Alabama Medicaid DUR Board Meeting Minutes Summary
April 26, 2023

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

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

Members Absent: Rachel Seaman, Marilyn Bulloch

Call to Order: The DUR meeting was called to order by D. Powell at approximately 1:00 p.m.

Review and Adoption of Minutes: The minutes of the January 25, 2023, meeting were presented, and M. Stallworth made a motion to approve the minutes. K. Tate 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 October 2022. She reported 13,659 manual PAs and overrides. There were 17,481 total electronic requests for the month of October 2022. From the Prior Authorization and Override Response Time Ratio report for October 2022, L. Thomas reported that approximately 15% of all manual PAs and 13% of all overrides were completed in less than two hours. Fifty-one percent of all manual PAs and 50% of all overrides were completed in less than four hours. Eighty-one percent of all manual PAs and of all overrides were completed in less than eight hours. L. Thomas reminded the Board Members that 75% of all PAs and overrides must be completed in under 8 hours. For the month of November 2022, L. Thomas reported 13,514 manual PA requests and 17,176 electronic PA requests were received. She reported that 5% of all manual PAs and of all overrides were completed in less than two hours. Thirty-six percent of all manual PAs and of all overrides were completed in less than four hours. Seventy-eight percent of all manual PAs and 81% of all overrides were completed in less than eight hours. For the month of December 2022, L. Thomas reported 13,408 manual PA requests and 16,518 electronic PA requests. L. Thomas reported that approximately 9% of all manual PAs and 8% of all overrides were completed in less than two hours. Twenty-seven percent of all manual PA requests and all overrides were completed in less than four hours. Seventy percent of all manual PAs and 74% 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 July 2022 through December 31, 2022. She reported 248,770 average recipients per month using pharmacy benefits, and an average paid per prescription of $139.08.

Cost Management Analysis: L. Thomas reported an average cost per claim of $148.35 for December 2022 and compared previous months contained in the table. L. Thomas pointed out the increase in recipients over the past few years due to the continuous enrollment conditions associated with the COVID-19 public health emergency (PHE). From the 4th Quarter Drug Analysis, L. Thomas reported 84% generic utilization, 8% brand single-source, 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 10/01/2022-12/31/2022, L. Thomas reported the top five drugs: amoxicillin, albuterol sulfate HFA, oseltamivir phosphate, cetirizine, and azithromycin. L. Thomas pointed out that amoxicillin remained at the top position like previous quarters. L. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 10/01/2022-12/31/2022: Humira® Citrate-free Pen, Vyvanse®, Trikafta®, Trulicity®, and Invega® Sustenna®. L. Thomas informed the Board Members that Trulicity® returned to preferred status on April 1, 2023. 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, Amphetamines, and Incretin Mimetics.

RDUR Intervention Report: L. Thomas presented the RDUR Activity Report for April 2022. She reported 500 profiles reviewed and 899 letters sent with 57 responses received as of the date of the report. She reported 29 of 53 physicians indicated that they found the RDUR letters "useful" or "extremely useful". The criteria for the cycle of intervention letters included Drug-Drug Interaction (Support Act criteria – pure opioid agonists and benzodiazepines); Drug-Drug Interaction (Support Act criteria – pure opioid agonists and antipsychotics); Drug-Drug Interactions (risk of gabapentinoids and CNS depressants).

Proposed Criteria: L. Thomas presented the proposed set of seven additional SUPPORT Act Monitoring criteria to the Board along with 46 RDUR criteria. She instructed the Board members to mark their ballots. Of the seven proposed SUPPORT Act criteria, results from the criteria vote returned four approved and 3 rejected. Of the 46 proposed RDUR criteria, results from the criteria vote returned 46 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. K. Newman reviewed the re-enrollment process for AL Medicaid recipients; the discontinuation of certain NDCs for monovalent COVID-19 vaccines; the extension of postpartum coverage; and the upcoming changes due to the end of the COVID-19 national PHE.

P & T Committee Update: K. Newman began the P & T Update by informing the Board that the last P & T meeting was held on February 8, 2023, and covered the calcitonin gene-related peptide antagonists; proton-pump inhibitors; skeletal muscle relaxants; opiate agonists and partial agonists; selective serotonin agonists; antiemetics; anxiolytics, sedatives, and hypnotics; skin and mucous membrane agents; and disease-modifying antirheumatic agents. The next meeting is scheduled for May 3, 2023, and will cover the wakefulness promoting agents; anti-infectives; and cerebral stimulants.

Next Meeting Date: D. Powell reminded the Board that the next DUR meeting will be held on July 26, 2023. L. Eddings-Haygood stated that the Board will vote for the Vice Chair position at the upcoming July 2023 meeting. A motion to adjourn the meeting was made by B. Olin and C. Deas seconded the motion. The meeting was adjourned at 2:25 p.m.

Respectfully submitted,

Lori Thomas, PharmD

Lori Thomas, PharmD.

ALABAMA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
SUPPORT ACT MONITORING
CRITERIA RECOMMENDATIONS

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
1. Short-Acting Opioids / Duplicate Therapy	√		

Alert Message: The patient is receiving therapeutic duplication of short-acting opioids. The SUPPORT Act of 2018 requires that Medicaid monitor the use of opioids.

Drugs/Diseases		
Util A	Util B	Util C **(Negating)**
Short-Acting Opioids		Malignancy

References:
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT Act; P.L. 115-271, 24 October 2018).

2. Long-Acting Opioids / Duplicate Therapy	√		

Alert Message: The patient is receiving therapeutic duplication of long-acting opioids. The SUPPORT Act of 2018 requires that Medicaid monitor the use of opioids.

Drugs/Diseases		
Util A	Util B	Util C **(Negating)**
Long-Acting Opioids		Malignancy

References:
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT Act; P.L. 115-271, 24 October 2018).

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

3. Opioids / MME ___√___ _____ _____

Alert Message: The CDC Guideline for Prescribing Opioids for Chronic Pain recommends that clinicians should carefully reassess evidence of individual benefits and risks when considering increasing opioid dosage to >/= 50 morphine mg equivalents (MME)/day and should avoid increasing dosage to >/= 90 MME/day or carefully justify a decision to titrate to >/= 90 MME/day. Higher opioid dosages are associated with increased opioid-related adverse effects, including respiratory depression, opioid use disorder, overdose, and death. The SUPPORT Act of 2018 requires that Medicaid monitor the use of opioids.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Benzhydrocodone		Malignancy
Codeine		
Fentanyl		
Dihydrocodeine		
Hydrocodone		
Hydromorphone		
Levorphanol		
Meperidine		
Methadone		
Morphine		
Oxycodone		
Oxymorphone		
Tapentadol		
Tramadol		
Buprenorphine (for pain)		

Day Supply: 89 days in 90 days

References:
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT Act; P.L. 115-271, 24 October 2018).
Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016. MMWR Recomm Rep. ePub: 15 March 2016. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1er

4. Solid Oral Opioids (excluding APAP containing opiates) / Quantity Limit 240 units per 30 days _____ _____ ___√___

Alert Message: The patient is receiving more than 240 units of opioids per 30 days. The SUPPORT Act of 2018 requires that Medicaid monitor the use of opioids.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Solid Oral Opioids (Excluding APAP containing opiate products, hydromorphone, meperidine, and morphine IR)		Malignancy

Max: 240 units in 30 days

References:
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT Act; P.L. 115-271, 24 October 2018).

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

5. APAP Containing Solid Oral Opioids / Quantity Limit 360 units per 30 days ___√_____ _____ _____

Alert Message: The patient is receiving more than 360 units of opioids per 30 days. The SUPPORT Act of 2018 requires that Medicaid monitor the use of opioids.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
APAP Containing Solid Oral Opioids		Malignancy

Max: 360 units in 30 days

References:
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT Act; P.L. 115-271, 24 October 2018).

6. Liquid Oral Opioids / Quantity Limit 500 ml per 30 days _____ _____ __√_____

Alert Message: The patient is receiving more than 500 mL of opioids per 30 days. The SUPPORT Act of 2018 requires that Medicaid monitor the use of opioids.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Liquid Oral Opioids		Malignancy

Max: 500 mL in 30 days

References:
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT Act; P.L. 115-271, 24 October 2018).

7. Injectable Opioids / Quantity Limit 30 units per 30 days _____ _____ __√_____

Alert Message: The patient appears to be receiving more than 30 units of injectable opioids. The SUPPORT Act of 2018 requires that Medicaid monitor the use of opioids.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Injectable Opioids		Malignancy

References:
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT Act; P.L. 115-271, 24 October 2018).

ALABAMA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
1. Daridorexant / Overuse Alert Message: Quviviq (daridorexant) may be over-utilized. The recommended dosage range is 25 mg to 50 mg of daridorexant taken orally no more than once per night within 30 minutes of going to bed (with at least 7 hours remaining prior to planned awakening). Conflict Code: ER - Overutilization Drugs/Diseases Util A: Daridorexant Util B: Util C (Negating): Hepatic Impairment Max Dose: 50 mg/day References: Clinical Pharmacology, 2022 Elsevier/Gold Standard. Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.	√		
2. Daridorexant / Overuse – Hepatic Impairment Alert Message: Quviviq (daridorexant) may be over-utilized. The maximum recommended dosage in patients with moderate hepatic impairment (Child-Pugh score 7–9) is 25 mg of daridorexant no more than once per night. Moderate hepatic impairment may increase daridorexant systemic exposure to a clinically relevant extent which may increase the frequency or severity of adverse reactions. Conflict Code: ER - Overutilization Drugs/Diseases Util A: Daridorexant Util B: Hepatic Impairment Util C: Max Dose: 25 mg/day References: Clinical Pharmacology, 2022 Elsevier/Gold Standard. Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.	√		

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

3. Daridorexant / Severe Hepatic Impairment ___√_____ _____ _____

Alert Message: Quviviq (daridorexant) is not recommended in patients with severe hepatic impairment (Child-Pugh score ≥ 10). Daridorexant has not been studied in this patient population.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Cirrhosis	
	Liver Failure	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

4. Daridorexant / Therapeutic Appropriateness ___√_____ _____ _____

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

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Daridorexant		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

5. Daridorexant / Narcolepsy ___√_____ _____ _____

Alert Message: Quviviq (daridorexant) is contraindicated in patients with narcolepsy.

Conflict Code: MC – Drug Disease
Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Narcolepsy	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

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

6. Daridorexant / Therapeutic Appropriateness - Duration ___√___ _____ _____

Alert Message: Because sleep disturbances may be the presenting manifestation of a medical and/or psychiatric disorder, treatment of insomnia should be initiated only after careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia or the emergence of new cognitive or behavioral abnormalities may be the result of an unrecognized underlying psychiatric or medical disorder and can emerge during the course of treatment with sleep-promoting drugs such as Quviviq (daridorexant).

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases

Util A	Util B	Util C
Daridorexant		

Day Supply: > 10 days

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

7. Daridorexant / Complex Sleep Behavior ___√___ _____ _____

Alert Message: Complex sleep behaviors, including sleepwalking, sleep-driving, and engaging in other activities while not fully awake (e.g., preparing and eating food, making phone calls, having sex), have been reported to occur with the use of hypnotics, including orexin receptor antagonists such as Quviviq (daridorexant). These events can occur in hypnotic-naïve as well as in hypnotic-experienced persons. Discontinue daridorexant immediately if a patient experiences a complex sleep behavior.

Conflict Code: MC - Drug/Disease Precaution

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Other Sleep Disorders	
	Sleepwalking	
	Parasomnia	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

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

8. Daridorexant /Depression & Suicidality ___√___ _____ _____

Alert Message: As with other hypnotics, Quviviq (daridorexant) should be administered with caution in patients exhibiting symptoms of depression. Worsening of depression or suicidal ideation may occur. Patients with psychiatric disorders, including insomnia, are at increased risk of suicide. In primarily depressed patients treated with hypnotics, worsening of depression and suicidal thoughts and actions (including completed suicides) have been reported.

Conflict Code: MC - Drug/Disease Precaution

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Depression	
	Suicidal Ideation	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

9. Daridorexant / Compromised Respiratory Function ___√___ _____ _____

Alert Message: The effects of Quviviq (daridorexant) on respiratory function should be considered if prescribed to patients with compromised respiratory function. Daridorexant has not been studied in patients with moderate OSA requiring CPAP or severe OSA. Daridorexant has not been studied in patients with severe COPD.

Conflict Code: MC - Drug/Disease Precaution

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	COPD	
	Obstructive Sleep Apnea	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

10. Daridorexant / Strong CYP3A4 Inhibitors ___√___ _____ _____

Alert Message: The concurrent use of Quviviq (daridorexant) with a strong CYP3A4 inhibitor is not recommended. Daridorexant is a CYP3A4 substrate, and concomitant use with a strong 3A4 inhibitor has been shown to significantly increase exposure to daridorexant, increasing the risk of daridorexant-related adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Indinavir	Ritonavir
	Itraconazole	Saquinavir
	Ketoconazole	Voriconazole
	Nefazodone	Darunavir

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

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

11. Daridorexant / Moderate CYP3A4 Inhibitors ___√___ _____ _____

Alert Message: Concomitant use with Quviviq (daridorexant) with a moderate CYP3A4 inhibitor increases exposure to daridorexant which may increase the risk of daridorexant-related adverse reactions. The recommended dose of daridorexant is 25 mg when used with a moderate CYP3A4 inhibitor.

Drugs/Diseases

Util A	Util B		Util C
Daridorexant	Atazanavir	Diltiazem	Verapamil
	Aprepitant	Dronedarone	
	Cimetidine	Erythromycin	
	Ciprofloxacin	Fluconazole	
	Crizotinib	Fluvoxamine	
	Cyclosporine	Imatinib	

Max Dose: 25 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

12. Daridorexant / Strong to Moderate CYP3A4 Inducers ___√___ _____ _____

Alert Message: Concomitant use of Quviviq (daridorexant) with a strong or moderate CYP3A4 inducer decreases exposure to daridorexant which may reduce the efficacy of daridorexant. Concomitant use of daridorexant with a strong or moderate inducer of CYP3A4 is not recommended.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

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

13. Daridorexant / CNS Depressants ___√___ _____ _____

Alert Message: Concomitant use of alcohol or other CNS depressants with Quviviq (daridorexant) may lead to additive impairment of psychomotor performance and risk of CNS depression. Use daridorexant with caution in patients receiving CNS depressants. Consider dose adjustment of daridorexant and/or the CNS depressant(s) if used concomitantly. Avoid alcohol consumption with daridorexant.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	CNS Depressants	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

14. Daridorexant / Pregnancy / Pregnancy Negating ___√___ _____ _____

Alert Message: There are no available data on Quviviq (daridorexant) use in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to daridorexant during pregnancy. Pregnant women exposed to daridorexant and their healthcare providers are encouraged to call and register with Idorsia Pharmaceuticals Ltd.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

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

15. Daridorexant / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: There are no data on the presence of Quviviq (daridorexant) in human milk, the effects on the breastfed infant, or the effects on milk production. Daridorexant and its metabolites were present in the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Infants exposed to daridorexant through breastmilk should be monitored for excessive sedation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for daridorexant and any potential adverse effects on the breastfed infant from daridorexant or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

16. Tezepelumab-ekko / Overuse ___√___ _____ _____

Alert Message: Tezspire (tezepelumab-ekko) may be over-utilized. The recommended dosage of tezepelumab-ekko is 210 mg administered subcutaneously once every 4 weeks.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko		

Max Dose: 210 mg q 4 weeks

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

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

17. Tezepelumab-ekko / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: The safety and effectiveness of Tezspire (tezepelumab-ekko) in patients younger than 12 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

18. Tezepelumab-ekko / Corticosteroids ___√_____ _____ _____

Alert Message: Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with Tezspire (tezepelumab-ekko). Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko	Corticosteroids	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

19. Tezepelumab-ekko / Helminth Infections ___√_____ _____ _____

Alert Message: Treat patients with pre-existing helminth infections before initiating therapy with Tezspire (tezepelumab-ekko). If patients become infected while receiving treatment with tezepelumab-ekko and do not respond to anti-helminth treatment, discontinue treatment with tezepelumab-ekko until the infection resolves.

Conflict Code: MC - Drug/Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko	Helminth Infection	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

20. Tezepelumab-ekko / Pregnancy / Pregnancy Negating ___√___

Alert Message: There are no available data on Tezspire (tezepelumab-ekko) use in pregnant women to evaluate for any drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Placental transfer of monoclonal antibodies such as tezepelumab-ekko is greater during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

Conflict Code: MC - Drug/Disease Precaution
Drugs/Diseases

Util A	Util B	Util C (Negate)
Tezepelumab-ekko	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

21. Tezepelumab-ekko / Lactation ___√___

Alert Message: There is no information regarding the presence of Tezspire (tezepelumab-ekko) in human milk, its effects on the breastfed infant, or its effects on milk production. However, tezepelumab-ekko is a human monoclonal antibody immunoglobulin (IgG2 lambda), and immunoglobulin G (IgG) is present in human milk in small amounts. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for tezepelumab-ekko and any potential adverse effects on the breastfed infant from tezepelumab-ekko or the underlying maternal condition.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

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

22. Tezepelumab-ekko / Non-adherence ___√_____ _____ _____

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

Conflict Code: LR – Non-adherence
Drugs/Diseases
Util A Util B Util C
Tezepelumab-ekko

References:
Osterberg L, Blaschke T. Adherence to Medication. N Enel J Med 2005; 353:487- 497.
Murphy AC, Proeschal A, Brightling CE, et al. The Relationship Between Clinical Outcomes and Medication Adherence in difficult-to-control Asthma. Thorax. 2012;67:751-753.
Lindsay JT, Heaney LG. Nonadherence in Difficult Asthma - Facts, Myths, and a Time to Act. Patient Prefer Adherence. 2013;7:329-336. Published 2013 Apr 19. doi:10.2147/PPA.S38208

23. Baclofen Oral Solution / Overuse ___√_____ _____ _____

Alert Message: Ozobax (baclofen oral solution) may be over-utilized. The maximum recommended dose of baclofen oral solution is 80 mg daily (20 mg four times a day).

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Baclofen Oral Solution

Max Dose: 80 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

24. Baclofen Oral Solution / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: The safety and effectiveness of Ozobax (baclofen oral solution) in pediatric patients below the age of 12 years have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C
Baclofen Oral Solution

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

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

25. Baclofen Oral Solution / Renal Impairment ___√___ _____ _____

Alert Message: Because baclofen is primarily excreted unchanged by the kidneys, Ozobax (baclofen oral solution) should be used with caution in patients with renal impairment. Dosage reduction may be necessary for patients with renal impairment.

Conflict Code: MC - Drug/Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Baclofen Oral Solution	Renal Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

26. Baclofen Oral Solution / Pregnancy / Pregnancy Negating ___√___ _____ _____

Alert Message: There are no adequate data on the risk of major birth defects, miscarriages, or other maternal adverse outcomes associated with the use of Ozobax (baclofen oral solution) in pregnant women. There are adverse effects on fetal outcomes associated with withdrawal from baclofen after delivery.

Conflict Code: MC - Drug/Disease Precaution
Drugs/Diseases

Util A	Util B	Util C (Negate)
Baclofen Oral Solution	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

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

27. Baclofen Oral Solution / Lactation ___√_____ _____ _____

Alert Message: At recommended oral doses, baclofen is present in human milk. There are no human data on the effects of baclofen on milk production. Withdrawal symptoms can occur in breastfed infants when maternal administration of Ozobax (baclofen oral solution) is stopped or when breastfeeding is stopped. There are no adequate data on other effects of baclofen on the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for baclofen oral solution and any potential adverse effects on the breastfed infant from baclofen oral solution or the underlying maternal condition.

Conflict Code: MC - Drug/Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Baclofen Oral Solution	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

28. Baricitinib / Overutilization ___√_____ _____ _____

Alert Message: The maximum recommended dose of Olumiant (baricitinib) for the treatment of alopecia areata is 4 mg per day.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Baricitinib		Strong OAT3 Inhibitors
		CKD Stage 3, 4, 5
		ESRD
		Dialysis
		Rheumatoid Arthritis

Max Dose: 4 mg/day

References:
Olumiant Prescribing Information, June 2022, Eli Lilly and Company.

29. Baricitinib / OAT3 Inhibitors / Alopecia Areata ___√___ _____ _____

Alert Message: The recommended dose of Olumiant (baricitinib) in patients with alopecia areata taking strong organic anion transporter 3 (OAT3) inhibitors is 2 mg once daily (half the maximum recommended dose of 4 mg). Baricitinib is an OAT3 substrate, and concurrent use with a strong inhibitor of OAT3 inhibitor may result in increased baricitinib exposure.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C (Include)
Baricitinib	Probenecid	Alopecia Areata
	Teriflunomide	
	Leflunomide	

Max Dose: 2 mg/day

References:
Olumiant Prescribing Information, June 2022, Eli Lilly and Company.

30. Baricitinib / Renal Impairment / Alopecia Areata ___√___ _____ _____

Alert Message: Olumiant (baricitinib) may be over-utilized. The recommended maximum dose of baricitinib in patients with alopecia areata with moderate renal impairment (estimated glomerular filtration rate (GFR) between 30 and 60 mL/min/1.73 m2) is 2 mg once daily. Baricitinib is not recommended for use in patients with alopecia areata and severe renal impairment (estimated GFR of less than 30 mL/min/1.73 m2).

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Included)
Baricitinib	CKD 3	Alopecia areata

References:
Olumiant Prescribing Information, June 2022, Eli Lilly and Company.

31. Baricitinib / Myocardial Infarction & Stoke ___√___ _____ _____

Alert Message: Olumiant (baricitinib), a Janus kinase inhibitor (JAK), should be discontinued in patients that have experienced a myocardial infarction or stroke. In a postmarketing safety study, RA patients ≥50 years of age with ≥1 cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (defined as cardiovascular death, myocardial infarction, and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Baricitinib	Myocardial Infarction	
	Stroke	

References:
Olumiant Prescribing Information, June 2022, Eli Lilly and Company.

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

32. GLP-1 Receptor Agonists / Gallbladder Disease ___√___ _____ _____

Alert Message: Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and postmarketing. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

Conflict Code: MC - Drug/Disease Precaution

Drugs/Diseases

Util A	Util B	Util C
Albiglutide	Cholelithiasis	
Dulaglutide	Biliary Colic	
Exenatide	Cholecystitis	
Liraglutide		
Lixisenatide		
Semaglutide		

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

33. Tirzepatide / Overuse ___√___ _____ _____

Alert Message: Mounjaro (tirzepatide) may be over-utilized. The maximum recommended dose of tirzepatide is 15 mg injected subcutaneously once weekly.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

Max Dose: 15 mg q weekly

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

34. Tirzepatide / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and effectiveness of Mounjaro (tirzepatide) have not been established in pediatric patients younger than 18 years of age.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

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

35. Tirzepatide / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: Mounjaro (tirzepatide) is contraindicated in patients with a personal or family history of MTC or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).

Drugs/Diseases

Util A	Util B	Util C (Include)
Tirzepatide		Medullary Thyroid Carcinoma
		HX of Medullary Thyroid Carcinoma
		Multiple Endocrine Neoplasia Syndrome 2

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

36. Tirzepatide / Therapeutic Appropriateness ___√_____ _____ _____

Alert Message: Mounjaro (tirzepatide) causes a statistically significant increase in thyroid C-cell tumors in rats. It is unknown whether tirzepatide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) in humans, as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.

Drugs/Diseases

Util A	Util B	Util C (Include)
Tirzepatide		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

37. Tirzepatide / Pancreatitis ___√_____ _____ _____

Alert Message: Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including Mounjaro (tirzepatide). Tirzepatide has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on tirzepatide. After initiation of tirzepatide, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue tirzepatide and initiate appropriate management.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Pancreatitis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

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

38. Tirzepatide / Kidney Injury ___√_____ _____ _____

Alert Message: In patients treated with GLP-1 receptor agonists, including Mounjaro (tirzepatide), there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of tirzepatide in patients with renal impairment reporting severe gastrointestinal adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Renal Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

39. Tirzepatide / Gastroparesis ___√_____ _____ _____

Alert Message: Use of Mounjaro (tirzepatide) has been associated with gastrointestinal adverse reactions, sometimes severe. Tirzepatide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Gastroparesis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

40. Tirzepatide / Diabetic Retinopathy ___√_____ _____ _____

Alert Message: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Mounjaro (tirzepatide) has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Diabetic Retinopathy	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

41. Tirzepatide / Gallbladder Disease ___√___ _____ _____

Alert Message: Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist (including tirzepatide) trials and postmarketing. In Mounjaro (tirzepatide) placebo-controlled clinical trials, acute gallbladder disease (cholelithiasis, biliary colic, and cholecystectomy) was reported by 0.6% of tirzepatide-treated patients and 0% of placebo-treated patients. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Cholelithiasis	
	Biliary Colic	
	Cholecystitis	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

42. Tirzepatide / Insulin & Insulin Secretagogues ___√___ _____ _____

Alert Message: Patients receiving Mounjaro (tirzepatide) in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Insulin	
	Insulin Secretagogues	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

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

43. Tirzepatide / Oral Drugs with NTI ___√___ _____ _____

Alert Message: Mounjaro (tirzepatide) delays gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with tirzepatide. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with tirzepatide.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Carbamazepine	Phenytoin
	Cyclosporine	Procainamide
	Digoxin	Tacrolimus
	Ethosuximide	Theophylline
	Levothyroxine	Warfarin
	Lithium	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

44. Tirzepatide / Pregnancy / Pregnancy Negating ___√___ _____ _____

Alert Message: Available data with Mounjaro (tirzepatide) use in pregnant women are insufficient to evaluate a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide during pregnancy. Tirzepatide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

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

45. Tirzepatide / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: There are no data on the presence of Mounjaro (tirzepatide) in animal or human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for tirzepatide and any potential adverse effects on the breastfed infant from tirzepatide or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

46. Tirzepatide / Non-adherence ___√___ _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus. Arch Intern Med. 2006;166:1836-1841.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.
Butler RJ, Davis TK, Johnson WL, et al. Effects of Non-adherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.
Polonsky WH, Henry RR. Poor Medication Adherence in Type 2 Diabetes: Recognizing the Scope of the Problem and its Key Contributors. Patient Prefer Adherence. 2016 Jul 22;10:1299-1307.

Stephanie McGee Azar, Commissioner (✓) Approve ( ) Deny 6/2/2023 Date

M Rowe, MD (✓) Approve ( ) Deny 5/24/2023 Date

Melinda Rowe, MD,
Medical Director

Ginger Carmack, Deputy Commissioner (✓) Approve ( ) Deny _____ Date