Alabama Medicaid DUR Board Meeting Minutes Summary
October 25, 2023

Members Present: Kelli Littlejohn Newman, Marilyn Bulloch, Crystal Deas, Bernie Olin, Dan McConaghy, Mary Stallworth, Melinda Rowe, Danielle Powell

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

Members Absent: Rachel Seaman, George Sutton

Call to Order: The DUR meeting was called to order by C. Deas at approximately 1:04 p.m.

Review and Adoption of Minutes: The minutes of the July 26, 2023, meeting were presented, and M. Stallworth made a motion to approve the minutes. D. McConaghy seconded the motion, and the motion was approved unanimously.

Prior Authorization and Overrides Update: L. Thomas began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of April 2023. She reported 14,133 manual PAs and overrides. There were 17,359 total electronic requests for the month of April 2023. From the Prior Authorization and Override Response Time Ratio report for April 2023, L. Thomas reported that approximately 3% of all manual PAs and 2% of all overrides were completed in less than two hours, but a total of 75% of all PAs were completed in under 2 hours (including electronic PA transactions). Nineteen percent of all manual PAs and eighteen percent of all overrides were completed in less than four hours. Fifty-six percent of all manual PAs and overrides were completed in less than eight hours. For the month of May 2023, L. Thomas reported 15,959 manual PA requests and 18,807 electronic PA requests were received. She reported that 6% of all manual PAs and 4% of all overrides were completed in less than two hours. Seventy-five percent of all prior authorizations were completed in less than two hours. Thirty percent of all manual PAs and 26% of all overrides were completed in less than four hours. Seventy-three percent of all manual PAs and 71% of all overrides were completed in less than eight hours. For the month of June 2023, L. Thomas reported 15,568 manual PA requests and 17,075 electronic PA requests. L. Thomas reported that approximately 12% of all manual PAs and 11% of all overrides were completed in less than two hours. Seventy-six percent of all prior authorizations were completed in less than two hours. Forty-seven percent of all manual PA requests and 42% of all overrides were completed in less than four hours. Seventy-eight percent of all manual PAs and 76% of all overrides were completed in less than eight hours.

Program Summary Review: L. Thomas briefly reviewed the Alabama Medicaid Program Summary for the months of January 2023 through June 30, 2023. She reported 246,440 average recipients per month using pharmacy benefits, and an average paid per prescription of $147.75.

Cost Management Analysis: L. Thomas reported an average cost per claim of $159.84 for June 2023 and compared previous months contained in the table. From the 2nd Quarter Drug Analysis, L. Thomas reported 84.4% generic utilization, 8.1% brand single-source, 3.4% brand multi-source (those requests which required a DAW override), and 4% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 04/01/2023 – 06/30/2023, L. Thomas reported the top five drugs: amoxicillin, cetirizine, albuterol sulfate HFA, fluticasone propionate, and montelukast sodium. L. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 04/01/2023 – 06/30/2023: Humira® Citrate-free Pen, Vyvanse®, Trulicity®, Invega Sustenna®, and Trikafta®. From the Top 15 Therapeutic Classes by Total Cost of Claims for the same time frame, L. Thomas reported the top five classes: Antipsychotic Agents, Disease-modifying Antirheumatic Agents, Skin and Mucous Membrane Agents, Incretin Mimetics, and Amphetamines.

Review of Palivizumab Utilization for the 2022 - 2023 Season: For this utilization report, the 2022-2023 Synagis® season was defined as October 2022 through March 2023. L. Thomas explained that during a typical RSV season, RSV activity in Alabama becomes significant in October. The season usually peaks in December and becomes statistically non-significant in January or February. According to the National Respiratory and Enteric Virus Surveillance System (NREVSS) website, RSV activity in Alabama became significant in the week ending 06/04/2022, peaked week ending 08/27/2022, and became statistically non-significant week ending 10/22/2022. L. Thomas reminded the Board that each recipient could receive a maximum of 5 doses per season and that all policies relating to Synagis® were based on clinical literature and recommendations. For the 2022-23 season, there were 2,433 claims for 496 recipients. The average cost per claim was $2,999 while the average cost per recipient was $14,710. L. Thomas pointed out that there were 1,480 prior authorizations requested over the course of the season, with an approval rate of 63%. L. Thomas briefly reviewed the top dispensing pharmacies and the top PA denial reasons. L. Thomas also reviewed the graphs comparing the total spend of all drugs compared to the total spend of Synagis® per RSV season. K. Newman reviewed the new monoclonal antibody, Beyfortus™, which is approved for children up to 24 months for the prevention of RSV and would be provided through the Vaccines for Children Program.

Proposed Criteria: L. Thomas presented the proposed set of 40 criteria to the Board and instructed the Board members to mark their ballots. Of the 40 proposed criteria, results from the criteria vote returned 40 approved.

Medicaid Update: K. 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 the MME phase down effective November 1, 2023, and a State Plan Amendment to cover additional adult vaccines.

P & T Committee Update: K. Newman began the P & T Update by informing the Board that the last P & T meeting was held on August 2, 2023, and covered the remaining anti-infective agents. The next meeting is scheduled for November 8, 2023, and will cover the antidiabetic agents; prenatal vitamins; antigout agents; and the genitourinary smooth muscle relaxants.

Next Meeting Date: C. Deas reminded the Board that the next DUR meeting will be held on January 24, 2024. A motion to adjourn the meeting was made by C. Deas and M. Bulloch seconded the motion. The meeting was adjourned at 2:00 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. Vonoprazan/Amoxicillin / Therapeutic Appropriateness	___√___	_____	_____

Alert Message: The safety and effectiveness of Voquezna Dual Pak (vonoprazan and amoxicillin) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

2. Vonoprazan/Amoxicillin / Rilpivirine-Containing Drugs ___√___ _____ _____

Alert Message: Concurrent use of Voquezna Dual Pak (vonoprazan and amoxicillin) with rilpivirine-containing products is contraindicated. Vonoprazan reduces intragastric acidity, which may alter the absorption of rilpivirine, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Rilpivirine	
	Rilpivirine/Cabotegravir	
	Rilpivirine/Dolutegravir	
	Rilpivirine/Emtricitabine/Tenofovir ala	
	Rilpivirine/Emtricitabine/Tenofovir dis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

3. Vonoprazan/Amoxicillin / Atazanavir-Containing Drugs ___√___ _____ _____

Alert Message: Concurrent use of Voquezna Dual Pak (vonoprazan and amoxicillin) with an atazanavir-containing product should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of atazanavir, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Atazanavir	
	Atazanavir Cobicistat	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

4. Vonoprazan/Amoxicillin / Nelfinavir ___√___ _____ _____

Alert Message: Concurrent use of Voquezna Dual Pak (vonoprazan and amoxicillin) with nelfinavir should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of nelfinavir, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Nelfinavir	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

5. Vonoprazan/Amoxicillin / Strong or Moderate CYP3A4 Inducers ___√___ _____ _____

Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a CYP3A substrate. Strong or moderate CYP3A inducers may decrease vonoprazan exposure, which may reduce the effectiveness of the vonoprazan and amoxicillin dual pack.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

6. Vonoprazan/Amoxicillin / CYP3A4 Substrates w/ NTI ___√___ _____ _____

Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a weak CYP3A inhibitor. Concurrent use of vonoprazan with CYP3A substrates where minimal concentration changes may lead to serious toxicities should be done with caution. Frequent monitoring of substrate concentrations and/or adverse reactions related to the substrate drugs is recommended when used with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Cyclosporine	
	Sirolimus	
	Tacrolimus	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

7. Vonoprazan/Amoxicillin / Clopidogrel ___√___ _____ _____

Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with clopidogrel, a CYP2C19 substrate, may result in reduced clopidogrel efficacy. Vonoprazan may reduce plasma concentrations of the active metabolite of clopidogrel and may cause a reduction in platelet inhibition. Carefully monitor the efficacy of clopidogrel and consider alternative anti-platelet therapy.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Clopidogrel	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

8. Vonoprazan/Amoxicillin / Citalopram ___√___ _____ _____

Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with citalopram, a CYP2C19 substrate, may result in increased citalopram exposure, increasing the risk for citalopram adverse reactions. The dose of citalopram should be limited to 20 mg/day when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Citalopram	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

9. Vonoprazan/Amoxicillin / Cilostazol ___√___ _____ _____

Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with cilostazol, a CYP2C19 substrate, may result in increased cilostazol exposure, increasing the risk for cilostazol-related adverse reactions. The dose of cilostazol should be limited to 50 mg twice daily when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Cilostazol	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

10. Vonoprazan/Amoxicillin / Severe Renal Impairment ___√___ _____ _____

Alert Message: The use of Voquezna Dual Pak (vonoprazan and amoxicillin) should be avoided in patients with severe renal impairment (eGFR less than 30 mL/minute) or renal failure. The pack does not allow for appropriate dosage adjustments needed in these patients. In pharmacokinetic studies, patients with severe renal impairment had increased systemic exposure (2.4-times greater) to vonoprazan compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	CKD Stage 4	
	CKD Stage 5	
	ESRD	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

11. Vonoprazan/Amoxicillin / Moderate to Severe Hepatic Impairment ___√___ _____ _____

Alert Message: Avoid the use of Voquezna Dual Pak (vonoprazan and amoxicillin) in patients with moderate to severe hepatic impairment (Child-Pugh Class B or C). The pack does not allow for appropriate dosage adjustments needed for these patients. In pharmacokinetic studies, patients with severe hepatic impairment exhibited increased systemic exposure of vonoprazan (2.6-times greater) as compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

12. Vonoprazan/Amoxicillin / Pregnancy / Pregnancy Negating ___√___ _____ _____

Alert Message: There are no adequate and well-controlled studies of Voquezna Dual Pak (vonoprazan and amoxicillin) in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Avoid the use of vonoprazan and amoxicillin dual pack during pregnancy unless other treatments are not clinically appropriate.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Vonoprazan/Amoxicillin	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

13. Vonoprazan/Amoxicillin / Lactation ___√___ _____ _____

Alert Message: There are no data regarding the presence of the vonoprazan component of the Voquezna Dual Pak (vonoprazan and amoxicillin) in human milk, the effects on the breastfed infant or the effects on milk production. Vonoprazan and its metabolites are present in rat milk. Liver injury occurred in offspring from pregnant and lactating rats administered oral vonoprazan. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, a woman should pump and discard human milk for the duration of vonoprazan therapy, and for 2 days after therapy ends, and feed her infant stored human milk (collected prior to therapy) or formula.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

14. Finasteride/Tadalafil / Overuse ___√___ _____ _____

Alert Message: Entadfi (finasteride/tadalafil) may be over-utilized. The maximum recommended dose is one capsule (5mg finasteride/ 5 mg tadalafil) once daily for up to 26 weeks.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil		

Max Dose: 1 capsule/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

15. Finasteride/Tadalafil / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and effectiveness of Entadfi (finasteride/tadalafil) have not been established in patients less than 18 years of age.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

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

16. Finasteride/Tadalafil / Severe Hepatic Impairment ___√___ _____ _____

Alert Message: Entadfi (finasteride/tadalafil) use is not recommended in patients with severe hepatic impairment (Child-Pugh Class C). The finasteride component of the combination product is extensively metabolized in the liver. Finasteride has not been studied in patients with hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

17. Finasteride/Tadalafil / Hepatic Impairment ___√___ _____ _____

Alert Message: Entadfi (finasteride/tadalafil) should be used with caution in patients with mild to moderate hepatic impairment (Child-Pugh Class A or B). The finasteride component of the combination product is extensively metabolized in the liver. Finasteride has not been studied in patients with hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil	Hepatic Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

18. Finasteride/Tadalafil / Renal Impairment ___√___ _____ _____

Alert Message: Entadfi (finasteride/tadalafil) use is not recommended in patients with creatinine clearance less than 50 mL/min or on hemodialysis. Due to increased tadalafil exposure (AUC), limited clinical experience, and the lack of ability to influence clearance by dialysis, finasteride/tadalafil use is not recommended in patients with creatinine clearance less than 50 mL/min or on hemodialysis.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil	CKD Stage 3	
	CKD Stage 4	
	CKD Stage 5	
	Hemodialysis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

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

19. Finasteride/Tadalafil / Pregnancy / Pregnancy Negating ___√_____ _____ _____

Alert Message: Entadfi (finasteride/tadalafil) is contraindicated in pregnancy and not indicated for use in females. Based on animal studies and its mechanism of action, finasteride, a component of finasteride/tadalafil, may cause abnormal development of external genitalia in a male fetus if administered to a pregnant female. Females of reproductive potential, including pregnant females, should not handle crushed or open finasteride/tadalafil capsules because of possible exposure of a male fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Finasteride/Tadalafil	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

20. Vericiguat / Overuse ___√_____ _____ _____

Alert Message: Verquvo (vericiguat) may be over-utilized. The recommended target maintenance dose of vericiguat is 10 mg once daily, as tolerated by patients.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat		

Max Dose: 10 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

21. Vericiguat / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: The safety and effectiveness of Verquvo (vericiguat) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

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

22. Vericiguat / Guanylate Cyclase Stimulators ___√___ _____ _____

Alert Message: The concurrent use of Verquvo (vericiguat) with another soluble guanylate cyclase (sGC) stimulator is contraindicated.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat	Riociguat	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

23. Vericiguat / PDE-5 Inhibitors ___√___ _____ _____

Alert Message: Coadministration of Verquvo (vericiguat) with phosphodiesterase type 5 (PDE-5) inhibitors is not recommended due to the potential for hypotension.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat	Avanafil	
	Sildenafil	
	Tadalafil	
	Vardenafil	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

24. Vericiguat / Pregnancy / Pregnancy Negating (Black Box) ___√___ _____ _____

Alert Message: Based on data from animal reproduction studies, Verquvo (vericiguat) may cause fetal harm when administered to a pregnant woman and is contraindicated during pregnancy.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

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

25. Vericiguat / Lactation ___√_____ _____ _____

Alert Message: There are no data on the presence of Verquvo (vericiguat) in human milk, the effects on the breastfed infant, or the effects on milk production. Vericiguat is present in the milk of lactating rats, and it is likely that vericiguat or its metabolites are present in human milk. Because of the potential for serious adverse reactions in breastfed infants from vericiguat, advise women not to breastfeed during treatment with vericiguat.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

26. Vericiguat / Therapeutic Appropriateness (Black Box) ___√_____ _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Verquvo (vericiguat) and for one month after the final dose. Verify the pregnancy status in females of reproductive potential prior to initiating vericiguat. Vericiguat may cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Vericiguat		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

27. Vericiguat / Non-adherence ___√_____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Verquvo (vericiguat). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Waxman A, Chen SY, Boulanger L, Golden G. Adherence to Phosphodiesterase Type 5 Inhibitors for the Treatment of Pulmonary Arterial Hypertension - A Real-World Analysis. *Chest*. 2011;140:736A.
Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending. Health Affairs. No.1 (2011):91-99.
Ho PM, Bryson CL, Rumsfeld JS. Medication Adherence: Its Importance in Cardiovascular Outcomes. Circulation. 2009;119:3028-3035.

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

28. Cannabidiol / Sensitive P-gp Substrates ___√___ _____ _____

Alert Message: Coadministration of Epidiolex (cannabidiol), a P-gp inhibitor, with a sensitive P-gp substrate (i.e., cyclosporine, digoxin, everolimus, sirolimus, and tacrolimus) may result in increased P-gp substrate exposure and risk of P-gp substrate-related toxicity. Increase monitoring of serum P-gp substrate concentrations and watch for potential signs and symptoms of clinical toxicity when starting, adjusting, or discontinuing cannabidiol. Dosage reduction of the P-gp substrate may be necessary.

Drugs/Diseases

Util A	Util B	Util C
Cannabidiol	Cyclosporine	
	Digoxin	
	Everolimus	
	Sirolimus	
	Tacrolimus	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

29. Deucravacitinib / Overuse ___√___ _____ _____

Alert Message: Sotyktu (deucravacitinib) may be over-utilized. The recommended dosage of deucravacitinib is 6 mg taken orally once daily with or without food.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib		

Max Dose: 6 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

30. Deucravacitinib / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and effectiveness of Sotyktu (deucravacitinib) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

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

31. Deucravacitinib / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: Sotyktu (deucravacitinib) is not recommended for use in patients with severe hepatic impairment (Child-Pugh C). No dose adjustment of deucravacitinib is recommended in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

32. Deucravacitinib / Serious Infections ___√_____ _____ _____

Alert Message: Avoid the use of Sotyktu (deucravacitinib) in patients with an active or serious infection. Serious infections have been reported in subjects with psoriasis who received deucravacitinib. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with deucravacitinib. A patient who develops a new infection during treatment with deucravacitinib should undergo prompt and complete diagnostic testing; appropriate antimicrobial therapy should be initiated, and the patient should be closely monitored. Interrupt deucravacitinib if a patient develops a serious infection. Do not resume deucravacitinib until the infection resolves or is adequately treated.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Serious Infections	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

33. Deucravacitinib / Tuberculosis ___√_____ _____ _____

Alert Message: Sotyktu (deucravacitinib) is not recommended for use in patients with active tuberculosis. Evaluate patients for active and latent tuberculosis (TB) infection prior to initiating treatment with deucravacitinib. If positive, start treatment for TB prior to deucravacitinib use.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Tuberculosis	
	History of Tuberculosis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

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

34. Deucravacitinib / Malignancies ___√___ _____ _____

Alert Message: Malignancies, including lymphomas, were observed in clinical trials with Sotyktu (deucravacitinib). Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with deucravacitinib, particularly in patients with a known malignancy (other than a successfully treated non-melanoma skin cancer) and patients who develop a malignancy when on treatment with deucravacitinib.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Malignancies	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

35. Deucravacitinib / Rhabdomyolysis & Symptoms ___√___ _____ _____

Alert Message: In clinical trials, cases of rhabdomyolysis were reported in subjects treated with Sotyktu (deucravacitinib), resulting in interruption or discontinuation of deucravacitinib dosing. Treatment with deucravacitinib was associated with an increased incidence of asymptomatic creatine phosphokinase (CPK) elevation and rhabdomyolysis compared to treatment with placebo. Discontinue deucravacitinib if markedly elevated CPK levels occur, or myopathy is diagnosed or suspected. Instruct patients to promptly report any unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Muscle Cramps	
	Muscle Spasm	
	Fever	
	Malaise	
	Abnormal Findings in Urine	
	Elevation of levels of liver transaminase	
	Rhabdomyolysis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

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

36. Deucravacitinib / Potential Risks of JAK Inhibitors ___√___ _____ _____

Alert Message: Sotyktu (deucravacitinib) is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of plaque psoriasis. It is not known whether TYK2 inhibition may be associated with the observed or potential adverse reactions of Janus Kinase (JAK) inhibition. In a large, randomized, postmarketing safety trial of a JAK inhibitor in rheumatoid arthritis (RA), patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of all-cause mortality, including sudden cardiovascular death, major adverse cardiovascular events, overall thrombosis, deep venous thrombosis, pulmonary embolism, and malignancies (excluding non-melanoma skin cancer) were observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. Deucravacitinib is not approved for use in RA.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Deep Vein Thrombosis	
	Thrombosis	
	Pulmonary Embolism	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

37. Deucravacitinib / Pregnancy / Pregnancy Negating ___√___ _____ _____

Alert Message: Available data from case reports on Sotyktu (deucravacitinib) use during pregnancy are insufficient to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Report pregnancies to the Bristol-Myers Squibb Company's Adverse Event reporting line at 1-800-721-5072.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

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

38. Deucravacitinib / Potent Immunosuppressants ___√___ _____ _____

Alert Message: Sotyktu (deucravacitinib) is not recommended for use in combination with other potent immunosuppressants. Concurrent use may result in enhanced immunosuppressive effects.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Immunosuppressants	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

39. Deucravacitinib / Lactation ___√___ _____ _____

Alert Message: There are no data on the presence of Sotyktu (deucravacitinib) in human milk, the effects on the breastfed infant, or the effects on milk production. Deucravacitinib is present in rat 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 deucravacitinib and any potential adverse effects on the breastfed infant from deucravacitinib or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

40. Deucravacitinib / Non-adherence ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Sotyktu (deucravacitinib). 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
Deucravacitinib		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Brown MT, Bussell J, Supmarna D, et al. Medication Adherence: Truth and Consequences. Am J Med Sci. 2016 Apr;351(4):387-399.
Thorneloe RJ, Bundy C, Griffiths CE, Ashcroft DM, Cordingley L. Nonadherence to Psoriasis Medication as an Outcome of Limited Coping Resources and Conflicting Goals: Findings From a Qualitative Interview Study with People with Psoriasis. Br J Dermatol. 2017 Mar;176(3):667-676. doi: 10.1111/bjd.15086. Epub 2016 Dec 17. PMID: 27664406; PMCID: PMC5363250.
Belinchon I, Rivera R, Blanch C, Comellas M, Lizan L. Adherence, Satisfaction and Preferences for Treatment in Patients with Psoriasis in the European Union: A Systematic Review of the Literature. Patient Prefer Adherence. 2016 Nov 17;10:2357-2367. doi: 10.2147/PPA.S117006. PMID: 27895471; PMCID: PMC5118025.

Stephanie McGee Azar, Commissioner (✓) Approve ( ) Deny 11/20/23 Date

Melinda Rowe, MD, (X) Approve ( ) Deny 11/16/2023 Date
Medical Director

Ginger Carmack, Deputy Commissioner (X) Approve ( ) Deny 11/16/23 Date