I. Requirements for Prior Authorization of Proton Pump Inhibitors (PPIs)

A. Prescriptions That Require Prior Authorization

Prescriptions for PPIs that meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred PPI, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred PPIs at:

2. A prescription for a preferred PPI with a prescribed quantity that exceeds the quantity limit established by the Department. See Quantity Limits for the list of drugs with quantity limits at:
   http://www.dpw.state.pa.us/ucmprd/groups/webcontent/documents/document/s_002077.pdf

3. A prescription for a preferred or non-preferred PPI for a child under six (6) years of age and the PPI has been prescribed for a total of four (4) months in the preceding 180 day period.

4. A prescription for an over-the-counter (OTC) PPI for a dual eligible, regardless of the quantity prescribed.

5. A prescription for a PPI when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs in PROMISe, the Department’s Claims Adjudication System, (therapeutic duplication)

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a PPI, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For a non-preferred PPI, whether the recipient has a history of therapeutic failure or intolerance of the preferred PPIs.

   AND

2. For either a non-preferred or a preferred PPI prescribed for a child under six (6) years of age and the PPI has been prescribed for a total of four (4) months in the preceding 180 day period, whether
chronic therapy is the most appropriate option as documented by at least one of the following:

a. The recipient has a chronic primary disease such as but not limited to cystic fibrosis, cerebral palsy, Down’s Syndrome/mental retardation, repaired esophageal atresia.

OR

b. The recipient’s chart documents evidence of a comprehensive evaluation and appropriate diagnostic testing confirming a diagnosis that requires chronic therapy.

OR

c. The recipient is being prescribed the medication by a gastroenterologist or in consultation with a gastroenterologist.

3. For over-the-counter (OTC) PPIs for a dual eligible, whether:

a. The drug is not being prescribed as part of a Medicare plan utilization management program, including a step-therapy or prior authorization program

AND

b. The MA recipient has a history of therapeutic failure or intolerance of the PPIs on the MA recipient’s Medicare plan formulary

4. For therapeutic duplication, whether:

a. The recipient is being titrated to, or tapered from, a drug in the same class

OR

b. Supporting peer reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested

5. In addition, if a prescription for either a preferred or non-preferred PPI is in a quantity that exceeds the quantity limit, the
determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

6. For either a preferred or non-preferred PPI that does not meet the clinical review guidelines listed above, when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

C Automated Prior Authorization Approvals

Prior authorization of a prescription for a non-preferred PPI at or below the quantity limit will be automatically approved when the PROMISe Point-of-Sale On-Line Claims Adjudication System verifies a record of paid claim(s) within 180 days prior to the date of service that documents that the guidelines to determine medical necessity listed above have been met.

Prior authorization of a prescription for a preferred or non-preferred PPI at or below the quantity limit will be automatically approved when the PROMISe Point-of-Sale On-Line Claims Adjudication System verifies that the recipient:

1. Is under 6 years of age, AND
2. Has a record of a prescription for a PPI for a total of four (4) months in the preceding 180 day period, AND
3. Has a record of a chronic primary disease

Automated prior authorization approvals do not apply to prescriptions for OTC PPIs for dual eligibles or PPIs that are duplicate therapy.

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for a PPI.

For a non-preferred PPI, if the guidelines in Sections B. are met, the reviewer will prior authorize the prescription. When the non-preferred PPI being prescribed is therapeutically equivalent to other non-preferred PPIs, the reviewer will take into account the cost of the drug, including the Federal Drug Rebate Program rebate. The reviewer will prior authorize a prescription for the least costly therapeutically equivalent non-preferred PPI. If the guidelines are not met, or if the prescriber does not agree to the therapeutically equivalent non-preferred PPI authorized by the reviewer, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior
authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

For a preferred PPI, if the Guidelines in Section B.2. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

E. Dose and Duration of Therapy

The Department will consider requests for prior authorization of PPIs for 12 months when, in the professional judgment of the reviewer, treatment for the condition is expected to be ongoing. Prescriptions may be refilled as long as the refills do not exceed a six (6) month or five (5) refill supply, whichever comes first, from the time of the original filling of the prescription. See 55 Pa Code § 1121.53(c). Thus, if a recipient receives either a six (6) month or five (5) refill supply, whichever comes first, a new prescription, using the same prior authorization number will be required.