Alabama Medicaid DUR Board Meeting Minutes Summary
January 25, 2023

Members Present: Kelli Littlejohn Newman, Danielle Powell, Crystal Deas, Marilyn Bulloch, Mary Stallworth, Kelly Tate, Melinda Rowe

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

Members Absent: Nina Ford Johnson, Amber Clark, Rachel Seaman, Bernie Olin, Dan McConaghy

Call to Order: The DUR meeting was called to order by D. Powell at approximately 1:10 p.m.

Review and Adoption of Minutes: The minutes of the October 26, 2022, meeting were presented, and C. Deas made a motion to approve the minutes. M. Bulloch 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 July 2022. She reported 12,484. There were 14,798 total electronic requests for the month of July 2022. From the Prior Authorization and Override Response Time Ratio report for July 2022, L. Thomas reported that approximately 46% of all manual PAs and 43% of all overrides were completed in less than two hours. Eighty-two percent of all manual PAs and 80% of all overrides were completed in less than four hours. Ninety-three percent of all manual PAs and of all overrides were completed in less than eight hours. For the month of August 2022, L. Thomas reported 14,797 manual PA requests and 17,484 electronic PA requests were received. She reported that 36% of all manual PAs and 32% of all overrides were completed in less than two hours. Eighty percent of all manual PAs and of all overrides were completed in less than four hours. Ninety-one percent of all manual PAs and 92% of all overrides were completed in less than eight hours. For the month of September 2022, L. Thomas reported 14,302 manual PA requests and 16,426 electronic PA requests. L. Thomas reported that approximately 18% of all manual PAs and 14% of all overrides were completed in less than two hours. Sixty-one percent of all manual PA requests and 58% of all overrides were completed in less than four hours. Eighty-six percent of all manual PAs and 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 April 2022 through September 30, 2022. She reported 3,881,061 total prescriptions, 234,003 average recipients per month using pharmacy benefits, and an average paid per prescription of $142.16.

Cost Management Analysis: L. Thomas reported an average cost per claim of $133.33 for September 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 3rd 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 07/01/2022-09/30/2022, L. Thomas reported the top five drugs: amoxicillin, cetirizine, albuterol sulfate HFA, azithromycin, and fluticasone propionate. L. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 07/01/2022-09/30/2022: Humira® Citrate-free Pen, Vyvanse®, Trikafta®, Trulicity®, and Invega® Sustenna®. L. Thomas informed the Board Members that Trulicity® became non-preferred January 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 Insulins. L. Thomas mentioned the top five were different than previous quarters.

RDUR Intervention Report: L. Thomas presented the RDUR Activity Report for January 2022. She reported 500 profiles reviewed and 527 letters sent with 43 responses received as of the date of the report. She reported 27 of 44 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 (triptans and SSRIs and SNRIs); Appropriate Use (concurrent use of buprenorphine and pure opiate agonists).

Proposed Criteria: L. Thomas presented the proposed set of 31 criteria to the Board and instructed the Board members to mark their ballots. Of the 31 proposed criteria, results from the criteria vote returned 31 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 reminded the Board members that the Agency is still preparing for the unwinding of the national COVID-19 PHE. K. Newman reviewed changes to the Hepatitis C medication criteria that were implemented in October 2022.

P & T Committee Update: K. Newman began the P & T Update by informing the Board that the last P & T meeting scheduled for November 9, 2022, was canceled due to lack of quorum. The next meeting scheduled for February 8, 2023, will be a double meeting and will cover 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.

Next Meeting Date: D. Powell reminded the Board that the next DUR meeting will be held on April 26, 2023. A motion to adjourn the meeting was made by K. Tate and C. Deas seconded the motion. The meeting was adjourned at 1:55 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. Metoclopramide Nasal Spray / Therapeutic Appropriateness	___√___	_____	_____

Alert Message: The safety and effectiveness of Gimoti (metoclopramide) in pediatric patients have not been established. Metoclopramide is not recommended for use in pediatric patients due to the risk of tardive dyskinesia (TD) and other extrapyramidal symptoms, as well as the risk of methemoglobinemia in neonates. Dystonias and other extrapyramidal symptoms associated with metoclopramide are more common in pediatric patients than in adults.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

2. Metoclopramide Nasal Spray / Tardive Dyskinesia (Black Box)	___√___	_____	_____

Alert Message: Gimoti (metoclopramide) is contraindicated in patients with a history of tardive dyskinesia (TS) or a dystonic reaction to metoclopramide. Metoclopramide can cause tardive dyskinesia (TD), a syndrome of potentially irreversible and disfiguring involuntary movements. The risk of developing TD and the likelihood that TD will become irreversible increases with duration of treatment and total cumulative dosage. Additionally, the risk of developing TD is increased among the elderly, especially elderly women, and in patients with diabetes mellitus. Due to the risk of developing TD, avoid treatment with metoclopramide for longer than 12 weeks. Metoclopramide is not recommended in geriatric patients as initial therapy.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		Tardive Dyskinesia

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

3. Metoclopramide Nasal Spray / Gastrointestinal Motility Issues	___√___	_____	_____

Alert Message: Gimoti (metoclopramide) is contraindicated in patients with conditions where stimulation of gastrointestinal motility might be dangerous (e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation).

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		GI Hemorrhage GI Obstruction GI Perforation

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

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

4. Metoclopramide Nasal Spray / Pheochromocytoma ___√___ _____ _____

Alert Message: Gimoti (metoclopramide) is contraindicated in patients with pheochromocytoma or other catecholamine-releasing paragangliomas. Metoclopramide may cause a hypertensive/pheochromocytoma crisis, probably due to the release of catecholamines from the tumor.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		Pheochromocytoma

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

5. Metoclopramide Nasal Spray / Epilepsy ___√___ _____ _____

Alert Message: Gimoti (metoclopramide) is contraindicated in patients with epilepsy. Metoclopramide may increase the frequency and severity of seizures.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		Epilepsy

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

6. Metoclopramide Nasal Spray / Depression ___√___ _____ _____

Alert Message: Avoid Gimoti (metoclopramide) use in patients with a history of depression. Depression has occurred in metoclopramide-treated patients with and without a history of depression. Symptoms have included suicidal ideation and suicide.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		Depression

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

7. Metoclopramide Nasal Spray / Hypertension ___√___ _____ _____

Alert Message: The use of Gimoti (metoclopramide) should be avoided in patients with hypertension. Metoclopramide may elevate blood pressure.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Hypertension	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

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

8. Metoclopramide Nasal Spray / Fluid Retention & Volume Overload ___√___ _____ _____

Alert Message: Because metoclopramide produces a transient increase in plasma aldosterone, patients with cirrhosis or congestive heart failure may be at risk of developing fluid retention and volume overload. Discontinue Gimoti (metoclopramide) if any of these adverse reactions occur.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal	Fluid Retention	Cirrhosis
	Volume Overload	Congestive Heart Failure

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

9. Metoclopramide Nasal Spray / Moderate to Severe Renal Impairment ___√___ _____ _____

Alert Message: Gimoti (metoclopramide) is not recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute), including those receiving hemodialysis and continuous ambulatory peritoneal dialysis. The clearance of metoclopramide is decreased, and the systemic exposure is increased in patients with moderate to severe renal impairment compared to patients with normal renal function, which may increase the risk of adverse reactions.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		CKD Stage 3, 4, and 5
		ESRD
		Hemodialysis

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

10. Metoclopramide Nasal Spray / Antipsychotics ___√___ _____ _____

Alert Message: The concurrent use of Gimoti (metoclopramide) with antipsychotics should be avoided. Both metoclopramide and antipsychotics can cause tardive dyskinesia (TD), other extrapyramidal symptoms (EPS), and neuroleptic malignant syndrome (NMS). Concomitant use of metoclopramide with these drugs may have an additive effect.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Antipsychotics	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

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

11. Metoclopramide Nasal Spray / Strong CY2D6 Inhibitors ___√___ _____ _____

Alert Message: The concurrent use of Gimoti (metoclopramide) with strong CYP2D6 inhibitors (e.g., bupropion, fluoxetine, paroxetine, and quinidine) is not recommended. Metoclopramide is a CYP2D6 substrate, and inhibition of CYP2D6-mediated metabolism may result in increased metoclopramide plasma concentrations and increased risk of adverse effects, including extrapyramidal symptoms.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Bupropion	
	Fluoxetine	
	Paroxetine	
	Quinidine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

12. Metoclopramide Nasal Spray / MAOIs ___√___ _____ _____

Alert Message: The concurrent use of Gimoti (metoclopramide) with monoamine oxidase inhibitors (MAOIs) should be avoided. Both metoclopramide and MAOIs can elevate blood pressure, and concurrent use of these drugs increase the risk of hypertension.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

13. Metoclopramide Nasal Spray / Drugs Decreasing Gastric Motility ___√___ _____ _____

Alert Message: Caution should be exercised when Gimoti (metoclopramide) is coadministered with a drug that impairs gastrointestinal motility. Metoclopramide stimulates gastric motility, and concurrent use with drugs that decrease gastric motility may cause a decrease in metoclopramide efficacy.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Anticholinergics	
	Opioids	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

14. Metoclopramide Nasal Spray / Dopamine Agonists ___√___ _____ _____

Alert Message: Gimoti (metoclopramide) is a dopamine antagonist, and concurrent use with a dopamine agonist (e.g., bromocriptine, levodopa, and rotigotine) may decrease the effectiveness of either drug. Avoid concomitant use of these agents if possible.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Apomorphine	
	Bromocriptine	
	Cabergoline	
	Levodopa	
	Pramipexole	
	Ropinirole	
	Rotigotine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

15. Metoclopramide Nasal Spray / Hepatic Impairment ___√___ _____ _____

Alert Message: Gimoti (metoclopramide) use is not recommended in patients with moderate or severe (Child-Pugh B or C) hepatic impairment. Patients with severe hepatic impairment (Child-Pugh C) have reduced systemic metoclopramide clearance (by approximately 50%) compared to patients with normal hepatic function. The resulting increase in metoclopramide blood concentrations increases the risk of adverse reactions. There are no pharmacokinetic data evaluating the safety of metoclopramide in patients with moderate hepatic impairment (Child-Pugh B).

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Hepatic Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

16. Abaloparatide / Overuse ___√___ _____ _____

Alert Message: Tymlos (abaloparatide) may be over-utilized. The recommended dose is 80 mcg subcutaneously once daily. The cumulative use of abaloparatide for more than 2 years during a patient's lifetime is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Abaloparatide		

Max Dose: 80 mcg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

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

17. Abaloparatide / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and effectiveness of Tymlos (abaloparatide) has not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Abaloparatide		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

18. Abaloparatide / Risk of Osteosarcoma ___√___ _____ _____

Alert Message: In animal studies, Tymlos (abaloparatide) caused a dose-dependent increase in the incidence of osteosarcoma in male and female rats. It is not known if abaloparatide will cause osteosarcoma in humans. The use of abaloparatide is not recommended in patients at increased risk for osteosarcoma, including those with Paget's disease of the bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton. The cumulative use of abaloparatide and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Drugs/Diseases

Util A	Util B	Util C (Include)
Abaloparatide		Paget's Disease
		Malignant Neoplasm of the Bone

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

19. Abaloparatide / Hypercalcemia ___√___ _____ _____

Alert Message: Tymlos (abaloparatide) may cause hypercalcemia. Abaloparatide use is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemia disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Drugs/Diseases

Util A	Util B	Util C (Include)
Abaloparatide		Hypercalcemia
		Primary Hyperparathyroidism

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

20. Abaloparatide / Hypercalciuria & Urolithiasis ___V___ _____ _____

Alert Message: Tymlos (abaloparatide) may cause hypercalciuria. It is unknown whether abaloparatide may exacerbate urolithiasis in patients with a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

Drugs/Diseases

Util A	Util B	Util C
Abaloparatide	Hypercalciuria	
	Urolithiasis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

21. Abaloparatide / Pregnancy / Pregnancy Negating ___V___ _____ _____

Alert Message: Tymlos (abaloparatide) is not intended for use in females of reproductive potential. There are no human data with abaloparatide use in pregnant women to inform any drug-associated risks. Animal reproduction studies with abaloparatide have not been conducted.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Abaloparatide	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

22. Abaloparatide / Therapeutic Appropriateness ___V___ _____ _____

Alert Message: Tymlos (abaloparatide) is not intended for use in females of reproductive potential. There is no information on the presence of abaloparatide in human milk, the effects on the breastfed infant, or the effects on milk production.

Drugs/Diseases

Util A	Util B	Util C
Abaloparatide	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

Criteria Recommendations	*Accepted*	*Approved As Amended*	*Rejected*
23. Baclofen Tablets / Overuse Alert Message: Baclofen may be over-utilized. The maximum recommended dose of baclofen is 80 mg daily (20 mg four times a day). Drugs/Diseases Util A / Util B / Util C Baclofen Tablets Max Dose: 80 mg/day References: Clinical Pharmacology, 2022 Elsevier/Gold Standard. Baclofen Tablets Prescribing Information, August 2019, Advagen Pharma Ltd.	√		
24. Baclofen Tablets / Therapeutic Appropriateness Alert Message: The safety and effectiveness of baclofen in pediatric patients below the age of 12 years have not been established. Drugs/Diseases Util A / Util B / Util C Baclofen Tablets Age Range: 0 – 11 yoa References: Clinical Pharmacology, 2022 Elsevier/Gold Standard. Baclofen Tablets Prescribing Information, August 2019, Advagen Pharma Ltd.	√		
25. Baclofen Tablets / Renal Impairment Alert Message: Baclofen is primarily excreted unchanged by the kidneys, and renal impairment may cause baclofen accumulation. Dosage reduction may be necessary for patients with renal impairment. Drugs/Diseases Util A / Util B / Util C Baclofen Tablets / Renal Impairment References: Clinical Pharmacology, 2022 Elsevier/Gold Standard. Baclofen Tablets Prescribing Information, August 2019, Advagen Pharma Ltd.	√		

26. Baclofen Tablets / 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 baclofen in pregnant patients. Baclofen should be used during pregnancy only if the benefit clearly justifies the potential risk to the fetus. There are adverse effects on fetal outcomes associated with withdrawal from baclofen after delivery.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Baclofen Tablets Prescribing Information, August 2019, Advagen Pharma Ltd.

27. Baclofen Tablets / 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 baclofen 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 suspension and any potential adverse effects on the breastfed infant from baclofen oral suspension or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Baclofen Tablets	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Baclofen Tablets Prescribing Information, August 2019, Advagen Pharma Ltd.

28. Dupilumab / Overutilization ___√___ _____ _____

Alert Message: The recommended maximum maintenance dose of Dupixent (dupilumab) for the treatment of eosinophilic esophagitis in adults and pediatric patients 12 years of age and older weighing at least 40 kg is 300 mg given every week.

Drugs/Diseases

Util A	Util B	Util C (Include)
Dupilumab		Eosinophilic Esophagitis

Maintenance Max Dose: 300mg every week.
Age Range: 12 - yoa

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Dupixent Prescribing Information, May 2022, Regeneron Pharmaceuticals, Inc.

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

29. Dupilumab / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and efficacy of Dupixent (dupilumab) for the treatment of eosinophilic esophagitis in pediatric patients less than 12 years of age and weighing less than 40 kg have not been established.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Dupilumab	Eosinophilic Esophagitis	Asthma
		Atopic Dermatitis

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Dupixent Prescribing Information, May 2022, Regeneron Pharmaceuticals, Inc.

30. Lurasidone / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and effectiveness of Latuda (lurasidone) for the treatment of bipolar depression in pediatric patients less than 10 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Lurasidone		Bipolar Depression

Age Range: 0 – 9 yoa

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

31. Mirtazapine / Therapeutic Appropriateness ___√___ _____ _____

Alert Message: The safety and effectiveness of mirtazapine have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Mirtazapine		

Age Range: 0 – 17 yoa

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

Stephanie McGee Azar, Commissioner (X) Approve ( ) Deny 2/21/23 Date

Melinda Rowe, MD (✓) Approve ( ) Deny 2/17/2023 Date
Melinda Rowe, MD,
Medical Director

Ginger Carmack, Deputy Commissioner (✓) Approve ( ) Deny 2-21-23 Date