Alabama Medicaid DUR Board Meeting Minutes
July 23, 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. Luke Engeriser, Dr. Janaki Nimmagadda, Dr. Rachel Seaman

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

Members Absent: Dr. Jeremy Osborn, Dr. Danielle Powell

Call to Order: The DUR Meeting was called to order by Dr. Bulloch at approximately 1:00 p.m.

Review and Adoption of Minutes: The minutes of the April 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 January 2025. She reported 12,978 manual PAs and overrides. Dr. Thomas reminded the Board Members that the previous quarter showed an increase in manual and electronic PA requests for the Respiratory Agents due to generic Symbicort® becoming non-preferred on October 1, 2024, but that the number of requests declined in January 2025. Dr. Thomas reported 25,343 total electronic requests for the month of January 2025. From the Prior Authorization and Override Response Time Ratio report for January 2025, Dr. Thomas reported that approximately 83% of all manual PAs and 85% of all overrides were completed in less than two hours. Ninety-four percent of all manual PAs and 93% of all overrides were completed in less than four hours. Ninety-five percent of all manual PAs and 94% of all overrides were completed in less than eight hours. For the month of February 2025, Dr. Thomas reported 12,560 manual PA requests and 22,916 electronic PA requests. She reported that 81% of all manual PAs and 83% of all overrides were completed in less than two hours. Ninety-two percent to 93% of all manual PAs and overrides were completed in less than four hours. Ninety-four percent of all manual PAs and 95% of all overrides were completed in less than eight hours. For the month of March 2025, Dr. Thomas reported 12,739 manual PA requests and 23,727 electronic PA requests. Dr. Thomas reported that approximately 78% of all manual PAs and 80% of all overrides were completed in less than two hours. Ninety-one percent of all manual PA requests and 92% of all overrides were completed in less than four hours. Ninety-four 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 October 1, 2024, through March 31, 2025. She reported 207,482 average recipients per month using pharmacy benefits, and an average paid per prescription of $166.93.

Cost Management Analysis: Dr. Thomas reviewed the Cost Management Analysis chart highlighting the number of recipients per month over the past two years and pointed out that the COVID-19 Public Health Emergency (PHE) ended May 2023, and the pharmacy flexibilities due to the COVID-19 pandemic ended on June 1, 2023. Dr. Thomas reported an average cost per claim of $184.35 for March 2025 and compared previous months contained in the table. From the 1st 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 01/01/2025 – 03/31/2025, Dr. Thomas reported the top five drugs: amoxicillin, cetirizine, albuterol sulfate HFA, azithromycin, and oseltamivir phosphate. Dr. Littlejohn Newman pointed out that hydrocodone-APAP was not listed in the top 25 chart. Dr. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 01/01/2025 – 03/31/2025: Humira® Citrate-free Pen,

Dupixent® Pen, Trikafta®, Invega Sustenna®, and Ozempic®. 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.

Proposed Criteria: Dr. Thomas presented a proposed set of 34 criteria to the Board and instructed Board members to mark their ballots. Of the 34 proposed criteria, results from the criteria vote returned 28 approved and 4 amended, and 2 rejected.

Code of Federal Regulations (CFR): Dr. Littlejohn Newman reviewed the Code of Federal Regulations (CFR) related to RDUR. She highlighted the role of the RDUR Board, educational program, and the annual report.

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. Dr. Wanschek reviewed the July 1, 2025, PDL updates and the Medicaid Medications for Opioid Use Disorder (MOUD) Project. L. Eddings-Haygood reminded the Board members that every July the Board votes for a Vice Chair. Ballots were distributed and members were asked to mark their ballots and pass them to the front. Results of the vote elected Dr. Sutton as Vice Chair. The current Vice Chair, Dr. Bulloch, will begin her term as Chairman of the Board beginning with the October 2025 meeting.

P & T Committee Update: Dr. Wanschek began the P & T Update by informing the Board that the last P & T meeting was held on May 7, 2025, and covered the Wakefulness Promoting Agents; the Anti-infectives; and the Cerebral Stimulants. The next meeting is scheduled for August 6, 2025, and will cover the Hepatitis C Antivirals and the remaining anti-infectives.

Next Meeting Date: Dr. Bulloch informed the Board that the next DUR Meeting will be held on October 22, 2025. A motion to adjourn the meeting was made by D. McConaghy and Dr. Kelley 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. Repotrectinib / Overuse Alert Message: Augtyro (repotrectinib) may be over-utilized. The recommended dosage of repotrectinib for adult and pediatric patients 12 years of age and older is 160 mg taken orally once daily with or without food for 14 days, then increase to 160 mg twice daily and continue until disease progression or unacceptable toxicity. Drugs/Diseases Util A Util B Util C Repotrectinib Max Dose: 320 mg/day References: Clinical Pharmacology, 2024 Elsevier/Gold Standard. Facts & Comparisons, 2024 Updates, Wolters Kluwer Health. Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.	√		
2. Repotrectinib / Therapeutic Appropriateness Alert Message: The safety and effectiveness of Augtyro (repotrectinib) have not been established in pediatric patients younger than 12 years of age with solid tumors who have an NTRK gene fusion. Drugs/Diseases Util A Util B Util C Repotrectinib Age Range: 0 – 12 yoa References: Clinical Pharmacology, 2024 Elsevier/Gold Standard. Facts & Comparisons, 2024 Updates, Wolters Kluwer Health. Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.	√		

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

3. Repotrectinib / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: The safety and effectiveness of Augtyro (repotrectinib) in pediatric patients with ROS1-positive NSCLC have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Repotrectinib		Neoplasm of Lungs

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

4. Repotrectinib / Hepatotoxicity _____ ___√_____ _____

Alert Message: Augtyro (repotrectinib) can cause hepatotoxicity. Among the 426 patients treated with repotrectinib in clinical trials, increased alanine transaminase (ALT) occurred in 38%, and increased aspartate aminotransferase (AST) occurred in 41%. The median time to onset of increased ALT or AST was 15 days (range: 1 day to 1.9 years). Monitor liver function tests, including ALT, AST, and bilirubin, every 2 weeks during the first month of treatment, then monthly thereafter and as clinically indicated. Withhold and then resume at the same or reduced dose upon improvement or permanently discontinue repotrectinib based on the severity.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib	Abnormal Liver Enzyme Test	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

5. Repotrectinib / Interstitial Lung Disease _____ _____ __√_____

Alert Message: Augtyro (repotrectinib) can cause interstitial lung disease (ILD)/pneumonitis. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold repotrectinib in patients with suspected ILD/pneumonitis and permanently discontinue repotrectinib if ILD/pneumonitis is confirmed.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib	Interstitial Lung Disease	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

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

6. Repotrectinib / Skeletal Fractures _____ _____ __√_____

Alert Message: Augtyro (repotrectinib) can cause skeletal fractures. Promptly evaluate patients with signs or symptoms (e.g., pain, changes in mobility, deformity) of fractures. There are no data on the effects of repotrectinib on the healing of known fractures and the risk of future fractures.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib	Bone Fractures	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

7. Repotrectinib / P-gp Inhibitors ___√_____ _____ _____

Alert Message: The concomitant use of Augtyro (repotrectinib), a P-gp substrate, with P-gp inhibitors should be avoided. Concomitant use of repotrectinib with a P-gp inhibitor may increase repotrectinib exposure, which may increase the incidence and severity of repotrectinib adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib	Abrocitinib	
	Amiodarone	
	Cyclosporine	
	Lapatinib	
	Quinidine	
	Ranolazine	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

8. Repotrectinib / Strong & Moderate CYP3A4 Inhibitors ___√_____ _____ _____

Alert Message: The concomitant use of Augtyro (repotrectinib) with strong or moderate CYP3A inhibitors should be avoided. Concurrent use of repotrectinib with a strong or moderate CYP3A inhibitor may increase repotrectinib exposure, which may increase the incidence and severity of adverse reactions of repotrectinib. Discontinue CYP3A inhibitors for 3 to 5 elimination half-lives of the CYP3A inhibitor prior to initiating repotrectinib.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

9. Repotrectinib / Strong or Moderate CYP3A4 Inducers ___√_____ _____ _____

Alert Message: The concomitant use of Augtyro (repotrectinib) with strong or moderate CYP3A inducers should be avoided. Concomitant use of repotrectinib with a strong or moderate CYP3A inducer may decrease repotrectinib plasma concentrations, which may decrease the efficacy of repotrectinib.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

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

10. Repotrectinib / Certain 3A4 Substrates w/ NTI ____ ___√____ ____

Alert Message: The concurrent use of Augtyro (repotrectinib) with a CYP3A4 substrate with a narrow therapeutic index should be avoided unless the use is otherwise recommended in the Prescribing Information for CYP3A substrates. Repotrectinib is a CYP3A4 inducer. Concomitant use of repotrectinib with a sensitive CYP3A4 substrate decreases the concentration of the CYP3A4 substrate, which can reduce the efficacy of the substrate. If concomitant use is unavoidable, increase the CYP3A4 substrate dosage in accordance with approved product labeling.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib	Sirolimus	
	Tacrolimus	
	Warfarin	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

11. Repotrectinib / Hormonal Contraceptives ___√____ ____ ____

Alert Message: Augtyro (repotrectinib) is a CYP3A4 inducer, which can decrease progestin or estrogen exposure to an extent that could reduce the effectiveness of hormonal contraceptives. Avoid concomitant use of repotrectinib with hormonal contraceptives. Advise females of reproductive potential to use an effective nonhormonal contraceptive.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib	Progestin Estrogen Contraceptives	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

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

12. Repotrectinib / Pregnancy / Pregnancy Negating ___√___ _____ _____

Alert Message: Based on literature reports in humans with congenital mutations leading to changes in tropomyosin receptor tyrosine kinase (TRK) signaling, findings from animal studies, and its mechanism of action, Augtyro (repotrectinib) can cause fetal harm when administered to a pregnant patient. Oral administration of repotrectinib to pregnant rats during the period of organogenesis resulted in fetal malformations at doses approximately 0.3 times the recommended 160 mg twice daily dose based on body surface area (BSA).

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

13. Repotrectinib / Lactation ___√___ _____ _____

Alert Message: There are no data on the presence of Augtyro (repotrectinib) in human milk or its effects on either the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children from repotrectinib, advise a lactating woman to discontinue breastfeeding during treatment with repotrectinib and for 10 days after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

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

14. Repotrectinib / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: Advise females of reproductive potential to use effective non-hormonal contraception during treatment with Augtyro (repotrectinib) and for 2 months following the last dose, since repotrectinib can render some hormonal contraceptives ineffective. Repotrectinib can cause embryo-fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

15. Repotrectinib / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: Based on genotoxicity findings, advise male patients with female partners of childbearing potential to use effective contraception during treatment with repotrectinib and for 4 months following the last dose.

Drugs/Diseases

Util A	Util B	Util C
Repotrectinib		

Gender: Male

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

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

16. Repotrectinib / Non-adherence ___√_____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Augtyro (repotrectinib). 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
Repotrectinib		

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.

17. Upadacitinib LQ / Therapeutic Appropriateness – Atopic Dermatitis ___√_____ _____ _____

Alert Message: The safety and effectiveness of Rinvoq LQ (upadacitinib oral solution) in pediatric patients with atopic dermatitis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, ulcerative colitis, or Crohn's disease have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Upadacitinib LQ		Atopic Dermatitis
		Ankylosing Spondylitis
		Non-Radiographic Axial Spondyloarthritis
		Ulcerative Colitis
		Crohn's Disease

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Rinvoq/Rinvoq LQ Prescribing Information, April 2024, AbbVie Inc.

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

18. Upadacitinib LQ / Psoriatic Arthritis and pJIA ___√_____ _____ _____

Alert Message: Rinvoq LQ (upadacitinib oral solution) may be overutilized. The recommended dosage of upadacitinib oral solution for the treatment of psoriatic arthritis or polyarticular juvenile idiopathic arthritis in pediatric patients is weight-based. For pediatric patients weighing 30 kg or more the recommended dose is 6 mg twice daily. Pediatric patients weighing 20 kg to less than 30 kg should receive 4 mg twice daily and patients weighing 10 kg to less than 20 kg should receive 3 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Upadacitinib LQ		Psoriatic Arthritis
		Polyarticular Juvenile Idiopathic Arthritis

Age Range: 2 – 17 yoa
Max Dose: 12 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Rinvoq/Rinvoq LQ Prescribing Information, April 2024, AbbVie Inc.

19. Ketorolac / Probenecid _____ ___√_____ _____

Alert Message: The concomitant use of ketorolac tromethamine and probenecid is contraindicated. In drug interaction studies, concomitant administration of ketorolac and probenecid resulted in decreased clearance and volume of distribution of ketorolac and significant increases in ketorolac plasma levels (total AUC increased approximately threefold from 5.4 mcg/h/mL to 17.8 mcg/h/mL), and terminal half-life increased approximately twofold from 6.6 hours to 15.1 hours.

Drugs/Diseases

Util A	Util B	Util C
Ketorolac	Probenecid	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ketorolac Tromethamine Prescribing Information, August 2024, Chartwell RX, LLC.

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

20. Xanomeline/Trospium / Overuse ___√_____ _____ _____

Alert Message: Cobenfy (xanomeline/trospium) may be over-utilized. The maximum recommended dose of xanomeline/trospium is 125 mg/30 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C
Xanomeline/Trospium		

Max Dose: 250 mg/60 mg per day
Age Range: 18 – 64 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

21. Xanomeline/Trospium / Overuse ___√_____ _____ _____

Alert Message: Cobenfy (xanomeline/trospium) may be over-utilized. The maximum recommended dose of xanomeline/trospium in geriatric patients is one 100 mg/20 mg capsule twice daily.

Drugs/Diseases

Util A	Util B	Util C
Xanomeline/Trospium		

Max Dose: 200 mg/40 mg per day
Age Range: ≥ 65 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

22. Xanomeline/Trospium / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: The safety and effectiveness of Cobenfy (xanomeline/trospium) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Xanomeline/Trospium		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

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

23. Xanomeline/Trospium / Urinary Retention ___√_____ _____ _____

Alert Message: Cobenfy (xanomeline/trospium) use is contraindicated in patients with pre-existing urinary retention. Xanomeline/trospium can cause urinary retention. Monitor xanomeline/trospium recipients for symptoms of urinary retention, including urinary hesitancy, weak stream, incomplete bladder emptying, and dysuria. In patients with symptoms, consider reducing the dose of the medication, discontinuing treatment, or referring patients for urologic evaluation as clinically indicated.

Drugs/Diseases

Util A	Util B	Util C (Include)
Xanomeline/Trospium		Urinary Retention

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

24. Xanomeline/Trospium / Hepatic Impairment ___√_____ _____ _____

Alert Message: Cobenfy (xanomeline/trospium) use is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh Class B & C) and not recommended in patients with mild hepatic impairment. Patients with hepatic impairment have higher systemic exposures of xanomeline, a component of the combination product, compared to patients with normal hepatic function, which may result in an increased incidence of xanomeline-related adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Xanomeline/Trospium	Hepatic Impairment	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

25. Xanomeline/Trospium / Gastric Retention ___√_____ _____ _____

Alert Message: Cobenfy (xanomeline/trospium) use is contraindicated in patients with gastric retention. The trospium component of the combination product is an antimuscarinic agent and may decrease gastrointestinal motility.

Drugs/Diseases

Util A	Util B	Util C
Xanomeline/Trospium	Gastroparesis	
	Pyloric Stenosis	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

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

26. Xanomeline/Trospium / Narrow Angle Glaucoma ___√_____ _____ _____

Alert Message: Cobenfy (xanomeline/trospium) use is contraindicated in patients with untreated narrow-angle glaucoma. Pupillary dilation may occur due to the anticholinergic effects of xanomeline/trospium and may trigger an acute angle closure attack in patients with anatomically narrow angles. In patients known to have anatomically narrow angles, xanomeline/trospium should only be used if the potential benefits outweigh the risks and with careful monitoring.

Drugs/Diseases

Util A	Util B	Util C
Xanomeline/Trospium	Narrow Angle Glaucoma	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

27. Xanomeline/Trospium / GI Obstruction ___√_____ _____ _____

Alert Message: Cobenfy (xanomeline/trospium) should be administered with caution in patients with gastrointestinal obstructive disorders because of the risk of gastric retention. The trospium component of the combination product is an antimuscarinic agent and can decrease gastrointestinal motility. Xanomeline/trospium use is contraindicated in patients with gastric retention.

Drugs/Diseases

Util A	Util B	Util C
Xanomeline/Trospium	GI Obstruction	
	Ulcerative Colitis	
	Intestinal Atony	
	Myasthenia gravis	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

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

28. Xanomeline/Trospium / Moderate to Severe Renal Impairment _____ ___√_____ _____

Alert Message: The use of Cobenfy (xanomeline/trospium) is not recommended in patients with moderate to severe renal impairment. The trospium component of the combination product is an anticholinergic agent and is substantially excreted by the kidney. Systemic exposure to trospium is higher in patients with moderate and severe renal impairment, and anticholinergic adverse reactions are expected to be greater in this patient population.

Drugs/Diseases

Util A	Util B	Util C (Include)
Xanomeline/Trospium		CKD Stage 3
		CKD Stage 4
		CKD Stage 5

29. Xanomeline/Trospium / Strong CYP2D6 Inhibitors ___√_____ _____ _____

Alert Message: The xanomeline component of the combination product Cobenfy (xanomeline/trospium) is a CYP2D6 substrate. Concomitant use of xanomeline/trospium with strong CYP2D6 inhibitors may increase xanomeline plasma concentrations, increasing the frequency and/or severity of xanomeline-related adverse reactions. Monitor patients for increased frequency and/or severity of xanomeline-related adverse reactions.

Drugs/Diseases

Util A	Util B		Util C
Xanomeline/Trospium	Bupropion	Quinidine	
	Fluoxetine	Terbinafine	
	Paroxetine		

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

30. Xanomeline/Trospium / Drugs Eliminated by Tubular Secretion ___√_____ _____ _____

Alert Message: Concomitant use of Cobenfy (xanomeline/trospium) with drugs that are eliminated by active tubular secretion may increase plasma concentrations of trospium, a component of the combination product, and/or the concomitantly used drug due to competition for this elimination pathway. Concurrent use may increase the frequency and/or severity of adverse reactions from xanomeline/trospium and/or the concurrent drug eliminated by active tubular secretion. Monitor patients for increased frequency and/or severity of adverse reactions.

Drugs/Diseases

Util A	Util B			Util C
Xanomeline/Trospium	Adefovir	Entecavir	Quinidine	
	Amiloride	Memantine	Ranitidine	
	Cimetidine	Midodrine	Tenofovir	
	Dofetilide	Procainamide	Trimethoprim	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

31. Xanomeline/Trospium / Sensitive CYP3A4 Substrates ___√_____ _____ _____

Alert Message: The xanomeline component of the combination product Cobenfy (xanomeline/trospium) is a CYP3A4 inhibitor. Concomitant use of xanomeline/trospium with sensitive CYP3A4 substrates may result in increased plasma concentrations of the sensitive 3A4 substrate and frequency and/or severity of adverse reactions related to the sensitive 3A4 substrate. Monitor patients for increased frequency and/or severity of adverse reactions related to the sensitive 3A4 substrate.

Drugs/Diseases

Util A	Util B				Util C
Xanomeline/Trospium	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.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

32. Xanomeline/Trospium / P-gp Substrates w/ NTI ___√_____ _____ _____

Alert Message: Concomitant use of Cobenfy (xanomeline/trospium) with drugs that are substrates of P-gp transport may increase plasma concentrations of the P-gp substrates, increasing the risk of P-gp substrate-related adverse reactions. The xanomeline component of the combination product transiently inhibits P-gp transport locally in the gut. Monitor patients for increased frequency and/or severity of adverse reactions related to oral drugs that are narrow therapeutic index substrates of P-gp transport.

Drugs/Diseases

Util A	Util B		Util C
Xanomeline/Trospium	Cyclosporine	Sirolimus	
	Digoxin	Tacrolimus	
	Everolimus		

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

33. Xanomeline/Trospium / Pregnancy / Pregnancy Negating ___√___ _____ _____

Alert Message: There are no available data on Cobenfy (xanomeline/trospium) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of xanomeline alone or in combination with trospium chloride during the period of organogenesis or pregnancy and lactation caused maternal toxicities of adverse clinical signs, decreased body weight, weight gain and food consumption, and/or maternal death. At these maternally toxic doses, embryofetal and developmental toxicities included decreased fetal and neonatal weight, stillborn pups, and/or neonatal deaths.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Xanomeline/Trospium	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

34. Xanomeline/Trospium / Lactation ___√___ _____ _____

Alert Message: There are no data on the presence of either component of Cobenfy (xanomeline/trospium) in human milk, the effects on the breastfed infant, or the effects on milk production. Xanomeline and trospium are present in animal milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for xanomeline/trospium and any potential adverse effects on the breastfed infant from xanomeline/trospium or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Xanomeline/Trospium	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

(✓) Approve ( ) Deny 8/22/2025

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

F. Darlene Traffanstedt, MD (✓) Approve ( ) Deny 8/20/2025

F. Darlene Traffanstedt, MD, Alabama Medicaid Medical Director — Date

(✓) Approve ( ) Deny 8/21/25

Ginger Carmack, Alabama Medicaid Deputy Commissioner — Date