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## **Topical Acne and Rosacea Agents**

### **NOTICE**

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### **BENEFIT APPLICATION**

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### **DESCRIPTION**

The intent of the prior authorization (PA) criteria for Topical Acne and Rosacea Agents is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines, encourage the use of more cost-effective generic and over-the-counter (OTC) agents prior to the use of a generic or brand name combination agents, a brand name agent, or a more costly generic when using for the treatment of acne or rosacea, and discourage the use of topical retinoid agents for cosmetic purposes while maintaining patient access for the treatment of medical skin conditions. For the single agent tretinoin products, prior authorization is not required for members under 36 years of age.

Renova and Refissa are indicated as adjunctive agents for use in the mitigation of fine facial wrinkles in patients who use comprehensive skin care and sunlight avoidance programs. Since the treatment of these indications is considered cosmetic and not a covered benefit, these products are not included in the criteria for coverage.

#### FDA-Approved Indications

Acanya, Benzaclin, Duac, Neuac, Onexton, and generic equivalents are combination topical products containing benzoyl peroxide and clindamycin indicated for the treatment of acne vulgaris in patients 12 years and older.

Differin, Plixda, and generic equivalents are topical retinoids indicated for the treatment of acne vulgaris in patients 12 years and older.

Epiduo and Epiduo Forte are combination topical products containing benzoyl peroxide and adapalene indicated for the treatment of acne vulgaris in patients 12 years and older.

Evoclin and generic equivalents are a topical foam formulation of clindamycin indicated for the treatment of acne vulgaris in patients 12 years and older.

Aczone is a topical anti-infective agent indicated for the treatment of acne vulgaris in patients 12 years and older.

Amzeeq is a topical anti-infective agent indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years and older

Zilxi is a topical foam formulation of minocycline indicated for the treatment of inflammatory lesions of rosacea in adults.

Fabior is a topical foam formulation of tazarotene indicated for the treatment of acne vulgaris in patients 12 years and older.

Azelex is a topical cream formulation of azelaic acid indicated for the treatment of mild to moderate inflammatory acne vulgaris.

Finacea 15% foam is a topical gel formulation of azelaic acid indicated for the treatment of inflammatory papules and pustules of mild to moderate rosacea.

Mirvaso is a topical gel indicated for the topical treatment of persistent (non-transient) facial erythema of rosacea in adults 18 years of age or older.

Soolantra is a topical cream indicated for the treatment of inflammatory lesions of rosacea.

Rhofade is a topical cream indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

Noritate 1% cream is a topical cream indicated for the topical treatment of inflammatory lesions and erythema of rosacea in adults.

Atralin, Avita, Retin-A, Retin-A Micro, Tretin-X gel and Tretin-X cream are indicated for topical application in the treatment of acne vulgaris.

Veltin and Ziana are indicated for the topical treatment of acne vulgaris in patients 12 years or older.

Altreno (tretinoin) 0.05% lotion is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Arazlo (tazarotene) 0.045% lotion is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Aklief (trifarotene) 0.005% cream is a retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

Winlevi (clascoterone) 1% cream is an androgen receptor inhibitor indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

## **POLICY**

### Criteria for Initial Approval

I. Acanya, Benzaclin, Duac, Neuac, Onexton, and generic equivalents may be considered medically necessary for the topical treatment of acne vulgaris in patients 12 years and older when the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to the combined use of the individual topical ingredients, clindamycin and over-the-counter benzoyl peroxide. Treatment failure cannot be caused by a lack of compliance to therapy or the unwillingness to take the two ingredients separately.

#### **Approval will be for 12 months**

II. Differin, Plixda and generic equivalents may be considered medically necessary for the topical treatment of acne vulgaris in patients 12 years and older when the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to over-the counter or prescription Differin 0.1% (adapalene) gel alone or in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

#### **Approval will be for 12 months**

III. Epiduo Forte Gel 0.3-2.5% may be considered medically necessary for the topical treatment of acne vulgaris in patients 12 years and older when ALL of the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to the combined use of the individual topical ingredients, over-the counter or prescription Differin 0.1% (adapalene) and over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs). Treatment failure cannot be caused by a lack of compliance to therapy or the unwillingness to take the two ingredients separately.
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to the combined use of the individual topical ingredients, prescription Differin 0.3% (adapalene) and over-the counter benzoyl peroxide. Treatment failure cannot be caused by a lack of compliance to therapy or the unwillingness to take the two ingredients separately.

#### **Approval will be for 12 months**

IV. Epiduo 0.1-2.5% may be considered medically necessary for the topical treatment of acne vulgaris in patients 9 years and older when ALL of the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to the combined use of the individual topical ingredients, over-the counter or prescription Differin 0.1% (adapalene) and over-the counter benzoyl peroxide. Treatment failure cannot be caused by a lack of compliance to therapy or the unwillingness to take the two ingredients separately.

#### **Approval will be for 12 months**

V. Evoclin (clindamycin 1% foam) and generic equivalents may be considered medically necessary for the topical treatment of acne vulgaris and folliculitis in patients 12 years and older when the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to another topical generic clindamycin formulation (i.e., gel, lotion, and solution). Treatment failure cannot be caused by a lack of compliance to therapy or the unwillingness to take the other formulations.

**Approval will be for 12 months**

VI. Brand and generic Aczone 5% may be considered medically necessary for the topical treatment of acne vulgaris in patients 12 years and older when ALL of the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical clindamycin in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to over-the counter or prescription Differin 0.1% (adapalene) alone or in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 12 months**

VII. Aczone 7.5% may be considered medically necessary for the topical treatment of acne vulgaris in patients 12 years and older when ALL of the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical clindamycin in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to over-the counter or prescription Differin 0.1% (adapalene) alone or in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to generic Dapsone 5% gel unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 12 months**

VIII. Fabior may be considered medically necessary for the topical treatment of acne vulgaris in patients 12 years and older when the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to generic tazarotene 0.1% cream.

**Approval will be for 12 months**

IX. Aklief may be considered medically necessary for the topical treatment of acne vulgaris in patients 9 years and older when ALL of the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical clindamycin in combination with over-the counter benzoyl peroxide unless the patient is

currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to over-the counter or prescription Differin 0.1% (adapalene) alone or in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 12 months**

X. Amzeeq may be considered medically necessary for the topical treatment of non-nodular moderate to severe acne vulgaris in patients 9 years and older when ALL of the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical clindamycin in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to over-the counter or prescription Differin 0.1% (adapalene) alone or in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 6 months**

XI. Winlevi may be considered medically necessary for the topical treatment of acne vulgaris in patients 12 years and older when ALL of the following criteria are met:

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical clindamycin in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to over-the counter or prescription Differin 0.1% (adapalene) alone or in combination with over-the counter benzoyl peroxide unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 12 months**

XII. Azelex may be considered medically necessary in patients 12 years and older when the following criteria are met:

- The patient has a diagnosis of acne vulgaris AND has experienced an inadequate response, adverse event, intolerance, or contraindication to ALL of the following agents, unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):
  - Topical clindamycin in combination with over-the counter benzoyl peroxide
  - Over-the counter or prescription Differin 0.1% (adapalene) alone or in combination with over-the counter benzoyl peroxide

**OR**

- The patient has a diagnosis of rosacea AND has experienced an inadequate response, adverse event, intolerance, or contraindication to ALL of the following agents, unless the patient is currently

receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):

- Topical metronidazole
- Oral doxycycline
- Brand or generic Finacea (azelaic acid) 15% gel

**Approval will be for 12 months**

- XIII. Treatment with topical retinoid acne products, Atralin, Altreno 0.05% lotion, Avita, Retin-A, Retin-A Micro, Tretin-X gel and Tretin-X cream, including generics, may be considered **medically necessary** for patients who have been diagnosed with a medical skin condition for which treatment with a topical retinoid is medically indicated.

**Approval will be for 12 months**

\*The use of topical retinoid acne products for the treatment of cosmetic conditions is **not covered**.

- XIV. Arazlo 0.045% lotion may be considered medically necessary in patients 9 years and older when the following criteria are met:
- The patient has a diagnosis of acne vulgaris AND has experienced an inadequate response, adverse event, intolerance, or contraindication to ALL of the following agents, unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs):
    - Topical clindamycin in combination with over-the counter benzoyl peroxide
    - Over-the counter or prescription Differin 0.1% (adapalene) alone or in combination with over-the counter benzoyl peroxide in patients 12 years of age and older

**Approval will be for 12 months**

- XV. Veltin and Ziana, including generics, may be considered **medically necessary** for the treatment of acne vulgaris when the following criteria are met:
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to the combined use of the individual active ingredients in the requested medication, topical tretinoin and topical clindamycin. Treatment failure cannot be caused by a lack of compliance to therapy or the unwillingness to take the other formulations.

**Approval will be for 12 months**

- XVI. Finacea 15% foam may be considered medically necessary for the topical treatment of rosacea in patients 18 years and older when the following criteria are met:
- Patient has a diagnosis of rosacea
  - Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical metronidazole unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
  - Patient must experience an inadequate response, adverse event, intolerance, or contraindication to brand or generic Finacea (azelaic acid) 15% gel
  - Patient must experience an inadequate response, adverse event, intolerance, or contraindication to oral doxycycline unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 12 months**

XVII. Brand and generic Soolantra (ivermectin topical) may be considered medically necessary for the topical treatment of rosacea in patients 18 years and older when the following criteria are met:

- Patient has a diagnosis of rosacea
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical metronidazole unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to brand or generic Finacea (azelaic acid) 15% gel unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to oral doxycycline unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 12 months**

XVIII. Mirvaso and Rhofade may be considered medically necessary for the topical treatment of rosacea in patients 18 years and older when the following criteria are met:

- Patient has a diagnosis of persistent facial erythema associated with rosacea

**Approval will be for 12 months**

XIX. Zilxi may be considered medically necessary for the topical treatment of inflammatory lesions in patients 18 years of age and older with rosacea when the following criteria are met:

- Patient has a diagnosis of rosacea
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical metronidazole unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to brand or generic Finacea (azelaic acid) 15% gel unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to oral doxycycline unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 12 months**

XX. Noritate 1% cream may be considered medically necessary for the topical treatment of rosacea in patients 18 years and older when the following criteria are met:

- Patient has a diagnosis of rosacea
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to topical metronidazole 1% gel AND topical metronidazole 0.75% cream

- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to brand or generic Finacea (azelaic acid) 15% gel unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).
- Patient must experience an inadequate response, adverse event, intolerance, or contraindication to oral doxycycline unless the patient is currently receiving a positive therapeutic outcome on the requested medication through health insurance (excludes obtainment as samples or via manufacturer's patient assistance programs).

**Approval will be for 12 months**

XXI. The aforementioned drugs are considered **not medically necessary** for patients who do not meet the criteria set forth above.

#### Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria above and have documentation of positive clinical response to the requested therapy.

#### Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

#### Quantity Limits

Amzeeq – 30 grams per 30 days

Mirvaso – 30 grams per 30 days

Rhofade – 30 grams per 30 days

Zilxi – 30 grams per 30 days

Winlevi – 60 grams per 30 days

### PROCEDURES AND BILLING CODES

***To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.***

- Code(s), if applicable

### REFERENCES

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- Differin 0.3% [Prescribing Information] Forth Worth, TX: Galderma Laboratories, L.P.; February 2012.
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- Evoclin [Prescribing Information] Palo Alto, CA: Connetics Corporation; January 2006.
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- Onexton [Prescribing Information] Bridgewater, NJ: Valeant Pharmaceuticals; November 2014.
- Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016;74(5):945-973.e33.
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- Mirvaso [Prescribing Information]. Fort Worth, TX: Galderma Labs; July 2016.
- Rhofade [Prescribing Information]. Irvine, CA: Allergan; January 2017.
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- Veltin [prescribing information]. Exton, PA: Aqua Pharmaceuticals; March 2014.
- Winlevi [prescribing information]. Milan, Italy: Cassiopea-Cosmo Technologies LTD; August 2020.
- Ziana [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; March 2017.
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- Darier disease. Office of Rare Disease Research. <https://rarediseases.info.nih.gov/gard/6243/darier-disease/resources/8>. Accessed June 2018.
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## POLICY HISTORY

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