STEP THERAPY POLICY

POLICY: Topical Antifungals for Seborrheic Dermatitis Step Therapy Policy

- Ciclopirox shampoo (generic only)
- Ciclopirox gel (generic only)
- Extina® (ketoconazole foam – Mylan, generic)
- Ketodan® (ketoconazole foam – Medimetriks)
- Ketodan Kit® (ketoconazole foam and salicyclic acid cleanser – Medimetriks)
- Ketoconazole foam (generic only)
- Ketoconazole shampoo (generic only)

REVIEW DATE: 07/16/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.[4] CCID non-preferentially recommend ciclopirox or ketoconazole for scalp and non-scalp SD; formulation is guided by patient preference.[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.

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

Step 2: Ketodan, Ketodan Kit, generic ketoconazole 2% foam, Extina Foam

Topical Antifungals for Seborrheic Dermatitis Step Therapy Policy **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.**

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

REFERENCES

1. Ciclopirox shampoo [prescribing information]. Parsippany, NJ: Actavis; October 2023.
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

Annual Revision	No criteria changes.	07/03/2024
Annual Revision	**Criteria:** The exception that if a patient has tried a combination product containing topical ciclopirox they could receive a Step 2 product was removed. Combination products containing topical ciclopirox have been obsolete for > 3 years.	07/16/2025