

**Alabama Medicaid DUR Board Meeting Minutes**  
**April 23, 2025**

**Members Present:** Dr. Kelli Littlejohn Newman, Dr. Danielle Powell, Dr. George Sutton, Dr. Marilyn Bulloch, Mary Stallworth, Dr. Melinda Rowe, Dr. Kristi Kelley, Dr. Darlene Traffanstedt, Dr. Crystal Deas, Dan McConaghy, Dr. Luke Engeriser, Dr. Janaki Nimmagadda

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

**Members Absent:** Dr. Jeremy Osborn, Dr. Rachel Seaman

**Call to Order:** The DUR Meeting was called to order by Dr. Powell at approximately 1:03 p.m.

**Review and Adoption of Minutes:** The minutes of the October 23, 2024, meeting were presented, and Dr. Sutton made a motion to approve the minutes. Dr. Deas 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 October 2024. She reported 14,576 manual PAs and overrides. Dr. Thomas reviewed the number of Synagis<sup>®</sup> requests received during the month of October 2024 and reminded the Board Members that there has been a significant reduction in the number of Synagis<sup>®</sup> requests due to the introduction of Beyfortus<sup>®</sup>. Dr. Thomas reported 24,191 total electronic requests for the month of October 2024. Dr. Thomas pointed out the increase in manual and electronic PA requests for the Respiratory Agents and reminded the Board Members that generic Symbicort<sup>®</sup> became non-preferred on October 1, 2024. From the Prior Authorization and Override Response Time Ratio report for October 2024, Dr. Thomas reported that approximately 34% of all manual PAs and 29% of all overrides were completed in less than two hours. Sixty-nine percent of all manual PAs and 66% of all overrides were completed in less than four hours. Eighty-five 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, and that CMS requires 100% of all PAs and overrides to be completed in under 24 hours. For the month of November 2024, Dr. Thomas reported 11,626 manual PA requests and 22,173 electronic PA requests. Dr. Thomas pointed out a decrease in the manual and electronic PA requests for the Respiratory Agents. She reported that 62% of all manual PAs and 64% of all overrides were completed in less than two hours. Eighty-seven to 88% of all manual PAs and overrides were completed in less than four hours. Ninety-one percent of all manual PAs and overrides were completed in less than eight hours. For the month of December 2024, Dr. Thomas reported 11,843 manual PA requests and 20,341 electronic PA requests. Dr. Thomas reported that approximately 77% of all manual PAs and 76% of all overrides were completed in less than two hours. Ninety-two percent of all manual PA requests and 91% of all overrides were completed in less than four hours. Ninety-four percent of all manual PAs and 93% of all overrides were completed in less than eight hours.

**Program Summary Review:** Dr. Thomas briefly reviewed the Alabama Medicaid Program Summary for the months of July 1, 2024, through December 31, 2024. She reported 208,270 average recipients per month using pharmacy benefits, and an average paid per prescription of \$164.98.

**Cost Management Analysis:** Dr. Thomas reviewed the Cost Management Analysis chart highlighting the number of recipients per month over the past two years and pointed out that pharmacy flexibilities due to the COVID-19 pandemic ended on June 1, 2023. Dr. Thomas reported an average cost per claim of \$160.94 for December 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, 5% brand multi-source (those requests which required a DAW-1 override), and 3% OTC and "other." From

the Top 25 Drugs Based on Number of Claims from 10/01/2024 – 12/31/2024, Dr. Thomas reported the top five drugs: amoxicillin, cetirizine, albuterol sulfate HFA, azithromycin, and fluticasone propionate. Dr. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 10/01/2024 – 12/31/2024: Trikafta<sup>®</sup>, Humira<sup>®</sup> Citrate-free Pen, Dupixent<sup>®</sup> Pen, Invega Sustenna<sup>®</sup>, and Ozempic<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, Incretin Mimetics, Tumor Necrosis Factor Inhibitors, Miscellaneous Skin and Mucous Membrane Agents, and Antineoplastic Agents.

**RDUR Intervention Report:** L. Thomas presented the RDUR Activity Report for the October 2024 DUR Cycle. She reported 500 profiles reviewed and 388 letters sent with 42 responses received as of the date of the report. She reported 28 of 42 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 (appropriate use of immediate-release opioids).

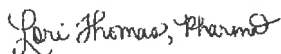
**Proposed Criteria:** Dr. Thomas presented the proposed set of 29 criteria from the canceled January 2025 meeting to the Board and instructed the Board members to mark their ballots. Of the 29 proposed criteria, results from the criteria vote returned 24 approved and 5 amended. Dr. Thomas also presented a proposed set of 32 criteria to the Board and instructed Board members to mark their ballots. Of the 32 proposed criteria, results from the criteria vote returned 31 approved and 1 amended.

**Medicaid Update:** Dr. Littlejohn Newman 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 April 1, 2025, PDL updates.

**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 February 5, 2025, and covered the Skin and Mucous Membrane Agents and the Disease-Modifying Antirheumatic Agents. The next meeting is scheduled for May 7, 2025, and will cover the Wakefulness Promoting Agents; the Anti-infectives; and the Cerebral Stimulants.

**Next Meeting Date:** Dr. Powell reminded the Board that the next DUR Meeting will be held on July 23, 2025. A motion to adjourn the meeting was made by Dr. Sutton and Dr. Deas seconded the motion. The meeting was adjourned at 2:00 p.m.

Respectfully submitted,



Lori Thomas, PharmD.

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

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**1. Erdafitinib / Overuse**

Alert Message: Balversa (erdafitinib) may be over-utilized. The recommended starting dose of maximum erdafitinib is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to a maximum of 9 mg (three 3 mg tablets) once daily based on tolerability, including hyperphosphatemia, at 14 to 21 days.

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Drugs/Diseases

Util A                      Util B                      Util C  
Erdafitinib

Max Dose: 9 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**2. Erdafitinib / Therapeutic Appropriateness**

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

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Drugs/Diseases

Util A                      Util B                      Util C  
Erdafitinib

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**3. Erdafitinib / Ocular Disorders**

Alert Message: Balversa (erdafitinib) can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect. Perform monthly ophthalmological examinations during the first 4 months of treatment and every 3 months afterward and urgently at any time for visual symptoms. Withhold or permanently discontinue erdafitinib based on severity and/or ophthalmology exam findings.

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Drugs/Diseases

Util A                      Util B                      Util C  
Erdafitinib                      Ocular Disorders

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**4. Erdafitinib / Hyperphosphatemia & Soft Tissue Mineralization**

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Alert Message: Balversa (erdafitinib) can cause hyperphosphatemia, leading to soft tissue mineralization, cutaneous calcinosis, non-uremic calciphylaxis, and vascular calcification. Increases in phosphate levels are a pharmacodynamic effect of erdafitinib. Monitor for hyperphosphatemia throughout treatment. Restrict dietary phosphate intake (600-800 mg daily) and avoid concomitant use of agents that may increase serum phosphate levels. If serum phosphate is above 7.0 mg/dL, consider adding an oral phosphate binder until serum phosphate levels returns < 7.0 mg/dL.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib	Hyperphosphatemia Soft Tissue Mineralization Cutaneous Calcinosis Non-uremic Calciphylaxis	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**5. Erdafitinib / Moderate CYP2C9 or Potent CYP3A4 Inhibitors**

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Alert Message: Co-administration of Balversa (erdafitinib) with moderate CYP2C9 or strong CYP3A4 inhibitors may result in increased erdafitinib plasma concentrations. Increased erdafitinib plasma concentrations may lead to increased drug-related toxicity. Consider alternative therapies that are not moderate CYP2C9 or strong CYP3A4 inhibitors during treatment with erdafitinib. If co-administration of a moderate CYP2C9 or strong CYP3A4 inhibitor is unavoidable, monitor closely for adverse reactions and consider modifications accordingly.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib	Amiodarone Cobicistat Darunavir Fluconazole Itraconazole	Clarithromycin Nefazodone Nelfinavir Itraconazole Ritonavir
		Ketoconazole Amiodarone Voriconazole Posaconazole Miconazole

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**6. Erdafitinib / Strong CYP3A4 Inducers**

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Alert Message: Avoid co-administration of strong CYP3A4 inducers with Balversa (erdafitinib). Co-administration of erdafitinib (a CYP3A4 substrate) with strong CYP3A4 inducers may cause decreased erdafitinib plasma concentrations and decreased efficacy.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**7. Erdafitinib / Moderate CYP3A4 Inducers**

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Alert Message: Co-administration of Balversa (erdafitinib) with moderate CYP3A4 inducers may result in decreased erdafitinib plasma concentrations and decreased efficacy. If a moderate CYP3A4 inducer must be co-administered at the start of erdafitinib treatment, administer erdafitinib at a dose of 9 mg daily. When a moderate CYP3A4 inducer is discontinued, continue erdafitinib at the same dose, in the absence of drug-related toxicity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib	Bosentan	Rifapentine
	Modafinil	Efavirenz
	Cenobamate	Etravirine
	Nafcillin	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**8. Erdafitinib / P-gp Substrates**

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Alert Message: Co-administration of Balversa (erdafitinib) with P-gp substrates may result in increased plasma concentrations of P-gp substrates. Increased plasma concentrations of P-gp substrates may lead to increased toxicity of the P-gp substrates. If co-administration of erdafitinib with P-gp substrates is unavoidable, separate erdafitinib administration by at least 6 hours before or after administration of P-gp substrates with a narrow therapeutic index.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib		

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**8. Erdafitinib / P-gp Substrates**

Alert Message: Co-administration of Balversa (erdafitinib) with P-gp substrates may result in increased plasma concentrations of P-gp substrates. Increased plasma concentrations of P-gp substrates may lead to increased toxicity of the P-gp substrates. If co-administration of erdafitinib with P-gp substrates is unavoidable, separate erdafitinib administration by at least 6 hours before or after administration of P-gp substrates with a narrow therapeutic index.

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Drugs/Diseases

Util A

Util B

Util C

Erdafitinib

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**9. Erdafitinib / Pregnancy / Pregnancy Negating**

Alert Message: Based on the mechanism of action and findings in animal reproduction studies, Balversa (erdafitinib) can cause fetal harm when administered to a pregnant patient. In an embryo-fetal toxicity study, oral administration of erdafitinib to pregnant rats during the period of organogenesis caused malformations and embryo-fetal death at maternal exposures that were less than the human exposures at the maximum human recommended dose based on the area under the curve (AUC). Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with erdafitinib and for one month after the last dose.

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Drugs/Diseases

Util A

Util B

Util C (Negate)

Erdafitinib

Pregnancy

Abortion

Delivery

Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**10. Erdafitinib / Lactation**

Alert Message: There are no data on the presence of Balversa (erdafitinib) in human milk, the effects of erdafitinib on the breastfed child, or milk production. Because of the potential for serious adverse reactions from erdafitinib in a breastfed child, advise lactating women not to breastfeed during treatment with erdafitinib and for one month following the last dose.

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Drugs/Diseases

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

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**11. Erdafitinib / Therapeutic Appropriateness**

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Balversa (erdafitinib) and for one month after the last dose. Based on the mechanism of action and findings in animal reproduction studies, erdafitinib can cause fetal harm when administered to a pregnant woman.

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Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib		

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**12. Erdafitinib / Therapeutic Appropriateness**

Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Balversa (erdafitinib) and for one month after the last dose.

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Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib		

Gender: Male

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**13. Erdafitinib / Non-adherence**

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Alert Message: Based on refill history, your patient may be under-utilizing Balversa (erdafitinib). 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

Erdafitinib

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.

Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734

Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

**14. Sitagliptin/metformin / Overuse**

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Alert Message: Zituvimet (sitagliptin/metformin) may be over-utilized. The manufacturer's recommended maximum dose is 100 mg sitagliptin /2000 mg metformin daily.

Drugs/Diseases

Util A

Util B

Util C

Sitagliptin/Metformin

Max Dose: 100 mg/2000mg day

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.

UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.

Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

**15. Sitagliptin/metformin / Therapeutic Appropriateness**

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Alert Message: The safety and effectiveness of Zituvimet (sitagliptin/metformin) have not been established in pediatric patients.

Drugs/Diseases

Util A

Util B

Util C

Sitagliptin/Metformin

Age Range: 0 – 17 yoa

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.

UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.

Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**16. Sitagliptin/metformin / Severe Renal Impairment**

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Alert Message: Zituvimet (sitagliptin/metformin) use is contraindicated in patients with severe renal impairment (eGFR below 30 mL/min/1.73m<sup>2</sup>). In clinical studies, a 4-fold increase in the plasma AUC of sitagliptin was observed in patients with severe renal impairment including patients with end-stage renal disease (ESRD) on hemodialysis, compared to normal healthy control subjects.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	CKD Stage 4 CKD Stage 5 ESRD Hemodialysis	

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.  
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.  
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

**17. Sitagliptin/metformin / Moderate Renal Impairment**

\_\_\_\_\_ v \_\_\_\_\_

Alert Message: Zituvimet (sitagliptin/metformin) use is not recommended in patients with an eGFR between 30 and less than 45 mL/min/1.73 m<sup>2</sup> because these patients require a lower dosage of sitagliptin than what is available in the fixed combination sitagliptin/metformin product.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	CKD Stage 3b	

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.  
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.  
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

**18. Sitagliptin/metformin / Type 1 Diabetes**

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Alert Message: Zituvimet (sitagliptin/metformin) should not be used in patients with type 1 diabetes mellitus.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	Type 1 Diabetes	

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.  
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.  
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

**19. Sitagliptin/metformin / Insulin & Insulin Secretagogues**

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Alert Message: The concurrent use of Zituvimet (sitagliptin/metformin) with insulin and insulin secretagogues can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with sitagliptin/metformin.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	Insulin	Insulin Secretagogues

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.  
 UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.  
 Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

**20. Sitagliptin/metformin / Pregnancy / Pregnancy Negating**

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

Alert Message: Available data with Zituvimet (sitagliptin/metformin) and sitagliptin use in pregnant women are not sufficient to inform a sitagliptin/metformin-associated or sitagliptin-associated risk for major birth defects and miscarriage. Published studies with metformin use during pregnancy have not reported a clear association with metformin and major birth defect or miscarriage risk. During pregnancy, consider appropriate alternative therapies. Sitagliptin/metformin should be used during pregnancy only if clearly needed.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Sitagliptin/Metformin	Pregnancy Delivery Miscarriage	Abortion

Gender: Female  
 Age Range: 11 – 50 yoa

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.  
 UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.  
 Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.  
 American Diabetes Association (ADA). 15. Management of Diabetes in Pregnancy. Standards of Care in Diabetes-2024. Diabetes Care 2024;47(Suppl. 1):S282-S294.

**21. Sitagliptin/metformin / Lactation**

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

Alert Message: There is no information regarding the presence of Zituvimet (sitagliptin/metformin) in human milk, the effects on the breastfed infant, or milk production. Sitagliptin is present in rat milk and, therefore, possibly in human milk. Limited published studies report that metformin is present in human milk. The developmental and health benefits of breastfeeding should be considered, along with the mother’s clinical need for sitagliptin/metformin and any potential adverse effects on the breastfed infant from sitagliptin/metformin or the underlying maternal condition.

Drugs/Diseases

Util A

Util B

Util C

Sitagliptin/Metformin

Lactation

Gender: Female

Age Range: 11 – 50 yoa

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.  
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

**22. Sitagliptin/metformin / Non-adherence**

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

Alert Message: Based on refill history, your patient may be under-utilizing Zituvimet (sitagliptin/metformin). 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

Sitagliptin/Metformin

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 in Diabetes Mellitus. Cardiology Review, April 2007, Vol. 24 No. 4. p.18-22.

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 Nonadherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

**Criteria Recommendations**

**Accepted Approved Rejected  
As  
Amended**

**23. Talicia / Overuse**

\_\_\_\_\_ v \_\_\_\_\_

Alert Message: Talicia (omeprazole/amoxicillin/rifabutin) may be over-utilized. The recommended maintenance dose is four (4) omeprazole/amoxicillin/rifabutin capsules 3 times daily (at least 4 hours apart) with food for 14 days.

Drugs/Diseases

Util A

Util B

Util C

Omeprazole/amoxicillin/rifabutin

Max Dose: 4 capsules/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

**24. Talicia / Therapeutic Appropriateness**

\_\_\_\_\_ v \_\_\_\_\_

Alert Message: The safety and effectiveness of Talicia (omeprazole/amoxicillin/rifabutin) in pediatric patients below the age of 18 years with H. pylori infection have not been established.

Drugs/Diseases

Util A

Util B

Util C

Omeprazole/amoxicillin/rifabutin

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

**25. Talicia / Overuse**

\_\_\_\_\_ v \_\_\_\_\_

Alert Message: Talicia (omeprazole/amoxicillin/rifabutin) may be over-utilized. The recommended duration of therapy with omeprazole/amoxicillin/rifabutin capsules is 14 days.

Drugs/Diseases

Util A

Util B

Util C

Omeprazole/amoxicillin/rifabutin

Max Duration: 14 days

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

**26. Talicia / Severe Renal Impairment**

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

Alert Message: The use of Talicia (omeprazole/amoxicillin/rifabutin) should be avoided in patients with severe renal impairment (GFR < 30 mL/min). The amoxicillin-component of the combination product is primarily eliminated by the kidney.

Drugs/Diseases

Util A

Omeprazole/amoxicillin/rifabutin

Util B

Util C (Include)

Chronic Kidney Disease Stage 4  
Chronic Kidney Disease Stage 5  
ESRD

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

**27. Talicia / Hepatic Impairment**

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

Alert Message: It is recommended to avoid the use of Talicia (omeprazole/amoxicillin/rifabutin) in patients with hepatic impairment. In patients with hepatic impairment (Child-Pugh Class A, B, or C) exposure to omeprazole substantially increased compared to healthy subjects.

Drugs/Diseases

Util A

Omeprazole/amoxicillin/rifabutin

Util B

Util C (Include)

Hepatic Impairment

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

**28. Talicia / Pregnancy / Pregnancy Negating**

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

Alert Message: Talicia (omeprazole/amoxicillin/rifabutin) may cause fetal harm when administered to a pregnant patient. The use of omeprazole/amoxicillin/rifabutin is not recommended for use during pregnancy. If omeprazole/amoxicillin/rifabutin is used during pregnancy, advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A

Omeprazole/amoxicillin/rifabutin

Util B

Pregnancy

Util C (Include)

Abortion  
Delivery  
Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

**29. Talicia / Lactation**

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

Alert Message: The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Talicia (omeprazole/amoxicillin/rifabutin) and any potential adverse effects on the breast-fed child from omeprazole/amoxicillin/rifabutin or the underlying condition.

Drugs/Diseases

Util A

Omeprazole/amoxicillin/rifabutin

Util B

Lactation

Util C

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

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

**Criteria Recommendations**

**Accepted   Approved   Rejected  
As  
Amended**

**1. Elagolix/Estradiol/Norethindrone / Overuse**

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

Alert Message: Oriahnn (elagolix/estradiol/norethindrone) may be over-utilized. The recommended dosage of elagolix/estradiol/norethindrone is one capsule in the morning and one capsule in the evening. The use of elagolix/estradiol/norethindrone should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone		

Max Dose: 2 caps/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**2. Elagolix/Estradiol/Norethindrone / Therapeutic Appropriateness**

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

Alert Message: The safety and effectiveness of Oriahnn (elagolix/estradiol/norethindrone) in pediatric patients have not been established.

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**3. Elagolix/Estradiol/Norethindrone / Thrombotic Disorders**

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

Alert Message: Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with a current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events. In general, the risk is greatest among women over 35 years of age who smoke and women with uncontrolled hypertension, dyslipidemia, vascular disease, or obesity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone		
	Deep Vein Thrombosis	
	Dyslipidemia	
	Migraine with Aura	
	Myocardial Infarction	
	Obesity	
	Pulmonary Embolism	
	Stroke	
	Vascular Disease	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**4. Elagolix/Estradiol/Norethindrone / Pregnancy / Pregnancy Negating**

  v   \_\_\_\_\_

Alert Message: Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women who are pregnant. Exposure to elagolix/estradiol/norethindrone in early pregnancy may increase the risk of early pregnancy loss.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Elagolix/Estradiol/Norethindrone	Pregnancy	Abortion Delivery Miscarriage

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**5. Elagolix/Estradiol/Norethindrone / Osteoporosis**

  v   \_\_\_\_\_

Alert Message: Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with known osteoporosis because of the risk of further bone loss. Elagolix/estradiol/norethindrone may cause a decrease in bone mineral density (BMD) in some patients. BMD loss is greater with increasing duration of use and may not be completely reversible after stopping treatment.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Elagolix/Estradiol/Norethindrone		Osteoporosis

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**6. Elagolix/Estradiol/Norethindrone / Hormonally-Sensitive Malignancies**

  v   \_\_\_\_\_

Alert Message: Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with breast cancer, a history of breast cancer or other hormonally-sensitive malignancies, and who are at increased risk for hormonally-sensitive malignancies.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Elagolix/Estradiol/Norethindrone		Breast Cancer Endometrial Cancer Ovarian Cancer Uterine Cancer

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**7. Elagolix/Estradiol/Norethindrone / Hepatic Impairment**

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

Alert Message: Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with known hepatic impairment or disease. Instruct patients to promptly seek medical attention if they develop symptoms or signs that may reflect liver injury, such as jaundice.

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone	Cirrhosis Chronic Hepatitis Fibrosis of Liver Inflammatory Liver Disease Jaundice Hepatic Failure Hepatic Impairment	

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**8. Elagolix/Estradiol/Norethindrone / OATP1B1 Inhibitors**

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

Alert Message: Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women taking inhibitors of organic anion transporting polypeptide (OATP)1B1 that are known or expected to significantly increase elagolix plasma concentration.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone	Asciminib Cobicistat Cyclosporine Darolutamide Eltrombopag Clarithromycin	Enasidenib Fostemsavir Gemfibrozil Glecaprevir Velpatasvir Encorafenib

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**9. Elagolix/Estradiol/Norethindrone / Suicidal Ideation & Depression**

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

Alert Message: In clinical trials Oriahnn (elagolix/estradiol/norethindrone)-treated women had a higher incidence of depression, depressed mood, and tearfulness compared to placebo-treated women. Suicidal ideation and behavior, including a completed suicide, occurred in women treated with lower doses of elagolix in clinical trials conducted for a different indication. Promptly evaluate patients with psychiatric symptoms to determine whether the risks of continued therapy outweigh the benefits.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone	Anxiety Depression Mood Disorders Suicidal Ideation	

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**10. Elagolix/Estradiol/Norethindrone / Gallbladder Disease**

Alert Message: Oriahnn (elagolix/estradiol/norethindrone) may increase the risk of gallbladder disease. For women with a history of cholestatic jaundice associated with past estrogen use or when pregnant, assess the risk-benefit of continuing therapy. Discontinue elagolix/estradiol/norethindrone if jaundice occurs.

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

Drugs/Diseases

Util A

Util B

Util C (Include)

Elagolix/Estradiol/Norethindrone

Diseases of Gallbladder

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**11. Elagolix/Estradiol/Norethindrone / Digoxin**

Alert Message: Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with digoxin may result in increased digoxin concentrations. Increase monitoring of digoxin concentrations and potential signs and symptoms of digoxin toxicity. Digoxin is a P-gp substrate and the elagolix component of the combination product is a P-gp efflux transport inhibitor. Digoxin dosage adjustment may be required.

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

Drugs/Diseases

Util A

Util B

Util C

Elagolix/Estradiol/Norethindrone

Digoxin

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**12. Elagolix/Estradiol/Norethindrone / Rosuvastatin**

Alert Message: Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with a rosuvastatin-containing product may result in decreased rosuvastatin exposure and loss of therapeutic effect. Monitor the patient for rosuvastatin efficacy. Dosage adjustment of rosuvastatin may be necessary during elagolix/estradiol/norethindrone therapy.

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

Drugs/Diseases

Util A

Util B

Util C

Elagolix/Estradiol/Norethindrone

Rosuvastatin

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**13. Elagolix/Estradiol/Norethindrone / Midazolam**

\_\_\_ v \_\_\_

Alert Message: Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with midazolam may result in decreased midazolam exposure. Monitor the patient for altered response to midazolam therapy. Consider increasing the dose of midazolam by no more than 2-fold and individualize midazolam therapy based on the patient’s response.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone	Midazolam	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**14. Elagolix/Estradiol/Norethindrone / Strong CYP3A4 Inducers**

\_\_\_ v \_\_\_

Alert Message: Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with a strong CYP3A inducer is not recommended. Elagolix, estradiol, and norethindrone are CYP3A4 substrates and concurrent use with a CYP3A4 inducer may decrease plasma concentrations of all substrates and efficacy.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone	Apalutamide Carbamazepine Enzalutamide Mitotane Phenobarbital Phenytoin Primidone	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**15. Elagolix/Estradiol/Norethindrone / Strong CYP3A4 Inhibitors**

\_\_\_ v \_\_\_

Alert Message: Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with strong CYP3A inhibitors are not recommended. Elagolix, estradiol, and norethindrone are CYP3A4 substrates, and concurrent use with a strong CYP3A4 inhibitor may increase plasma concentrations of all substrates, increasing the risk of adverse reactions.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone	Clarithromycin Darunavir Cobicistat Darunavir Itraconazole Ketoconazole	Nelfinavir Nefazodone Posaconazole Ritonavir Voriconazole

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**16. Elagolix/Estradiol/Norethindrone / Rifampin**

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

Alert Message: Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with rifampin is not recommended. The concurrent use of rifampin with an elagolix-containing agent may result in increased elagolix plasma concentrations, increasing the risk of adverse reactions.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone	Rifampin	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**17. Elagolix/Estradiol/Norethindrone / Lactation**

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

Alert Message: The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Oriahnn (elagolix/estradiol/norethindrone) and any potential adverse effects on the breastfed child from elagolix/estradiol/norethindrone or the underlying maternal condition. There is no information on the presence of elagolix or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Estrogen administration to nursing women has been shown to decrease the quantity and quality of breast milk. Detectable amounts of estrogen and progestin have been identified in the breast milk of women receiving estrogen and progestin combinations.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Elagolix/Estradiol/Norethindrone	Lactation	

Gender: Female  
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

**18. Pirtobrutinib / Overuse**

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

Alert Message: Jaypirca (pirtobrutinib) may be over-utilized. The recommended dosage of pirtobrutinib is 200 mg orally once daily until disease progression or unacceptable toxicity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Pirtobrutinib		CKD Stage 4

Max Dose: 200 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**19. Pirtobrutinib / CKD Stage 4**

Alert Message: For patients with severe renal impairment (eGFR 15-29 mL/min), reduce the Jaypirca (pirtobrutinib) dose to 100 mg once daily if the current dose is 200 mg once daily; otherwise, reduce the dose by 50 mg. If the current dosage is 50 mg once daily, discontinue pirtobrutinib. No dosage adjustment of pirtobrutinib is recommended in patients with mild to moderate renal impairment (eGFR 30-89 mL/min).

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

Drugs/Diseases

Util A

Util B

Util C (Include)

Pirtobrutinib

CKD Stage 4

Max Dose: 100 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**20. Pirtobrutinib / Therapeutic Appropriateness**

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

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

Drugs/Diseases

Util A

Util B

Util C

Pirtobrutinib

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**21. Pirtobrutinib / Infections**

Alert Message: Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients treated with Jaypirca (pirtobrutinib). In the clinical trial, Grade 3 or higher infections occurred in 24% of 593 patients, most commonly pneumonia (14%), with fatal infections occurring in 4.4% of patients. Monitor patients for signs and symptoms of infection, evaluate promptly and treat appropriately. Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

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

Drugs/Diseases

Util A

Util B

Util C

Pirtobrutinib

Infections

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**22. Pirtobrutinib / Hemorrhage** \_\_\_\_\_v\_\_\_\_\_

Alert Message: Fatal and serious hemorrhage has occurred with Jaypirca (pirtobrutinib). Major hemorrhage occurred in 3% of 593 patients treated with pirtobrutinib. Bleeding of any grade, excluding bruising and petechiae, occurred in 17% of patients. Major hemorrhage occurred in 2.3% of patients taking pirtobrutinib without antithrombotic agents and 0.7% of patients taking pirtobrutinib with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with pirtobrutinib. Monitor patients for signs of bleeding. Based on the severity of bleeding, reduce the dose, temporarily withhold, or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Gastrointestinal hemorrhage Hematemesis Hematochezia Intracerebral hemorrhage Intracranial hemorrhage Melena	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**23. Pirtobrutinib / Cytopenias** \_\_\_\_\_v\_\_\_\_\_

Alert Message: Jaypirca (pirtobrutinib) can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. In the clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%) developed in patients treated with pirtobrutinib. Grade 4 decreased neutrophils developed in 14% of patients, and Grade 4 decreased platelets developed in 6% of patients. Monitor complete blood counts regularly during pirtobrutinib treatment. Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Neutropenia Thrombocytopenia Anemia	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**24. Pirtobrutinib / Arrhythmias** \_\_\_\_\_v\_\_\_\_\_

Alert Message: Cardiac arrhythmias, including atrial fibrillation and atrial flutter, were reported in recipients receiving Jaypirca (pirtobrutinib). Atrial fibrillation or flutter were reported in 3.2% of patients, with Grade 3 or 4 atrial fibrillation or flutter reported in 1.5% of 593 patients in the clinical trial. Patients with cardiac risk factors, such as hypertension or previous arrhythmias, may be at increased risk. Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately. Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Arrhythmias	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**25. Pirtobrutinib / Hepatotoxicity**

Alert Message: Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including Jaypirca (pirtobrutinib). Evaluate bilirubin and transaminases at baseline and throughout treatment with pirtobrutinib. For patients who develop abnormal liver tests after pirtobrutinib, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold pirtobrutinib. Upon confirmation of DILI, discontinue pirtobrutinib.

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Abnormal Results of Liver Function Studies Anorexia Chronic Fatigue Jaundice Nausea	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**26. Pirtobrutinib / Strong CYP3A4 Inhibitors**

Alert Message: Avoid concomitant use of strong CYP3A inhibitors with Jaypirca (pirtobrutinib). If concomitant use of a strong CYP3A inhibitor is unavoidable, reduce the pirtobrutinib dose by 50 mg. If the current dosage is 50 mg once daily, interrupt pirtobrutinib treatment for the duration of strong CYP3A inhibitor use. After discontinuation of a strong CYP3A inhibitor for 5 half-lives, resume the pirtobrutinib dose that was taken prior to initiating the strong CYP3A inhibitor.

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Clarithromycin Cobicistat Darunavir Itraconazole Ketoconazole	Nefazadone Nelfinavir Posaconazole Ritonavir Voriconazole

Max Dose: 150 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**27. Pirtobrutinib / Strong or Moderate CYP3A4 Inducers**

Alert Message: Avoid concomitant use of strong or moderate CYP3A inducers with Jaypirca (pirtobrutinib). If concomitant use with moderate CYP3A inducers is unavoidable and the current dosage of pirtobrutinib is 200 mg once daily, increase the dose to 300 mg. If the current dosage is 50 mg or 100 mg once daily, increase the dose by 50 mg.

\_\_\_\_\_√\_\_\_\_\_

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Apalutamide Bosentan Carbamazepine Efavirenz Etravirine Phenobarbital Phenytoin Primidone Rifabutin Rifampin Rifapentine	

References:

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

**28. Pirtobrutinib / Sensitive CYP2C8, 2C19, 3A, P-gp, & BCRP Substrates**

Alert Message: Jaypirca (pirtobrutinib) is a P-gp inhibitor, a moderate CYP2C8 and BCRP inhibitor, and a weak CYP2C19 and CYP3A inhibitor. Concomitant use of pirtobrutinib with sensitive P-gp, CYP2C8, BCRP, CYP2C19, or CYP3A substrates increases the substrate plasma concentrations, which may increase the risk of substrate-related adverse reactions. Follow the recommendations for sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP substrates provided in their approved product labeling.

\_\_\_\_\_√\_\_\_\_\_

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Buspirone Citalopram Cyclosporine Edoxaban Everolimus Felodipine Dabigatran Digoxin Lonafarnib Sirolimus Tacrolimus Triazolam Warfarin	

References:

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

**29. Pirtobrutinib / Antithrombotic Agents**

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

Alert Message: Consider the risks and benefits of antithrombotic agents when co-administered with Jaypirca (pirtobrutinib). In a clinical trial, major hemorrhage occurred in 3% of 593 patients treated with pirtobrutinib. Monitor patients for signs of bleeding. Based on the severity of bleeding, reduce the dose, temporarily withhold, or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Apixaban	Fondaparinux
	Dabigatran	Heparin
	Dalteparin	Rivaroxaban
	Edoxaban	Warfarin
	Enoxaparin	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**30. Pirtobrutinib / Pregnancy / Pregnancy Negating**

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

Alert Message: Based on findings from animal studies, Jaypirca (pirtobrutinib) can cause fetal harm when administered to a pregnant woman. There are no available data on pirtobrutinib use in pregnant women to evaluate for a drug-associated risk. In an animal reproduction study, administration of pirtobrutinib to pregnant rats during organogenesis resulted in adverse developmental outcomes at maternal exposures approximately 3-times those in patients at the recommended daily dose of 200 mg. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**31. Pirtobrutinib / Lactation**

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

Alert Message: There are no data on the presence of Jaypirca (pirtobrutinib) in human milk or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with pirtobrutinib and for one week after the last dose.

Drugs/Diseases

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

Gender: Female  
Age Range: 11 – 50 yoa

References:  
Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**32. Pirtobrutinib / Non-adherence**

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

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib		

References:  
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.  
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.  
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734  
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

  
Stephanie McGee Azar, Alabama Medicaid  
Commissioner

Approve

Deny

5-28-2025

Date

  
F. Darlene Traffanstedt, MD,  
Alabama Medicaid Medical Director

Approve

Deny

5/22/2025

Date

  
Ginger Carmack, Alabama Medicaid  
Deputy Commissioner

Approve

Deny

5-27-25

Date