aocd.org/?page=GroversDisease>. Accessed June 2017.
20. Darier disease. Office of Rare Disease Research. <https://rarediseases.info.nih.gov/gard/6243/darier-disease/resources/8>. Accessed June 2017.
21. Darier Disease. American Osteopathic College of Dermatology.
http://www.aocd.org/skin/dermatologic_diseases/darier_disease.html. Accessed June 2017.
22. Lamellar ichthyosis. Office of Rare Disease Research.
<https://rarediseases.info.nih.gov/gard/10803/lamellar-ichthyosis/resources/8>. Accessed June 2017.
23. Pityriasis rubra pilaris. Office of Rare Disease Research.
<https://rarediseases.info.nih.gov/gard/7401/pityriasis-rubra-pilaris/resources/8>. Accessed June 2017.
24. Pityriasis Rubra Pilaris. American Osteopathic College of Dermatology.
<http://www.aocd.org/?page=PityriasisRubraPil>. Accessed June 2017.