

**Alabama Medicaid DUR Board Meeting Minutes**  
**October 23, 2024**

**Members Present:** Dr. Kelli Littlejohn Newman, Dr. Danielle Powell, Dr. George Sutton, Dr. Marilyn Bulloch, Dr. Mary Stallworth, Dr. Melinda Rowe, Dr. Kristi Kelley, Dr. Rachel Seaman, Dr. Darlene Traffanstedt, Dr. Crystal Deas

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

**Members Absent:** Dr. Jeremy Osborn, Dan McConaghy

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

**Review and Adoption of Minutes:** The minutes of the July 24, 2024, meeting were presented, and Dr. Sutton made a motion to approve the minutes. Dr. Bulloch seconded the motion, and the motion was approved unanimously.

**Prior Authorization and Overrides Update:** Dr. Thomas began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of April 2024. She reported 14,863 manual PAs and overrides. There were 19,199 total electronic requests for the month of April 2024. From the Prior Authorization and Override Response Time Ratio report for April 2024, Dr. Thomas reported that approximately 17% of all manual PAs and 15% of all overrides were completed in less than two hours, but a total of 78% of all PAs were completed in under 2 hours (including electronic PA transactions). Fifty-seven percent of all manual PAs and 55% of all overrides were completed in less than four hours. Eighty-one percent of all manual PAs and overrides were completed in less than eight hours. Dr. Thomas 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 May 2024, Dr. Thomas reported 14,066 manual PA requests and 18,209 electronic PA requests were received. She reported that 18% of all manual PAs and 15% of all overrides were completed in less than two hours. Fifty-nine percent of all manual PAs and 58% of all overrides were completed in less than four hours. Eighty-two percent of all manual PAs and 83% of all overrides were completed in less than eight hours. For the month of June 2024, Dr. Thomas reported 12,533 manual PA requests and 14,729 electronic PA requests. Dr. Thomas reported that approximately 20% of all manual PAs and 18% of all overrides were completed in less than two hours. Sixty-four percent of all manual PA requests and 62% of all overrides were completed in less than four hours. Eighty-one percent of all manual PAs and overrides were completed in less than eight hours.

**Program Summary Review:** Dr. Thomas briefly reviewed the Alabama Medicaid Program Summary for the months of January 1, 2024, through June 30, 2024. She reported 216,367 average recipients per month using pharmacy benefits, and an average paid per prescription of \$159.99.

**Cost Management Analysis:** Dr. Thomas reviewed the Cost Management Analysis chart highlighting the number of recipients per month over the past two years. Dr. Thomas reported an average cost per claim of \$172.13 for June 2024 and compared previous months contained in the table. From the 2<sup>nd</sup> Quarter 2024 Drug Analysis, Dr. Thomas reported 85% generic utilization, 7% brand single-source, 4% brand multi-source (those requests which required a DAW-1 override), and 4% OTC and "other." From the Top 25 Drugs Based on Number of Claims from 04/01/2024 – 06/30/2024, Dr. Thomas reported the top five drugs: amoxicillin, cetirizine, albuterol sulfate HFA, fluticasone propionate, and montelukast sodium. Dr. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 04/01/2024 – 06/30/2024: Humira<sup>®</sup>, Citrate-free Pen, Trikafta<sup>®</sup>, Invega Sustenna<sup>®</sup>, Dupixent<sup>®</sup> Pen, and Concerta<sup>®</sup>. From the Top 15 Therapeutic Classes by Total Cost of Claims for the same time frame, Dr. Thomas

reported the top five classes: Antipsychotic Agents, Tumor Necrosis Factor Inhibitors, Incretin Mimetics, Antineoplastic Agents, and Miscellaneous Skin and Mucous Membrane Agents.

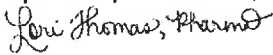
**Review of Palivizumab Utilization for the 2023 - 2024 Season:** For this utilization report, the 2023-2024 Synagis<sup>®</sup> season was defined as October 2023 through March 2024. Dr. Thomas began the discussion by reminding the Board Members that Beyfortus<sup>®</sup> (nirsevimab), a long-acting monoclonal antibody product was approved by the U.S. Food and Drug Administration (FDA) on July 17, 2023, for use in newborns and infants to protect against respiratory syncytial virus (RSV). On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) voted unanimously in favor of recommending use of nirsevimab as a vaccine, rendering it available through the federal Vaccines for Children (VFC) program. Since the VFC program is administered through the Alabama Department of Public Health (ADPH), nirsevimab is not available to be reimbursed by Alabama Medicaid as an outpatient drug. During the beginning of the 2023-2024 season, Beyfortus<sup>®</sup> was allocated due to short supply; therefore, Synagis<sup>®</sup> requests were submitted, reviewed, and approved in accordance with AAP guidelines throughout the remainder of the season. Dr. Thomas explained that during a typical RSV season, RSV activity in Alabama becomes significant in October. The season usually peaks in December and becomes statistically non-significant in January or February. According to the National Respiratory and Enteric Virus Surveillance System (NREVSS) Dashboard for RSV activity based on U.S. Department of Health and Human Services (HHS) Region 4, RSV activity in this region became significant in the week ending 10/14/2023, peaked week ending 11/18/2023, and became statistically non-significant week ending 12/16/2023. For the 2023-24 season, there were 1,182 claims for 389 recipients. The average cost per claim was \$3,175 while the average cost per recipient was \$9,648. Dr. Thomas pointed out that there were 770 prior authorizations requested over the course of the season, with an approval rate of 63%, and compared the prior authorization requests totals to previous years. Dr. Thomas briefly reviewed the top dispensing pharmacies and the top PA denial reasons. Dr. Thomas also reviewed the graphs comparing the total spend of all drugs compared to the total spend of Synagis<sup>®</sup> per RSV season.

**Proposed Criteria:** Dr. Thomas presented the proposed set of 25 criteria to the Board and instructed the Board members to mark their ballots. Of the 25 proposed criteria, results from the criteria vote returned 24 approved and 1 rejected.

**Medicaid Update:** Dr. Littlejohn Newman introduced Dr. Darlene Traffanstedt as the new Medical Director of Alabama Medicaid. She also reminded the Board Members that all updated Medicaid drug lists and ALERTs were provided to them electronically and are also available online. Dr. Littlejohn Newman reviewed the information regarding patient copays, over-the-counter (OTC) COVID-19 tests, and COVID-19 vaccine reimbursement that went into effect October 1, 2024.

**P & T Committee Update:** Dr. Littlejohn Newman began the P & T Update by informing the Board that the last P & T meeting was held on August 21, 2024, and covered the Growth Hormone Agents, Respiratory Agents: Eye, Ear, Nose and Throat Preparations, and Complement Inhibitors. The next meeting is scheduled for November 6, 2024, and will cover the Opiate Partial Agonists; Opiate Agonists; Antiemetics; Skeletal Muscle Relaxants; Anxiolytics, Sedatives, and Hypnotics; and the Antiulcer Agents and Acid Suppressants.

**Next Meeting Date:** Dr. Powell reminded the Board that the next DUR Meeting will be held on January 22, 2025. A motion to adjourn the meeting was made by Dr. Sutton and Dr. Deas seconded the motion. The meeting was adjourned at 2:10 p.m.

Respectfully submitted,  
  
Lori Thomas, PharmD.

**ALABAMA MEDICAID  
RETROSPECTIVE DRUG UTILIZATION REVIEW  
CRITERIA RECOMMENDATIONS**

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**1. Macitentan/Tadalafil / Overuse**

\_\_\_<sup>v</sup>\_\_\_    \_\_\_    \_\_\_

Alert Message: Opsyngvi (macitentan/tadalafil) may be over-utilized. The maximum recommended dose of macitentan/tadalafil is one 10 mg/40 mg tablet once daily.

Drugs/Diseases

Util A                      Util B                      Util C  
Macitentan/Tadalafil

Max Dose: 10mg/40 mg per day

References:

Opsyngvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**2. Macitentan/Tadalafil / Therapeutic Appropriateness**

\_\_\_<sup>v</sup>\_\_\_    \_\_\_    \_\_\_

Alert Message: The safety and efficacy of Opsyngvi (macitentan/tadalafil) in children have not been established.

Drugs/Diseases

Util A                      Util B                      Util C  
Macitentan/Tadalafil

Age Range: 0 – 17 yoa

References:

Opsyngvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**3. Macitentan/Tadalafil / Hepatic**

\_\_\_<sup>v</sup>\_\_\_    \_\_\_    \_\_\_

Alert Message: The macitentan component of Opsyngvi (macitentan/tadalafil) is an endothelin receptor antagonist (ERA), and other ERAs have been shown to cause elevated hepatic enzymes, hepatotoxicity, and liver failure. Obtain liver enzyme tests prior to initiation of macitentan/tadalafil and repeat during treatment as clinically indicated. If clinically relevant aminotransferase elevations occur, or if elevations are accompanied by an increase in bilirubin > 2 x ULN, or by clinical symptoms of hepatotoxicity, discontinue macitentan/tadalafil. Do not initiate macitentan/tadalafil in patients with elevated aminotransferases (> 3 x upper limit of normal [ULN]) at baseline.

Drugs/Diseases

Util A                      Util B                      Util C  
Macitentan/Tadalafil      Elevated Liver Transaminase Levels

References:

Opsyngvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**4. Macitentan/Tadalafil / Severe Hepatic Impairment**

\_\_\_v\_\_\_ \_\_\_\_\_ \_\_\_\_\_

Alert Message: The macitentan component of Opsynvi (macitentan/tadalafil) is an endothelin receptor antagonist (ERA), and other ERAs have been shown to cause elevated hepatic enzymes, hepatotoxicity, and liver failure. Patients with severe hepatic cirrhosis (Child-Pugh Class C) have not been studied, and, therefore, avoid the use of macitentan/tadalafil in these patients.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Macitentan/Tadalafil	Cirrhosis	

References:

Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**5. Macitentan/Tadalafil / Pulmonary Edema**

\_\_\_v\_\_\_ \_\_\_\_\_ \_\_\_\_\_

Alert Message: The macitentan component of Opsynvi (macitentan/tadalafil) is a pulmonary vasodilator and may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD). Should signs of pulmonary edema occur, the possibility of PVOD should be considered and, if confirmed, discontinue treatment with macitentan/tadalafil.

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Macitentan/Tadalafil	Pulmonary Edema	

References:

Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**6. Macitentan/Tadalafil / Dual CYP3A4 & 2C9 Inhibitors**

\_\_\_v\_\_\_ \_\_\_\_\_ \_\_\_\_\_

Alert Message: Avoid concomitant use of Opsynvi (macitentan/tadalafil) with moderate dual inhibitors of CYP3A4 and CYP2C9 (such as fluconazole and amiodarone). Concomitant use of moderate dual inhibitors of CYP3A4 and CYP2C9 such as fluconazole is predicted to increase macitentan exposure approximately 4-fold.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Macitentan/Tadalafil	Amiodarone Fluconazole	

References:

Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**7. Macitentan/Tadalafil / Strong CYP3A4 Inducers**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: The use of Opsynvi (macitentan/tadalafil) with strong CYP3A4 inducers should be avoided. Concurrent use of macitentan/tadalafil with strong inducers of CYP3A4 significantly reduces macitentan exposure.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Macitentan/Tadalafil	Apalutamide Carbamazepine Enzalutamide Mitotane Phenobarbital Phenytoin Primidone Rifampin	

References:

Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**8. Macitentan/Tadalafil / Strong CYP3A4 Inhibitors**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: Avoid concomitant use of Opsynvi (macitentan/tadalafil) with strong CYP3A4 inhibitors such as ritonavir, ketoconazole and itraconazole. Concomitant use with a strong CYP3A4 inhibitor increases exposure to both macitentan and tadalafil. Use other PAH treatment options when strong CYP3A4 inhibitors are needed.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Macitentan/Tadalafil	Clarithromycin Cobicistat Darunavir Itraconazole Ketoconazole Nefazodone	Nelfinavir Posaconazole Ritonavir Voriconazole

References:

Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**9. Macitentan/Tadalafil / Alpha-1 Adrenergic Blockers**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: Caution should be exercised when Opsynvi (macitentan/tadalafil) is co-administered with an alpha-1 adrenergic blocker. Tadalafil and alpha-adrenergic blocking agents are both vasodilators with blood-pressure-lowering effects. In patients who are taking alpha-1 blockers, concomitant administration of tadalafil may lead to symptomatic hypotension.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Macitentan/Tadalafil	Alfuzosin Doxazosin Prazosin Silodosin Tamsulosin Terazosin	

References:

Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**10. Macitentan/Tadalafil / Pregnancy / Pregnancy Negating (Box Warning)**

\_\_\_v\_\_\_ \_\_\_\_\_ \_\_\_\_\_

Alert Message: Opsynvi (macitentan/tadalafil) may cause fetal harm when administered to a pregnant woman. The use of macitentan/tadalafil is contraindicated in females who are pregnant. The macitentan component of the combination product was consistently shown to have teratogenic effects when administered to animals. If macitentan/tadalafil is used during pregnancy, advise the patient of the potential risk to a fetus.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Macitentan/Tadalafil	Pregnancy	Abortion Delivery Miscarriage

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**11. Macitentan/Tadalafil / Lactation (Box Warning)**

\_\_\_v\_\_\_ \_\_\_\_\_ \_\_\_\_\_

Alert Message: Because of the potential for serious adverse reactions in breastfed infants from Opsynvi (macitentan/tadalafil), advise women not to breastfeed during treatment with macitentan/tadalafil. There are no data on the presence of tadalafil, macitentan, and/or their metabolites in human milk, the effects on the breastfed infant, or the effect on milk production. Tadalafil and/or its metabolites are 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.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Macitentan/Tadalafil	Lactation	

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**12. Macitentan/Tadalafil / Contraceptives (Negating)**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: In females of reproductive potential, exclude pregnancy prior to initiation of Opsynvi (macitentan/tadalafil) therapy, ensure the use of acceptable contraceptive methods and obtain monthly pregnancy tests. Macitentan/tadalafil may cause fetal harm when administered during pregnancy and is contraindicated for use in females who are pregnant.

Drugs/Diseases

Util A                      Util B                      Util C (Negate)  
Macitentan/Tadalafil                      Contraceptives

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Opsynvi Prescribing Information, March 2024, Janssen.  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

**13. Macitentan/Tadalafil / Non-adherence**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: Based on refill history, your patient may be under-utilizing Opsynvi (macitentan/tadalafil). 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  
Macitentan/Tadalafil

References:  
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.  
Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Spending. Health Affairs No. 1 (2011):91-99.  
Dean BB, Saundankar V, Stafkey-Mailey D, Anguiano RH, Nelsen AC, Gordon K, Classi P. Medication Adherence and Healthcare Costs Among Patients with Pulmonary Arterial Hypertension Treated with Oral Prostacyclins: A Retrospective Cohort Study. Drugs Real World Outcomes. 2020 Sep;7(3):229-239. doi: 10.1007/s40801-020-00183-x. Erratum in: Drugs Real World Outcomes. 2020 Jun 5;: PMID: 32144746; PMCID: PMC7392967.  
Ho PM, Bryson CL, Rumsfeld JS. Medication Adherence: Its Importance in Cardiovascular Outcomes. Circulation. 2009 Jun 16;119(23):3028-3035.

**14. Reslizumab / Therapeutic Appropriateness**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: The safety and effectiveness of Cinqair (reslizumab) in pediatric patients less than 18 years of age have not been established.

Drugs/Diseases

Util A                      Util B                      Util C  
Reslizumab

Age Range: 0 – 17 yoa

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**15. Reslizumab / Pregnancy / Pregnancy Negating**

  v      \_\_\_\_\_    \_\_\_\_\_

Alert Message: The data on pregnancy exposure to Cinqair (reslizumab) from the clinical trials are insufficient to inform on drug-associated risk. Monoclonal antibodies, such as reslizumab, are transported across the placenta in a linear fashion as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Reslizumab	Pregnancy	Abortion Delivery Miscarriage

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

**16. Reslizumab / Lactation**

  v      \_\_\_\_\_    \_\_\_\_\_

Alert Message: It is not known whether Cinqair (reslizumab) is present in human milk, and the effects of reslizumab on the breastfed infant and milk production are not known. However, human IgG is known to be present in human milk. Reslizumab was present in the milk of lactating mice following dosing during pregnancy. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for reslizumab and any potential adverse effects on the breastfed child from reslizumab or the underlying maternal condition.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Reslizumab	Lactation	

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

**17. Reslizumab / Helminth Infection**

  v      \_\_\_\_\_    \_\_\_\_\_

Alert Message: Eosinophils may be involved in the immunological response to some helminth infections. It is unknown if Cinqair (reslizumab) will influence the immune response against parasitic infections. Treat patients with pre-existing helminth infections before initiating reslizumab. If patients become infected while receiving treatment with reslizumab and do not respond to anti-helminth treatment, discontinue treatment with reslizumab until infection resolves.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Reslizumab	Helminth Infection	

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**18. Mepolizumab / Therapeutic Appropriateness - CRSwNP**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: The safety and effectiveness of Nucala (mepolizumab) in patients less than 18 years of age with chronic rhinosinusitis with nasal polyps (CRSwNP) have not been established.

Drugs/Diseases

Util A                      Util B                      Util C (Include)  
Mepolizumab                      Nasal Polyps

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

**19. Mepolizumab / Therapeutic Appropriateness - HES**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: The safety and effectiveness of Nucala (mepolizumab) in pediatric patients less than 12 years of age with hypereosinophilic syndrome (HES) have not been established.

Drugs/Diseases

Util A                      Util B                      Util C (Include)  
Mepolizumab                      Hypereosinophilic Syndrome

Age Range: 0 – 11 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

**20. Mepolizumab / Overutilization - HES**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: The manufacturer's recommended dose of Nucala (mepolizumab) for hypereosinophilic syndrome (HES) is 300 mg administered once every 4 weeks by subcutaneous injection.

Drugs/Diseases

Util A                      Util B                      Util C (Include)  
Mepolizumab                      Hypereosinophilic Syndrome

Max Dose: 3 injections/4 weeks

Age Range: ≥ 12 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**21. Oteseconazole / Therapeutic Appropriateness**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: The safety and effectiveness of Vivjoa (oteseconazole) have not been established in pre-menarchal pediatric females.

Drugs/Diseases

Util A

Util B

Util C

Oteseconazole

Age Range: 0 – 10 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

**22. Oteseconazole / Therapeutic Appropriateness**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: Vivjoa (oteseconazole) use is contraindicated in females of reproductive potential and pregnant or lactating women. Based on animal studies, oteseconazole may cause fetal harm.

Drugs/Diseases

Util A

Util B

Util C (Negate)

Oteseconazole

Pregnancy

Hysterectomy

Lactation

Postmenopausal

Salpingo-oophorectomy

Tubal Ligation

Age Range: 11– 50 yoa

Gender: Female

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

**23. Oteseconazole / Pregnancy / Pregnancy Negating**

\_\_\_<sup>v</sup>\_\_\_

Alert Message: Vivjoa (oteseconazole) use is contraindicated in pregnant women. Based on animal studies, oteseconazole may cause fetal harm. Ocular abnormalities were observed in a pre- and postnatal animal study in the offspring of rats administered oteseconazole.

Drugs/Diseases

Util A

Util B

Util C (Negate)

Oteseconazole

Pregnancy

Abortion

Delivery

Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**24. Oteseconazole / Lactation**

Alert Message: Vivjoa (oteseconazole) use is contraindicated in lactating women. Ocular abnormalities were observed in the offspring of pregnant rats dosed at 7.5 mg/kg/day during organogenesis through lactation in pre- and postnatal developmental studies.

\_\_\_<sup>v</sup>\_\_\_

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Oteseconazole	Lactation	

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

**25. Oteseconazole / BCRP Substrates**

Alert Message: Vivjoa (oteseconazole) is a BCRP inhibitor. Concomitant use of oteseconazole with a BCRP substrate may increase the exposure of the BCRP substrate, which may increase the risk of adverse reactions associated with the substrate. Use the lowest possible starting dose of the BCRP substrate or consider reducing the dose of the substrate drug and monitor for adverse reactions.

\_\_\_<sup>v</sup>\_\_\_

Drugs/Diseases

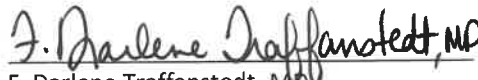
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Oteseconazole	Atorvastatin Alpelisib Dolutegravir Pazopanib Rosuvastatin Sulfasalazine Talazoparib Tenofovir ala Tenofovir dis Topotecan Ubrogepant	

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

  
Stephanie McGee Azar, Alabama Medicaid  
Commissioner

Approve    ( ) Deny

11/21/24  
Date

  
F. Darlene Traffanstedt, MD,  
Alabama Medicaid Medical Director

Approve    ( ) Deny

11/20/2024  
Date

  
Ginger Carmack, Alabama Medicaid  
Deputy Commissioner

Approve    ( ) Deny

11-2-24  
Date