



ALABAMA MEDICAID PHARMACIST

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A Service of Alabama Medicaid

PDL Update

Effective October 1, 2013, 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*
Patanase—EENT Preparations/ Antiallergic Agents	Tyzine—EENT Preparations/ Vasoconstrictors
Pataday—EENT Preparations/ Antiallergic Agents	
Combivent Respimat— Respiratory/Respiratory Beta- adrenergic Agonists	
Ciprodex—EENT Preparations/Antibacterial	
Vigamox—EENT Preparations/ Antibacterial	

*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.

The HID Help Desk is open Monday–Friday from 8am to 7pm and on Saturdays 10am to 2pm. If you need a form, wish to review criteria, or have other questions, please access our website at hidmedicaid.hidinc.com or the Agency website at medicaid.alabama.gov.

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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Health Information Designs (HID)
 Medicaid Pharmacy Administrative Services
 PO Box 3210
 Auburn, AL 36832-3210
 Fax 800-748-0116
 Phone 800-748-0130



American College of Rheumatology Guideline Update

In May 2012, the American College of Rheumatology (ACR) updated their recommendations for the use of disease-modifying antirheumatic drugs (DMARDs) and biologic agents in the treatment of rheumatoid arthritis (RA). Guidelines begin with some very important terms and definitions:

<u>DMARDs</u>	Hydroxychloroquine, Leflunomide, Methotrexate, Minocycline, and Sulfasalazine
<u>DMARD combination therapy</u>	Methotrexate + Hydroxychloroquine, Methotrexate + Leflunamide, Methotrexate + Sulfasalazine, Sulfasalazine + Hydroxychloroquine, Methotrexate + Hydroxychloroquine + Sulfasalazine
<u>Anti-TNF biologics</u>	Adalimumab, Certolizumab pegol, Etanercept, Infliximab, Golimumab
<u>Non-TNF biologics</u>	Abatacept, Rituximab, Tocilizumab
<u>Early RA</u>	RA disease duration < 6 months from diagnosis
<u>Established RA</u>	RA disease duration ≥ 6 months
<u>Disease activity</u>	Categorized as low, moderate, and high as per validated common scales or the treating clinician's formal assessment
<u>RA remission</u>	A tender joint count, swollen joint count, C-reactive protein level, and patient global assessment of ≤ 1 each or a simplified Disease Activity Score of ≤ 3.3
<u>Poor prognosis</u>	Presence of ≥ 1 of the following features: functional limitation, extra-articular disease, positive rheumatoid factor or <u>anti-cyclic citrullinated peptide antibodies</u> , and/or bony erosions by radiograph

The ACR recommends targeting remission or low disease activity in RA. Below are their recommendations of step-therapy to best achieve decreased disease activity balanced with lower probability of adverse events based on severity of disease. Therapies that were approved after the original literature review are not included in these recommendations.

Recommendations and Indications for Starting, Resuming, Adding, or Switching DMARDs or Biologic Agents

Early Rheumatoid Arthritis

- For low disease activity and for moderate to high disease activity without the presence of poor prognostic features, DMARD monotherapy is recommended.
- For moderate or high disease activity with the presence of poor prognostic features, DMARD combination therapy is recommended.
- Also for high disease activity with the presence of poor prognostic features, anti-TNF biologic agents (with or without methotrexate) can be used. The only exception is infliximab; it should be used in combination with methotrexate, and not as monotherapy.

Established Rheumatoid Arthritis

Initiating and switching among DMARDs:

- If, after 3 months of DMARD monotherapy, a patient deteriorates, DMARD combination therapy should be implemented.
- If, after another 3 months of DMARD combination therapy, a patient still has moderate or high disease activity, add another non-methotrexate DMARD or switch to a different non-methotrexate DMARD.

Switching from DMARDs to biologic agents:

- If after 3 months of DMARD or DMARD combination therapy, the patient still has moderate or high disease activity, adding or switching to an anti-TNF biologic, abatacept, or rituximab is recommended.

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Switching from DMARDs to biologic agents:

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Switching among biologic agents due to lack of benefit or loss of benefit:

- If after 3 months of anti-TNF biologic therapy, a patient still has moderate to high disease activity, switching to another anti-TNF biologic or non-TNF biologic is recommended.
- If after an additional 6 months on a non-TNF agent, switching to another non-TNF biologic or an anti-TNF biologic is recommended.

Switching among biologic agents due to harms/adverse events:

- If a patient has high disease activity after failing an anti-TNF biologic because of a serious adverse event, switch to a non-TNF biologic.
- If a patient has moderate or high disease activity after failing an anti-TNF biologic because of non-serious adverse events, switch to another anti-TNF biologic or a non-TNF biologic.
- If a patient has moderate or high disease activity after failing a non-TNF biologic because of an adverse event (serious or non-serious), switch to another non-TNF biologic or an anti-TNF biologic.

Use of Biologic Agents in RA Patients with Hepatitis, Malignancy, or CHF, Qualifying for More Aggressive Treatment

Hepatitis B or C

- Hepatitis B: ACR recommends not using biologic agents in RA patients with untreated chronic hepatitis B and in RA patients with treated Hepatitis B with Child-Pugh class B and higher
- Hepatitis C: Etanercept could potentially be used in RA patients with hepatitis C requiring RA treatment

Malignancy

- For patients who have been treated for solid malignancies or nonmelanoma skin cancer > 5 years ago, ACR recommends starting or resuming any biologic agent if those patients would otherwise qualify for this RA management.
- Rituximab can be used in those patients treated for solid malignancies or nonmelanoma skin cancer within the past 5 years

CHF

- ACR recommends against using any anti-TNF biologic in RA patients with CHF that is NYHA class III or IV and who have an ejection fraction of $\leq 50\%$.

In summary, in patients with early RA, DMARD monotherapy and combination therapy should be utilized initially, and then can be adapted to accommodate increasing severity of disease. In patients with established RA and either not on current or currently on medication, DMARD combination therapy or biologic agents can be considered. Certain comorbid diseases, TB infections, and vaccinations can be greatly influenced by the type of antirheumatic treatment initiated.

References:

- Saag KG, Teng GG, Patkar NM, Anuntiyo J, et al. American college of rheumatology 2008 recommendations for the use of nonbiologic and biologic disease-modifying antirheumatic drugs in rheumatoid arthritis. American College of Rheumatology. 2008 June;59(6):762-784.
- Singh JA, Furst De, Bharat A, Curtis JR, et al. 2012 update of the 2008 American college of rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. American College of Rheumatology. 2012 May;64(5):625-639.

Proper Vaccine Storage

Proper storage of vaccines can ensure vaccine potency, adequate immune response and adequate protection against disease. Some vaccines require freezer storage; some require refrigerator storage and some can be stored in either the freezer or refrigerator. Calibrated thermometers should be stored in the refrigerator and freezer. The temperature should be read and documented in the morning and at the end of every work day.

Vaccines that require freezer storage must be stored between -58°F and +5°F until reconstitution and administration. Rapid deterioration can occur if the vaccine is removed from the freezer. Vaccines should be placed in a central area of the freezer, in their original packaging and positioned 2 to 3 inches away from freezer walls. Never store vaccines in the freezer door.

Vaccines that require refrigerator storage must be stored between 35°F and 46°F, with a desired average temperature of 40°F. Temperatures outside of this range may result in reduced vaccine potency and increased risk of vaccine-preventable diseases. Vaccines should be placed in the central area of the refrigerator and should never be stored in the deli, fruit, and vegetable drawers, in the door, or on the floor of the refrigerator. The top shelf of a combination unit may be colder than the recommended temperature range due to cold air venting from the freezer. It is best to store those vaccines that are least sensitive to the coldest temperatures in this area. Vaccines should be stored in their original packaging.

Diluents that are packaged separately from the corresponding freeze-dried vaccine and that do not contain antigen can be stored at room temperature or in the refrigerator. Diluents that contain antigen or that are packaged with their vaccines should be stored in the refrigerator next to their corresponding vaccine. Diluents should never be stored in the freezer.

Refer to the table on the next page for storage and handling guidelines.



Proper Vaccine Storage

The following chart details the proper storage and handling of certain vaccines*:

Vaccine(s)	Diluent – Store Between:	Vaccine – Store Between:	Protect from Light
DTaP, DT, Tdap, Td	No diluent	35°F to 46°F	
Hepatitis A	No diluent		
Hepatitis B	No diluent		
Hib (Hiberix)	36°F to 46°F		√
Hib (ActHIB, PedvaxHIB)	No diluent		
HPV (Gardasil, Cervarix)	No diluent		√
Influenza (LAIV)	No diluent		
Influenza (TIV)	No diluent		√
Meningococcal (MCV4 – Menactra)	No diluent		
Meningococcal (MCV4 – Menveo)	36°F to 46°F		√
Meningococcal (MPSV4)	35°F to 46°F		
Pneumococcal (PCV, PPSV)	No diluent		
Polio (IPV)	No diluent		√
Rotavirus (RV-5 RotaTeq)	No diluent		√
Rotavirus (RV-1 Rotarix)	68°F to 77°F	√	
M-M-R II	36°F to 46°F	-58°F to +46°F	√
Varicella (Varivax III)	36°F to 77°F	-58°F to +46°F	√
Varicella (Varilrix)	36°F to 77°F	36°F to 46°F	
Zoster (Zostavax)	36°F to 77°F	-58°F to +5°F	√
Combination Vaccines			
DTap-IPV (Kinrix)	No diluent	35°F to 46°F	
DTap-Hep B-IPV (Pediatrix)	No diluent		
DTap-IPV/Hib (Pentacel)	No diluent		
Hep A-Hep B (Twinrix)	No diluent		
Hib-HepB (Comvax)	No diluent		
MMRV (ProQuad)	36°F to 77°F	-58°F to +5°F	√

*List is not all-inclusive

Package Inserts [2013 June 12]. Immunization Action Coalition. Retrieved from: <http://www.immunize.org/packageinserts/>

Center for Disease Control and Prevention. Vaccine Storage and Handling Toolkit. November 2012 November. Available from: <http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf>

October 1st Pharmacy Changes

To: Pharmacies, Physicians, Physician Assistants, Nurse Practitioners, Oral Surgeons, Optometrists, Dentists, FQHCs, RHCs, Mental Health Service Providers, Hospitals, and Nursing Homes

Effective October 1, 2013, the Alabama Medicaid Agency will:

- Discontinue coverage of over-the-counter medications (OTCs) for adults and children; *OTC insulin and nutritional products will remain covered.*
- Decrease Wholesale Acquisition Cost (WAC) ingredient reimbursement to WAC + 0% from WAC + 9.2% for drugs without an Average Acquisition Cost (AAC).

Effective October 1, 2013, the Alabama Medicaid Agency will begin phasing in the following changes for an effective date of January 1, 2014. Informational edits and/or overrides will be available during the phase in period; providers are encouraged to use the phase in period to coordinate/find the best schedule for each individual recipient. Changes include:

- Implementation of a mandatory three month maintenance supply program for selected medication classes. A maintenance supply prescription will only be counted towards the prescription limit in the month in which it is filled. The selected classes include:

Medication Class	Medications Included
ACE Inhibitors	Preferred generics and brands
Antidepressants	Preferred generics and brands
Asthma	Generic montelukast only
Beta Blockers	Preferred generics and brands
Calcium Channel Blockers	Preferred generics and brands
Contraceptives	Oral, vaginal rings, patches only
Diabetic Agents/Supplies	Generic metformin, OTC insulins, and syringes
Diuretics	Preferred generics and brands
Lithium	All covered products
Statins	Preferred generics and brands
Thyroid Replacement	All covered products

- Limit the number of outpatient pharmacy prescriptions to five total drugs (including up to four brands) per month for adults. Children under 21 and nursing home recipients are excluded. In no case can total prescriptions exceed ten per month per recipient. Allowances will be made for up to five additional (10 total) prescriptions for brand and generic antipsychotics, antiretrovirals, and anti-epileptic drugs.

Additional pharmacy-specific billing information and override information can be found on the [Pharmacy Services](http://www.medicaid.alabama.gov/CONTENT/4.0_Programs/4.5_Pharmacy_Services.aspx) page of the Alabama Medicaid Agency website at http://www.medicaid.alabama.gov/CONTENT/4.0_Programs/4.5_Pharmacy_Services.aspx.