Drug Use Research & Management Program
Oregon State University, 500 Summer Street NE, E35
Salem, Oregon 97301-1079
Phone 503-947-5220 | **Fax** 503-947-1119

Policy Evaluation: Proton Pump Inhibitors (PPIs)

Research Questions:

1. Has the utilization of proton pump inhibitors (PPIs) for unfunded diagnoses decreased since the implementation of prior authorization criteria? Has there been an increase in prescribing of PPIs for funded diagnoses?
2. Has the percent of patients on PPI therapy > 8 weeks decreased since implementation of the prior authorization criteria?
3. Has the PA resulted in an interruption in therapy for those with severe conditions?
4. Has the utilization rate of other acid-blocking agents [histamine-receptor antagonists (H2As) or antacids] changed since the PPI policy change?

Conclusions:

- Utilization of PPIs for unfunded diagnoses has decreased since the implementation of the prior authorization criteria. Before the criteria, 9.4% of claims were for unfunded diagnoses and after the criteria, only 2.7% of claims were for unfunded diagnoses.
- The prior authorization criteria did not result in an increase in prescribing for funded diagnoses.
- The PA criteria successfully limited the use of PPIs for this indication as illustrated by the decrease in PPI therapy for esophageal reflux and esophagitis for > 8 weeks between the control and study groups (7.9% vs. 0.4%).
- Of the identified index events without a paid claim, none of the claims in either group had a prior severe condition.
- There was a limited number of claims for H2As or antacids in the 90 days after the index event in both groups (30 claims in the control group versus 35 claims in the study group).

Recommendations:

- Maintain current PA policy for PPIs
- Future policy evaluation to evaluate additional safety concerns such as possible increase in hospitalization

Background:

Gastroesophageal reflux disease (GERD) is a common condition encountered in the Western World, with a prevalence of about 10 to 20 percent.[1] PPIs are the mainstay of treatment for erosive esophagitis due to GERD and other conditions such as Zollinger-Ellison syndrome, *Helicobacter pylori* (*H. pylori*) GI tract infection, duodenal ulcers, gastric ulcers and Crohn's disease related ulcers.[2] PPIs are commonly used long-term for acid suppression in patients with GERD; however, there is insufficient evidence to support the use of PPIs for greater than 8 weeks for the treatment of GERD.[3] Long-term use of PPIs may be associated with significant risks including *Clostridium difficile* infection, pneumonia, and bone fractures of the hip, wrist and spine.[4] Additional FDA safety alerts include nutritional deficiencies such as low magnesium levels and cyanocobalamin (vitamin B-12) deficiency with long-term PPI use.[3]

A recently published randomized controlled trial, that included 38,019 men and women aged 45 years and older, concluded that PPI use was associated with an increased risk of infectious gastroenteritis hospitalizations.[5] Additionally, they found that there is a dose response relationship, with higher doses being

associated with higher risk of hospitalization due to infectious gastroenteritis.[5] Preliminary, observational data presented at the American Heart Association's Scientific Sessions 2016, reported that PPI use increased overall ischemic stroke risk by 21% (relative risk).[6]

Due to safety concerns and limited long term efficacy of PPIs, the Health Evidence Review Committee (HERC) determined long-term (>8 weeks) treatment of GERD or esophagitis were no longer funded conditions.[7] A complete list of PPI indications, corresponding diagnosis codes, and the corresponding Oregon Health Plan (OHP) funding line are listed in **Appendix 2.** PPIs are also used for the treatment of dyspepsia and dyskinesia of the esophagus, which are also unfunded conditions. Other Food and Drug Administration (FDA) approved indications for PPIs and H2As remain funded conditions.

The symptoms of GERD or other GI related conditions may be non-specific and concerning, such as non-cardiac chest pain, which may prompt a visit to the ED. Other common symptoms include heartburn, epigastric or abdominal pain, bloating, nausea and vomiting.[1] Antacids and H2As are also used for the treatment of GERD and dyspepsia which remain unrestricted by OHP FFS.[3] Evidence shows there is no difference in the effectiveness of H2As for the treatment of GERD.[3]

The previous drug use evaluation performed by the Drug Use Research & Management Program in March 2015 found that PPI use >8 weeks occurred in approximately 75% of the Oregon Health Plan (OHP) Fee-for-Service (FFS) population. Prior authorization (PA) criteria was established and implemented on June 8, 2016 to restrict the use of PPIs for more than 60 days for unfunded diagnoses (**Appendix 3**). The goals of this review are to assess the impact of the PA criteria on the utilization and duration of PPIs, determine if the PA resulted in an unintended interruption in therapy for severe conditions, and its effect on the utilization of other acid-lowering agents.

Methods:
Patients were included in this analysis if they had a paid or denied FFS drug claim for a PPI in **Appendix 1** from 6/1/15 through 12/7/16.

This analysis used a pre- and post-observational cohort to compare utilization before and after the implementation of the PA criteria, which occurred on 6/8/16. Patients with a paid or denied FFS claim for PPIs defined in **Appendix 1** from 6/1/15 to 11/30/15 were defined as the control group; patients with a paid or denied FFS claim for PPIs defined in **Appendix 1** from 6/8/16 through 12/7/16 were defined as the study group. Denied claims were defined as claims with an Explanation of Benefit (EOB) Code 1056 ("PA Required") or 1059 ("Non-Preferred Drug") with no simultaneous EOB code of 0154 ("Bill Part D"), 0389 ("Bill Part B"), 1109 ("Drug Covered by Medicare Part D") or 2017 ("Bill Managed Care"). If patients were identified in both cohorts, they were excluded from both groups. The first PPI paid or denied claim per patient during the control and study periods was designated the index event (IE) and this was used to compare utilization between control and study group.

Patients were excluded if they had Medicare Part D coverage as indicated by benefit packages of BMM, BMD, MND or MED. Patients were also excluded if they had less than 75% days of combined FFS or coordinated care organization eligibility from 11 months prior to the index month to 2 months after the index month. Patients were excluded if they had a prior claim (FFS or CCO) for a PPI within the 90 days prior to the IE to capture new starts only. Baseline characteristics of age, gender, and ethnicity were assessed at the time of the IE. Patients with an IE for a PPI, paid FFS or CCO claims for an H2A or antacid listed in **Appendix 1** within 90 days of the IE, were identified.

Patients were categorized into groups based on any of the diagnoses of interest in **Appendix 2** during the 12 months prior to the index claim in either encounter or FFS claims. These groups are mutually exclusive; if a funded diagnosis was identified, an unfunded diagnosis was not included in the search. To compare PPI therapy > 8 weeks before and after the PA was implemented, patients with continuous PPI therapy (any drug in PPI class,) without a gap in therapy > 15 days

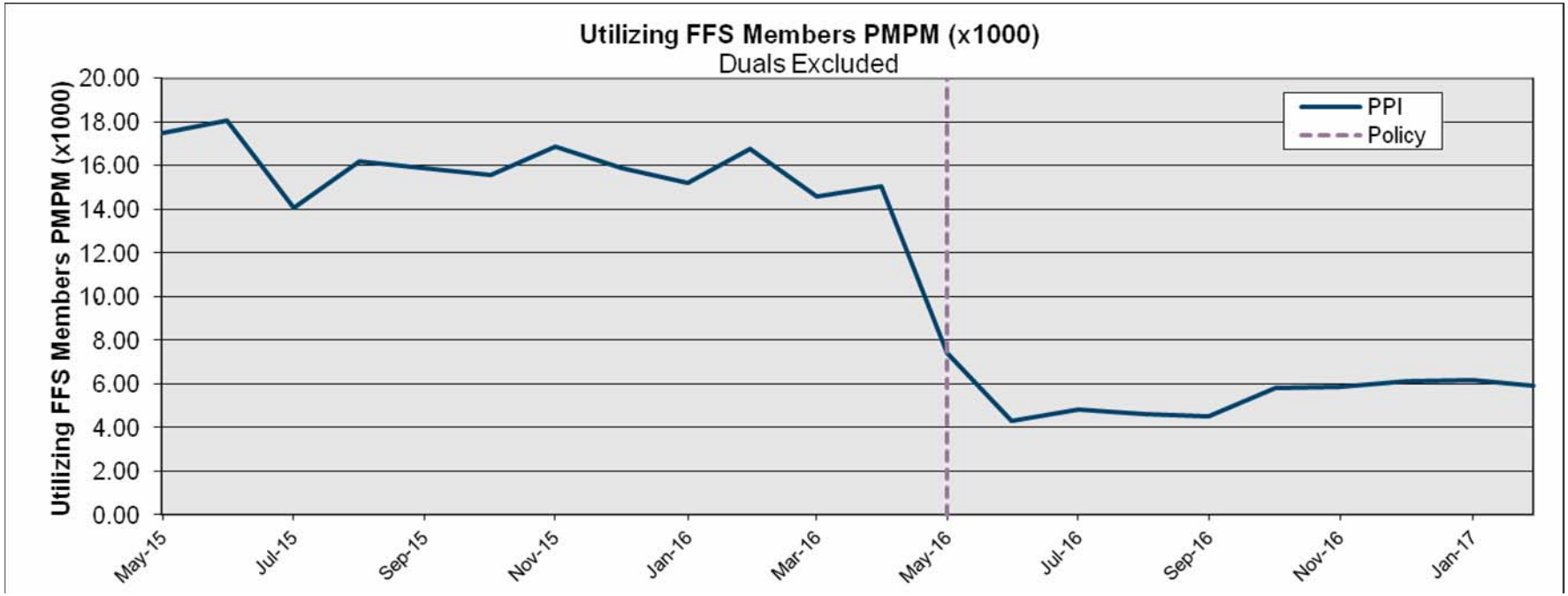
were included. Patients with less than 60 days of continuous therapy were excluded. This group was also flagged for any diagnosis in **Appendix 2** during the 12 months prior to the index claim.

Patients with a denied index claim, those who did not receive a PPI within 14 days, between 15 and 90 days, or who never received the drug were identified within FFS and CCO claims. Those who never received the drug with an ICD-9 or ICD-10 diagnosis for a severe condition listed in **Appendix 2**, were identified.

Results:

Figure 1 shows the utilization of PPIs by FFS per member per month (PMPM) from June 2015 to March 2017. A significant decrease in utilization occurred near June 2016 following the PA policy implementation (from 15 PMPM to 7.4 PMPM).

Figure 1: Utilization of PPIs: Unique patients per 10,000 members per month



Demographics of FFS members in the control and study groups are listed in Table 1. A total of 1,310 IEs were identified in the control group and 1,390 IEs were identified in the study group. The majority of FFS members in both the control and study groups (approximately 88% in both groups) had a mean age of 19-64 years. The percentage of patients < 19 years old and > 64 years old were similar in both groups. The amount of females in each group was similar as well (69.4% in the control group and 62.9% in the study group). There were significantly less paid claims for therapy > 8 weeks in the study group (12.1%) compared to the control group (30.4%). There were more claims for H2As or antacids in the 90 days after the IE in the study group (71 total claims) compared to the control group (43 total claims). Within the study group, there were more H2A claims if the PPI IE was a denied claim.

Author: Melissa Smith, PharmD and Megan Herink, PharmD Date: May 2017

Table 1: Demographics

	Before PA (Control Group)						After PA (Study Group)					
	All Index Events		**Index Event Paid Claim**		**Index Event Denied Claim**		**All Index Events**		**Index Event Paid Claim**		**Index Event Denied Claim**	
N=	**1,310**		1,178	89.9%	132	10.1%	**1,387**		743	53.6%	644	46.4%
Mean age (range)	37.2	(0-87)	37.7	(3-87)	32.5	(0-64)	37.7	(0-73)	36.6	(2-73)	39.0	(0-66)
< 19 years	119	11.8%	119	9.1%	36	2.7%	164	11.8%	99	7.1%	65	4.7%
19-64 years	1,051	87.6%	1,051	80.2%	96	7.3%	1,216	87.7%	641	46.2%	575	41.7%
> 64 years	8	0.6%	8	0.6%	0	0.0%	7	0.5%	3	0.2%	4	0.3%
Female	909	69.4%	816	62.3%	93	7.1%	872	62.9%	461	33.2%	411	29.6%
White	498	38.0%	441	33.7%	57	4.4%	360	26.0%	182	13.1%	178	12.8%
Therapy > 8 Weeks	400	30.5%	398	30.4%	2	0.2%	178	12.8%	168	12.1%	10	0.7%
FFS or CCO H2A claim in 90 days after IE	35	2.7%	25	1.9%	10	0.8%	60	4.3%	18	1.3%	42	3.0%
FFS or CCO Antacid claim in 90 days after IE	8	0.6%	8	0.6%	0	0.0%	11	0.8%	8	0.6%	3	0.2%

Table 2 compares associated diagnoses in the control and study groups. Of the 1,310 IEs identified in the control group, the majority (89.9%) were paid claims. Of the 1,387 IEs identified in the study group, following PA implementation, there were 743 (53.6%) paid claims and 644 (46.4%) denied claims. Only 2 IEs in the study group were for severe funded conditions, both of which were paid claims. There were no claims for severe funded conditions in the control group. Four hundred thirty-six claims (33.3%) in the control group were for funded conditions compared to 278 claims (20%) in the study group. However, there was a larger number of IEs without diagnoses identified in the study group (77%), compared to the control group (57.3%). Of the 436 IEs for funded conditions, 283 of these were for esophageal reflux or esophagitis < 8 weeks duration, with less IEs for this indication in the study group (63 of 276; 4.5%). There were more IEs for PPIs for esophageal reflux or esophagitis > 8 weeks duration in the control group (7.9%) compared to the study group (0.4%). All of these were paid claims in both groups.

Author: Melissa Smith, PharmD and Megan Herink, PharmD

Date: May 2017

Table 2: Use of PPIs based on diagnoses

	Before PA (Control Group)						After PA (Study Group)					
	All Index Events		Index Event Paid Claim		Index Event Denied Claim		All Index Events		Index Event Paid Claim		Index Event Denied Claim	
N=	1,310		1,178	89.9%	132	10.1%	1,390		742	53.4%	648	46.6%
Funded (Severe conditions)	**0**	**0.0%**		**0.0%**		**0.0%**	**2**	**0.1%**	**2**	**0.1%**		**0.0%**
Malignant mast cell tumors	0	0.0%		0.0%		0.0%	1	0.1%	1	0.1%		0.0%
Neoplasm of uncertain behavior of other and unspecified endocrine glands	0	0.0%		0.0%		0.0%	1	0.1%	1	0.1%		0.0%
Multiple endocrine neoplasia (MEN) type I	0	0.0%		0.0%		0.0%	0	0.0%		0.0%		0.0%
Zollinger-Ellison	0	0.0%		0.0%		0.0%	0	0.0%		0.0%		0.0%
Funded	**436**	**33.3%**	**384**	**29.3%**	**52**	**4.0%**	**278**	**20.0%**	**142**	**10.2%**	**136**	**9.8%**
GI Ulcers; Gastritis; Duodenitis; GI hemorrhage	194	14.8%	182	13.9%	12	0.9%	216	15.6%	121	8.7%	95	6.8%
H. pylori infection	24	1.8%	21	1.6%	3	0.2%	19	1.4%	12	0.9%	7	0.5%
Perforation of esophagus	0	0.0%		0.0%		0.0%	0	0.0%		0.0%		0.0%
Stricture and stenosis of esophagus	6	0.5%	6	0.5%		0.0%	12	0.9%	3	0.2%	9	0.6%
Barrett's esophagus with dysplasia; Cancer of esophagus	13	1.0%	12	0.9%	1	0.1%	4	0.3%	1	0.1%	3	0.2%
Barrett's esophagus without dysplasia	0	0.0%		0.0%		0.0%	9	0.6%	3	0.2%	6	0.4%
Esophageal reflux; Esophagitis (< 8 weeks duration)	283	21.6%	241	18.4%	42	3.2%	63	4.5%	20	1.4%	43	3.1%
Unfunded	**123**	**9.4%**	**121**	**9.2%**	**2**	**0.2%**	**39**	**2.8%**	**24**	**1.7%**	**15**	**1.0%**
Esophageal reflux; Esophagitis (> 8 weeks duration)	103	7.9%	103	7.9%		0.0%	5	0.4%	5	0.4%		0.0%
Esophageal spasm; Diverticulum of esophagus	11	0.8%	11	0.8%		0.0%	22	1.6%	11	0.8%	11	0.8%
Dyspepsia	18	1.4%	16	1.2%	2	0.2%	12	0.9%	10	0.7%	2	0.1%
Dyskinesia of esophagus	2	0.2%	2	0.2%		0.0%	3	0.2%	1	0.1%	2	0.1%
None of the Above	**751**	**57.3%**	**673**	**51.4%**	**78**	**6.0%**	**1,068**	**77.0%**	**575**	**41.5%**	**493**	**35.5%**

Table 3 highlights the disposition of denied claims in both the control and study groups. Of the 132 denied claims in the control group, 38 (28.8%) received the drug (through FFS or CCOs) within 14 days and 10 (7.6%) received the drug within 15 to 90 days. Of the 644 denied claims in the study group, 132 (20.5%) received the drug within 14 days and 124 (19.3%) received the drug within 15 to 90 days. There were 84 IEs in the control group and 388 in the study group who never received the drug, however none of these in either group had a prior severe condition. Table 4 shows the majority of patients with a denied claim never followed through with a PA request in both the control group (n=107; 81.1%) and study group (n=468; 72.7%). This is similar to results from previous policy evaluations.

Table 3: Disposition of denied claims (both FFS and CCO)

Before PA (Control Group)

			Days to Claim	
Patients with Denied Pharmacy Claim	**132**	**%**	**Avg**	**(min-max)**
Receive drug within 14 days	38	28.8%	3.7	(0-14)
Receive drug between 15 and 90 days	10	7.6%	38	(17-81)
Never receive drug (or more than 90 days)	84	63.6%	n/a	n/a
- Never receive a drug - with prior severe condition	0			

After PA (Study Group)

			Days to Claim	
Patients with Denied Pharmacy Claim	**644**	**%**	**Avg**	**(min-max)**
Receive drug within 14 days	132	20.5%	5.0	(0-14)
Receive drug between 15 and 90 days	124	19.3%	42	(15-89)
Never receive drug (or more than 90 days)	388	60.2%	n/a	n/a
- Never receive a drug - with prior severe condition	0			

Table 4: PA Status for Patients with Denied Pharmacy Claim as Index Event

PA Requested within 14 days of Denied Claim

	Control Group		Study Group	
Patients with Denied Claim =	132		644	
PA Requested	25	18.9%	176	27.3%
Approved	25	18.9%	174	27.0%
Denied	0	0.0%	2	0.3%
No PA Request	107	81.1%	468	72.7%

Discussion:

A decrease in PPI utilization was observed following the PA criteria implementation in June 2016, which limits the use of PPIs for esophageal reflux and esophagitis to no more than 8 weeks. The PA criteria successfully limited the use of PPIs for this indication as illustrated by the decrease in IEs for esophageal reflux and esophagitis for > 8 weeks between the control and study groups (7.9% vs. 0.4%). There were significantly less paid claims for therapy > 8 weeks in the study group (12.8%) compared to the control group (30.5%). There was overall low utilization for severe conditions and the PA criteria did not result in a barrier to therapy for those with a severe funded condition. There were a large number of events in both groups without a correlating diagnosis (57.3% in the control group and 77% in the study group). This is somewhat expected for this class of medications, as they are often continued following hospital admissions or used for gastrointestinal ulcer prophylaxis with other agents, such as non-steroidal anti-inflammatory drugs. There were limited claims in FFS and CCO drug claims for H2As or antacids after IEs and there was no difference in claims between the control and study groups. Therefore, it does not appear that the PA criteria resulted in an increase in these other classes.

Similar to what has been seen in other policy evaluations, the impact of having a PA policy in place has a significant impact on utilization. The majority of denied claims were not followed through with a PA request. However, for those who never received the drug, there were no patients who had a severe condition.

Limitations:

The data that was collected and analyzed were claims data, which makes it difficult to connect a specific diagnosis with the medication prescribed. Assumptions are made as to whether the medication is being prescribed for a certain diagnosis. This evaluation only looked at the first claim, or IE. More inclusive data would also include recurring claims for the medications of interest.

Another limitation of this review is the majority of the medications included for review are also available over the counter, without a prescription. If a patient is purchasing a PPI, H2A, or antacid over the counter, that data will not be included in the claims data collected. The high percentage of patients who never received the drug following a denied claim (63.6% in the control group and 61.9% in the study group), may be increased due to the availability of PPIs over the counter.

Additionally, due to the time constraints of this evaluation, data regarding other potential consequences of the PA criteria, such as hospitalization due to GERD symptoms, could not be included. In further analyses, this may be a potential area to review in order to determine additional impact of the PA criteria.

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Author: Melissa Smith, PharmD and Megan Herink, PharmD Date: May 2017

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Appendix 1: Codes identifying PPI/H2A/Antacid in claims data

HSN	Generic
Drug Class: PPI	
004673	OMEPRAZOLE
011115	OMEPRAZOLE MAGNESIUM
033512	OMEPRAZOLE/SODIUM BICARBONATE
022008	PANTOPRAZOLE SODIUM
021607	ESOMEPRAZOLE MAGNESIUM
008993	LANSOPRAZOLE
036085	DEXLANSOPRAZOLE
018847	RABEPRAZOLE SODIUM
Drug Class: H2A	
004520	RANITIDINE HCL
004518	CIMETIDINE
009793	CIMETIDINE HCL
004521	FAMOTIDINE
021332	FAMOTIDINE/CA CARB/MAG HYDROX
004522	NIZATIDINE
Drug Class: Antacid	
001163	CALCIUM CARBONATE
001153	CALCIUM CARB/MAGNESIUM HYDROX
001162	CALCIUM CARBONATE/SIMETHICONE
001179	ALUMINUM HYDROXIDE
001172	MAG CARB/AL HYDROX/ALGINIC AC
001168	MAG HYDROX/AL HYDROX/SIMETH
001173	MAGNESIUM CARBONATE/AL HYDROX
001169	MAGNESIUM, ALUMINUM HYDROXIDE
001142	MG TRISILICATE/ALH/NAHCO3/AA
001152	CALCIUM CARB/MAG HYDROX/SIMETH
001185	DIHYDROXYALUMINUM SODIUM CARB
001170	MAGNESIUM HYDROXIDE

Appendix 2: PPI Diagnoses with correlating OHP funding line

Unfunded Diagnoses

Diagnosis	Diagnosis Code		OHP Funding Line
	ICD-9	ICD-10	
Esophageal reflux (> 8 weeks duration); Esophagitis (> 8 weeks duration)	530.10 – 530.19; 530.81	K20.8-K20.9; K21.0-K21.9	516
Esophageal spasm; Diverticulum of esophagus, acquired; Asymptomatic diaphragmatic hernia	530.20; 530.6x; 553.3x	K22.10; K22.5; K44.9	516
Dyspepsia	536.8x	K30	531
Dyskinesia of esophagus	530.5x	K22.4	664

Funded Diagnoses

Diagnosis	Diagnosis Code		OHP Funding Line
	ICD-9	ICD-10	
GI Ulcers; Gastritis; Duodenitis; GI hemorrhage; H. pylori infection (2 weeks duration) (Ulcer of esophagus; Gastro-esophageal laceration-hemorrhage syndrome; Esophageal hemorrhage; Esophageal leukoplakia; Unspecified disorder of esophagus; Gastric ulcer; Duodenal ulcer; Peptic ulcer, site unspecified; Gastrojejunal ulcer; Gastritis and duodenitis)	041.86x; 456.1x-456.20; 456.8x; 530.21; 530.7x; 530.82; 530.83; 530.89-535.71; 777.8	B96.81; I85.00-I85.11; I86.4; K22.11; K22.6; K22.8; K25.0 - K29.91; P78.82	60
Perforation of esophagus	530.4x	K22.3	231
Cancer of esophagus; Barrett's esophagus with dysplasia	150.0x-150.9x; 171.5x; 230.0x; 284.11; 530.85; V10.03	C15.3-C15.9; C49.A1; D00.0; D61.810; K22.710-K22.719; Z85.01	319
Achalasia and cardiospasm; Stricture and stenosis of esophagus	530.0x; 530.3x	K22.0; K22.2	383
Barrett's esophagus without dysplasia	530.85	K22.70	385
Esophageal reflux (8 weeks duration); Esophagitis (8 weeks duration)	530.10 – 530.19; 530.81	K20.8-K20.9; K21.0-K21.9	385
Severe Conditions			
Malignant mast cell tumors	202.6x	C96.2	162
Neoplasm of uncertain behavior of other and unspecified endocrine glands	237.4x	D44.0; D44.2	215, 229
Multiple endocrine neoplasia (MEN) type I	258.01	E31.21	260
Zollinger-Ellison	251.5x	E16.4	347

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Appendix 3: Prior Authorization Criteria

Proton Pump Inhibitors (PPIs)

Goals:

- Promote PDL options
- Restrict PPI use to patients with OHP-funded conditions

Requires PA:

- Preferred PPIs beyond 60 days' duration
- Non-preferred PPIs

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org
- Individual components for treatment of *H. pylori* that are preferred products

Approval Criteria		
1. What diagnosis is being treated?	Record ICD9 code.	
2. Is the request for a preferred PPI?	Yes: Go to 5	No: Go to 3
3. Is the treating diagnosis an OHP-funded condition (see **Table**)?	Yes: Go to 4	No: Pass to RPh; deny, not funded by OHP.
4. Will the prescriber consider changing to a preferred PPI product? Message: Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Pharmacy and Therapeutics (P&T) Committee.	Yes: Inform prescriber of covered alternatives.	No: Go to 5
5. Has the patient already received 68 days of PPI therapy for either of the following diagnoses: • GERD [esophageal reflux (53081), esophagitis (53010 – 53019)] or • *H. pylori* infection (04186)?	Yes: Go to 6	No: Go to 7
6. Does the patient have recurrent, symptomatic erosive esophagitis that has resulted in previous emergency department visits or hospitalizations?	Yes: Approve for 1 year	No: Pass to RPh; not funded by OHP. RPh may approve a quantity limit of 30 doses (not to exceed the GERD dose in the **Table**) over 90 days if time is needed to taper off PPI. Note: No specific PPI taper regimen has proven to be superior. H2RAs may be helpful during the taper. Preferred H2RAs are available without PA.

7. Does the patient have a history of gastrointestinal ulcer or bleed and have one or more of the following risk factors? • Age 65 years or older • Requires at least 3 months of continuous daily: i. Anticoagulant, ii. Aspirin or non-selective NSAID, or iii. Oral corticosteroid	Yes: Approve for 1 year	No: Go to 8
8. Are the indication, daily dose and duration of therapy consistent with criteria outlined in the **Table**? Message: OHP-funded conditions are listed in the **Table**.	Yes: Approve for recommended duration.	No: Pass to RPh. Deny; medical appropriateness or not funded by OHP Message: Patient may only receive 8 weeks of continuous PPI therapy.