Alabama Medicaid Pharmacist

Published Quarterly by Health Information Designs, Winter 2017 edition **A Service of Alabama Medicaid**

PDL Update

Effective January 3, 2017, the Alabama Medicaid Agency will update the Preferred Drug List (PDL) to reflect the recent Pharmacy and Therapeutics (P&T) Committee recommendations as well as quarterly updates. The updates are listed below:

PDL Additions	PDL Deletions*
Omnaris—Intranasal Corticosteroids	Anoro Ellipta—Respiratory Beta-adrenergic Agonists
Viekira XR[cc]—HCV Antivirals	mometasone nasal spray (generic Nasonex)—Intranasal Corticosteroids
	Nasonex—Intranasal Corticosteroids
	Provida DHA—Prenatal Vitamins
	tobramycin inhalation solution (generic Tobi and Kitabis) —Aminoglycosides

[cc] Preferred with Clinical Criteria

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Auburn, AL 36832-3210
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Please fax all prior authorization and override requests *directly* to Health Information Designs at 800-748-0116. If you have questions, please call 800-748-0130 to speak with a call center representative.

FDA Warning on Using Opioids in Combination with Benzodiazepines

On August 31, 2016, the FDA announced the requirement of *Boxed Warnings* to the labeling of opioid pain medicine, opioid cough medicine, and benzodiazepines. This is the strongest warning the FDA can put on a prescription drug. In doing so, the FDA is limiting the use of these products together. Health care professionals should only prescribe opioid medications with benzodiazepines or other CNS depressants for patients in whom alternatives would not be adequate for treatment. Patients should understand the risks of taking these medications in combination and know when to seek medical attention.

The FDA also revised the patient medication guides class-wide to reflect the data gathered from the latest studies of using opioids and benzodiazepines together. They are requiring patient-focused medication guides with information about the serious risks of using these medications at the same time including risks of extreme sleepiness, respiratory depression, coma, and death. In reviewing the data, the FDA found that physicians prescribed significantly more opioids and benzodiazepines together in 2014 than they did in 2002. This prescribing increase is associated with the increase in adverse outcomes, emergency department visits, and overdose deaths.

The FDA's requirements now match the guidelines from the CDC on the warnings of co-prescribing opioids and benzodiazepines. The FDA's announcement is also a response to a citizen petition from local and state public health officials. The petition was asking for changes in order to decrease the inappropriate prescribing of opioids and benzodiazepines.

Boxed Warning for Opioid Analgesics:

WARNING: RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Risks From Concomitant Use With Benzodiazepines OR Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death *[see Warnings and Precautions (5.X), Drug Interactions (7.X)].*

- **Reserve concomitant prescribing of [TRADENAME] and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

FDA Warning on Using Opioids in Combination with Benzodiazepines, continued

Boxed Warning for Opioid Cough Medications:

WARNING: RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS

Risks From Concomitant Use With Benzodiazepines OR Other CNS Depressants

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death *[see Warnings and Precautions (5.1), Drug Interactions (7.1)].* Avoid use of opioid cough medications in patients taking benzodiazepines, other CNS depressants, or alcohol.

Boxed Warning for Benzodiazepines:

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death *[see Warnings and Precautions (5.1), Drug Interactions (7.X)].*

- **Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate.**
- **Limit dosages and durations to the minimum required.**
- **Follow patients for signs and symptoms of respiratory depression and sedation.**

References:

Drug Safety and Availability. FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requiring its strongest warning. [August 31, 2016]. Available from: http://www.fda.gov/Drugs/DrugSafety/ucm518473.htm

Information by Drug Class. New Safety Measures Announced for Opioid Analgesics, Prescription Opioid Cough Products, and Benzodiazepines. [August 31, 16]. Available from: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm518110.htm

Press Announcements. FDA requires strong warnings for opioid analgesics, prescription opioid cough products, and benzodiazepine labeling related to serious risks and death from combined use. [August 31, 2016]. Available from: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm

Smoking Cessation Products

Smoking cessation products are covered by Alabama Medicaid. Products will be covered for Plan First recipients without prior authorization. All other recipients require prior authorization for smoking cessation products.

Prior Authorization requests must be submitted to Health Information Designs for approval. A copy of the Department of Public Health's Alabama Tobacco Quitline Patient Referral/Consent Form signed by the recipient MUST be submitted to the Quitline. Additionally, a copy of the signed consent form must be submitted along with the PA form to Health Information Designs for approval.

A list of covered nicotine products can be found on the Alabama Medicaid Agency website (Pharmacy Services/DME: Smoking Cessation Services) . To check if a particular NDC is covered, please refer to the Drug Look Up site on the Pharmacy Services page of the Alabama Medicaid Agency website at www.medicaid.alabama.gov.

All forms and information regarding smoking cessation coverage can be found on the Alabama Medicaid Agency website, www.medicaid.alabama.gov. They are located by clicking the Programs tab: Pharmacy Services/DME: Smoking Cessation Services.

Smoking Cessation Counseling

Beginning January 1, 2014, the Alabama Medicaid Agency began coverage of smoking cessation counseling services for Medicaid-eligible pregnant women. Medicaid will reimburse for up to four face-to-face counseling sessions in a 12-month period. The reimbursement period will begin in the prenatal period and continue through the postpartum period (60 days after delivery or pregnancy end). Documentation must support each counseling session. Pharmacies must bill for these services with their DME National Provider Identification Number (NPI).

The following CPT Codes are applicable:

- 99406—Smoking and tobacco use cessation counseling visit; intermediate, greater than three minutes up to 10 minutes ($8.60)
- 99407—Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes ($17.12)

The following diagnosis codes must be billed on the claim (UB-04 or CMS-1500 claim form) in order to be reimbursed by Medicaid:

- V220-V222—Normal pregnancy
- V230-V233—Supervision of high-risk pregnancy
- V2341-V237—Pregnancy with other poor obstetric history, **or**
- V242—Routine postpartum follow-up

  AND
- 3051—Tobacco use disorder

Gastroesophageal Reflux Disease

Gastroesophageal reflux disease (GERD) is a disease in which stomach acid or contents reflux back into the esophagus. The frequent acid reflux associated with GERD can be due to a weakened or abnormal esophageal sphincter. This sphincter normally remains closed when food is not being consumed. Constant acid re-flux can irritate the esophageal lining and cause inflammation. This inflammation can lead to further damage such as scar tissue-induced esophageal narrowing (strictures), esophageal ulcers, and precancerous changes to the esophagus (Barrett's esophagus).

GERD can be diagnosed due to frequent signs and symptoms or by actual damage to the esophagus. The severity of GERD can vary. Some people may manage their disease with OTC medications and lifestyle modifications, while others need prescription medications. Signs and symptoms of GERD include heartburn, acid reflux, difficulty swallowing, chest pain, dry cough, and sore or lumpy sensation in throat.

Common Risk Factors:

- Obesity
- Pregnancy
- Smoking
- Dry mouth
- Asthma
- Diabetes
- Delayed stomach emptying
- Connective tissue disorders
- Hiatal hernia

Non-Pharmacologic Recommendations:

- Weight loss for patients with BMI ≥ 25
- Elevate the head of the bed by 6-8 inches
- Avoid eating meals 2-3 hours before bedtime
- Eliminate trigger foods such as caffeine, alcohol, spicy foods, and chocolate

Step-Up Approach	Maintenance Therapy	Step-Down Approach
• Encourage patient to make lifestyle changes and use OTC medications. • If symptoms prevail after 2 weeks of therapy, patient should visit their physician and get prescription strength acid suppression therapy. • If the patient fails to respond to long-term pharmacologic treatment, experiences complications, or has refractory symptoms, they should then consider anti-reflux surgery.	• For a patient with mild symptoms, low dose PPI or alternate day dosing is recommended. • PPI is the drug of choice for maintenance in moderate to severe GERD. • Consider long-term maintenance therapy for patients who have symptomatic relapse following discontinuation of therapy.	• Once the patient has successfully used medication to control GERD symptoms, they should consider stepping down therapy. • For example, if a patient has used a PPI twice a day for three years, they should consider decreasing their dose to once a day. • Then, if the patient remains successful on once daily dosing, they may try taking the medication every other day.

January 3rd Pharmacy Changes

Effective January 3, 2017, the Alabama Medicaid Agency will:

1. **Require prior authorization (PA) for payment of mometasone nasal spray (generic Nasonex).**

2. **Require prior authorization (PA) for generic tobramycin inhalation solution (generic Tobi and Kitabis). Brand Kitabis will remain preferred without a PA.** Use Dispense as Written (DAW) Code of 9 for brand Patanase. DAW Code of 9 indicates the following: Substitution Allowed by Prescriber but Plan Requests Brand. This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted, but the Plan requests the brand product to be dispensed.

3. **Update the PDL to reflect the quarterly updates. The updates are listed below:**

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Omnaris—Intranasal Corticosteroids	Anoro Ellipta—Respiratory Beta-adrenergic Agonists
Viekira XR[cc]—HCV Antivirals	mometasone nasal spray (generic Nasonex)—Intranasal Corticosteroids
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	Provida DHA—Prenatal Vitamins
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For additional PDL and coverage information, visit our drug look-up site at https://www.medicaid.alabamaservices.org/ALPortal/NDC%20Look%20Up/tabId/39/Default.aspx.

The PA request form and criteria booklet, as well as a link for a PA request form that can be completed and submitted electronically online, can be found on the Agency's website at www.medicaid.alabama.gov and should be utilized by the prescriber or the dispensing pharmacy when requesting a PA. Providers requesting Pas by mail or fax should send requests to:

Health Information Designs (HID)
Medicaid Pharmacy Administrative Services
P. O. Box 3210 Auburn, AL 36832-3210
Fax: 1-800-748-0116
Phone: 1-800-748-0130

Incomplete PA requests or those failing to meet Medicaid criteria will be denied. If the prescribing physician believes medical justification should be considered, the physician must document this on the form or submit a written letter of medical justification along with the prior authorization form to HID. Additional information may be requested. Staff physicians will review this information.