

Dermatologics: Acne Products – Isotretinoin

Medical policy no. 90.05.00.AA

Effective Date: TBD

Related medical policies:

- <insert name of related medical policies>

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: <https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx>

Background:

Isotretinoin is a synthetic analogue of vitamin A and is FDA indicated for the treatment of severe, recalcitrant nodulocystic acne. Isotretinoin is teratogenic which requires wholesalers, patients, providers, and pharmacies to participate in the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) program to better ensure safe use of medication.

Medical necessity

| Drug | Medical Necessity |
|---|---|
| Absorica (isotretinoin) Absorica LD (isotretinoin) Accutane (isotretinoin) Amnesteem (isotretinoin) Claravis (isotretinoin) Isotretinoin Myorisan (isotretinoin) Zenatane (isotretinoin) | Dermatologic isotretinoin products may be considered medically necessary when ONE of the following apply: <ul style="list-style-type: none"> • conditions listed under Indications and Usage in approved drug labeling (prescribing information) from the Food and Drug Administration (FDA); OR • conditions listed as medically-accepted indications in any of the compendia of drug information recognized by Medicaid |

Clinical policy:

| Clinical Criteria | |
|---------------------------------------|---|
| <p>Moderate to Severe Acne</p> | Isotretinoin may be considered medically necessary when ALL of the following are met: <ol style="list-style-type: none"> 1. Diagnosis of moderate or severe acne; AND 2. Client is 12 years of age or older; AND 3. For non-preferred isotretinoin products, greater than or equal to (≥) 2 preferred products (each product taken for at least 15 weeks) unless preferred product is not tolerated; AND |

| | |
|--|---|
| | <p>4. Trial and failure with ONE of the following therapies in combination with topical benzoyl peroxide or a topical retinoid (i.e. tretinoin) for at least 1 month:</p> <ol style="list-style-type: none"> Oral antibiotics (i.e. doxycycline, erythromycin, trimethoprim-sulfamethoxazole); OR For female patients, oral contraceptives (excludes progestin-only products); OR For female patients, spironolactone; AND <p>5. Client has not been treated with a full course of isotretinoin for the past 2 months.</p> <p>If ALL criteria are met, the request will be approved for 20 weeks.</p> <p>If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.</p> |
| | Criteria (Reauthorization) |
| | <p>Isotretinoin may be reauthorized when ALL of the following are met:</p> <ol style="list-style-type: none"> Client experiences recurrent or persistent moderate to severe acne; AND Clinical documentation submitted demonstrating positive response and clinical benefit from isotretinoin therapy; AND Client has not been treated with isotretinoin for the past 2 months. <p>If ALL criteria are met, the request will be approved for 20 weeks.</p> <p>If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.</p> |

Dosage and quantity limits

| Indication | Dose and Quantity Limits |
|---------------------------------------|---|
| Severe Recalcitrant Nodulocystic Acne | <ul style="list-style-type: none"> Absorica/Accutane/Amnesteem/Claravis/Myorisan/Zenatane/ Isotretinoin: Up to 2mg/kg/day Absorica LD: Up to 1.6mg/kg/day |

Coding:

| HCPCS Code | Description |
|--------------|-------------|
| <HCPCS Code> | |

References

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Last Updated 05/25/2021

1. Product Information: Absorica™/ Absorica LD™ oral capsules. Ranbaxy (per FDA). Jacksonville, FL, 2020.
2. Product Information: Accutane® oral capsules. Roche (per FDA). Nutley, New Jersey, 2021.
3. Product Information: Amnesteem oral capsules. Mylan (per FDA). Morgantown, WV, 2018.
4. Product Information: Claravis oral capsules. (TEVA per FDA). North Wales, PA, 2018.
5. Product Information: Myorisan oral capsules. (Douglas Pharms per FDA). Marietta, GA, 2019.
6. Product Information: Zenatane oral capsules. (Dr Reddys Labs per FDA). Princeton, NJ, 2019.
- 7.

History

| Date | Action and Summary of Changes |
|------------|-------------------------------|
| 03/29/2021 | New Policy |
| | |
| | |

DRAFT

Dermatologics: Acne Products – Isotretinoin

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

| | | | |
|---|----------------------|--------------------|-----------------|
| Date of request: | Reference #: | MAS: | |
| Patient | Date of birth | ProviderOne ID | |
| Pharmacy name | Pharmacy NPI | Telephone number | Fax number |
| Prescriber | Prescriber NPI | Telephone number | Fax number |
| Medication and strength | | Directions for use | Qty/Days supply |
| <p>1. Is this request for a continuation of existing therapy? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, is there documentation showing a positive clinical response? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>2. Indicate the patient's diagnosis: <input type="checkbox"/> Moderate to severe acne <input type="checkbox"/> Other. Specify: _____</p> <p>3. Are the provider and patient enrolled in the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) program? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>4. Has the patient tried and failed at least two (2) preferred products for at least 15 weeks? <input type="checkbox"/> Yes, specify the medications and duration: <input type="checkbox"/> Preferred product is not tolerated. Specify: <input type="checkbox"/> Other. Specify:</p> <p>5. Has the patient tried and failed any of the following in combination with topical benzoyl peroxide or a topical retinoid? Check all that apply. <input type="checkbox"/> Oral antibiotics (i.e. doxycycline, erythromycin, trimethoprim-sulfamethoxazole) <input type="checkbox"/> For female patients: Oral contraceptives (excludes progestin-only products) <input type="checkbox"/> For female patients: Spironolactone <input type="checkbox"/> Other. Specify: <input type="checkbox"/> None of the above</p> <p>6. Has the patient previously been treated with a full course of isotretinoin for acne, and has it been at least 2 months since completion of the previous treatment? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> | | | |
| <p>REQUIRED WITH THIS REQUEST:</p> <ul style="list-style-type: none"> • Chart notes • Labs • Diagnostic tests results | | | |
| Prescriber signature | Prescriber specialty | Date | |