

Dermatologics: Acne Products - Isotretinoin

Medical policy no. 90.05.00.AA

Effective Date: December, 1, 2021

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)	<p>Isotretinoin may be considered medically necessary in patients who meet the criteria described in the clinical policy below.</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> <p>Clients new to Apple Health or new to an MCO, who are requesting regimens for continuation of therapy should be reviewed following the reauthorization criteria listed below.</p>

Clinical policy:

Clinical Criteria	
Moderate to Severe Acne	<p>Isotretinoin may be considered medically necessary when ALL of the following are met:</p> <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, a trial and failure of greater than or equal to (\geq) 2 preferred isotretinoin 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 a product containing topical benzoyl peroxide or a topical retinoid (i.e. tretinoin) for at least 1 month:</p> <ul style="list-style-type: none"> a. Oral antibiotics (i.e. doxycycline, erythromycin, trimethoprim-sulfamethoxazole); OR b. For female patients, oral contraceptives (excludes progestin-only products); OR c. 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> <p style="background-color: #0056b3; color: white; text-align: center; padding: 2px;">Criteria (Reauthorization)</p> <p>Isotretinoin may be reauthorized when ALL of the following are met:</p> <ul style="list-style-type: none"> 1. Client experiences recurrent or persistent moderate to severe acne; AND 2. Clinical documentation submitted demonstrating positive response and clinical benefit from isotretinoin therapy; AND 3. 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>
<p>Moderate to Severe Rosacea</p>	<p>Isotretinoin may be considered medically necessary when ALL of the following are met:</p> <ul style="list-style-type: none"> 1. Diagnosis of moderate to severe rosacea; AND 2. Client is 18 years of age or older; AND 3. For non-preferred isotretinoin products, a trial and failure of greater than or equal to (\geq) 2 preferred isotretinoin products (each product taken for at least 2 months) unless preferred product is not tolerated; AND 4. Trial and failure with ONE of the following therapies in combination with oral antibiotics (i.e. doxycycline, clarithromycin, metronidazole) for at least 1 month: <ul style="list-style-type: none"> a. Topical ivermectin b. Topical antibiotics (i.e. metronidazole) <p>If ALL criteria are met, the request will be approved for 6 months.</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"> 1. Client experiences recurrent or persistent moderate to severe rosacea; AND 2. Clinical documentation submitted demonstrating positive response and clinical benefit from isotretinoin therapy. <p>If ALL criteria are met, the request will be approved for 6 months.</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
Moderate to Severe 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
Moderate to Severe Rosacea	<ul style="list-style-type: none"> • Absorica/Accutane/Amnesteem/Claravis/Myorisan/Zenatane/ Isotretinoin: Up to 2mg/kg/day

References

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.

History

Date	Action and Summary of Changes
09/01/2021	Updating clinical criteria to include rosacea as a compendia-supported indication. Updating clinical criteria for moderate to severe acne to specify benzoyl peroxide containing products.

06/16/2021	Approved by DUR Board
03/29/2021	New Policy