**Alabama Medicaid DUR Board Meeting Minutes**
**April 24, 2024**

**Members Present:** Kelli Littlejohn Newman, Crystal Deas, Danielle Powell, George Sutton, Dan McConaghy, Marilyn Bulloch, Mary Stallworth, Melinda Rowe, Jeremy Osborn

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

**Members Absent:** R. Seaman, K. Kelley

**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 January 24, 2024, meeting were presented, and M. Bulloch made a motion to approve the minutes. D. Powell 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 2023. She reported 15,138 manual PAs and overrides. L. Thomas pointed out the number of Synagis requests received during this time. There were 17,011 total electronic requests for the month of October 2023. From the Prior Authorization and Override Response Time Ratio report for October 2023, L. Thomas reported that approximately 10% of all manual PAs and 9% of all overrides were completed in less than two hours, but a total of 76% of all PAs were completed in under 2 hours (including electronic PA transactions). Forty-one percent of all manual PAs and 43% of all overrides were completed in less than four hours. Seventy percent of all manual PAs and 73% of all overrides were completed in less than eight hours. K. Newman reminded the Board Members that 75% of all PAs and overrides must be completed in under 8 hours to meet contractual obligations. For the month of November 2023, L. Thomas reported 14,406 manual PA requests and 16,338 electronic PA requests were received. She reported that 8% of all manual PAs and 9% 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-five percent of all manual PAs and 37% of all overrides were completed in less than four hours. Seventy-eight percent of all manual PAs and 79% of all overrides were completed in less than eight hours. For the month of December 2023, L. Thomas reported 12,902 manual PA requests and 14,640 electronic PA requests. L. Thomas reported that approximately 17% of all manual PAs and overrides were completed in less than two hours. Seventy-eight percent of all prior authorizations were completed in less than two hours. Fifty percent of all manual PA requests and 48% of all overrides were completed in less than four hours. Eighty-one percent of all manual PAs and 83% 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 October 2023 through December 31, 2023. She reported 241,071 average recipients per month using pharmacy benefits, and an average paid per prescription of $151.23.

**Cost Management Analysis:** L. Thomas reported an average cost per claim of $147.57 for December 2023 and compared previous months contained in the table. From the 4th Quarter Drug Analysis, L. Thomas reported 85.7% generic utilization, 6.6% brand single-source, 4.2% brand multi-source (those requests which required a DAW-1 override), and 3.6% OTC and "other." From the Top 25 Drugs Based on Number of Claims from 10/01/2023-12/31/2023, L. Thomas reported the top five drugs: amoxicillin, cetirizine, albuterol sulfate HFA, azithromycin, and oseltamivir phosphate. L. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 10/01/2023-12/31/2023: Humira®

Citrate-free Pen, Trikafta®, Trulicity®, Invega Sustenna®, and Dupixent® Pen. 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 Miscellaneous Anticonvulsants.

**RDUR Intervention Report:** L. Thomas presented the RDUR Activity Report for October 2023. She reported 500 profiles reviewed and 419 letters sent with 48 responses received as of the date of the report. She reported 28 of 48 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); Therapeutic Appropriateness (appropriate use of immediate-release opioids).

**Proposed Criteria:** L. Thomas presented the proposed set of 35 criteria to the Board and instructed the Board members to mark their ballots. Of the 35 proposed criteria, results from the criteria vote returned 32 approved and 3 approved as amended.

**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 provided information about the Gold Standard Program to the Board members. K. Newman reviewed the MME phase down effective April 1, 2024, and the April 2024 PDL updates. K. Newman and K. Graham also reviewed the clinical criteria implemented on April 1, 2024, for the GLP-1 agonists.

**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 7, 2024, and covered the anticoagulants, cardiac agents, antihyperlipidemics, and antidepressants. The next meeting is scheduled for May 8, 2024, and will cover the skin and mucus membrane immunomodulators, antihypertensives, and Alzheimer's agents.

**Next Meeting Date:** C. Deas reminded the Board that the next DUR meeting will be held on July 24, 2024. A motion to adjourn the meeting was made by C. Deas and J. Osborn seconded the motion. The meeting was adjourned at 1:54 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. Sotagliflozin / Overuse**<br>Alert Message: Inpefa (sotagliflozin) may be over-utilized. The recommended maintenance dose of sotagliflozin is 400 mg once daily.<br><br>Drugs/Diseases<br>Util A: Sotagliflozin<br>Util B:<br>Util C:<br><br>Max Dose: 400 mg/day<br><br>References:<br>Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.<br>Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc. | √ | | |
| **2. Sotagliflozin / Therapeutic Appropriateness**<br>Alert Message: The safety and effectiveness of Inpefa (sotagliflozin) in pediatric patients under 18 years of age have not been established.<br><br>Drugs/Diseases<br>Util A: Sotagliflozin<br>Util B:<br>Util C:<br><br>Age Range: 0 – 17 yoa<br><br>References:<br>Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.<br>Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc. | √ | | |
| **3. Sotagliflozin / Therapeutic Appropriateness**<br>Alert Message: Inpefa (sotagliflozin) can cause intravascular volume depletion, which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. Patients with impaired renal function (eGFR < 60 mL/min/1.73 m2), elderly patients, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Before initiating sotagliflozin in patients with one or more of these characteristics, assess volume status and renal function. Monitor for signs and symptoms of hypotension and renal function after initiating therapy.<br><br>Drugs/Diseases<br>Util A: Sotagliflozin<br>Util B: CKD Stage 3, CKD Stage 4, CKD Stage 5<br>Util C:<br>References:<br>Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.<br>Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc. | √ | | |

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

**4. Sotagliflozin / Loop Diuretics** ___√_____ _____ _____

Alert Message: Inpefa (sotagliflozin) can cause intravascular volume depletion, which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. Patients with impaired renal function (eGFR < 60 mL/min/1.73 m2), elderly patients, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Before initiating sotagliflozin in patients with one or more of these characteristics, assess volume status and renal function. Monitor for signs and symptoms of hypotension and renal function after initiating therapy.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Sotagliflozin | Bumetanide | |
| | Ethacrynic Acid | |
| | Furosemide | |
| | Torsemide | |

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

**5. Sotagliflozin / Urinary Tract Infection** ___√_____ _____ _____

Alert Message: Treatment with SGLT2 inhibitors, including Inpefa (sotagliflozin), increases the risk for urinary tract infections. Serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization have been reported. Evaluate patients for signs and symptoms of urinary tract infections, and promptly treat if indicated.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Sotagliflozin | Pyelonephritis | |
| | Urinary Tract Infection | |

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

**6. Sotagliflozin / Genital Mycotic Infections** __√_____ _____ _____

Alert Message: Inpefa (sotagliflozin) use increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections. Monitor and treat appropriately.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Sotagliflozin | Candida Balanitis | |
| | Candidiasis of vulva and vagina | |
| | Urogenital Candidiasis | |

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

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

**7. Sotagliflozin / Insulin and Insulin Secretagogues** ___√_____ _____ _____

Alert Message: Insulin and insulin secretagogues are known to cause hypoglycemia. Inpefa (sotagliflozin) may increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when these agents are used in combination with sotagliflozin.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Sotagliflozin | Insulin | |
| | Insulin Secretagogues | |

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

**8. Sotagliflozin / Digoxin** _____ ___√_____ _____

Alert Message: The concurrent use of Inpefa (sotagliflozin) with digoxin may increase digoxin serum concentrations and the risk of digoxin-related adverse effects. Patients taking sotagliflozin with digoxin should be monitored appropriately. Sotagliflozin is a P-gp efflux transport inhibitor, and digoxin is a P-gp substrate.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Sotagliflozin | Digoxin | |

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

**9. Sotagliflozin / Rifampin** ___√_____ _____ _____

Alert Message: The concurrent use of Inpefa (sotagliflozin) with rifampin may decrease sotagliflozin serum concentrations and result in decreased sotagliflozin efficacy. Rifampin is an UGT1A9 inducer, and sotagliflozin is an UGT1A9 substrate. Patients taking sotagliflozin with rifampin should be monitored appropriately.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Sotagliflozin | Rifampin | |

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

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

**10. Sotagliflozin / Lithium** _____ ___√_____ _____

Alert Message: The concurrent use of Inpefa (sotagliflozin) with lithium may decrease lithium serum concentrations and result in decreased lithium efficacy. Monitor serum lithium concentration more frequently during sotagliflozin initiation and dosage changes.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Sotagliflozin | Lithium | |

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

**11. Sotagliflozin / Pregnancy / Pregnancy Negating** ___√_____ _____ _____

Alert Message: Based on animal data showing renal effects, Inpefa (sotagliflozin) is not recommended during the second and third trimesters of pregnancy. In rats, renal changes were observed when sotagliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy.

Drugs/Diseases

| Util A | Util B | Util C (Negate) |
|---|---|---|
| Sotagliflozin | Pregnancy | Abortion |
| | | Delivery |
| | | Miscarriage |

Gender: Female
Age Range: 11 – 50 yoa

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

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

**12. Sotagliflozin / Lactation** ___√_____ _____ _____

Alert Message: There are no data on the presence of Inpefa (sotagliflozin) in human milk, the effects on the breastfed infant, or the effects on milk production. Sotagliflozin is present in rat milk. When a drug is present in animal milk, it is likely to be present in human milk. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because of the potential for serious adverse reactions in a breastfed infant, advise women that breastfeeding is not recommended while taking sotagliflozin.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Sotagliflozin | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

**13. Sotagliflozin / Non-adherence** __√_____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Inpefa (sotagliflozin). 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 |
|---|---|---|
| Sotagliflozin | | |

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.
Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

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

**14. Tafamidis Meglumine / Overuse** ___√___ _____ _____

Alert Message: Vyndaqel (tafamidis meglumine) may be over-utilized. The recommended dosage of tafamidis meglumine is 80 mg (four 20 mg tafamidis meglumine capsules) once daily.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Tafamidis Meglumine | | |

Max Dose: 80 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

**15. Tafamidis Meglumine / Therapeutic Appropriateness** ___√___ _____ _____

Alert Message: The safety and effectiveness of Vyndaqel (tafamidis meglumine) have not been established in pediatric patients.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Tafamidis Meglumine | | |

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

**16. Tafamidis Meglumine / BCRP Substrates** ___√___ _____ _____

Alert Message: Vyndaqel (tafamidis meglumine) inhibits breast cancer resistant protein (BCRP) in humans. Coadministration of tafamidis and drugs that are BCRP substrates may increase the exposure of the BCRP substrates (e.g., methotrexate, rosuvastatin, and imatinib) and the risk of substrate-related toxicities. Monitor for signs of BCRP substrate-related toxicities and modify the dosage of the substrate if appropriate.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Tafamidis Meglumine | Alpelisib | Prazosin |
| | Berotralstat | Rosuvastatin |
| | Dolutegravir | Talazoparib |
| | Glyburide | Tenofovir |
| | Methotrexate | Topotecan |
| | Pazopanib | Ubrogepant |
| | Pibrentasvir | Vemurafenib |

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

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

**17. Tafamidis Meglumine / Pregnancy / Pregnancy Negating** ___√_____ _____ _____

Alert Message: Based on findings from animal studies, Vyndaqel (tafamidis meglumine) may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Report pregnancies to the Pfizer reporting line at 1-800-438-1985.

Drugs/Diseases

| Util A | Util B | Util C (Negating) |
|---|---|---|
| Tafamidis Meglumine | Pregnancy | Abortion |
| | Delivery | |
| | Miscarriage | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

**18. Tafamidis Meglumine / Therapeutic Appropriateness** ___√_____ _____ _____

Alert Message: There are no available data on the presence of Vyndaqel (tafamidis meglumine) in human milk, the effect on the breastfed infant, or the effect on milk production. Tafamidis is present in rat milk. When a drug is present in animal milk, it is likely the drug will be present in human milk. Based on findings from animal studies that suggest the potential for serious adverse reactions in the breastfed infant, advise patients that breastfeeding is not recommended during treatment with tafamidis meglumine.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Tafamidis Meglumine | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

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

**19. Tafamidis Meglumine / Non-adherence** ___√_____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Vyndaqel (tafamidis meglumine). 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 |
|---|---|---|
| Tafamidis Meglumine | | |

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.
Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

**20. Lacosamide XR / Overuse** ___√_____ _____ _____

Alert Message: Motpoly XR (lacosamide extended-release) may be over-utilized. The maximum recommended maintenance dose of extended-release lacosamide is 400 mg once daily.

Drugs/Diseases

| Util A | Util B | Util C (Negating) |
|---|---|---|
| Lacosamide XR | | CKD Stage 5<br>ESRD<br>Hepatic Impairment |

Max Dose: 400 mg/day

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Motpoly XR Prescribing Information, May 2023, Aucta Pharmaceuticals, Inc.

**21. Lacosamide XR / Overuse – Severe Renal Impairment** ___√_____ _____ _____

Alert Message: Motpoly XR (lacosamide extended-release) may be over-utilized. For patients with severe renal impairment [creatinine clearance (CLcr) less than 30 mL/min as estimated by the Cockcroft-Gault equation for adults; CLcr less than 30 mL/min/1.73m2 as estimated by the Schwartz equation for pediatric patients] or end-stage renal disease, the maximum recommended dosage is 300 mg. For patients with mild or moderate renal impairment, no dosage is necessary.

Drugs/Diseases

| Util A | Util B | Util C (Include) |
|---|---|---|
| Lacosamide XR | | CKD Stage 5<br>ESRD |

Max Dose: 300 mg/day

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Motpoly XR Prescribing Information, May 2023, Aucta Pharmaceuticals, Inc.

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

**22. Lacosamide XR / Overuse – Hepatic Impairment** ___√_____ _____ _____

Alert Message: Motpoly XR (lacosamide extended-release) may be over-utilized. For patients with mild or moderate hepatic impairment, the maximum recommended dosage is 300 mg. The dose initiation and titration should be based on clinical response and tolerability in patients with hepatic impairment. Extended-release lacosamide use is not recommended in patients with severe hepatic impairment.

Drugs/Diseases

| Util A | Util B | Util C (Include) |
|---|---|---|
| Lacosamide XR | | Hepatic Impairment |

Max Dose: 300 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Motpoly XR Prescribing Information, May 2023, Aucta Pharmaceuticals, Inc.

**23. Lacosamide / Drugs Effecting Cardiac Conduction** ___√_____ _____ _____

Alert Message: Motpoly XR (lacosamide extended-release) should be used with caution in patients on concomitant medications that affect cardiac conduction (sodium channel blockers, beta-blockers, calcium channel blockers, potassium channel blockers), including those that prolong PR interval (including sodium channel blocking AEDs), because of a risk of AV block, bradycardia, or ventricular tachyarrhythmia. In such patients, obtaining an ECG before beginning lacosamide and after lacosamide is titrated to steady-state is recommended.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Lacosamide XR | Beta-Blockers | |
| | Calcium Channel Blockers | |
| | Potassium Channel Blockers | |
| | Sodium Channel Blockers | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

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

**24. Lacosamide XR / Non-adherence** ___√_____ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Motpoly XR (lacosamide extended-release). 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 |
|---|---|---|
| Lacosamide XR | | |

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught RE, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

**25. Risperidone ER Suspension / Therapeutic Appropriateness** _____ ___√_____ _____

Alert Message: The safety and effectiveness of Rykindo (risperidone extended-release suspension) in pediatric patients have been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Risperidone ER Suspension | | |

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Rykindo Prescribing Information, Jan. 2023, Shandong Luye Pharmaceutical Co., Ltd.

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

**26. Risperidone ER Suspension / Strong CYP2D6 Inhibitor** ___√_____ _____

Alert Message: Concomitant use of Rykindo (risperidone extended-release suspension) with strong CYP2D6 inhibitors may increase the plasma concentration of risperidone and lower the concentration of 9-hydroxyrisperidone, a major active metabolite of risperidone. Refer to the official prescribing information for dosage adjustment for risperidone when initiating or discontinuing concurrent use of a strong CYP2D6.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Risperidone ER Suspension | Bupropion | |
| | Fluoxetine | |
| | Paroxetine | |
| | Quinidine | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Rykindo Prescribing Information, Jan. 2023, Shandong Luye Pharmaceutical Co., Ltd.

**27. Risperidone ER Suspension / Strong CYP3A3 Inducers** ___√_____ _____ _____

Alert Message: Concomitant use of Rykindo (risperidone extended-release suspension) with strong CYP3A4 inducers may decrease the combined plasma concentrations of risperidone and 9-hydroxyrisperidone, which could lead to decreased efficacy of risperidone treatment. Refer to the official prescribing information for dosage adjustment for risperidone when initiating or discontinuing concurrent CYP3A4 inducers.

Drugs/Diseases

| Util A | Util B | | Util C |
|---|---|---|---|
| Risperidone ER Suspension | Apalutamide | Phenobarbital | |
| | Carbamazepine | Phenytoin | |
| | Enzalutamide | Primidone | |
| | Mitotane | | |

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Rykindo Prescribing Information, Jan. 2023, Shandong Luye Pharmaceutical Co., Ltd.

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

**28. Odevixibat / Overuse** ___√_____ _____ _____

Alert Message: Bylvay (odevixibat) may be over-utilized. The recommended dosage of odevixibat is 40 mcg/kg once daily in the morning with a meal. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Odevixibat | | |

Max Dose: 6 mg/day

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

**29. Odevixibat / Therapeutic Appropriateness** ___√_____ _____ _____

Alert Message: The safety and effectiveness of Bylvay (odevixibat) for the treatment of pruritus in progressive familial intrahepatic cholestasis (PFIC) in adult patients, including those 65 years of age and older, have not been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Odevixibat | | |

Age Range: 18 - 999 yoa

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

**30. Odevixibat / Vitamin Deficiency** ___√_____ _____ _____

Alert Message: Bylvay (odevixibat) may affect the absorption of fat-soluble vitamins (FSV). Obtain serum FSV levels at baseline and monitor during treatment, along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue odevixibat if FSV deficiency persists or worsens despite adequate FSV supplementation.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Odevixibat | Vitamin Deficiency A, D, E, & K | |

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

**31. Odevixibat / Liver Test Abnormalities & Portal HTN** ___√_____ _____ _____

Alert Message: Bylvay (odevixibat) can cause elevations of liver tests or worsening of liver tests relative to baseline values. Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption of odevixibat may be required if abnormalities occur. For persistent or recurrent liver test abnormalities, consider treatment discontinuation. Permanently discontinue treatment if a patient progresses to portal hypertension or experiences a hepatic decompensation event (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Odevixibat | Abnormal Liver Function Studies | |
| | Ascites | |
| | Hepatic Encephalopathy | |
| | Portal Hypertension | |
| | Liver Failure | |

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

**32. Odevixibat / Diarrhea** __√_____ _____ _____

Alert Message: Bylvay (odevixibat) treatment may cause diarrhea. If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt odevixibat dosing if a patient experiences persistent diarrhea. Restart odevixibat at 40 mcg/kg/day when diarrhea resolves, and increase the dose as tolerated if appropriate. If diarrhea persists and no alternate etiology is identified, stop odevixibat treatment.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Odevixibat | Diarrhea | |

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.

**33. Odevixibat / Bile Acid Resins** ___√_____ _____ _____

Alert Message: Bile acid binding resins may bind Bylvay (odevixibat) in the gut which may reduce odevixibat efficacy. Administer bile acid binding resins (e.g., cholestyramine, colesevelam, or colestipol) at least 4 hours before or 4 hours after administration of odevixibat.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Odevixibat | Cholestyramine | |
| | Colesevelam | |
| | Colestipol | |

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

**34. Odevixibat / Pregnancy / Pregnancy Negating** ___√_____ _____ _____

Alert Message: There are no human data on Bylvay (odevixibat) use in pregnant persons to establish a drug-associated risk of major birth defects, miscarriage, or adverse developmental outcomes. Based on findings from animal reproduction studies, odevixibat may cause cardiac malformations when a fetus is exposed during pregnancy.

Drugs/Diseases

| Util A | Util B | Util C (Negate) |
|---|---|---|
| Odevixibat | Pregnancy | Abortion |
| | | Delivery |
| | | Miscarriage |

Gender: Female
Age Range: 11 – 50 yoa

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

**35. Odevixibat / Lactation** ___√_____ _____ _____

Alert Message: There are no data on the presence of Bylvay (odevixibat) in human milk, the effects on the breastfed infant, or the effects on milk production. Odevixibat has low absorption following oral administration, and breastfeeding is not expected to result in exposure of the infant to odevixibat at the recommended doses; however, odevixibat may reduce the absorption of fat-soluble vitamins (FSV). Monitor FSV levels and increase FSV intake, if FSV deficiency is observed during lactation. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for odevixibat and any potential adverse effects on the breastfed child from odevixibat or the underlying maternal condition.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Odevixibat | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

Stephanie McGee Azar, Commissioner — (✓) Approve ( ) Deny — 6/6/24 Date

Melinda Rowe, MD,
Medical Director — (✓) Approve ( ) Deny — 5/28/2024 Date

Ginger Carmack, Deputy Commissioner — (✓) Approve ( ) Deny — 6/5/24 Date