

# Proton Pump Inhibitor Therapy Assessment Guide



For each new, follow-up, or refill prescription consultation for a proton-pump inhibitor medication, answer the following questions with a "Yes" or "No" response. A "Yes" response to any question suggests a potential drug therapy problem exists and you should refer to the item number on the reverse side of this guide for additional information.

## NEW RX PROFILE REVIEW

- |   | Drug Therapy Problem No. |
|---|--------------------------|
| 1) Is prescribed PPI therapy above recommended initial dose?..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 1                        |
| 2) If patient is taking PPI for GERD, are they also taking an anti-cholinergic, barbiturate, diazepam, calcium channel blocker, theophylline or nitrate? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No                               | 2                        |
| 3) If patient is taking PPI for PUD, are they also taking tetracyclines, bisphosphonates, quinidine, potassium chloride, iron salts, aspirin, or non-steroidal anti-inflammatory drug? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No | 3                        |

## NEW RX PATIENT INTERVIEW

- |  |   |
|--|---|
| 1) Do you have heartburn symptoms 2 times per week or less? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 4 |
| 2) Do you exhibit fewer than 3 of the following symptoms:  |   |
| a. Unintentional weight loss?..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 5 |
| b. Difficulty or pain upon swallowing? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 5 |
| c. Indigestion? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 5 |
| d. Stomach contents in mouth or back of throat? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 5 |
| e. Coughing or choking feeling associated with heartburn or indigestion? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 5 |
| 3) If you recently had a procedure where your doctor examined the inside of your stomach and esophagus, did your doctor tell you the results were normal? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No | 5 |
| 4) Does the cost of this medication represent a financial burden to you?..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 6 |
| 5) Are you interested in less expensive medications?..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 6 |
| 6) Do you:   |   |
| a. Smoke? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 7 |
| b. Have difficulty maintaining a healthy weight? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 7 |
| c. Eat fatty foods several times per day? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 7 |
| d. Lie down or go to bed within three hours of eating? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 7 |
| e. Frequently eat spicy foods, chocolate or mint flavored food? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 7 |
| f. Frequently drink alcohol, coffee, tomato or orange juice? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 7 |
| g. Typically wear clothing that is tight or restrictive in the waistline? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 7 |
| h. Often have to bend over to perform your job or home activities? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 7 |

## REFILL/FOLLOW-UP PROFILE REVIEW

- |   |    |
|---|----|
| 1) Is patient early or late for their refill based on the days supply dispensed? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No | 8  |
| 2) Has the patient been taking a PPI for more than 8 weeks? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No                      | 11 |

## REFILL/FOLLOW-UP PATIENT INTERVIEW

- |   |    |
|---|----|
| 1) Do you sometimes forget to take your medications? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No                                     | 8  |
| 2) Do you sometimes forget to take your medication at least 30 minutes before your meal? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No | 8  |
| 3) Have you experienced any of the following symptoms since starting to take this medication:   |    |
| a. Diarrhea, nausea or vomiting? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 9  |
| b. Constipation?..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 9  |
| c. Abdominal pain? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 9  |
| d. Excess gas?..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 9  |
| e. Unintentional weight loss?..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 10 |
| f. Bleeding from your rectum or throat? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 10 |
| g. Difficulty or pain upon swallowing? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No   | 10 |
| 4) Have your heartburn symptoms become more frequent or severe recently? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No                 | 10 |
| 5) Have your heartburn symptoms completely disappeared?..... <input type="checkbox"/> Yes <input type="checkbox"/> No                                   | 11 |
| 6) Are you dissatisfied with your drug therapy? ..... <input type="checkbox"/> Yes <input type="checkbox"/> No  | 11 |

## Potential Drug Therapy Problems:

- 1) **Excessive Dose - Proton Pump Inhibitor** Regimens with more than once daily or twice daily PPI administration are recommended for patients whose symptoms are not controlled or for patients whose erosive esophagitis is still present after a 4-8 week course of therapy. **Recommend:** Reduction in dose of initial acid suppressive PPI therapy to no more than omeprazole 20mg or 40mg qd, lansoprazole 15mg or 30mg qd, rabeprazole 20mg qd, pantoprazole 40mg qd, or esomeprazole 20mg or 40mg qd.
- 2) **Adverse Drug Reaction - GERD-Inducing Drugs** Anti-cholinergics, barbiturates, diazepam, calcium channel blockers, theophylline, and nitrates may induce symptoms of GERD. **Recommend:** Modification or change in therapy where possible based on patient's clinical status. If therapy must be continued, initiate most appropriate acid-suppressive therapy for patient's condition.
- 3) **Adverse Drug Reaction - Ulcerative Drugs** Tetracyclines, bisphosphonates, quinidine, potassium chloride, iron salts, aspirin, and non-steroidal anti-inflammatory drugs can be irritating to GI mucosa. **Recommend:** Modification or change in therapy where possible based on patient's clinical status. Patients taking bisphosphonates should remain upright for at least 30 minutes after administration of the drug with a full glass of water on an empty stomach. If other therapies must be continued, irritating drugs should be taken with a full glass of water and food. PUD patients should use alternatives to NSAIDs, such as acetaminophen or nonacetylated salicylates (salsalate). In patients who cannot discontinue NSAID therapy, the NSAID dose should be decreased or a less-damaging agent (COX-2 inhibitor) used.
- 4) **Unnecessary Therapy - Proton Pump Inhibitor** Acid-suppression therapy with PPI or prescription strength H2RA is typically recommended for patients with heartburn more than 2 times per week for at least 3 weeks that negatively impacts their quality of life. **Recommend:** Lifestyle modifications along with intermittent antacids (non-calcium) and/or non-prescription strength H2RA using manufacturers' published dosage.
- 5) **Suboptimal Drug Selection - H2RA More Cost-Effective** For mild GERD, H2RAs relieve symptoms in 80% of patients and heal esophagitis in about 60-75% of patients after 8-12 weeks. Patients with atypical respiratory symptoms, dysphagia, weight loss, or odynophagia should be referred for further evaluation. If patient complains of dyspepsia, water brash, or regurgitation or if erosive esophagitis has been documented on endoscopy, therapy should always be initiated with a PPI. **Recommend:** Change PPI therapy to twice daily H2RA regimen at the following total daily dosage amounts: cimetidine 1200mg, ranitidine 300mg, famotidine 40mg, nizatidine 300mg.
- 6) **Cost Efficacy Management - H2RA or OTC PPI More Cost-Effective** For H. pylori eradication, combining a twice-daily H2RA with bismuth, metronidazole and tetracycline four times per day for 14 days is an approved regimen. The H2RA should be continued for an additional two weeks. Regimens that incorporate a PPI and less frequent dosing are also recommended. H2RA based regimens are best reserved for patients who are likely to be able to comply with the complicated regimen and desire a less costly alternative. An OTC PPI may be a cost-effective alternative as well. **Recommend:** If appropriate for H. pylori eradication, ranitidine 150mg bid, bismuth 525mg qid, metronidazole 250mg qid and tetracycline 500mg qid all for two weeks with continuation of ranitidine for an additional two weeks.
- 7) **Non-Compliance - Incorrect Administration/Technique** Common sense suggests, although not scientifically proven, that elevation of the head of the bed, smoking cessation, decreased ingestion of fatty foods, and avoiding recumbency for three hours after eating decreases the potential for reflux. Spicy foods, chocolate, peppermint, and spearmint, as well as alcohol, coffee, orange juice, and tomato juice have demonstrated the ability to increase esophageal reflux. Weight loss, wearing loose fitting clothing and limiting bending over may also improve symptoms of reflux. **Recommend:** Modification of behaviors that may contribute to reflux.
- 8) **Non-Compliance - Incorrect Administration** Missed doses of PPIs reduce the drugs' ability to inhibit gastric acid secretion, thereby increasing the likelihood of persistent symptoms and suboptimal healing of esophagitis. PPIs are most effective when given before meals because they only inhibit those proton pumps that are actively secreting acid. The absorption of pantoprazole and rabeprazole is not altered by the presence of food, but it is preferable to take all PPIs prior to mealtime. Morning doses appear to have superior 24-hour acid suppression, but patients with persistent nocturnal symptoms may benefit from an evening dosing schedule. **Recommend:** Patient should take PPI at same time each day at least 30-60 minutes before a morning or evening meal.
- 9) **Adverse Drug Reaction - Proton Pump Inhibitor** While PPIs are generally well tolerated, the most frequent adverse effects involve the GI tract (diarrhea, nausea, constipation, abdominal pain, flatulence, vomiting) and the CNS (headache, dizziness). **Recommend:** If side effects are intolerable for patient, switch from PPI to H2RA. Add metoclopramide 10mg up to 4 times per day if symptoms uncontrolled or esophagitis persists with H2RA therapy alone.
- 10) **Insufficient Dose or Needs Therapy - Persistent Symptoms** The large majority of patients will experience symptomatic relief of heartburn within one week of initiating therapy with a PPI. If there is no improvement, unintentional weight loss, bleeding, dysphagia or odynophagia, additional evaluation and/or a change in therapy is indicated. **Recommend:** Refer patient for additional evaluation if endoscopic evaluation not already completed or new symptoms develop. If no new symptoms and esophagitis already confirmed, increase PPI dose to twice daily regimen and add nighttime dose of H2RA. If symptoms persist, add metoclopramide 10mg up to 4 times per day.
- 11) **Unnecessary Therapy - Proton Pump Inhibitor** Patients with GERD that respond to treatment should continue therapy for at least eight weeks. If patient is symptom-free, the drug can be discontinued and the patient monitored for recurrence. If symptoms recur, a second course of therapy for 4-8 weeks is indicated. Recurrence after a second course suggests the need for chronic maintenance therapy or referral to a gastroenterologist. **Recommend:** Discontinue PPI therapy if symptoms have resolved. Monitor patient monthly for recurrence of symptoms and re-initiate therapy for an additional 4-8 weeks. If recurrence occurs after second treatment period, chronic maintenance therapy with standard doses of either an H2RA or PPI may be necessary.

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