MEDICAL MUTUAL®

Drug Policy

Policy:	**Isotretinoin Products Preferred Step Therapy**	**Annual Review Date:** **03/20/2025**
Impacted Drugs:	**Absorica (isotretinoin) capsules**	**Last Revised Date:** **03/20/2025**

OVERVIEW

Absorica, Claravis, Myorisan, Accutane and Zenatane (isotretinoin capsules) are all retinoid products indicated for the treatment of severe recalcitrant nodular acne. Isotretinoin must not be used by female patients who are or may become pregnant due to an extremely high risk of severe birth defects (Pregnancy Category X). Due to these risks, Absorica, Claravis, Myorisan, Accutane, Amnesteem, isotretinoin, and Zenatane are available only through a restricted program called iPLEDGE. Prescribers, patients, pharmacies, and distributors must all be enrolled in the iPLEDGE program for the administration of any of these drugs.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

*Note: Absorica with DAW9 (indicating that substitution is allowed by the prescriber but the Plan requests brand) will also count as a preferred medication.

Automation: A patient with a history of one preferred medication within the 130-day look-back period is excluded from Step Therapy.

Preferred Medications

- Claravis
- Myorisan
- Zenatane
- Amnesteem
- Accutane
- Isotretinoin capsules (all generic isotretinoin products (authorized and true))

Non-Preferred Medications

- Absorica*

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list specific diagnosis and/or specific patient characteristics ~; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the specific contraindications to each preferred agent ~; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as ~. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

~ Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not

medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Claravis® (isotretinoin) capsules [prescribing information]. North Wales, PA. Teva Pharmaceuticals USA, Inc; August 2022.
2. Myorisan ® (isotretinoin) capsules [prescribing information]. Marietta, GA. VersaPharm, Inc; September 2015.
3. Zenatane ® (isotretinoin) capsules [prescribing information]. Bachupally, India. Dr. Reddy's Laboratories Limited; June 2015.
4. Williams HC, Dellavalle RP, Garner S. Acne vulgaris. *Lancet*. 2012;379:361-72.
5. Isotretinoin. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 11 March 2025. Accessed on 18 March 2025.
6. Absorica and Absorica LD (isotretinoin) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; October 2019.