Alabama Medicaid Pharmacist

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PDL Update

Effective July 1, 2023, the Alabama Medicaid Agency updated 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
Daytrana®—Cerebral Stimulants/Agents used for ADHD (Long-acting)
Amphetamine-dextroamphetamine ER (generic Adderall XR®)—Cerebral Stimulants/Agents Used for ADHD (Long-acting)
PDL Deletions
Methylphenidate transdermal patch (generic Daytrana® transdermal patch)—Cerebral Stimulants/Agents Used for ADHD (Long-acting)
Cimzia®—DMARDs

Inside This Issue

Please fax all prior authorization and override requests *directly* to Kepro at 800-748-0116. If you have questions, please call 800-748-0130 to speak with a call center representative.

Kepro

Medicaid Pharmacy Administrative Services

P.O. Box 3570

Auburn, AL 36831

Changes to Hepatitis C Prior Authorization (PA) Criteria

Effective October 1, 2022, the Alabama Medicaid Agency removed the requirement of absence of alcohol and illicit drug use by recipients for the prior approval of antiviral drugs used in the treatment of hepatitis C. A copy of the patient's drug and alcohol screening lab report will no longer be required. All other criteria remain, including the patient consent form with the patient's and physician's signature, which must be submitted with requests.

The updated Prior Authorization (PA) request form and criteria booklet should be utilized by the prescriber or the dispensing pharmacy when requesting a PA. Updated forms and criteria can be found here: https://medicaid.alabama.gov/content/9.0_Resources/9.4_Forms_Library/9.4.13_Pharmacy_Forms.aspx.

Providers requesting PAs by mail or fax should send requests to:

Kepro
Medicaid Pharmacy Administrative Services
P.O. Box 3570
Auburn, AL 36831
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 prescriber believes medical justification should be considered, the prescriber must document this on the form or submit a written letter of medical justification along with the PA form to Kepro. Additional information may be requested. Staff physicians will review this information.

Questions related to this policy update can be directed to the Alabama Medicaid Clinical Services Division at (334) 242-5050.

Provider Enrollment—Revalidation

All Medicaid providers are required to revalidate (or renew) their enrollment record periodically to maintain Medicaid billing privileges. If providers do not revalidate, their enrollment will be closed.

To learn more about revalidation, please visit https://medicaid.alabama.gov/content/10.0_Contact/10.3_Provider_Contacts/10.3.4_Provider_Enrollme%20nt.aspx and scroll to the bottom of the page.

Note: The website pathway is https://medicaid.alabama.gov, select the 'Providers' tab, then click on the 'Provider Enrollment' link and scroll to the bottom of the page.

Providers may contact the Gainwell Provider Enrollment Unit at **1-888-223-3630** and speak to a Provider Enrollment Specialist.

Medication Expiration Dates

In 1979, the Food and Drug Administration (FDA) passed a law stating that prescription and over-the-counter medications must have an expiration date. This date was to be determined by appropriate stability testing to ensure the drug meets "standards of identity, strength, quality, and purity" set by the FDA at the time the medication is used if it is kept in its original sealed container. This law also stated that the expiration date should be related to how the product is stored. Stability testing by drug manufacturers is required by law to determine appropriate storage conditions and expiration dates of drug products. Hence, the expiration date is the final day the manufacturer guarantees the full potency and safety of the drug. The expiration date should be displayed on the immediate container and the outer drug packaging, except if the drug is in single-dose packaging. If this is the case, the expiration date must only be displayed on the outer packaging instead of the immediate container.

There are some exceptions to the expiration labeling. Among these include new investigational drugs if they meet the standards or specifications for stability studies conducted during clinical investigations. However, if the drug is reconstituted before dispensing, it must have an expiration date on its label specifically for the reconstituted drug product. Homeopathic drugs and allergenic extracts labeled "No U.S. Standard of Potency" are also exempt from this law.

Since the expiration date of a drug product is based upon storage in the original sealed container, the expiration date may no longer apply once the seal is punctured. Examples include insulin and other injectable anti-diabetic products and some formulations of nitroglycerin. Sublingual nitroglycerin has been shown to lose potency due to environmental factors once its container has been opened. Because of this, ensuring the patient understands how to properly store their medications and when and how to discard leftover medications is important. Table 3 may serve as a guide for proper storage of some common insulin products.

Beyond Use Dates

A "Beyond Use Date" or BUD is like an expiration date but specific to reconstituted and compounded drugs. The United States Pharmacopeia (USP) created BUD guidelines for sterile and nonsterile compounded drugs. USP <795> contains information regarding nonsterile preparations. In 2019, the USP added a "water activity" concept to assess susceptibility to microbial contamination and degradation to determine the appropriate BUD more accurately for nonsterile preparations. The updated guidelines are listed in Table 1.

USP <797> contains information regarding sterile preparations. The main update to these guidelines in 2019 was eliminating the contamination risk levels of low-, medium-, and high-risk and replacing them with Category 1 and Category 2. These categories are separated based on the conditions under which the preparation is made, the potential for microbial growth, and the time for which the preparation must be used. Category 2 preparations are prepared in a cleanroom and can have a longer BUD than Category 1. The revised BUD dates for sterile preparations are listed in Table 2.

For reconstituted medications, the use-by date varies based on the drug. Information regarding how to reconstitute the drug and how long the reconstituted drug product is good for can be found in the package insert. These dates can vary significantly based on the route of administration and the ingredients. For example, amoxicillin oral suspension, an antibiotic commonly used for ear and throat infections in children, should be discarded 14 days after reconstitution. Whereas the oral suspension for Xofluza® (baloxavir marboxil), a drug indicated for the treatment of influenza, must be administered within 10 hours after reconstitution because the product does not contain a preservative.

Medication Expiration Dates, continued

Medication Disposal

Failing to dispose of old, unwanted, or expired medications safely could have detrimental consequences if they fall into the wrong hands. The Centers for Disease Control and Prevention estimated that there were over 100,000 fatalities in the US associated with drug poisoning between August 2021 and August 2022. According to data from calls to US poison control centers, analgesics were the most common cause of pediatric fatalities reported to Poison Control between 2017 and 2021. Pain medications were also the leading implication of adult exposures reported to Poison Control in 2021, followed by sedatives, antipsychotics, and antidepressants.

The best way to dispose of unwanted or expired medications is by taking them to a drug take-back program. The Drug Enforcement Administration, or DEA, coordinates a National Prescription Drug Take-Back Day periodically to educate the public about the importance of proper medication disposal and to assist in disposing of unwanted or expired medications. Information about the event can be found on the DEA's website, where people can look up the city they reside in to find the closest collection site. If a drug take-back program is unavailable, the FDA created recommendations to help educate people on how to dispose of their medications safely. They recommend mixing unwanted medications with unpalatable substances such as dirt, used coffee grounds, or cat litter and placing the mixture into a sealed container to throw away in the household garbage. Some medications that are especially harmful if taken accidentally can also be flushed down the toilet or sink. The FDA has a "flush list" for medications that can and cannot be flushed on their website with the active ingredient and brand name examples listed.

Table 1

Revised USP <795>[5] (June 1, 2019)	
Non-preserved Aqueous	14 days
Preserved Aqueous	35 days
Nonaqueous Dosage Forms	90 days
Solid Dosage Forms	180 days

Table 2

Revised USP <795>[5] (June 1, 2019)	
Category 1	≤ 12 hours at controlled room temperature (CRT) ≤ 24 hours in a refrigerator
Category 2	Aseptically processed, no sterility, only sterile starting components: -4 days at CRT -10 days in a refrigerator -45 days in a freezer
	Aseptically processed, no sterility, one or more nonsterile starting components: -1 day at CRT -4 days in a refrigerator -45 days in a freezer

Medication Expiration Dates, continued

Table 3

Insulin Storage Recommendations (list not all inclusive)			
Product Name	***Unopened Refrigerated***	***Unopened Room Temperature***	***Seal Punctured/In-use; Refrigerated or Room Temperature***
Apidra® vial and Apidra® SoloSTAR	Labeled expiration date	28 days	28 days *do not refrigerate pen
Fiasp® vial and Fiasp® FlexTouch®	Labeled expiration date	28 days	28 days *do not refrigerate pen
Humalog® 50/50 vials; 75/25 vials; Humalog KwikPen®	Labeled expiration date	28 days	28 days *do not refrigerate pen
Humalog® 50/50 KwikPen® ; Humalog® 70/30 KwikPen®	Labeled expiration date	10 days	10 days *do not refrigerate pen
Humulin R; N; 70-30; U-100; U-500 vials	Labeled expiration date	31 days	31 days
Humulin® N KwikPen®	Labeled expiration date	14 days	14 days *do not refrigerate pen
Humulin® 70/30 KwikPen®	Labeled expiration date	10 days	10 days *do not refrigerate pen
Lantus® vial and Lantus® Solostar®	Labeled expiration date	28 days	28 days *do not refrigerate pen
Levemir® vial and Levemir® FlexTouch®	Labeled expiration date	42 days	42 days *do not refrigerate pen
NovoLog® FlexPen® and vial; NovoLog® Mix 70/30 vial	Labeled expiration date	28 days	28 days *do not refrigerate pen
NovoLog® Mix 70/30 FlexPen®	Labeled expiration date	14 days	14 days *do not refrigerate pen
Toujeo® vial	Labeled expiration date	42 days	42 days
Toujeo® Solostar®	Labeled expiration date	28 days	28 days *do not refrigerate pen
Tresiba® vial and Tresiba® FlexTouch®	Labeled expiration date	56 days	56 days

USP Compounding Standards and Beyond-Use Dates (BUDs). *United States Pharmacopeia.* 2019. Accessed June 26, 2023.https://www.usp.org/sites/default/files/usp/document/our-work/compounding/usp-bud-factsheet.pdf

Don't be tempted to use expired medicines. FDA. Published online February 8, 2021. Accessed June 26, 2023. https://www.fda.gov/drugs/special-features/don't-be-tempted-use-expired-medicines

Preferred Drug List (PDL) and Pharmacy Quarterly Update

Effective July 1, 2023, the Alabama Medicaid Agency:

1. **Required Prior Authorization (PA) for methylphenidate transdermal patch (generic Daytrana® transdermal patch). Brand Daytrana® will be added as preferred.**
2. **Required Daytrana to be billed with a Dispense as Written (DAW) Code of 9.** 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. **Updated the PDL to reflect the quarterly updates listed below:**

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Cimzia®—DMARDs

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.

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