PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ISOTRETINOINS (ALL ORAL)**
BRAND NAME (generic)	**ABSORICA, ABSORICA LD (isotretinoin)** **AMNESTEEM (isotretinoin)** **CLARAVIS (isotretinoin)** **MYORISAN (isotretinoin)** **ZENATANE (isotretinoin)**

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Absorica, Absorica LD

Absorica and Absorica LD are indicated for the treatment of severe recalcitrant nodular acne in non-pregnant patients 12 years of age and older with multiple inflammatory nodules with a diameter of 5 mm or greater. Because of significant adverse reactions associated with its use, Absorica and Absorica LD are reserved for patients with severe nodular acne who are unresponsive to conventional therapy, including systemic antibiotics.

Limitations of Use:
If a second course of Absorica/Absorica LD therapy is needed, it is not recommended before a two-month waiting period because the patient's acne may continue to improve following a 15 to 20-week course of therapy

Amnesteem, Claravis, Myorisan, Zenatane

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 – refractory[7]

Cutaneous T-cell Lymphoma (CTCL) (e.g., mycosis fungoides, Sézary syndrome)[6]
Keratosis follicularis (Darier Disease) – severe[7]
Lamellar ichthyosis – severe skin involvement[6]
Neuroblastoma[7]
Pityriasis rubra pilaris[6]
Rosacea – severe refractory[7]
Squamous Cell Cancers – to reduce the development of precancers and skin cancers in high risk patients[7]
Transient acantholytic dermatosis (Grover's Disease) – severe[7]

COVERAGE CRITERIA

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

- The patient has any of the following diagnoses: A) severe recalcitrant nodular acne vulgaris, B) refractory acne vulgaris, C) severe refractory rosacea
  AND
  - The patient has tried and had an 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.; November 2018.
2. Amnesteem [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; April 2018.
3. Claravis [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; May 2018.
4. Myorisan [package insert]. Marietta, GA: VersaPharm Incorporated; October 2018.
5. Zenatane [package insert]. Bachupally, India: Dr. Reddy's Laboratories Limited; January 2019.
6. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. http://online.lexi.com/. Accessed June 2019.
7. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. http://www.micromedexsolutions.com/. Accessed June 2019.
8. Questions and Answers about Acne. National Institute of Arthritis and Muskuloskeletal and Skin Diseases. http://www.niams.nih.gov/Health_Info/Acne/#acne_g. Accessed June 2019.
9. 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.
10. Questions and Answers about Rosacea. National Institute of Arthritis and Muskuloskeletal and Skin Diseases. http://www.niams.nih.gov/Health_Info/Rosacea/default.asp#6. Accessed June 2019.
11. Granulomatous Rosacea. https://rarediseases.info.nih.gov/diseases/6548/granulomatous-rosacea. Accessed June 2019.
12. 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 2019.
13. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Squamous Cell Skin Cancer. Version 2.2019. NCCN Guidelines Available at: www.nccn.org. Accessed June 2019.
14. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. T-Cell Lymphomas. Version 2.2019. Available at: www.nccn.org. Accessed June 2019.
15. National Comprehensive Cancer Network. NCCN Drugs & Biologics Compendium. https://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed June 2019.
16. 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 2019.
17. National Organization for Rare Disorders, Inc. Grover's Disease. https://rarediseases.org/rare-diseases/grovers-disease. Accessed June 2019.
18. American Osteopathic College of Dermatology. Grover's Disease. http://www.aocd.org/?page=GroversDisease. Accessed June 2019.

19. Darier disease. Office of Rare Disease Research. https://rarediseases.info.nih.gov/gard/6243/darier-disease/resources/8. Accessed June 2019.
20. Darier Disease. American Osteopathic College of Dermatology. http://www.aocd.org/skin/dermatologic_diseases/darier_disease.html. Accessed June 2019.
21. Lamellar ichthyosis. Office of Rare Disease Research. https://rarediseases.info.nih.gov/gard/10803/lamellar-ichthyosis/resources/8. Accessed June 2019.
22. Pityriasis rubra pilaris. Office of Rare Disease Research. https://rarediseases.info.nih.gov/gard/7401/pityriasis-rubra-pilaris/resources/8. Accessed June 2019.
23. Pityriasis Rubra Pilaris. American Osteopathic College of Dermatology. http://www.aocd.org/?page=PityriasisRubraPil. Accessed June 2019.