



STEP THERAPY POLICY

- POLICY:** Topical Antifungals for Seborrheic Dermatitis Step Therapy Policy
- Ciclopirox shampoo (generic)
 - Ciclopirox gel (generic)
 - Extina[®] (ketoconazole foam – Mylan)
 - Ketodan[®] (ketoconazole foam – Medimetriks)
 - Ketodan Kit[®] (ketoconazole foam and salicylic acid cleanser – Medimetriks)
 - Ketoconazole foam (generic)

REVIEW DATE: 07/05/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

These topical antifungal agents are indicated for the treatment of **seborrheic dermatitis** caused by *Malassezia* yeast.^{1,2,3}

- Ciclopirox shampoo/gel and ketoconazole shampoo/foam are indicated for the treatment of scalp and non-scalp seborrheic dermatitis. All ciclopirox products are indicated in **patients ≥ 16 years of age** while all ketoconazole products are indicated in **patients ≥ 12 years of age**.

GUIDELINES

The American Academy of Family Physicians (AAFP) 2015 and Clinical, Cosmetic, and Investigational Dermatology (CCID) 2022 provide recommendations on management of seborrheic dermatitis (SD). AAFP note ciclopirox shampoo or ketoconazole shampoo may be used for scalp SD and ciclopirox gel or ketoconazole foam may be used for non-scalp SD. CCID non-preferentially recommend ciclopirox

or ketoconazole for scalp and non-scalp SD; formulation is guided by patient preference.^{4,5}

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Topical Antifungals for Seborrheic Dermatitis product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.

Step 1: generic ketoconazole 2% shampoo, generic ciclopirox 1% shampoo, generic ciclopirox 0.77% gel

Step 2: Ketodan, Ketodan Kit, Generic ketoconazole 2% foam, Brand Extina Foam

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient has tried a combination product containing topical ciclopirox, approve a Step 2 product.

REFERENCES

1. Ciclopirox shampoo [prescribing information]. Parsippany, NJ: Actavis; September 2019.
2. Ciclopirox gel [prescribing information]. Mahwah, NJ: Glenmark; January 2017.
3. Ketodan® foam [prescribing information]. Fairfield, NJ: Medimetriks; September 2021.
4. Clark GW, Pope SM, Jaboori KA. Diagnosis and Treatment of Seborrheic Dermatitis. *Am Fam Physician*. 2015;91(3):185-190.
5. Dall'Oglio F, Nasca MR, Gerbino G, et al. An overview of the diagnosis and management of seborrheic dermatitis. *Clinical, Cosmetic and Investigational Dermatology* 2022;15 1537-1548.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/05/2023

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