

Louisiana Medicaid Acne Agents, Topical

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for non-preferred topical acne agents, ~~topical (preferred and non-preferred)~~. Criteria for approval of tazarotene for psoriasis is found on the next page.

Additional Point-of-Sale edits may apply.

*These agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

For Acne

Approval Criteria for Non-Preferred Acne Agents

- For tretinoin topical cream (generic for Retin-A®) – there has been a treatment failure or intolerable side effect with or contraindication to brand Retin-A®; **OR**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- If the request is for a non-Preferred use of a preferred agent/product - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred product; **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
 - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
 - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- The recipient is less than 21 years of age on the date of the request; **AND**
- For trifarotene, the recipient is at least 9 years of age on the date of the request; **AND**
- The recipient has a diagnosis of acne; **AND**
- The Investigator's Global Assessment (IGA) severity score is **stated on the request** and is one of the following:
 - Grade 2; OR
 - either Grade 3-moderately severe, or nodulocystic acne (numerous papules and pustules; the occasional inflamed nodule; the back and chest may also be affected);
OR or
 - Grade 4-severe nodulocystic acne (numerous large, painful pustules and nodules; inflammation); **AND**
- For tazarotene used for acne, the product requested is either 0.1% cream or 0.1% gel; **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that would limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Reauthorization criteria for a diagnosis of acne

- The recipient continues to meet all initial criteria with improved disease severity; **AND**
- The request **states the current acne severity**, which is an improvement from baseline.

Duration of initial and reauthorization approval for acne: 12 months (or up to the recipient's 21st birthday, whichever is less).

For Tazarotene Cream or Gel for Psoriasis

Approval Criteria for Both Initial Approval and Reauthorization

- The recipient has a diagnosis of psoriasis; **AND**
- If the request is for a non-preferred agent - **ONE** of the following is required:
 - The recipient has had a *treatment failure* with at least one preferred topical antipsoriatic product (see Dermatology – Antipsoriatics, Topical on PDL); **OR**
 - The recipient has had an *intolerable side effect* to at least one preferred topical antipsoriatic product (see Dermatology – Antipsoriatics, Topical on PDL); **OR**
 - The recipient has a *documented contraindication(s)* to all of the preferred topical antipsoriatic products that are appropriate to use for the condition being treated (see Dermatology – Antipsoriatics, Topical on PDL); **OR**
 - There is *no preferred topical antipsoriatic product that is appropriate* to use for the condition being treated (see Dermatology – Antipsoriatics, Topical on PDL); **AND**
- By submitting the authorization request, the prescriber attests to the following:
 - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
 - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
 - The recipient has no concomitant drug therapies or disease states that would limit the use of the requested medication and will not be receiving the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial and reauthorization approval for tazarotene cream or gel for psoriasis: 12 months

References

Aklief (trifarotene) [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; October 2019. https://www.galderma.com/us/sites/g/files/jcdfhc341/files/2020-06/P54485-AkliefPumpPI%28052181_052183%29101019CLEAN%5B5%5D.pdf

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; Retrieved from <https://www.clinicalkey.com/pharmacology/>

DiPiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey L. eds. *Pharmacotherapy: A Pathophysiologic Approach, 10e* New York, NY: McGraw-Hill; Retrieved from <https://accesspharmacy.mhmedical.com/book.aspx?bookid=186>

Tazorac cream (tazarotene) [package insert]. Exton, PA: Almirall, LLC; August 2019. [Prescribing Information for Tazorac Cream \(almirall.us\)](#)

Tazorac gel (tazarotene) [package insert]. Exton, PA: Almirall, LLC; August 2019. [Prescribing Information for TAZORAC® \(tazarotene\) Gel \(almirall.us\)](#)

US Food and Drug Administration Center for Drug Evaluation and Research. *Guidance for Industry: acne vulgaris: establishing effectiveness of drugs intended for treatment*. May 2018. FDA Guidance for Industry - Establishing Effectiveness of Drugs Intended for Treatment of Acne Vulgaris

Revision / Date	Implementation Date
Removed POS information, formatting changes, updated references / July 2020	July 2020
Added Aklief®, formatting changes / July 2020	August 2020
Added specific wording for use of Retin-A®, formatting changes, updated references / April 2021	July 2021
<u>Removed clinical PA requirement for preferred agents, Added severity grade 2, updated references / January 2022</u>	<u>July 2022</u>