Alabama Medicaid Pharmacist

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PDL Update

Effective July 1, 2016, 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*
Kitabis—Aminoglycosides	Intuniv—Cerebral Stimulants/ADHD
guanfacine ER—Cerebral Stimulants/ADHD	alogliptin—DDP-4 Inhibitors
Cimzia[CC]—Disease-modifying Antirheumatic Agents	alogliptin/metformin—DPP-4 Inhibitors
Enbrel[CC]—Disease-modifying Antirheumatic Agents	alogliptin/pioglitazone—DPP-4 Inhibitors
Humira[CC]—Disease-modifying Antirheumatic Agents	Kombiglyze—DPP-4 Inhibitors
Toviaz—Genitourinary Smooth Muscle Relaxants	Onglyza—DPP-4 Inhibitors
Harvoni[CC]—HCV Antivirals	Tradjenta—DPP-4 Inhibitors
Technivie[CC]—HCV Antivirals	Jentadueto—DPP-4 Inhibitors
Viekira PAK[CC]—HCV Antivirals	methadone—Opiate Agonists
	Ventolin HFA*—Respiratory Beta-adrenergic Agonists

[CC] Preferred with Clinical Criteria

* Product was temporarily preferred due to shortage of preferred agents

Inside This Issue

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.

Updated COPD Guidelines

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) issued updated guidance for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (COPD) in early 2016.

COPD, a common preventable and treatable disease, is the fourth leading cause of death in the world. COPD is characterized by persistent, progressive airflow limitation that is usually associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles, such as cigarette smoke, or gases. COPD results from induction of parenchymal tissue destruction, which leads to emphysema, and disruption of normal repair and defense mechanisms, which results in small airway fibrosis (narrowing) and increased airway resistance. These changes to the airway cause air to become trapped and diminishes the ability of the airways to remain open during expiration.

A diagnosis of COPD should be considered in patients who present with dyspnea, chronic cough or sputum production, a history of exposure to risk factors for the disease, and a family history of COPD. Worldwide, cigarette smoking is the most commonly encountered risk factor for COPD. Patients who smoke should be offered smoking cessation counseling. First-line pharmacotherapies for tobacco dependence, such as nicotine gum, nicotine patch, varenicline, or bupropion, should be offered.

Pharmacologic therapy for COPD is used to reduce symptoms, reduce the frequency and severity of exacerbations, and improve health status and exercise tolerance. No medications have been shown to decrease the rate of lung function decline. Bronchodilators alter airway smooth muscle tone, improve emptying of the lungs, reduce hyperinflation at rest and during exercise, and improve exercise performance.

Specific recommendations for bronchodilators:

- Long-acting beta$_2$-agonists (LABA) are preferred over short-acting beta$_2$-agonists (SABA) for the treatment of stable COPD.
- Combinations of SABA and LABAs and anticholinergics may be considered if symptoms are not improved with single agents.
- Theophylline is not recommended unless no other options are available.

Specific recommendations for corticosteroids:

- Long-term treatment with inhaled corticosteroids is recommended for patients with severe and very severe COPD and frequent exacerbations that are not adequately controlled by long acting bronchodilators.
- Long-term monotherapy with oral corticosteroids is not recommended.
- Long-term monotherapy with inhaled corticosteroids is not recommended in COPD because it is less effective than the combination of inhaled corticosteroids with long- acting beta2-agonists.

Other pharmacologic treatments:

- Influenza vaccination can reduce lower respiratory tract infections that can lead to hospitalization.
- Inactivated influenza vaccine should be used in the elderly.
- Pneumococcal vaccines are recommended for COPD patients 65 years and older and in younger patients with comorbid conditions.

Updated COPD Guidelines, continued

Generic Name	Trade Name	AL Medicaid Coverage Status
Short-acting Beta$_2$-agonists (SABAs)		
Levalbuterol* HFA	Xopenex HFA®	Non-preferred
Levalbuterol inhalation solution	Xopenex® Inhalation Solution	Generic preferred Brand name non-preferred
Albuterol*	ProAir® HFA Proventil® HFA Ventolin® HFA	Preferred Preferred Non-preferred
Long-acting Beta$_2$-agonists (LABAs)		
Arformoterol	Brovana®	Non-preferred
Indacaterol	Arcapta™ Neohaler™	Non-preferred
Olodaterol	Striverdi® Respimat®	Non-preferred
Salmeterol	Serevent® Diskus®	Preferred
Short-acting Anticholinergics		
Ipratropium bromide		Preferred
Long-acting Anticholinergics		
Aclidinium bromide	Tudorza® Pressair®	Non-preferred
Tiotropium	Spiriva®	Preferred
Umeclidinium	Incruse® Ellipta®	Non-preferred
Combination LABAs plus Anticholinergic		
Indacaterol/glycopyrrolate	Utibron™ Neohaler®	Non-preferred
Olodaterol/tiotropium	Stiolto® Respimat®	Non-preferred
Vilanterol/umeclidinium	Anoro® Ellipta®	Preferred
Combination LABAs plus Corticosteroids		
Formoterol/budesonide	Symbicort®	Non-preferred
Formoterol/mometasone	Dulera®	Preferred
Salmeterol/fluticasone	Advair®	Preferred
Vilanterol/fluticasone	Breo® Ellipta®	Preferred

*Off-label use in COPD

Reference

Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (GOLD). 2016. Retrieved June 23, 2016 from: http://www.goldcopd.com.

FDA Revises Metformin Labeling

Since the FDA approval of metformin in 1995, labeling has included a contraindication against the use of metformin in some patients with renal disease or dysfunction. Originally, the FDA had a black box warning for metformin contradicting its use in men with a serum creatinine greater than 1.5 mg/dL and in women with a serum creatinine greater than 1.4 mg/dL in women. The FDA has recently relaxed the stringent black box warning pertaining to the use of metformin in patients with kidney failure. The FDA now recommends basing metformin dosing on creatinine clearance rather than serum creatinine. The recommendations also increase the level of kidney failure a patient must have before metformin is contraindicated.

The FDA has concluded that metformin can be used safely and effectively in patients with mild impairment in kidney function and in some patients with moderate impairment in kidney function. Starting metformin is not recommended in patients that have a creatinine clearance less than 45 mL/min/1.73 m^2. Patients who have a GFR greater than 45 mL/min/1.73 m^2 at initiation of therapy, but then have a GFR less than 45 mL/min/1.73 m^2 during treatment, should be assessed for benefits and risks of continuing treatment with metformin. Metformin is now contraindicated in patients with a creatinine clearance less than 30 mL/min/1.73 m^2. GFR should be obtained at least annually for all patients taking metformin.

Reference:

FDA Drug Safety Communication: FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function. (2016, April 08). Retrieved June 23, 2016, from http://www.fda.gov/Drugs/DrugSafety/ucm493244.htm

Integrated Provider System (IPS) Project Guidance

In order to assist providers and Regional Care Organizations (RCOs) to better understand the Integrated Provider System (IPS) program and to clarify the intended focus of IPS projects, Alabama Medicaid has posted an "IPS Guidance" summary on the IPS webpage, at http://www.medicaid.alabama.gov/CONTENT/2.0_Newsroom/2.7.3.9_RCO_IPS.asp.

Given the volume of funding requests reflected in the IPS letter of intent (LOI) submissions, Alabama Medicaid realizes the importance of clarifying its funding parameters, so that RCOs and providers are aware of the limits of the IPS funding, and particularly the IPS projects that Alabama Medicaid does not intend to approve.

Providers that submitted an IPS LOI or that are interested in developing an IPS application should read this guidance document before moving forward. Although the IPS application timeline and due date are still to be determined, interested providers should begin to work with a sponsoring RCO to develop an IPS application.

Please email questions related to the IPS program to RCOQuality@Medicaid.Alabama.gov.

Days' Supply

Days' supply is an instrumental portion of a legitimate claim. Retroactive audits may consider the days' supply billed, along with quantity of medication billed, in regards to the original prescription. Days' supply billed should be clinically appropriate according to the prescriber's instructions on the prescription. Claims billed with an incorrect days' supply may be recouped, including claims billed for a quantity sufficient for a 90 day supply but billed for a 30 days' supply. Medications that are not included in the maintenance supply program should not be dispensed in a 90 day quantity for a 30 day supply.

July 1st Pharmacy Changes

Effective July 1, 2016, the Alabama Medicaid Agency will:

1. **Include the Disease-Modifying Antirheumatic Drugs (DMARDs) in the Preferred Drug List (PDL).**

2. **Implement a "Preferred with Clinical Criteria" program. For select drug classes, Alabama Medicaid will require clinical criteria be submitted for preferred products on the PDL.** Preferred products will require a prior authorization (PA) request be submitted. Clinical criteria must be met in order to be approved. Non-preferred products will continue to require prior authorization; for a non-preferred product to be approved, failure with a designated number of preferred agents and clinical criteria must be met. Alabama Medicaid will begin with the following drug classes:
   - **DMARDs**
   - **Hepatitis C Antivirals**
3. **Require prior authorization (PA) for payment of all methadone products (including generic).**
4. **Update the PDL to reflect the quarterly updates. The updates are listed below and are continued on page 6:**

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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.

Policy questions concerning this provider notice should be directed to the Pharmacy Program at (334) 242-5050. Questions regarding prior authorization procedures should be directed to the HID help desk at 1-800-748-0130.