Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Topical Acne Medications**

Effective: April 1, 2026

Guideline Type	☒ Prior Authorization ☒ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Adapalene, adapalene/benzoyl peroxide, tazarotene, tretinoin, tretinoin/clindamycin:
Topical retinoids are beneficial for both comedonal (noninflammatory) and inflammatory acne and are routinely included in the initial management of most patients. There are several topical retinoid acne medications including adapalene, tazarotene, and tretinoin that may be covered, in generic and/or brand formulation, for the treatment of acne in patients 26 years of age or older.

Winlevi (clascoterone) is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

Clinical Guideline Coverage Criteria

I. Topical Acne Medications

Note: Retinoids for the topical treatment of acne vulgaris include the following:

- Adapalene cream, gel, lotion, or solution
- Adapalene-benzoyl peroxide gel
- Tazarotene cream, gel, foam
- Tretinoin cream, gel, or microspheres
- Tretinoin-clindamycin gel

The plan may authorize coverage of the above listed topical acne mediations for patients 26 years of age or older when **ALL** of the following criteria are met:

1. Patient is 26 years or age or older

AND

2. Documented diagnosis of one of the following:
   a. Acne vulgaris
   b. Comedones (white heads)
   c. Actinic keratosis

In addition, the plan may authorize coverage of **tazarotene** (Tazorac) for patients 26 years of age or older when the following criteria are met:

1. Patient is 26 years or age or older

AND

2. Documented diagnosis of one of the following:
   a. Plaque psoriasis
   b. Basal cell carcinoma
   c. Early stage mycosis fungoides

II. Winlevi

The plan may authorize coverage of Winlevi for patients when **ALL** of the following criteria are met:

Initial Authorization Criteria:

1. Documented diagnosis of acne vulgaris

AND

2. Member is 12 years of age or older

AND

3. Documentation of inadequate response, adverse reaction or contraindication to a topical retinoid

AND

4. Documentation of inadequate response, adverse reaction or contraindication to a topical antibiotic in combination with benzoyl peroxide

AND

5. Documentation of inadequate response, adverse reaction or contraindication to an adequate trial of topical dapsone

Reauthorization Criteria:

1. Documented diagnosis of acne vulgaris

AND

2. Documentation of positive clinical response to the requested medication

Off-label Use Coverage for Other Cancer Diagnoses

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provision of the "Sullivan Law": (M.G.L. c.175, s.47K).

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a "Medically Acceptable Indication" according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

***Note*:** The plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treatment the intended malignancy, including the applicable NCCN guideline(s).

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, the plan will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless otherwise directed by the commissioner, and accept clinical documentation referenced in one of the other "Standard Reference Compendia" noted below or supported by clinical research that appears in a regular edition of a "Peer-Reviewed Medical Literature" noted below.

"Standard Reference Compendia"

1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs

"Peer Reviewed Medical Literature"

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

When the plan evaluates the evidence in published, peer-reviewed medical literature, consideration will be given to the following:

1. Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
4. Whether the study is appropriate to address the clinical question.
    a. appropriate to address the investigative question (for example, in some clinical studies it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover);
    b. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,
    c. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

Limitations

1. The plan will only authorize coverage of topical acne products for the criteria listed above.
2. The plan will not authorize coverage of topical retinoid products for cosmetic applications such as reduction and prevention of wrinkles.
3. Initial approval of Winlevi will be authorized for 6 months. Reauthorization of Winlevi will be authorized for 12 months.
4. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Atralin gel (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; July 2016.
2. Avita (tretinoin) cream [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; July 2018.
3. Avita (tretinoin) gel [prescribing information]. Morgantown, WV: Mylan Pharmaceuticals; January 2018.
4. Retin-A (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; June 2018.
5. Retin-A Micro (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; January 2015.
6. Retin-A Micro gel (tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; October 2017.
7. Differin Cream (adapalene) [prescribing information]. Fort Worth, TX: Galderma; November 2015.
8. Differin Gel 0.1% (adapalene) [prescribing information]. Fort Worth, TX: Galderma; June 2018.
9. Differin Gel 0.3% (adapalene) [prescribing information]. Fort Worth, TX: Galderma; February 2018.
10. Differin Lotion (adapalene) [prescribing information]. Fort Worth, TX: Galderma; July 2014.
11. Arazlo (tazarotene) [prescribing information]. Bridgewater, NJ: Bausch Health US. LLC; December 2019.
12. Fabior (tazarotene) [prescribing information]. Greenville, NC: Mayne Pharma; June 2018.
13. Tazorac cream, gel (tazarotene) [prescribing information]. Exton, PA: Almirall, LLC; August 2019.
14. Epiduo (adapalene and benzoyl peroxide) [prescribing information]. Fort Worth, TX: Galderma; February 2018.
15. Epiduo Forte (adapalene and benzoyl peroxide) [prescribing information]. Fort Worth, TX: Galderma; July 2015.
16. Veltin (clindamycin phosphate and tretinoin) [prescribing information]. Exton, PA: Almirall, LLC; June 2019.
17. Ziana (clindamycin phosphate and tretinoin) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.
18. Twyneo (tretinoin and benzoyl peroxide) [prescribing information]. Fort Worth, Texas: Galderma Laboratories, L.P.; March 2022.
19. Aklief (trifarotene) [prescribing information]. Fort Worth, Texas: Galderma Laboratories, L.P.; May 2020.
20. Winlevi (clascoterone cream) [prescribing information]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc. January 2025.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 8, 2023: No changes
- August 13, 2024: No changes
- August 12, 2025: No changes
- December 9, 2025: Updated title of Medical Necessity Guideline (MNG) from Topical Retinoids to Topical Acne Medications. Added criteria for nonformulary medication, Winlevi. Added initial and reauthorization approval durations for Winlevi under

limitation section. (eff 4/1/26).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.