Alabama Medicaid DUR Board Meeting Minutes
October 22, 2025

Members Present: Dr. Kelli Littlejohn Newman, Dr. Danielle Powell, Dr. George Sutton, Dr. Marilyn Bulloch, Mary Stallworth, Dr. Melinda Rowe, Dr. Kristi Kelley, Dr. Darlene Traffanstedt, Dr. Crystal Deas, Dan McConaghy, Dr. Janaki Nimmagadda, Dr. Rachel Seaman

Also Present: Dr. Lori Thomas, Julie Jordan, LaQwanda Eddings-Haygood, Heather Vega, Dr. Jack Wanschek, Amanda Singletary, ACHN Pharmacists

Members Absent: Dr. Jeremy Osborn, Dr. Luke Engeriser

Call to Order: The DUR Meeting was called to order by Dr. Bulloch at approximately 1:07 p.m. Dr. Bulloch called roll and Dr. Littlejohn Newman took a moment to address the Board about Alabama Code 1975 § 36-25A-5.1§ 36-25A-5.1., which allows the DUR Board meetings to be conducted in a hybrid format.

Review and Adoption of Minutes: The minutes of the July 23, 2025, meeting were presented, and Dr. Sutton made a motion to approve the minutes. Dr. Deas seconded the motion, and the motion was approved unanimously.

Prior Authorization and Overrides Update: Dr. Thomas began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of April 2025. She reported 13,140 manual PAs and overrides. Dr. Thomas reported 25,273 total electronic requests for the month of April 2025. Dr. Thomas reviewed the electronic PA criteria requirements for the Opioid Use Disorder medication class and reviewed the manual and electronic PA approvals and denials. From the Prior Authorization and Override Response Time Ratio report for April 2025, Dr. Thomas reported that approximately 80% of all manual PAs and 77% of all overrides were completed in less than two hours. Ninety-two percent of all manual PAs and 91% of all overrides were completed in less than four hours. Ninety-four percent of all manual PAs and 93% of all overrides were completed in less than eight hours. For the month of May 2025, Dr. Thomas reported 11,977 manual PA requests and 23,278 electronic PA requests. She reported that 79% of all manual PAs and 81% of all overrides were completed in less than two hours. Ninety-one percent to 92% of all manual PAs and overrides were completed in less than four hours. Ninety-three percent of all manual PAs and 94% of all overrides were completed in less than eight hours. For the month of June 2025, Dr. Thomas reported 11,457 manual PA requests and 21,506 electronic PA requests. Dr. Thomas reported that approximately 77% of all manual PAs and 78% of all overrides were completed in less than two hours. Eighty-nine percent of all manual PA requests and overrides were completed in less than four hours. Ninety-two percent of all manual PAs and overrides were completed in less than eight hours.

Program Summary Review: Dr. Thomas briefly reviewed the Alabama Medicaid Program Summary for the months of January 1, 2025, through June 30, 2025. She reported 192,771 average recipients per month using pharmacy benefits, and an average paid per prescription of $175.83.

Cost Management Analysis: Dr. Thomas reviewed the Cost Management Analysis chart highlighting the number of recipients per month over the past two years. Dr. Thomas reported an average cost per claim of $191.85 for June 2025, and compared previous months contained in the table. From the 2nd Quarter 2025 Drug Analysis, Dr. Thomas reported 85% generic utilization, 7% brand single-source, 5% brand multi-source (those requests which required a DAW-1 override), and 3% OTC and "other." From the Top 25 Drugs Based on Number of Claims from 04/01/2025 - 06/30/2025, Dr. Thomas reported the top five drugs: cetirizine, amoxicillin, albuterol sulfate HFA, fluticasone propionate, and gabapentin. Dr. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 04/01/2025 - 06/30/2025: Dupixent® Pen, Humira® Citrate-free Pen, Trikafta®, Ozempic®, and Invega Sustenna®. From

the Top 15 Therapeutic Classes by Total Cost of Claims for the same time frame, Dr. Thomas reported the top five classes: Antipsychotic Agents, Incretin Mimetics, Tumor Necrosis Factor Inhibitors, Miscellaneous Skin and Mucous Membrane Agents, and Antineoplastic Agents.

Provider Education and Intervention Program: Dr. Thomas introduced the Provider Education and Intervention Summary from the Federal Fiscal Year (FFY) 2024 CMS RDUR Annual Report. Dr. Thomas reviewed the RDUR Program. She then reviewed the top ten criteria and problem types for which interventions were taken during FFY 2024. A total of 3,303 recipients met the criteria for intervention letters and Dr. Thomas provided a detailed chart showing how many recipients were reviewed per criteria, the number of recipients selected for intervention letters, the number of letters generated, and the number of letters mailed.

Proposed Criteria: Dr. Thomas presented a proposed set of 29 criteria to the Board and instructed Board members to mark their ballots. Of the 29 proposed criteria, results from the criteria vote returned 23 approved and 5 amended, and 1 rejected.

Medicaid Update: Dr. Littlejohn Newman reminded the Board Members that all updated Medicaid drug lists and ALERTs were provided to them electronically and are also available online. She reviewed several ALERTs related to radiology changes, colorectal screenings, continuous blood glucose monitoring, and RSV/Synagis. Dr. Wanschek reviewed the October 1, 2025, PDL updates.

P & T Committee Update: Dr. Wanschek began the P & T Update by informing the Board that the last P & T meeting was held on August 6, 2025, and covered the Hepatitis C Antivirals and the remaining anti-infectives. The next meeting is scheduled for November 5, 2025, and will cover the antidiabetic agents, first generation antihistamines, multiple sclerosis agents, antigout agents, estrogens, and prenatal vitamins.

Next Meeting Date: Dr. Bulloch informed the Board that the next DUR Meeting will be held on January 21, 2026. A motion to adjourn the meeting was made by D. McConaghy and Dr. Sutton seconded the motion. The meeting was adjourned at 2:36 p.m.

Respectfully submitted,

Lori Thomas, PharmD

Lori Thomas, PharmD.

ALABAMA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
1. Nirogacestat / Overuse Alert Message: Ogsiveo (nirogacestat) may be over-utilized. The recommended dosage of nirogacestat is 150 mg administered orally twice daily until disease progression or unacceptable toxicity. Drugs/Diseases Util A: Nirogacestat Util B: Util C: Max Dose: 300 mg/day References: Clinical Pharmacology, 2025 Elsevier/Gold Standard. Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.	√		
2. Nirogacestat / Therapeutic Appropriateness Alert Message: The safety and effectiveness of Ogsiveo (nirogacestat) have not been established in pediatric patients. Drugs/Diseases Util A: Nirogacestat Util B: Util C: Age Range: 0 – 17 yoa References: Clinical Pharmacology, 2025 Elsevier/Gold Standard. Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.	√		
3. Nirogacestat / Diarrhea Alert Message: Diarrhea, sometimes severe, can occur in patients treated with Ogsiveo (nirogacestat). In the clinical trial for nirogacestat efficacy, diarrhea occurred in 84% of patients treated with nirogacestat, including Grade 3 events in 16% of patients. For diarrhea persisting for greater than 3 days despite maximal medical therapy, withhold nirogacestat until resolved to Grade 1 or baseline, then restart at a dose of 100 mg twice daily. Drugs/Diseases Util A: Nirogacestat Util B: Diarrhea Util C: References: Clinical Pharmacology, 2025 Elsevier/Gold Standard. Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.	√		

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

4. Nirogacestat / Elevated Liver Enzymes - Dose _____ ___√___ _____

Alert Message: ALT or AST elevations occurred in 30% and 33% of patients who received Ogsiveo (nirogacestat) in the clinical trial, respectively. Grade 3 ALT or AST elevations (> 5 × ULN) occurred in 6% and 2.9% of patients, respectively. Monitor liver function tests regularly and modify dose as recommended for patients with Grade 2 (>/= 3 to 5 x ULN) ALT or AST increased withhold nirogacestat until ALT, AST, or both are resolved to < 3 x ULN or baseline, then restart at a dose of 100 mg twice daily. Permanently discontinue nirogacestat if the patient has Garde 3 or 4 (> 5 x ULN).

Drugs/Diseases

Util A	Util B	Util C
Nirogacestat	Abnormal Liver Function Studies	

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

5. Nirogacestat / Electrolyte Abnormalities ___√_____ _____ _____

Alert Message: Electrolyte abnormalities can occur in patients treated with Ogsiveo (nirogacestat). In the clinical trial, electrolyte abnormalities included decreased phosphate (65%) and decreased potassium (22%). If Grade 3 or 4 hypophosphatemia persists for >/= 3 days despite maximal replacement therapy withhold nirogacestat until resolved to Grade 1 or lower or baseline, then restart at a dose of 100 mg twice daily. If Grade 3 or 4 hypokalemia occurs despite maximal replacement therapy, withhold nirogacestat until resolved to Grade 1 or lower, or baseline, then restart at a dose of 100 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C
Nirogacestat	Hypokalemia	
	Hypophosphatemia	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

6. Nirogacestat / Ovarian Toxicity ___√____ _____ _____

Alert Message: Female reproductive function and fertility may be impaired in patients being treated with Ogsiveo (nirogacestat). The long-term effects of nirogacestat on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment with nirogacestat. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.

Drugs/Diseases

Util A	Util B	Util C
Nirogacestat		

Gender: Female
Age Range: 18 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

7. Nirogacestat / Strong or Moderate CYP3A4 Inhibitors ___√____ _____ _____

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with a strong or moderate CYP3A inhibitor should be avoided. Nirogacestat is a CYP3A substrate, and concomitant use with a strong or moderate CYP3A inhibitor may increase nirogacestat exposure, which may increase the risk of nirogacestat adverse reactions.

Drugs/Diseases

Util A	Util B		Util C
Nirogacestat	Atazanavir	Idelalisib	
	Aprepitant	Itraconazole	
	Clarithromycin	Ketoconazole	
	Cobicistat	Nefazodone	
	Crizotinib	Darunavir	
	Diltiazem	Posaconazole	
	Dronedarone	Ritonavir	
	Erythromycin	Tipranavir	
	Fluconazole	Verapamil	
	Fluvoxamine	Voriconazole	
	Fosamprenavir	Nelfinavir	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

8. Nirogacestat / Strong or Moderate CYP3A4 Inducers ___√____ _____ _____

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with a strong or moderate CYP3A inducer should be avoided. Nirogacestat is a CYP3A substrate, and concomitant use with a strong or moderate CYP3A inducer may decrease nirogacestat exposure, which may reduce the effectiveness of nirogacestat.

Drugs/Diseases

Util A	Util B	Util C
Nirogacestat	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

9. Nirogacestat / PPIs & H-s Antagonists _____ ___√____ _____

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with proton pump inhibitors and H2 blockers should be avoided. Nirogacestat is poorly soluble at pH ≥ 6. Gastric acid-reducing agents may decrease serum nirogacestat exposure, which may reduce the effectiveness of nirogacestat. If concomitant use cannot be avoided, nirogacestat can be staggered with antacids (e.g., administer nirogacestat 2 hours before or 2 hours after antacid use).

Drugs/Diseases

Util A	Util B		Util C
Nirogacestat	Dexlansoprazole	Cimetidine	
	Esomeprazole	Famotidine	
	Lansoprazole	Nizatidine	
	Omeprazole		
	Rabeprazole		

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

10. Nirogacestat / CYP3A4 Substrates w/NTI _____ ___√_____ _____

Alert Message: Avoid the concomitant use of Ogsiveo (nirogacestat) with CYP3A4 substrates where minimal concentration changes may lead to serious adverse substrate-related reactions. Nirogacestat is a CYP3A4 inhibitor, and concurrent use with a CYP3A4 substrate with a narrow therapeutic index may increase CYP3A substrate exposure, which may increase the risk of substrate-related adverse reactions.

Drugs/Diseases

Util A	Util B					Util C
Nirogacestat	Avanafil	Eletriptan	Lurasidone	Simvastatin	Vardenafil	
	Budesonide	Eplerenone	Maraviroc	Sirolimus		
	Buspirone	Everolimus	Midazolam	Tacrolimus		
	Conivaptan	Felodipine	Naloxegol	Ticagrelor		
	Darifenacin	Ibrutinib	Nisoldipine	Tipranavir		
	Darunavir	Lomitapide	Quetiapine	Tolvaptan		
	Dronedarone	Lovastatin	Sildenafil	Triazolam		

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

11. Nirogacestat / Pregnancy / Pregnancy Negating ___√_____ _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Ogsiveo (nirogacestat) can cause fetal harm or loss of pregnancy when administered to a pregnant woman. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and embryo-fetal death at maternal exposures below the human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Nirogacestat	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

12. Nirogacestat / Lactation ___√_____ _____ _____

Alert Message: There are no data on the presence of Ogsiveo (nirogacestat) or its metabolites in human milk or the effects of nirogacestat on a breastfed child or milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with nirogacestat and for 1 week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Nirogacestat	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

13. Nirogacestat /Therapeutic Appropriateness _____ ____√____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Ogsiveo (nirogacestat) and for 1 week after the last dose. Ogsiveo (nirogacestat) can cause fetal harm or loss of pregnancy when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C
Nirogacestat		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

14. Nirogacestat /Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Ogsiveo (nirogacestat) and for 1 week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Nirogacestat		

Gender: Male

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

15. Nirogacesta / Non-adherence ___√_____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Ogsiveo (nirogacestat). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Nirogacestat		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

16. Paliperidone ER Injection / Overuse ___√_____ _____ _____

Alert Message: Erzofri (paliperidone extended-release injection) may be over-utilized. The maximum recommended dose of paliperidone extended-release injection is 234 mg monthly.

Drugs/Diseases

Util A	Util B	Util C (Exclude)
Paliperidone ER Injection		Renal Impairment

Max Dose: 234 mg/month

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

17. Paliperidone ER Injection / Therapeutic Appropriateness ____√____ _____ _____

Alert Message: The safety and effectiveness of Erzofri (paliperidone extended-release injection) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Paliperidone ER Injection		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

18. Paliperidone ER Injection / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: The use of Erzofri (paliperidone extended-release injection) is not recommended in patients with moderate or severe renal impairment (creatinine clearance < 50 mL/min). Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Paliperidone ER Injection		CKD Stage 3b
		CKD Stage 4
		CKD Stage 5
		ESRD

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

19. Paliperidone ER Injection / Mild Renal Impairment ___√_____ _____ _____

Alert Message: Dose reduction of Erzofri (paliperidone extended-release injection) is recommended for patients with mild renal impairment. Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment. For patients with mild renal impairment (creatinine clearance >/= 50 mL/min to < 80 mL/min (Cockcroft-Gault Formula), initiate paliperidone extended-release injection with a dose of 234 mg on treatment Day 1 in the deltoid muscle. Follow with the recommended monthly dosage of 78 mg, administered in either the deltoid or gluteal muscle. Adjust monthly dosage based on tolerability and/or response within the strengths of 39 mg, 78 mg, 117 mg, or 156 mg. The maximum monthly dosage is 156 mg for patients with mild renal impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Paliperidone ER Injection		Mild Renal Impairment

Max Dose: 156 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

20. Semaglutide Tabs / Overuse ___√_____ _____ _____

Alert Message: Rybelsus (semaglutide formulation R2) may be over-utilized. The recommended maximum daily dose of oral semaglutide is 9 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Semaglutide R2 Tabs		

Max Dose: 9 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Dec. 2024, Novo Nordisk, Inc.

21. Topiramate Oral Solution / Overuse - Migraine ____√____ _____ _____

Alert Message: The recommended total daily dose of topiramate oral solution for the preventive treatment of migraines in patients 12 years of age and older is 100 mg per day in two divided doses.

Drugs/Diseases

Util A	Util B	Util C (Include)
Topiramate Sol		Migraine

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

22. Aripiprazole / Overuse _____ _____ ___√___

Alert Message: Opipza (aripiprazole) may be over-utilized. The manufacturer's recommended maximum dose of aripiprazole for the treatment of schizophrenia is 30 mg/day; major depressive disorder or irritability associated with autistic disorder is 15 mg/day; and for Tourette's disorder it is 10 mg/day in patients < 50 kg or 15 mg/day for patients 50 kg or more.

Drugs/Diseases

Util A	Util B	Util C
Aripiprazole Film		

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Opipza Prescribing Information, March 2025, Carwin Pharmaceutical Associates.

23. Benzgalantamine / Overuse ___√___ _____ _____

Alert Message: Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine is 15 mg twice a day (a total of 30 mg/day).

Drugs/Diseases

Util A	Util B	Util C (Negating)
Benzgalantamine		Moderate to Severe Hepatic Impairment Moderate to Severe Renal Impairment

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

24. Benzgalantamine / Overuse – Moderate Hepatic Impairment ___√_____ _____ _____

Alert Message: Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine in patients with moderate hepatic impairment is 10 mg twice a day (a total of 20 mg/day).

Drugs/Diseases

Util A	Util B	Util C (Include)
Benzgalantamine		Moderate Hepatic Impairment

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

25. Benzgalantamine / Severe Hepatic Impairment ___√_____ _____ _____

Alert Message: Zunveyl (benzgalantamine delayed-release) use is not recommended in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Benzgalantamine		Severe Hepatic Impairment

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

26. Benzgalantamine / Overuse – Mod to Severe Renal Impairment _____ ___√_____ _____

Alert Message: Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine in patients with creatinine clearance of 9 to 59 mL/min is 10 mg twice a day (total 20 mg/day). In patients with creatinine clearance of less than 9mL/min, the use of benzgalantamine is not recommended. In pharmacokinetic studies, the AUC increased by 37% and 67% in patients with moderate and severe renal impairment, respectively, compared with normal volunteers.

Drugs/Diseases

Util A	Util B	Util C (Include)
Benzgalantamine		CKD Stage 3
		CKD Stage 3a
		CKD Stage 3b
		CKD Stage 4
		CKD Stage 5
		ESRD

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*

27. Benzgalantamine / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: The safety and effectiveness of Zunveyl (benzgalantamine delayed-release) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Benzgalantamine		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

28. Benzgalantamine / Non-adherence ___√_____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Zunveyl (benzgalantamine delayed-release). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Benzgalantamine		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Brown MT, Bussell J, Suparna D, et al. Medication Adherence: Truth and Consequences. Am J Med Sci. 2016 Apr;351(4):387-399.
Arlt S, Lindner R, Rosler A, et al., Adherence to Medication in Patients with Dementia, Predictors and Strategies for Improvement. Drugs Aging 2008;25(12):1033-1047.

29. Topiramate XR / Overuse - Migraine ___√_____ _____ _____

Alert Message: The recommended total daily dose of topiramate extended-release for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Topiramate XR	Migraine	

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

(✓) Approve ( ) Deny 11/25/25

Timothy "Bo" A. Offord, Jr.
Alabama Medicaid Commissioner
Date

F. Darlene Traffanstedt, MD
F. Darlene Traffanstedt, MD (Nov 18, 2025 10:13:38 CST)

■ Approve ☐ Deny Nov 18, 2025

F. Darlene Traffanstedt, MD
Medical Director
Date