Policy: Antifungals

Reference Number: OR.CP.PMN.1011
Effective Date: 04.01.22
Last Review Date: 02.25
Line of Business: Medicaid – Trillium Oregon Health Plan

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Goal(s):

- Approve use of antifungals only for OHP-funded diagnoses. Minor fungal infections of the skin, such as dermatophytosis and candidiasis are only funded when complicated by an immunocompromised host. See section III for conditions that are not covered for treatment.
- Allow case-by-case review for members covered under the EPSDT program.

Requires PA:

- Non-preferred drugs.

Covered Alternatives:

- Current Trillium Preferred Drug List listed at:
  - https://www.trilliumohp.com/providers/pharmacy.html

I. Initial Approval Criteria

A. All Indications (must meet all)**:**

1. Member meets one of the following (a, b, c, d or e):
   a. Diagnosis is funded by OHP (see examples in Table 1);
   b. Member is immunocompromised (meets ANY of the following):
      i. Prescribed by a hematology, oncology or infectious disease specialist and is for voriconazole;
      ii. Member has a current (not history of) diagnosis of cancer AND is currently undergoing Chemotherapy or Radiation;
      iii. Member has a diagnosis of HIV/AIDS;
      iv. Member has a diagnosis of sickle cell anemia;
      v. Member has poor nutrition, elderly or chronically ill;
      vi. Currently taking an immunosuppressive drug, see Appendix A for examples;
      vii. Member has a condition determined to put them in an immunocompromised state;
   c. Request is for treatment of a foot condition and all of the following are met (i, ii, and iii)
      i. The member is at high risk for nail/foot complications due to severe circulatory insufficiency and/or areas of desensitization OR resides in an institutional setting (e.g., skilled nursing/rehabilitation facility, group home, etc.);
      ii. There is clinical evidence of mycosis of the toenail;

iii. The member has documented marked limitation of ambulation, pain, an/or secondary bacterial infection resulting from the thickening and dystrophy of the infected toenail plate;

d. Member is eligible for EPSDT review and was born in or after the year 2004;

2. Request is for a preferred product or member has failed treatment with at least two preferred drugs; supported by one of the following (a, b, or c):
   a. Presence of claims in pharmacy claims history;
   b. Documented contraindication(s) or clinically significant adverse effects to ALL PDL agents within the same therapeutic class or PDL drugs that are recognized as standards of care for the treatment of member's diagnosis;
   c. Drug sample logs which include all of the following: medication name, dose/strength, lot number, expiration date, quantity dispensed, date sample was provided, and initials/title of the dispenser;
3. If request is for oteseconazole, all the following must be met (a, b and c):
   a. Member has diagnosis of recurrent vulvovaginal candidiasis (RVVC) defined as a history of 3 or more episodes of acute vulvovaginal candidiasis (VCC) in the previous 12 months;
   b. Has failed to have benefit with a course of oral fluconazole for recurrent vulvovaginal candidiasis unless contraindicated or clinically significant adverse effects are experienced;
   c. Member is not pregnant, lactating or has reproductive potential;
4. Requested medication is FDA approved for the submitted indication;
5. Dose does not exceed FDA approved dose;

Approval duration: Approve for treatment course. If length of therapy is unknown, approve for 3-months.

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

Approval duration: Approve for treatment course. If length of therapy is unknown, approve for 3-months.

II. Continued Therapy

A. All Indications (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;

b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed FDA approved dose for indication;

Approval duration: up to 12 months. If length of therapy is unknown, approve for 3-months.

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. The following conditions are not conditions that covered by the Oregon Health Plan for treatment: erythematosquamous dermatosis; diaper or napkin rash; other atopic dermatitis and related conditions; contact dermatitis and other eczema; erythematous conditions; lichen planus; rosacea or acne; pityriasis versicolor; tinea blanca; black piedra; mycoses, superficial; cutaneous candidiasis; candidiasis, unspecified; rash and other nonspecific skin eruption;

B. Diagnoses that are not an OHP funded condition unless member is <21 years of age and EPSDT program policy requirements are met: OR.CP.PMN.234.

C. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Immunosuppressive Drugs

Azathioprine	Leflunomide
Basiliximab	Mercaptopurine
Cyclophosphamide	Methotrexate
Cyclosporine	Mycophenolate
Etanercept	Rituximab
Everolimus	Sirolimus
Hydroxychloroquine	Tacrolimus
Infliximab	

Appendix B: Examples of OHP FUNDED *indications*

ICD-10	Description
B37.3	Candidiasis of vulva and vagina (vaginitis and cervicitis)
B37.1	Candidiasis of the lung
B37.7	Disseminated Candidiasis
B37.5-37.6, B37.8-37.84, B37.89-37.90	Candidiasis of other specified sites
B38.0-B38.4, B38.7, B38.9	Coccidiomycosis various sites
B39.0-39.5, B39.9, G02, I32, I39, J17	Histoplasmosis, subacute meningitis, acute bacterial meningitis
B40.9, B41.0, B41.9, B48.0	Blastomycosis
B42.0-42.9, B43.9, B44.9-45.0, B45.7, B45.9, B46.9, B48.1-48.2, B48.8, B49	Rhinosporidosis, Sporotrichosis, Chromoblastomycosis, Aspergillosis, Mycotis Mycetomas, Cryptoccosis, Allescheriosis, Zygomycosis, Dematiacious Fungal Infection, Mycoses Nec and NOS
B48.8	Mycosis, Opportunistic
B44.81	Bronchopulmonary Aspergillus, Allergic
N73.9-75.1, N76.0-N77.1	Acute inflammatory pelvic disease
L30.019, L30.029, L30.039, L30.049	Cellulitis and abscess of finger and toe
P37.5	Neonatal Candida infection
B37.42, B37.49	Candidiasis of other urogenital sites
L30.4	Severe intertrigo (see HERC guideline note 21 for definition of severe inflammatory sin disease)

Appendix C: Examples of OHP NON-FUNDED *indications*

ICD-10	Description
L2.083, L2.10-2.11, L21.8-21.9	Erythematosquamous dermatosis
L22	Diaper or napkin rash
L20.0-20.84, L20.89-20.9	Other atopic dermatitis and related conditions
L24.0-24.2, L25.1-25.5, L57.8, L57.9,	Contact dermatitis and other eczema
L23.0, L23.81, L24.81, L25.0, L25.2, L25.8-25.9, L55.1-55.2, L56.8, L58.9	
L53.0-53.2, L51.0, L51.8-51.9, L52, L71.0-71.1, L71.8, L93.0, L93.2, L49.0-L49.9, L26, L30.4, L53.8, L92.0, L95.1, L98.2, L53.9	Erythematous conditions

L43.8, L44.1-44.3, L44.9, L66.1	Lichen Planus
L70.0-70.2, L70.8	Rosacea or acne
B36.0	Pityriasis versicolor
B36.2	Tinea blanca
B36.3	Black piedra
B36.8, B36.9	Mycoses, superficial
B37.2	Cutaneous candidiasis
B37.9	Candidiasis, unspecified
R21	Rash and other nonspecific skin eruption

Appendix D: Criteria driven diagnoses

ICD-10	Description
B35.0	Dermatophytosis of scalp and beard (tinea capitis/ tinea barbae)
B35.1	Tinea unguium (onychomycosis)
B35.2	Dermatophytosis of hand (tinea manuum)
B35.6	Dermatophytosis of groin and perianal area (tinea cruris)
B35.3	Dermatophytosis of foot (tinea pedis)
B35.5	Dermatophytosis of body (tinea corporis / tinea imbricate)
B35.8	Deep seated dermatophytosis
B35.8-B35.9	Dermatophytosis of other specified sites - unspecified site
B36.1	Tinea nigra
B37.83	Candidiasis of mouth

V. References

1. Antifungals. Oregon Health Plan Current Drug Use Criteria. Available at: http://orpdl.org/drugs/index.php. Accessed January 17, 2025.
2. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed January 17, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.1814 Antifungals. No significant changes.	12.20.21	01.06.22
1Q 2023 annual review: no significant changes; updated tables in appendix; references reviewed and updated.	12.15.22	01.05.23
1Q 2024 annual review: Updated initial coverage criteria per FFS criteria updates: added condition for coverage for EPSDT program members, added condition for coverage of high risk nail/foot infections, added oteseconazole specific coverage requirements; template changes applied to other diagnoses/indications and continued therapy section; updated tables in appendix; references reviewed and updated.	01.08.24	02.20.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added standard YSHCN language to I.A. for new 2025 OHP program coverage.	10.16.24	11.19.24
1Q 2025 annual review: no significant changes; references reviewed and updated.	01.17.25	02.11.25

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.