MEDICAL MUTUAL®

Drug Policy

Policy: **Impacted Drugs:**	**Proton Pump Inhibitors (PPI) Preferred Step Therapy Program** • **Dexlansoprazole** • **Esomeprazole DR** • **Lansoprazole** • **Pantoprazole oral packets (generic)** • **Voquezna**	**Annual Review Date:** **01/18/2024** **Last Revised Date:** **02/15/2024**

OVERVIEW

Proton pump inhibitors (PPIs) [i.e., esomeprazole, dexlansoprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole] are commonly used antisecretory agents that are highly effective at suppressing gastric acid and subsequently treating associated conditions, including gastroesophageal reflux disease (GERD).

POLICY STATEMENT

A step therapy program has been developed to encourage the use of one generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration. **Please note** that not all plans cover over-the-counter drugs, please check corresponding benefit materials for additional information.

Preferred Medications (step 1)

- Omeprazole delayed release capsules and tablets (generic, Rx and OTC)
- Pantoprazole delayed release tablets (generic)

Non-Preferred Medications (step 2)

- Dexlansoprazole delayed release capsule (generic)
- Esomeprazole delayed release capsules (generic)
- Esomeprazole oral packets (generic)
- Lansoprazole delayed release capsules (generic, Rx and OTC)
- Lansoprazole orally disintegrating tablets (generic, Rx and OTC)
- Pantoprazole oral packets (generic)
- Voquezna tablets

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a Step 1 PPI under the supervision of a physician, then authorization may be given for a Step 2 PPI product. **Note:** A trial of a generic OTC PPI would qualify if OTC PPIs are a covered benefit and the patient was using it for at least 14 days.

2. If the patient is < 1 year of age OR has difficulty swallowing, then authorization may be given for generic esomeprazole delayed release granules for oral suspension (packets), lansoprazole orally disintegrating tablets, or pantoprazole delayed release oral suspension (packets). **Note:** Esomeprazole is indicated down to 1 month of age.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

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Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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