Topical Acne Agents

**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 Agents is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or guidelines, and to encourage 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.

**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 Forte is a combination topical product 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 antimicrobial agent indicated for the treatment of acne vulgaris in patients 12 years and older.

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

All other indications are considered experimental/investigational and are not a covered benefit.

**POLICY**

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. 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

V. 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 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 topical clindamycin 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 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

VI. 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 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 topical clindamycin 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 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

VII. 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

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

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

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

- Differin 0.3% [Prescribing Information] Forth Worth, TX: Galderma Laboratories, L.P.; February 2012.

POLICY HISTORY

Policy #: 05.01.114
Policy Creation: July 2016
Reviewed: October 2018
Revised: October 2018
Current Effective Date: December 19, 2018