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Oregon Health Authority

Quality Improvement Proposal: Combination Inhaler Policy

In January 2011, the Oregon Medicaid fee-for-service (FFS) program implemented a prior authorization (PA)[1] for the use of combination inhalers (Appendix 1). A meta-analysis showing an increase in asthma exacerbations with combination inhaler treatment compared to inhaled corticosteroids (ICS) alone (OR 3.65 95% CI 1.39-9.55).[2] The PA was designed to promote appropriate use of asthma controllers according to the most recent evidence-based guidelines.[3,4]

A recent policy evaluation found that those patients who encountered a PA requirement had an increased adjusted odds of experiencing either an emergency department or hospital claim for asthma or COPD within 60 days versus those who did not experience the PA (OR 2.26 95% CI 1.01 - 5.0).[5] Patients with providers requesting the PA had higher asthma disease severity indicating that the purpose of the PA was successful. But, a concerning finding was that less than a third of patients with claims requiring a PA had one requested by a provider.

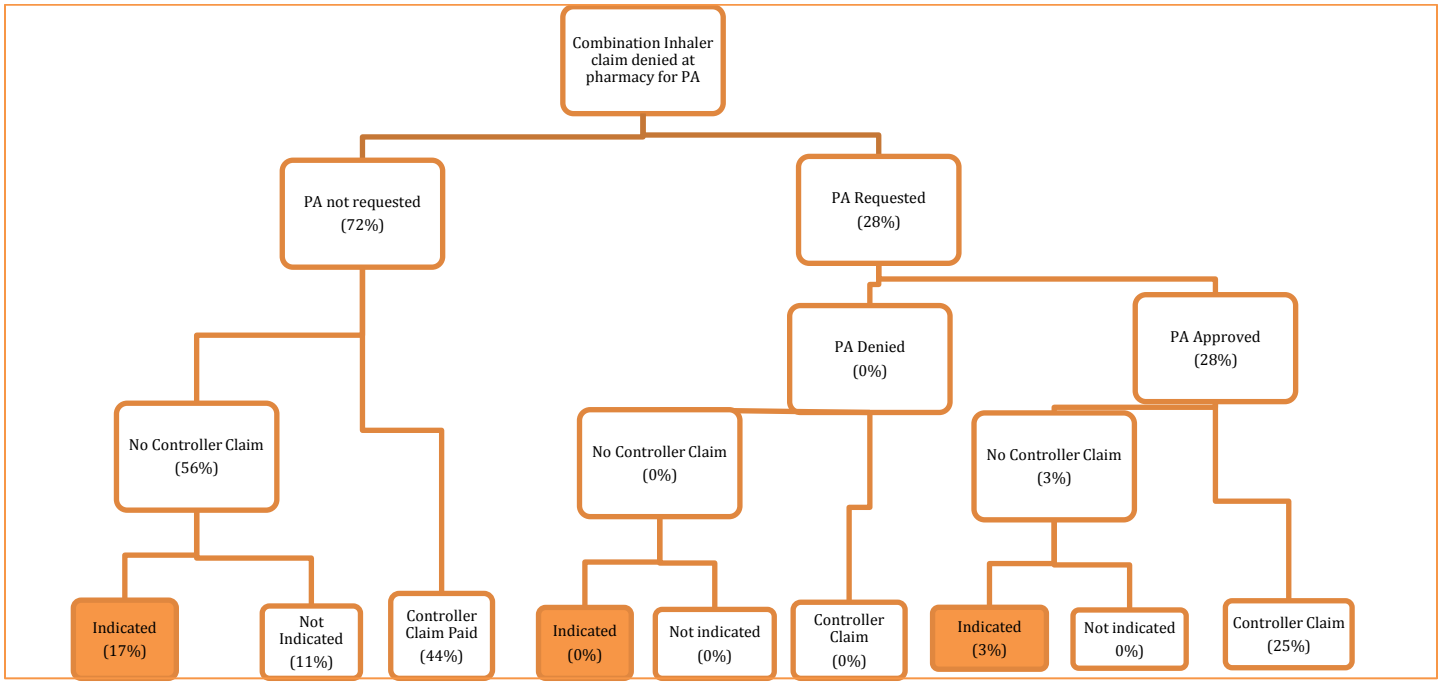
As a result of these findings, this quality improvement project was initiated. The primary objective of this project was to target patients at greatest risk for an adverse outcome associated with the PA policy and develop interventions to prevent them.

Methods:
A schematic was developed using the data from the previous evaluation to identify, categorize and quantify the patients likely at increased risk for adverse outcomes (Figure 1).[2] Patients considered at most risk were those without any paid controller claim within 60 days when it was indicated and despite the PA status. Patients were classified as "indicated" if they had any of the "Disease Severity Indicators" in the year prior to the index PA event in the previous evaluation. Approximately 20% of patients encountering the PA met the "indicated" criteria and did not have a paid controller claim.

Patients were selected for intervention immediately following the claim load into the database each week on Tuesdays and using criteria approximating the "indicated" definitions. Patients were included if they had a *denied* FFS combination inhaler claim within 17-24 days prior with Explanation of Benefit (EOB) code equal to "1056-Prior Authorization Required. " They were excluded if they carried a concurrent EOB of "2017 - Patient enrolled in MCO." EOB 2017 indicated the patient was enrolled in a Medicaid managed care organization (i.e. Coordinated Care Organization) and the claim was submitted to the wrong payer. Patients were excluded if they had a paid FFS or encounter claim for combination inhaler or alternative controller within 14 days after the denied claim. These patients do not need intervention. Patients were also excluded if they had no paid FFS or encounter claim for a short-acting beta-agonist and no prior claims with diagnosis codes for asthma (493.xx), COPD (491.2x, 492, 492.0, 492.8, 496, 506.4, 518.1, 518.2) or any controller medication within the

last 6 months, as it was assumed this indicated less severe disease and no need for intervention (See Table 1). Drugs were identified and classified using the criteria in Appendix 1.

Figure 1 – Schematic of patient disposition at 60 days from policy evaluation



The medical and pharmacy claim profiles of the intervention patients were then manually reviewed by a fourth year Doctor of Pharmacy student each week from June 14 thru July 4, 2014 to determine the accuracy of the selection criteria and assess what types of interventions could be made. The profiles included claims with service dates starting January 1, 2013 thru the present. Patients were placed in one of four categories and computer generated flags were created and manually checked during the reviews (Table 1). The four categories were: 1) Patients with COPD defined as paid FFS or encounter claim in prior 12 months with diagnosis codes 491.2x, 492, 492.0, 492.8, 496, 506.4, 518.1 or 518.2 or a paid FFS or encounter claim for anticholinergic inhaler or phosphodiesterase type 4 inhibitor , 2) Patients with asthma defined as paid FFS or encounter claim in prior 6 months with diagnosis code 493xx or a paid FFS or encounter claim for combination inhaler, inhaled corticosteroid , or leukotriene antagonist , 3) Patients with no FFS or encounter short-acting beta-agonist or controller claims and no medical claims with asthma or COPD diagnosis codes in prior 6 months or 4) Patients with only short-acting beta-agonist claims.

Data were collected from the manual reviews to determine workload and to direct implementation plans. Adjustments to the automated PA policy were made to approve patients at highest risk of adverse outcome (i.e. those with prior claims evidence COPD and moderate severity asthma). These changes were implemented on September 1, 2014. The far right column of Table 1 demonstrates the impact of that change.

An evaluation of the literature identified potential interventions to improve prescribing practices. Other Medicaid programs had success with retrospective letters mailed to physicians or letters targeting both physicians and pharmacists.[6] North Carolina Medicaid used a streamlined PA approval process to prompt

prescribing of preferred proton pump inhibitors and to reduce burden to both pharmacist and physicians seen with the traditional PA process.[7] The process allowed prescribers to document patient-specific approval criteria on a pre-printed prescription form. Both physicians and pharmacists reported a decrease in time required per patient with the streamlined program versus the traditional PA program and both preferred the streamlined PA method.[1] It was also successful at changing prescribing practice. The North Carolina model was adapted for the intervention patient in this project.

Results:

Analysis of the patients identified and reviewed each week revealed that only 32% of patients that experienced the PA had a combination inhaler or alternative controller within 14days (Table 1). This was significantly fewer than at 60 days in the prior evaluation (i.e. 69% from Figure 1). Of the remaining patients who did not get any controller within 14 days (68%), 22% probably were not appropriate for asthma controller therapy as there were no prior claims with asthma or COPD diagnoses and no prior claims for short-acting beta agonists or other controllers. Approximately 10% had prior claims evidence of a COPD diagnosis. Since the safety warnings for long-acting beta agonists do not apply to COPD treatment,the existing automatic PA criteria were modified to better identify these patients. Approximately 24% of patients had prior claims evidence of asthma with or without prior controller use. The existing automatic PA criteria were also modified to better identify these patients for automatic approval at the pharmacy. The remaining 12%, approximately 8 patients per week, with only a history of short-acting beta-agonist were targeted for retrospective review and intervention.

A proposed retrospective intervention was created and called the “Patient Safety Notice: Combination Inhaler” form (Appendix 2). It will be sent to prescribers auto-populated with patient information and prompting use of inhaled corticosteroid over combination inhalers. Prescribers will either return the form to the pharmacy or E-prescribe a new prescription for a preferred inhaled corticosteroid or, they will return fax the form, with exemption criteria documented by the physician, to the Medicaid PA desk where a PA will be approved and the pharmacy notified. This process was adapted from the North Carolina “MD Easy” form which was a pre-populated form that gave providers a choice of three options including: 1) switch to a preferred agent, 2) indicate patient exemption criteria for preferred agent, or 3) utilize the traditional PA process. They would select their preferred option and send the form back to the pharmacy. In the case of North Carolina, the pharmacy was provided a PA override code if appropriate documentation was obtained from the prescriber requesting the need for a non-preferred agent. In contrast, Oregon will not provide the pharmacy with the override code but instruct the providers to fax the form back to the PA desk if a combination inhaler is indicated for PA approval.

Table 1: Patient Selection and Categorization Summary

Patient Selection Flow	6/14/2014 n=	6/21/2014 n=	6/28/2014 n=	Total for all Weeks in June n=		8/30/2014 (after AutoPA adjustment) n=
1) Included patients with denied FFS combination inhaler claim with EOB 1056 – PA Required	102	83	70	255		33
2) Excluded patients with EOB 2017 (this indicates the patient was enrolled in a CCO at the time so the pharmacy billed the wrong insurance)	42	34	24	100		16
3) #1 - #2 = Patients who were affected by the PA policy	60	49	46	155	100%	17
4) Excluded patients with paid claim for combination inhaler or alternative controller within 14 days (no intervention needed)	23	14	13	50	32%	9
5) #3 - #4 = Patients affected by PA policy with no controller therapy	37	35	33	105	68%	8
Patient Categories						
1) Patients with no FFS or MCO short-acting beta-agonist claim, or select medical claims, in prior 6 months (patients that don't need intervention)	10	15	9	34	22%	3
2) Patients with COPD (patients that should be coded for auto-approval)	4	3	8	15	10%	0
3) Patients with prior claims evidence of asthma (patients that should be coded for auto-approval)	14	13	10	37	24%	0
4) Patients with only short-acting beta-agonists (intervention patients)	9	4	6	19	12%	5

Discussion:

This report describes a quality improvement process to address the increased OR of adverse outcomes observed in patients encountering a PA requirement for combination inhalers. Patients were candidates for intervention if they encountered the PA and were not prescribed an alternate controller agent. These patients were determined to be at greatest need of intervention because their asthma was likely poorly controlled which potentially prompted initial prescribing of a combination inhaler. Because these patients did not have a paid claim for a combination inhaler or an alternate controller, their risk of exacerbation or hospitalization is likely greater and warrants intervention. Only 32% of patients were found to have been prescribed any controller agent 17-24 days after encountering the PA.

Approximately 22% of the patients analyzed did not appear to be candidates for combination inhaler therapy. This was determined because their claims data did not have a diagnosis code for asthma, COPD or history of short-acting beta-agonist use. This would indicate that they are likely experiencing less severe symptoms and appropriate initial therapy based on guideline recommendations would include short-acting beta-agonist for as needed use and potentially an inhaled corticosteroid, first line, if symptoms were considered moderate

persistent. It was also noted, there were a small number of patients whose claims history indicated COPD (10%) or asthma (24%) which, based on the PA electronic approval criteria, should have warranted automatic approval. It was discovered that the electronic approval process did not look back far enough to identify COPD and asthma claim history. With this information, adjustment of the approval criteria was indicated and implemented.

The remaining 12% of patients analyzed are those in need of targeted intervention. These patients had a diagnosis of asthma and had previously been prescribed a short-acting beta-agonist. They encountered the PA but were not provided an alternate controller agent.

Recommendation:

1) Implement a weekly review of patients encountering the combination inhaler PA and that meet the criteria established above for intervention. Send prescribers the Patient Safety Notice: Combination Inhaler (Appendix 2) to insure patients a controller, if indicated.
2) Evaluate this policy in 1 year.

References:

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2. Salpeter SR, Wall AJ, Buckley NS. Long-acting Beta-Agonists with and without Inhaled Corticosteroids and Catastrophic Asthma Events. *Am. J. Med.* 2010;123(4):322-328.e2. doi:10.1016/j.amjmed.2009.07.035.

3. US Department of Health and Human Services, National Heart, Lung and Blood Institute. National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma; 2007. *US Dep. Health Hum. Serv. Natl. Heart Lung Blood Inst.* 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf. Accessed May 23, 2012.

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5. Ketchum KL. Policy Evaluation: Prior authorization of combination inhalers for asthma. 2014.

6. Ho M-J, Venci J. Improving the success of mailed letter intervention programs to influence prescribing behaviors: a review. *J. Manag. Care Pharm. JMCP* 2012;18(8):627–649. http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=15780. Accessed September 30, 2014.

7. Vann JCJ, Christofferson S, Humble CG, Wegner SE, Feaganes JR, Trygstad TK. Pharmacist and physician satisfaction and rates of switching to preferred medications associated with an instant prior authorization program for proton pump inhibitors in the North Carolina Medicaid program. *J Manag Care Pharm* 2010;16(4):250–63.

Appendix 1 – Drug identification and classification specifications

Combination Inhalers

HSN	Route Desc	Generic
019963	INHALATION	FLUTICASONE/SALMETEROL
021993	INHALATION	BUDESONIDE/FORMOTEROL FUMARATE
037050	INHALATION	MOMETASONE/FORMOTEROL
040319	INHALATION	FLUTICASONE/VILANTEROL

Alternative controllers:

Group	HSN	Route Desc	Generic
ANTICHOLINERGIC	000057	INHALATION	IPRATROPIUM BROMIDE
ICS	000070	INHALATION	BECLOMETHASONE DIPROPIONATE
ICS	000072	INHALATION	FLUNISOLIDE
ICS	003329	INHALATION	MOMETASONE FUROATE
ICS	006545	INHALATION	BUDESONIDE
LABA	007393	INHALATION	SALMETEROL XINAFOATE
ICS	007873	INHALATION	FLUTICASONE PROPIONATE
ANTICHOLINERGIC	009040	INHALATION	IPRATROPIUM/ALBUTEROL SULFATE
LABA	010747	INHALATION	FORMOTEROL FUMARATE
ANTICHOLINERGIC	024024	INHALATION	TIOTROPIUM BROMIDE
ICS	032691	INHALATION	CICLESONIDE
LABA	034087	INHALATION	ARFORMOTEROL TARTRATE
LABA	037011	INHALATION	INDACATEROL MALEATE
P4I	037123	ORAL	ROFLUMILAST
ANTICHOLINERGIC	039528	INHALATION	ACLIDINIUM BROMIDE
LTA	012321	ORAL	ZILEUTON
LTA	016911	ORAL	MONTELUKAST SODIUM
LTA	011815	ORAL	ZAFIRLUKAST

Short-Acting beta-agonists:

HSN	RouteDesc	Generic
019858	INHALATION	LEVALBUTEROL HCL
002058	INHALATION	METAPROTERENOL SULFATE
002073	INHALATION	ALBUTEROL SULFATE
002075	INHALATION	BITOLTEROL MESYLATE
002076	INHALATION	PIRBUTEROL ACETATE
032814	INHALATION	LEVALBUTEROL TARTRATE

Appendix 2 – Form

Patient Safety Notice: Combination Inhaler
ACTION NEEDED

This notice was generated by Oregon Medicaid because your NPI was linked to a denied combination inhaler claim for this patient AND no prior authorization was requested and no alternate controller was filled. For questions call: (888) 202-2126

- Current evidence and the National Heart, Lung, and Blood Institute Guidelines for the Diagnosis and Management of Asthma indicate patients with moderately severe asthma should be initially be prescribed an inhaled corticosteroid. Use of a low to medium dose inhaled corticosteroid is recommended before use of a long acting beta agonist / corticosteroid combination inhaler.
- A Food and Drug Administration public health advisory recommends a long-acting beta-agonist be only used for those who remain symptomatic while on another asthma controller medication and for the shortest possible duration.

Prescriber Information

Prescriber Name:

[PRESCRIBER NAME]

Prescriber Phone:	Prescriber Fax:
[PRESCRIBER PHONE]	[PRESCRIBER FAX]

Patient Information

Patient Name:	Patient DOB:	Patient Medicaid Number:
[PATIENT NAME]	[PATIENT DOB]	[MEMBER ID]

Medication Denial

Requested Medication:	Denial Date:
[Drug Name] [Drug Strength] [Drug Dose] [Day Supply]	[PRESCRIPTION DATE]

Select one of the following two options:

Switch the patient to a preferred inhaled corticosteroid:

- Beclomethasone (Qvar™):40mcg/actuation 1 puff BID
- Beclomethasone (Qvar™):80mcg/actuation 1 puff BID
- Fluticasone (Flovent HFA™): 44mcg /actuation 2 puffs BID
- Fluticasone (Flovent Diskus™) 100mcg/actuation 1 puff BID

To switch to one of the above options, either generate a new ePrescription or complete the faxable prescription on the following page.

Provide information required for approval of [REQUESTED DRUG]

Please check all that apply to this patient:

- ☐ COPD
- ☐ Failure or contraindication to inhaled corticosteroids
- ☐ 2 or more exacerbations requiring oral systemic corticosteroids in the past year
- ☐ Asthma step 3 or higher (2007 Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma)
- ☐ Hospital admission or emergency department visit related to asthma or reactive airway disease in the past 365 days.

If one or more of the above apply, fax this completed form to (888) 346-0178 OR call (888) 202-2126 for immediate authorization of the original prescription.

Prescribers Signature: _____ Date: _____

Prescriber Name : [PRESCRIBER NAME] NPI: [PRESCRIBER NPI]

[CURRENT DATE]

TO:
[PHARMACY NAME]
[PHARMACY ADDRESS]
Telephone: [PHARMACY TELEPHONE]
Fax: [PHARMACY FAX]

FROM:
[PRESCRIBER NAME] NPI: [PRESCRIBER NPI]
[PRESCRIBER ADDRESS]
Telephone: [PRESCRIBER TELEPHONE]
Fax: [PRESCRIBER FAX]

Patient: [Patient Name]
Date of Birth: [Patient DOB]
Medicaid Member ID: [MEMBER ID]
Address: [Patient Address]

Rx

Check one:

- ☐ Beclomethasone (Qvar™): 40mcg/actuation
  Directions: One puff twice daily
  Dispense: One inhaler (120 inhalations)

- ☐ Beclomethasone (Qvar™):80mcg/actuation 1 puff BID
  Directions: One puff twice daily
  Dispense: One inhaler (120 inhalations)

- ☐ Fluticasone (Flovent HFA™): 44mcg /actuation
  Directions: Two puffs twice daily
  Dispense: One inhaler (120 inhalations)

- ☐ Fluticasone (Flovent Diskus™) 100mcg/actuation
  Directions: One puff twice daily
  Dispense: One inhaler (60 blisters)

Refills_____

_____
Physicians Signature

_____