Pharmacy Medical Necessity Guidelines:
Retinoids for the Topical Treatment of Acne Vulgaris and Psoriasis

Effective: January 1, 2018

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This pharmacy medical necessity guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

**Fax Numbers:**
RXUM: 617.673.0988

**Note:** This pharmacy medical necessity guideline applies to commercial products. For Tufts Health Plan Medicare Preferred members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**
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 Atralin™, Avita®, Differin®, Fabior™, Renova®, Retin-A®, Retin-A Micro™, Tazorac®, Tretin-X™ and tretinoin cream or gel that may be covered, in generic and/or brand formulation, for the treatment of acne in Members 26 years of age or older.

**COVERAGE GUIDELINES**

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

1. Adapalene cream, gel or lotion (generic)
2. Avita™ (tretinoin 0.025%)
3. Differin OTC 0.1% gel
4. Fabior™ (tazarotene foam)
5. Refissa (tretinoin cream 0.05%)
6. Renova® (tretinoin 0.02%)
7. Tazorac® (tazarotene)
8. Tretin-X™ (tretinoin 0.375% and 0.75%)
9. Tretinoin cream, gel, or microspheres (generic)

The plan may authorize coverage of the preceding topical acne products for Members 26 years of age or older, when one of the following criteria is met:

1. Physician-documented diagnosis of acne vulgaris
2. Physician-documented diagnosis of comedones (white heads)
3. Physician-documented diagnosis of actinic keratosis

In addition, the plan may authorize coverage of Tazorac (tazarotene) for Members 26 years of age or older, when either one of the following criteria is met:

1. Physician-documented diagnosis of plaque psoriasis
2. See Off-label Use Coverage for Other Cancer Diagnoses

**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 provisions of the "Sullivan Law": (M.G.L. c.175, s.47K ).

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The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a "Medically Accepted 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 treating 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, Tufts Health 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 Tufts Health 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. whether the experimental design, in light of the drugs and conditions under investigation, is 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 in above.
2. The following brands are not covered for both small and large group formularies: Atralin, Differin, Retin-A, and Retin-A Micro.
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CODES
None

REFERENCES

APPROVAL HISTORY
October 2001: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- December 14, 2004: Change Topic from "Topical Medications for the Treatment of Acne" to "Topical Retinoids for the Treatment of Acne". Delete current coverage Limitations: No topical acne products will be covered for cosmetic uses, such as wrinkle reduction, photodamage or melasma. Add "Tufts Health Plan will only authorize coverage of topical acne products for criteria listed above" as a coverage limitation.
- December 13, 2005: No changes
- November 14, 2006: Changed topic from "Topical Retinoids for the Treatment of Acne" to "Retinoids for the Topical Treatment of Acne Vulgaris and Psoriasis". Added Tretinoin gel (generic) and Tazorac (tazarotene) to list of topical retinoids. Defined form of acne by adding "vulgaris" under clinical coverage criteria. Added additional coverage criteria for Tazorac (tazarotene) for the diagnosis of plaque psoriasis or skin cancer.
- November 13, 2007: Removed Altinac from criteria
- May 13, 2008: Added Atralin to pharmacy coverage guidelines
- January 13, 2009: Inserted updated language for Off-label Use Coverage for Other Cancer Diagnoses
- March 10, 2009: Added criteria #3 to Pharmacy Coverage Guidelines for topical acne products for Members 26 years of age or older, “Physician-documented diagnosis of actinic keratosis.”
- January 1, 2010: Removal of Tufts Medicare Preferred language (separate criteria have been created specifically for Tufts Medicare Preferred)
- January 12, 2010: Added Tretin-X to pharmacy coverage guidelines
- July 13, 2010: Added adapalene 0.1% gel to pharmacy coverage guidelines
- September 14, 2010: Removed adapalene 0.1% gel and replaced with adapalene cream or gel
- January 11, 2011: Administrative Update: Effective 4/1/2011, Off-label Use Coverage for Other Cancer Diagnoses language updated. Tufts Health Plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s)
- September 13, 2011: No changes
- September 11, 2012: Administrative Update: Code information removed replaced with None
- March 12, 2013: Added Refissa to the list of retinoids for the topical treatment of acne vulgaris
December 10, 2013: Added Fabior and tretinoin microspheres to the list of retinoids for the topical treatment of acne vulgaris
December 9, 2014: No changes
November 10, 2015: Effective 1/1/16: Added limitations regarding brand names that are not covered for the Small Group and Individual formularies.
January 1, 2016: Administrative change to rebranded template.
November 15, 2016: No changes
April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
June 13, 2017: Added Differin OTC to list of drugs included in the MNG.
October 17, 2017: Moved brands Atralin, Differin, Retin-A, and Retin-A Micro to the list of NC drugs for all Commercial formularies.

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. They are used in conjunction with a member’s benefit document and in coordination with the member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan members or to certain delegated service arrangements. Unless otherwise noted in the member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.