

## New Drug Policy

### **Goal:**

- Restrict coverage of selected new drugs until the Oregon Pharmacy & Therapeutics Committee can review the drug for appropriate coverage. New drug criteria will apply until drug specific criteria are developed or for a maximum of 1 year (whichever is less). This policy does not apply to new oncology drugs.
- Allow case-by-case review for members covered under the EPSDT program.

### **Length of Authorization:**

- Up to 6 months

### **Requires PA:**

- A new drug, identified by the reviewing pharmacist during the weekly claim processing drug file load, which is not subject to existing prior authorization criteria, costing more than \$5,000 per claim or \$5,000 per month based on wholesale acquisition cost.

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code	
2. Is the medication FDA-approved for the requested indication and does the requested dosing align with the FDA-approved dosing?	<b>Yes:</b> Go to #3	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
3. Is the drug being used to treat an OHP-funded condition?	<b>Yes:</b> Go to #5	<b>No:</b> If not eligible for EPSDT review: Pass to RPh. Deny; not funded by the OHP  If eligible for EPSDT review: Go to #4
4. Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?	<b>Yes:</b> Go to #5	<b>No:</b> Pass to RPh. Deny; medical necessity.
5. Is baseline monitoring recommended for efficacy or safety and has the provider submitted documentation of recommended monitoring parameters?	<b>Yes:</b> Go to #6	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
6. Does the requested therapy have an orphan drug designation and is this the only FDA-approved therapy for the funded condition?	<b>Yes:</b> Approve for up to 6 months or length of treatment (whichever is less).	<b>No:</b> Go to #7

## Approval Criteria

### 7. Pass to RPh.

If funded: The prescriber must provide documentation that alternative drugs approved by the FDA for the funded condition are not appropriate due to history of therapeutic failure, an adverse event, or a contraindication. Otherwise, the prescriber must provide medical literature supporting use for the funded condition. RPh may use clinical judgement to approve drug for up to 6 months or deny request based on documentation provided by prescriber.

If not funded:

- a. If member is eligible for EPSDT review; Is there documentation that the condition is of sufficient severity that it impacts the patient's health (e.g., quality of life, function, growth, development, ability to participate in school, perform activities of daily living, etc)?
  - i. Is yes, The prescriber must provide documentation that alternative drugs approved by the FDA for the funded condition are not appropriate due to history of therapeutic failure, an adverse event, or a contraindication. Otherwise, the prescriber must provide medical literature supporting use for the funded condition. RPh may use clinical judgement to approve drug for up to 6 months or deny request based on documentation provided by prescriber.
  - ii. If No, Deny (medical appropriateness)
- b. If member is not eligible for EPSDT review: Deny; not funded by the OHP.

*P&T / DUR Review:* 7/18 (SS); 11/17; 11/15; 12/09  
*Implementation:* 8/15/18; 1/1/18; 1/1/16; 1/1/10