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Objective:

- I. To ensure the clinically appropriate prescription and use of pharmaceuticals by Tuality Health Alliance (THA) providers and members, respectively.

Definitions:

Formulary – a list of common medications that are covered by the THA plan, as well as medications that require prior authorization for coverage determination based on medical necessity. The formulary is the cornerstone of drug therapy quality assurance and cost containment efforts.

Drug Prior Authorization – an administrative tool submitted by the healthcare provider as a formal request for a member's specialty/non-formulary prescription medications.

Step Therapy – step therapy refers to the trial and failure of one or more first-line drugs before the prior authorization approval and coverage of a related second-line specialty or high-cost drug.

Policy:

- I. Prescription drugs are a covered benefit for THA members, as based on utilization and medical necessity guidelines.
- II. THA pharmacy services are administered through the Oregon Health & Science University (OHSU) Pharmacy Benefits Management (PBM) Company.
- III. Each prescribed medication must be filled at a THA-authorized pharmacy and must be covered under the *THA Drug Formulary*, unless otherwise approved through the prior authorization process.
- IV. **The *THA Drug Formulary***
The *THA Drug Formulary* is a listing of the common medications for each therapeutic class, as approved by the Federal Drug Administration (FDA). The formulary established by THA is to be utilized in providing prescribed medications and approved over-the-counter items.
 - a. The *THA Drug Formulary* is revised at least annually; The THA Pharmacy & Therapeutics (P&T) Committee, which consists of providers and pharmacists collaborate with THA nurse case managers to develop and update the formulary. The P&T Committee invites any THA network provider to actively participate in formulary optimization.
 - b. THA providers receive the *THA Drug Formulary* at the time of updated formulary approval. The formulary is posted on the THA website and is available in hard copy any time, upon request. OHSU PBM software also features the formulary in an online/interactive form to encourage formulary

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compliance.

- c. Formulary and/or therapeutic change inquiries should be forwarded to the THA Medical Director. If a provider requests that a new or existing medication be added to the formulary, a letter indicating the significant advantages of the drug product over current formulary medications should be sent to the THA Medical Director:

Tuality Health Alliance
Attn: Medical Director
P.O. Box 925
Hillsboro, OR 97123-0925
Fax: (503) 681-1823

- d. Unless exceptions are noted, all drug strengths and forms (i.e., tablet, capsule, liquid, and topical) are included in the formulary to be covered by THA. If a new strength of an approved form of a formulary medication becomes available, it will automatically be added to the formulary.
- e. When the patent on a brand name medication expires and a generic equivalent becomes available at a lower cost than the brand name, the OHSU PBM will replace the brand name medication with the generic equivalent on the THA formulary.
- f. The formulary applies only to prescription medications dispensed to outpatients by participating pharmacies. The formulary does not apply to inpatient medications.
- g. If a pharmacy's prescription claim is denied by the OHSU PBM system because a drug is not in the approved formulary, the pharmacist must call the prescribing physician to identify an appropriate formulary alternative.

V. Drug Prior Authorizations

THA maintains a closed formulary and has a prior authorization process for consideration of medically necessary drugs that are not covered within the formulary. Such drugs include certain specialty drugs, drugs with high quantity levels, drugs with high costs, and drugs that require step therapy. Drugs that require prior authorization are designated within the formulary with "PA" (Prior Authorization) written next to the drug name.

a. Step Therapy Drugs

THA may require that a first-line generic or therapeutic drug that is equivalent to a second-line (high-cost or highly toxic) drug be tried and failed before the prior authorization approval and coverage of the second-line drug. When requesting a second-line step therapy drug, the prescribing provider must submit documented evidence of the member's trial and failure of a relative

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first-line drug along with the *THA Drug Prior Authorization Form*. Second-line step therapy medications are designated within the formulary with “ST” (Step Therapy) written beside the drug name.

b. High Cost Drugs

Drugs that exceed \$500 will require prior authorization to ensure appropriateness.

c. Quantity Level Limits

Some drugs may be subject to quantity level limits based on the drug manufacturer’s packaging size or adopted clinical guidelines. These drugs are designated within the formulary with “QL” (Quantity Level written beside the drug name.

d. The *THA Drug Prior Authorization Form*

The *THA Drug Prior Authorization Form* must be used for all THA member medication pre-authorizations. The form must be filled out completely and accurately to ensure timely processing. The form should include the following information:

- The member’s name, THA ID number, and birth date;
- The name and contact information for all involved healthcare providers;
- A current ICD-9 code diagnosis that accurately reflects the condition for which the member is seeking medication;
- The name, dose, and directions for use of the medication being requested;
- Notification of the member’s current medication use, including related or step-therapy medications;
- The signature of the prescribing practitioner; and
- Attached copies of legible and relevant chart notes, lab or radiology reports, etc.

e. Drug Prior Authorization Determinations

THA Medical Management staff utilizes established guidelines and timelines for making coverage determinations on drug pre-authorizations for members. Refer to *THA Policy V-3: Referrals & Pre-Authorizations* for details.

Upon approval of a drug pre-authorization, the following steps are followed:

1. The provider who requested the pre-authorization, as well as the pharmacy (if indicated), are notified via fax of the approval.
2. The THA Referral Coordinator places an override in the OHSU PBM system to remove administrative barriers to filling the prescribed medication.

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Upon denial of a drug pre-authorization, the following steps are followed:

1. A *Notice of Action* denial letter, with instructions for requesting an appeal and/or administrative hearing, is mailed to the THA member.
2. The *Notice of Action* with appeal instructions, and THA contact information, is faxed to all involved providers.

If a drug cannot be approved within 24 hours of receipt of the prior authorization request, and the nature of the member's condition requires immediate use of the drug, THA will provide for the dispensing of a 72-hour drug supply.

VI. Member PBM System Eligibility

- a. Pharmacies will access member eligibility records online.
- b. THA is responsible for transmitting current member eligibility data and prior authorization overrides to the PBM system in a timely manner.
- c. If a member presents to a pharmacy and is not included in the PBM online eligibility records, the pharmacist may contact the THA Referral Coordinator or designated THA staff. If THA staff is not available, the pharmacist has the authority to provide a three-day supply of the prescription and must immediately notify THA of the transaction.

VII. Prescriptions for Physician Assisted Suicide under the Oregon Death with Dignity Act are excluded from THA pharmacy services; payment is governed solely by OAR 410-121-0150.

VIII. THA will not authorize payment for any Drug Efficacy Study Implementation (DESI) Less Than Effective (LTE) drugs which have reached the FDA Notice of Opportunity for Hearing stage, as specified in OAR 410-121-0420. The DESI LTE drug list is available at <http://www.cms.hhs.gov/MedicaidDrugRebateProgram/12LTEIRSDrugs.asp>.

IX. THA does not cover 7/11 Carve-Out Drugs – these are covered through the Oregon Health Plan Division of Medical Assistance Programs on a fee-for-service basis. The 7/11 Carve-Out Drug List is available at <http://www.oregon.gov/oha/healthplan/tools/7-11%20Drug%20Carveout%20List,%20November%202013.pdf>.

X. THA will make every effort to assist Medicare dual eligible members with their Medicare D benefits; THA will cover drugs excluded from Medicare, which include, but are not limited to, the following:

- Benzodiazepines;

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- Over-the-counter (OTC) drugs; and
- Barbiturates.

References: OAR 410-141-0070
Oregon Health Authority Health Plan Services Contract 2014
THA Policy V-3: Referrals & Pre-Authorizations
THA Drug Formulary (2012-2016)

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