WEST VIRGINIA Medicaid

Gastrointestinal Agents DUE

Educational RetroDUR Mailing	☑Initial Study ❑Follow – up /Restudy

Executive Summary

Purpose:	To promote safe, cost-effective use of anti-secretory agents in the management of gastrointestinal disorders, including peptic ulcer disease (PUD) and gastroesophageal reflux disease (GERD).	
Why Issue was Selected:	Gastrointestinal (GI) agents account for a significant portion of the drug budget for most payors. From 07/01/12 – 09/30/12, GI agents ranked third among therapy classes, by the total amount paid, for West Virginia Medicaid..	
Program Specific Information:	Performance Indicators	Candidates
	• Extended duration of H_2 receptor antagonist or proton pump inhibitor therapy with unknown diagnosis	2,862
	• Extended duration of proton pump inhibitor therapy in patients with PUD	212
	• Duplicate anti-secretory therapy	101
	• Increased risk of adverse event: Concomitant H_2 receptor antagonist and NSAID therapy in patients with PUD	7
	• Increased risk of adverse event: Concomitant anti-secretory therapy and NSAID therapy in patients with PUD from multiple prescribers	35
	• Increased risk of adverse event: Concomitant H_2 receptor antagonist and NSAID therapy in patients at high risk for PUD	167
	• Increased risk of adverse drug event: Bisphosphonate therapy in patients with GERD	389
	• Increased risk of adverse drug event: Medications potentially aggravating GERD	12,974
	• Twice daily dosing of proton pump inhibitors	738
Setting & Population:	All patients receiving a proton pump inhibitor (PPI) or H2 receptor antagonist (H2RA).	
Types of Intervention:	Cover letter with individual patient profiles.	
Main Outcome Measures:	The results of this intervention will be measured six months post-intervention. Targeted patient cases will be re-examined to determine whether changes in therapy have been made. The baseline number of patients identified with	

	problematic therapy will be compared to the rates at six months post-intervention.
Anticipated Results:	• Decrease in the number patients receiving unnecessary H2RA or PPI therapy. • Decrease in the number of patients receiving duplicate anti-secretory agents. • Decrease in the number of patients potentially at risk for NSAID-induced ulcers. • Decrease in the number of patients receiving medications potentially aggravating their symptoms of GERD. • Decrease in the number of patients receiving twice daily proton pump inhibitors.

Performance Indicator #1: Extended Duration of H2RA or PPI Therapy with Unknown Diagnosis

Why has this indicator been selected?	Anti-secretory therapy is indicated for 8 weeks or less in the majority of patients with PUD with maintenance therapy used in patients with a high-risk of ulcer recurrence (e.g. recurrent or H. pylori negative ulcers, or patients with a history of ulcer complications such as bleeding or perforation).[1,2] Due to the high rate of placebo response and variable efficacy of drug regimens for other GI diagnoses like non-ulcer dyspepsia, periodic reevaluation of anti-secretory therapy and trial off medication, if appropriate, should be considered.
How will the patients be selected ?	
Candidates (denominator):	Patients receiving an H2RA or PPI without a diagnosis of PUD or any condition requiring longer lengths of therapy.
Exception criteria (numerator):	Candidates receiving H2RAs or PPIs for greater than 12 weeks.

Performance Indicator #2: Extended Duration of PPI Therapy in Patients with PUD

Why has this indicator been selected?	PPIs effectively heal peptic ulcers in 4 to 8 weeks and are not generally indicated for maintenance therapy in PUD, except for refractory cases. Currently H.pylori testing is recommended in all patients with a history of, or active PUD. Treating patients testing positive for H.pylori has been shown to decrease ulcer recurrence greater than acid suppression alone.[2,3]
How will the patients be selected ?	
Candidates (denominator):	Patients receiving a PPI for greater than 12 weeks within the last 16 weeks of claims history.
Exception criteria (numerator):	Candidates receiving a PPI for greater than 12 weeks without history of PUD, diagnosis of H.pylori, and/or treatment for H.pylori.

Performance Indicator #3: Duplicate Anti-Secretory Therapy

Why has this indicator been selected?	Within-class (H2RA or PPI) duplicate therapy increases cost without increasing efficacy. Patients may have continued therapy when therapy is changed from a PPI to H2RA (or vice versa) due to misunderstanding

	directions. A minority of patients who continue to have nighttime symptoms despite PPI therapy may benefit from this combination (daytime PPI and nighttime H2RA), but there is no evidence of improved long-term efficacy[4] When multiple prescribers are involved, coordination of care issues may need to be resolved. Additionally, combination therapy with a PPI and H2RA is not routinely recommended.
How will the patients be selected ?	
Candidates (denominator):	Patients receiving an H2RA or PPI within in the last 60 days of claims history.
Exception criteria (numerator):	Candidates receiving more than one drug within each class; candidates receiving both a PPI and H2RA from >1 prescriber.

Performance Indicator #4: Increased Risk of Adverse Drug Event: Concomitant H2RA and NSAID Therapy in Patients with PUD

Why has this indicator been selected?	NSAID use is one of the critical factors underlying recurrent or refractory ulceration. Every effort should be made to reduce or eliminate NSAID use in patients with PUD. Additionally, H2RAs are not recommended for the prevention of NSAID-induced ulcers.[1,5,6]
How will the patients be selected ?	
Candidates (denominator):	Patients who received a NSAID and an H2RA concurrently within the last 60 days of claims history unless they received misoprostol, PPI/NSAID combination product, or a COX-2 inhibitor from the same prescriber.
Exception criteria (numerator):	Candidates with a history of PUD receiving an H2RA.

Performance Indicator #5: Increased Risk of Adverse Drug Event: Concomitant Anti-Secretory Agent and NSAID Therapy in Patients with PUD from Multiple Prescribers

Why has this indicator been selected?	NSAID use is one of the critical factors underlying recurrent or refractory ulceration. Every effort should be made to reduce or eliminate NSAID use in patients with PUD. When multiple prescribers are involved, coordination of care issues may need to be resolved.[1,5,6]
How will the patients be selected ?	
Candidates (denominator):	Patients who received a NSAID and anti-secretory agent concurrently within the last 60 days of claims history.
Exception criteria (numerator):	Candidates with history of PUD receiving a PPI or H2RA from a different prescriber than the NSAID prescriber.

Performance Indicator #6: Increased Risk of Adverse Drug Event: Concomitant H2RA and NSAID Therapy in Patients at High Risk for a NSAID-Induced Ulcer

Why has this indicator been selected?	NSAID use is an important factor in the development of PUD. Several factors have been identified that place patients with NSAID use at risk for GI complications. Every effort should be made to reduce or eliminate NSAID use in patients with risk factors for the development of NSAID-induced ulcers. These include a history of ulcer or GI hemorrhage, age greater than 60 years, high dosage of NSAID or use of multiple NSAIDs, and concurrent use of corticosteroids or anticoagulants. Additionally, H2RA are not recommended for the prevention of NSAID-induced ulcers.[5,6]
How will the patients be selected ?	
Candidates (denominator):	Patients who received an H2RA and NSAID concurrently within the last 60 days of claims history unless they have received misoprostol, PPI/NSAID combination product, or a COX-2 inhibitor from the same prescriber.
Exception criteria (numerator):	Candidates having risk factors (listed above) for the development of NSAID-induced ulcers that are receiving a H2RA.

Performance Indicator #7: Increased Risk of Adverse Drug Event: Bisphosphonate Therapy in Patients with GERD

Why has this indicator been selected?	Oral bisphosphonate therapy has been associated with dysphagia, esophagitis, and upper esophageal ulcers and should be used with caution in patients with upper GI disorders. Avoiding use of these medications in patients with GERD and/or proper patient medication administration may reduce the risk of potentially worsening symptoms associated with concomitant use.[7-10]
How will the patients be selected ?	
Candidates (denominator):	Patients who received an oral bisphosphonate within the last 45 days of claims history.
Exception criteria (numerator):	Candidates with a history of GERD in the last 2 years receiving an oral bisphosphonate.

Performance Indicator #8: Increased Risk of Adverse Drug Event: Drugs Potentially Aggravating GERD

Why has this indicator been selected?	A number of factors have been reported to worsen the symptoms of GERD, including certain medications. Avoiding use of these medications in patients with GERD, if possible, may reduce the risk of potentially worsening symptoms associated with concomitant use.[11]
How will the patients be	

selected ?	
Candidates (denominator):	Patients with a submitted diagnosis of GERD in the last 2 years.
Exception criteria (numerator):	Patients receiving a medication reported to worsen GERD symptoms. (listed in Appendix, Table 2)

Performance Indicator #9: Twice Daily Dosing of PPIs

Why has this indicator been selected?	Current literature does not strongly support the use of higher than standard doses of PPIs for most indications. Additionally, the majority of efficacy studies for PPIs utilize once daily dosing. If inadequate symptom response is obtained with once daily dosing in patients with GERD, twice daily dosing is recommended. Twice daily dosing is currently recommended in the treatment of H.pylori and in Zollinger Ellison syndrome for all of the PPIs except rabeprazole, lansoprazole, and dexlansoprazole.[3,4,12]
How will the patients be selected ?	
Candidates (denominator):	Patients receiving a proton pump inhibitor in the last 30 days.
Exception criteria (numerator):	Patients receiving 2 doses of a PPI daily. Patients receiving 2 doses of omeprazole/esomeprazole/pantoprazole with a diagnosis of Zollinger Ellison syndrome are excluded since these PPIs are indicated to be dosed twice daily for this indication.

References

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Appendixes

Table 1. American College of Gastroenterology Recommended Treatment Regimens for *H. Pylori* Infection[3]

	Regimen	Total Duration	FDA Approved
H2RA + BMT	**B**SS 525 mg QID x 14d **M**etronidazole 250 mg QID x 14d **T**etracycline 500 mg QID x 14d H2RA QD x 28d	28 days	Yes
	Helidac® *(BMT components listed above packaged together)*		
1. PPI + BMT	**B**SS 525 mg QID x 10-14d **M**etronidazole 250 mg QID x 10-14d **T**etracycline 500 mg QID x 10-14d Standard dose PPI* QD or BID x 10-14d	10-14 days	No†
	Pylera™ (BMT components below packaged together dosed at 3 capsules bid with omeprazole) Bismuth subcitrate potassium 420 mg QID x 10d Metronidazole 375 mg QID x 10d Tetracycline 375 mg QID x 10d Omeprazole 20 mg BID x 10d	10 days	Yes
2. PPI + AC	**A**moxicillin 1 gram BID x 10-14d **C**larithromycin 500 mg BID x 10-14d Standard dose PPI* BID x 10-14d	10-14 days	Yes**
	Prevpac® (amoxicillin, clarithromycin & lansoprazole components listed above packaged together; 10 or 14 day regimen)	10-14 days	Yes
PPI + MC	**M**etronidazole 500 mg BID x 10-14d **C**larithromycin 500 mg BID x 10-14d Standard dose PPI* BID x 10-14d	10-14 days	No

H2RA: H2-receptor antagonist; PPI: proton pump inhibitor; BSS: bismuth subsalicylate

† 10 day regimen approved by FDA. Continue omeprazole 20 mg QD for an additional 18 days in the presence of active ulcer disease.

*Lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, rabeprazole 20 mg, esomeprazole 40 mg (esomeprazole is given QD)

**Omeprazole, esomeprazole, lansoprazole, and rabeprazole given 40 mg daily are FDA approved. The following twice daily doses of PPIs are considered equivalent: omeprazole 20 mg, lansoprazole 30 mg, pantoprazole 40 mg, rabeprazole 20 mg, esomeprazole 20 mg.[24]

3. Table 2. Medications Potentially Aggravating GERD[11]

- α-adrenergic blockers
- Anticholinergic agents
- β2-adrenergic agonists
- Calcium channel blockers
- Diazepam
- Dopamine
- Estrogen
- Meperidine
- Morphine
- Progesterone
- Theophylline
- Tricyclic antidepressants