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

Effective: November 10, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

Pharmacy Benefit:
RXUM: 617-673-0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

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™, 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. Tazorac®(tazarotene)
6. Tretin-X™ (tretinoin 0.375% and 0.75%)
7. 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).

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 (Rx), Retin-A, and Retin-A Micro.

CODES

None

REFERENCES

1. American College of Dermatology Web site. URL: aad.org. Available on the internet Accessed August 2012.
2. Atralin (tretinoin) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC,. October 2014
3. Avita (tretinoin) [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; November 2013.
4. Differin (adapalene) [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; November 2015.
5. Differin (adapalene) Lotion [package insert]. Fort Worth, TX: Galderma Laboratories, L.P.; September 2011.
6. Gamble R, Dunn J, Dawson A, et al. Topical antimicrobial treatment of acne vulgaris: an evidence-based review. Am J Clin Dermatol. June 2012;13(3):141-52.
7. Fabior (tazarotene) Foam [package insert]. Greenville, NC: Mayne Pharma. November 2016.
8. McEvoy, G. ed. 2001 AHFS Drug Information. Maryland: American Society of Health-System Pharmacists
9. Renova (tretinoin) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. March 2017.
10. Retin-A (tretinoin) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. November 2016.
11. Retin-A Micro (tretinoin) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC. September 2016.
12. Tazorac (tazarotene) [package insert]. Irvine, CA: Allergan, Inc.; July 2017.
13. TretinX (tretinoin) [package insert]. Cumberland, RI: Onset Dermatologics, LLC. August 2013.
14. Walsh, P. ed. 2013 Physician's Desk Reference. New Jersey Medical Economics Company.

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.
- December 11, 2018: Effective 4/1/19: removed Renova and Refissa from MNG, as they have cosmetic indications and are not indicated for the treatment of acne vulgaris
- December 10, 2019: No changes
- November 10, 2020: No changes

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.