Alabama Medicaid Pharmacist

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PDL Update

Effective July 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	
CitraNatal 90 DHA—Prenatal Vitamins	Betaseron—Immunomodulatory Agents used to treat MS
CitraNatal Assure—Prenatal Vitamins	Copaxone—Immunomodulatory Agents used to treat MS
CitraNatal B-Calm—Prenatal Vitamins	Extavia—Immunomodulatory Agents used to treat MS
CitraNatal DHA—Prenatal Vitamins	Gilenya—Immunomodulatory Agents used to treat MS
CitraNatal Harmony—Prenatal Vitamins	Rebif—Immunomodulatory Agents used to treat MS
Aubagio—Immunomodulatory Agents used to treat MS	Tysabri—Immunomodulatory Agents used to treat MS
PDL Deletions*	
Vyvanse Chewable—ADHD	

**Denotes that these brands will no longer be preferred but are still covered by Alabama Medicaid and will require prior authorization (PA) for payment. Available covered generic equivalents (unless otherwise specified) will remain preferred.*

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.

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Use of Tramadol and Codeine in Children and Breastfeeding Women

Codeine is a controlled substance used to treat pain or cough in adults. Codeine can be used alone or in combination with many other medications to treat these indications. Small amounts of codeine are metabolized by the cytochrome p450 enzyme 2D6 to morphine, which activates opioid receptors in the central nervous system. Opiate receptor activation causes generalized central nervous system depression, and inhibition of the ascending pain pathway causing a decreased perception of pain. Also, opiate receptor activation in the medulla causes respiratory depression, which is useful to suppress cough symptoms. Some patients have a genetic polymorphism which causes the increased metabolism of codeine into morphine, and can cause unintentionally high levels of morphine in these patients leading to significant respiratory depression and even death. Codeine's active metabolite, morphine, is excreted in the breastmilk of nursing mothers. The concentrations present in the breastmilk are dependent upon dose and the mother's metabolism of codeine.

Tramadol is also a controlled substance used to treat moderate to severe pain in adults. Tramadol is a synthetic form of codeine and has a weaker affinity for the opioid receptor than codeine. Therefore, tramadol generally has less abuse potential and respiratory depression than codeine. Tramadol also has a secondary mechanism by which it inhibits the reuptake of norepinephrine and serotonin in the brain, which aids in its ability to treat pain. The blockade of norepinephrine and serotonin reuptake induces side effects similar to monoamine oxidase inhibitors, which can include serotonergic toxicity induced seizures. Tramadol is metabolized by the cytochrome P450 enzymes 2D6 and 3A4, and those patients with abnormal hepatic metabolism would be more likely to experience tramadol toxicity. Additionally, cytochrome P450 2D6 metabolism has been shown to be highly variable in patients less than 12 years old, including genetic 2D6 polymorphisms. Tramadol and its active metabolite are excreted into the breastmilk of nursing mothers.

The Food and Drug Administration has issued new warnings on the use of codeine and tramadol in children and breastfeeding women. The FDA used data from its FDA Adverse Event Reporting System from 1969 to 2015 to identify cases of fatal or life-threatening respiratory depression in pediatric and adolescent patients after the use of codeine or tramadol containing products. This data was used to establish the need for new warnings of the increased risk of respiratory depression and death with codeine and tramadol in certain patient groups. Also, the FDA reviewed medical literature to determine that breastfed infants could be inadvertently exposed to codeine, tramadol and their active metabolites if the mothers had taken the medication. The warning announcement additionally emphasizes that tramadol and single-ingredient codeine are only approved for use in adult patients. The FDA recommends against the use of these medications in children less than 12 years old, specific patients less than 18 years old, and breastfeeding mothers of any age. To accompany the recommendation, the FDA added contraindications to the labeling of both tramadol and codeine products for use in patients less than 12 years of age. Also, tramadol received a contraindication for its use in patients under the age of 18 for postoperative pain management after an adenoidectomy and/or tonsillectomy. The same contraindication was applied to codeine in 2013.

Use of Tramadol and Codeine in Children and Breastfeeding Women, continued

Warnings were added to the labeling of tramadol and codeine products to recommend against their use in patients between 12 and 18 years old with obesity or severe pulmonary conditions such as obstructive sleep apnea. The warnings about the risk of breastfeeding while taking these medications were emphasized due to the serious risks to breastfed infants including excessive sedation, and fatal respiratory depression. The FDA recommends that alternative analgesics should be used in place of tramadol and codeine for the treatment of pain in these patients. Also, they recommend that since cough is generally a symptom of other pathology, antitussive intervention may not be necessary, especially with codeine.

References:

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Tobias JD, Green TP, Cote CJ, AAP Section on Anesthesiology and Pain Medicine, AAP Committee on Drugs. Codeine: time to say "no". Pediatrics 2016;138:e20162396. http://pediatrics.aappublications.org/content/138/4/e20162396.long

DEA Drug Take-Back Day

On Saturday, April 29th, the DEA held its 13th National Prescription Drug Take-Back Day. This event collected more unused prescription drugs than any of the 12 previous National Prescription Drug Take-Back Days. There were 5,500 sites across the United States that participated in this initiative and there were 450 tons (900, 386 lbs) of unused medications collected. Since the initiative began in September 2010, there have been 4,052 tons of unused medications collected. The state of Alabama had 80 collections sites which brought in 6,287 lbs.

The next National Prescription Drug Take-Back Day is scheduled for Saturday, October 28th. For more information on this initiative, please visit http://www.deadiversion.usdoj.gov/drug_disposal/takeback/.

Dispense as Written (DAW) Code 9 Medication List

In cases of cost-effectiveness, the Alabama Medicaid Agency sometimes allows for reimbursement of certain brand named medications while requiring prior authorization for the generic alternative. In these cases, a Dispense as Written (DAW) code of 9 must be utilized when dispensing the preferred brand named medication. A DAW Code of 9 indicates that substitution is allowed by the prescriber but Alabama Medicaid requests the brand product be dispensed. The list is subject to change. 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.

Preferred Brand	Non-preferred Generic
Adderall XR	Amphetamine Salts XR
Catapres-TTS	Clonidine Patches
Copaxone	Glatopa
Diastat	Diazepam Rectal Kit
Diastat Accudial	Diazepam Rectal Kit
Focalin IR	Dexmethylphenidate
Focalin XR	Dexmethylphenidate ER
Kapvay	Clonidine ER
Kitabis	Tobramycin Inhalation Solution
Nexium	Esomeprazole Magnesium
Patanase	Olapatadine Nasal Spray
Provigil	Modafinil
Pulmicort Inhalation Solution	Budesonide Inhalation Solution

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 3rd Pharmacy Changes

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

1. **Include the Immunomodulatory Agents used to treat Multiple Sclerosis in the Preferred Drug List (PDL).**
2. **Require the Alabama Medicaid Pharmacy Opioid Dependence Treatment Agreement and Patient Consent Form be submitted for requests for opioid dependence drugs (Bunavail, Suboxone, Zubsolv, buprenorphine, and buprenorphine/naloxone).** Prior authorization requests for opioid dependence medications must be accompanied by the Alabama Medicaid Pharmacy Opioid Dependence Treatment Agreement and Patient Consent Form and must be signed and dated by the patient and prescriber. The form can be found on the Agency website at: http://www.medicaid.alabama.gov/documents/9.0_Resources/9.4_Forms_Library/9.4.3_Consent_Forms/9.4.3_Form_391_Opioid_Dependence_Patient_Consent_7-3-17.pdf
3. In addition to the patient consent form being submitted, Alabama Medicaid will also require attestation from the prescribing physician stating that the Prescription Drug Monitoring Program (PDMP) record for the patient has been reviewed prior to prescribing an opioid dependence medication. Urine drug screens will also be required for renewal requests.
4. **Require prior authorization for Glatopa (glatiramer), the generic version of Copaxone. Copaxone will be preferred.** Use Dispense as Written (DAW) Code of 9 for brand Copaxone. 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.
5. **Update the PDL to reflect the quarterly updates.** The updates are listed below (and continue to page 6):

PDL Additions	
CitrNatal 90 DHA	Prenatal Vitamins
CitraNatal Assure	Prenatal Vitamins
CitraNatal B-Calm	Prenatal Vitamins
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CitraNatal Harmony	Prenatal Vitamins

July 3rd Pharmacy Changes

PDL Additions , Continued	
Aubagio	Immunomodulatory Agents used to treat MS
Betaseron	Immunomodulatory Agents used to treat MS
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PDL Deletions	
Vyvanse Chewable	ADHD

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.