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

**Members Present:** Kelli Littlejohn Newman, Crystal Deas, Bernie Olin, George Sutton, Rachel Seaman, Melinda Rowe, Danielle Powell, Jeremy Osborn

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

**Members Absent:** Dan McConaghy, Marilyn Bulloch, Mary Stallworth

**Call to Order:** The DUR meeting was called to order by C. Deas at approximately 1:05 p.m.

**Review and Adoption of Minutes**: The minutes of the October 25, 2023, meeting were presented, and B. Olin 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 July 2023. She reported 14,118 manual PAs and overrides. There were 15,651 total electronic requests for the month of July 2023. From the Prior Authorization and Override Response Time Ratio report for July 2023, L. Thomas reported that approximately 13% of all manual PAs and 11% of all overrides were completed in less than two hours, but a total of 77% of all PAs were completed in under 2 hours (including electronic PA transactions). Forty-six percent of all manual PAs and 44% of all overrides were completed in less than four hours. Seventy-eight percent of all manual PAs and 76% of all overrides were completed in less than eight hours. L. Thomas reminded the Board Members that 75% of all PAs and overrides must be completed in under 8 hours to meet contractual obligations. For the month of August 2023, L. Thomas reported 15,843 manual PA requests and 18,003 electronic PA requests were received. She reported that 9% of all manual PAs and 8% 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-seven percent of all manual PAs and 34% of all overrides were completed in less than four hours. Seventy-two percent of all manual PAs and 73% of all overrides were completed in less than eight hours. For the month of September 2023, L. Thomas reported 13,680 manual PA requests and 15,501 electronic PA requests. L. Thomas reported that approximately 15% 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. Sixty percent of all manual PA requests and 61% of all overrides were completed in less than four hours. Eighty-two percent of all manual PAs and 84% of all overrides were completed in less than eight hours.

**Program Summary Review:** L. Thomas briefly reviewed the Alabama Medicaid Program Summary for the months of April 2023 through September 30, 2023. She reported 238,806 average recipients per month using pharmacy benefits, and an average paid per prescription of $152.39.

**Cost Management Analysis:** L. Thomas reported an average cost per claim of $147.99 for September 2023 and compared previous months contained in the table. From the 3rd Quarter Drug Analysis, L. Thomas reported 84.6% generic utilization, 6.9% brand single-source, 4.7% brand multi-source (those requests which required a DAW-1 override), and 3.8% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 07/01/2023 – 09/30/2023, L. Thomas reported the top five drugs: amoxicillin, cetirizine, albuterol sulfate HFA, fluticasone propionate, and azithromycin. L. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 07/01/2023 – 09/30/2023: Humira® Citrate-free Pen, Trikafta®, Trulicity®, Invega Sustenna®, and Vyvanse®. 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.

**Proposed Criteria:** L. Thomas presented the proposed set of 46 criteria to the Board and instructed the Board members to mark their ballots. Of the 46 proposed criteria, results from the criteria vote returned 45 approved and 1 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 reviewed the MME phase down effective November 1, 2023, the January 2024 PDL updates, and the use of DAW-8 for brand name Focalin XR due to the shortage of the generic product.

**P & T Committee Update:** K. Newman began the P & T Update by informing the Board that the last P & T meeting was held on November 8, 2023, and covered the antidiabetic agents; prenatal vitamins; antigout agents; and the genitourinary smooth muscle relaxants. The next meeting is scheduled for February 7, 2024, and will cover the anticoagulants, cardiac agents, antihyperlipidemics, and antidepressants.

**Next Meeting Date:** C. Deas reminded the Board that the next DUR meeting will be held on April 24, 2024. A motion to adjourn the meeting was made by C. Deas and B. Olin seconded the motion. The meeting was adjourned at 1:55 p.m.

Respectfully submitted,

Lori Thomas, PharmD

Lori Thomas, PharmD.

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

| *Criteria Recommendations* | *Accepted* | *Approved As Amended* | *Rejected* |
|---|---|---|---|
| **1. Pemigatinib / Overuse**<br>Alert Message: Pemazyre (pemigatinib) may be over-utilized. The maximum recommended dosage (intermittent or continuous schedule) of pemigatinib is 13.5 mg per day.<br><br>Drugs/Diseases<br>Util A: Pemigatinib<br>Util B:<br>Util C (Negating): CKD Stage 4, 5, & ESRD; Cirrhosis; Liver Failure<br><br>Max Dose: 13.5 mg/day<br><br>References:<br>Clinical Pharmacology, 2022 Elsevier/Gold Standard.<br>Pemazyre Prescribing Information, August 2022, Incyte Corporation. | √ | | |
| **2. Pemigatinib / Overuse**<br>Alert Message: Pemazyre (pemigatinib) may be over-utilized. The maximum recommended dosage (intermittent or continuous) of pemigatinib in patients with severe renal impairment is 9.0 mg per day.<br><br>Drugs/Diseases<br>Util A: Pemigatinib<br>Util B:<br>Util C (Include): CKD Stage 4, 5, & ESRD<br><br>Max Dose: 9.0 mg/day<br><br>References:<br>Clinical Pharmacology, 2022 Elsevier/Gold Standard.<br>Pemazyre Prescribing Information, August 2022, Incyte Corporation. | √ | | |
| **3. Pemigatinib / Overuse**<br>Alert Message: Pemazyre (pemigatinib) may be over-utilized. The maximum recommended dosage (intermittent or continuous) of pemigatinib in patients with severe hepatic impairment (total bilirubin > 3 x ULN with any AST) is 9.0 mg per day.<br><br>Drugs/Diseases<br>Util A: Pemigatinib<br>Util B:<br>Util C (Include): Cirrhosis; Liver Failure<br><br>Max Dose: 9.0 mg/day<br><br>References:<br>Clinical Pharmacology, 2022 Elsevier/Gold Standard.<br>Pemazyre Prescribing Information, August 2022, Incyte Corporation. | √ | | |

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

**4. Pemigatinib / Therapeutic Appropriateness** ___√___ _____ _____

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

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Pemigatinib | | |

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

**5. Pemigatinib / Ocular Toxicity** ___√___ _____ _____

Alert Message: Pemazyre (pemigatinib) can cause retinal pigment epithelial detachment (RPED), which may cause symptoms such as blurred vision, visual floaters, or photopsia. Perform a comprehensive ophthalmological examination, including OCT prior to initiation of pemigatinib and every 2 months for the first 6 months and every 3 months thereafter during treatment. For the onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of pemigatinib. Modify the dose or permanently discontinue pemigatinib as recommended.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Pemigatinib | Blurred Vision | |
| | Photopsia | |
| | Serous Detachment of Retinal Pigment Epithelium | |
| | Vitreous Opacities | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

**6. Pemigatinib / Strong & Moderate CYP3A4 Inducers** ___√___ _____ _____

Alert Message: Concomitant use of Pemazyre (pemigatinib) with a strong or moderate CYP3A inducer decreases pemigatinib plasma concentrations, which may reduce the efficacy of pemigatinib. Avoid concomitant use of strong and moderate CYP3A inducers with pemigatinib.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Pemigatinib | Apalutamide | |
| | Bosentan | |
| | Carbamazepine | |
| | Efavirenz | |
| | Etravirine | |
| | Phenobarbital | |
| | Phenytoin | |
| | Primidone | |
| | Rifabutin | |
| | Rifampin | |
| | Rifapentine | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

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

**7. Pemigatinib / Strong & Moderate CYP3A4 Inhibitors** ___√___ _____ _____

Alert Message: The concurrent use of Pemazyre (pemigatinib) with strong and moderate CYP3A4 inhibitors should be avoided. Coadministration of pemigatinib with strong or moderate CYP3A inhibitors increases pemigatinib plasma concentrations, which increases the incidence and severity of adverse reactions. If concomitant use with a strong or moderate CYP3A inhibitor cannot be avoided, reduce the pemigatinib dose from 13.5 mg to 9 mg or if taking 9 mg to 4.5 mg. If concomitant use of the CYP3A inhibitor is discontinued, increase the pemigatinib dosage (after 3 plasma half-lives of the CYP3A inhibitor) to the dosage that was used before starting the CYP3A4 inhibitor.

Drugs/Diseases

| Util A | Util B | | Util C |
|---|---|---|---|
| Pemigatinib | Atazanavir | Fosamprenavir | |
| | Aprepitant | Idelalisib | |
| | Cimetidine | Indinavir | |
| | Ciprofloxacin | Itraconazole | |
| | Clarithromycin | Ketoconazole | |
| | Clotrimazole | Nefazodone | |
| | Cobicistat | Nelfinavir | |
| | Crizotinib | Posaconazole | |
| | Cyclosporine | Ritonavir | |
| | Darunavir | Saquinavir | |
| | Diltiazem | Tipranavir | |
| | Dronedarone | Verapamil | |
| | Erythromycin | Voriconazole | |
| | Fluconazole | | |
| | Fluvoxamine | | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

**8. Pemigatinib / Pregnancy / Pregnancy Negating** ___√___ _____ _____

Alert Message: Based on findings in an animal study and its mechanism of action, Pemazyre (pemigatinib) can cause fetal harm when administered to a pregnant woman. Oral administration of pemigatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure based on area under the curve (AUC) at the clinical dose of 13.5 mg. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with pemigatinib and for 1 week after the last dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

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

**9. Pemigatinib / Lactation** ___√___ _____ _____

Alert Message: There are no data on the presence of Pemazyre (pemigatinib) or its metabolites in human milk or their effects on either the breastfed child or milk production. Because of the potential for serious adverse reactions in breastfed children from pemigatinib, advise women not to breastfeed during treatment and for 1 week after the last dose.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Pemigatinib | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

**10. Pemigatinib / Therapeutic Appropriateness** ___√___ _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Pemazyre (pemigatinib) and for 1 week after the last pemigatinib dose.

Drugs/Diseases

| Util A | Util B | Util C (Negating) |
|---|---|---|
| Pemigatinib | | Contraceptives |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

**11. Pemigatinib / Therapeutic Appropriateness** ___√___ _____ _____

Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Pemazyre (pemigatinib) and for 1 week after the last dose.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Pemigatinib | | |

Gender: Male

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

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

**12. Pemigatinib / Non-adherence** ___√___ _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Pemazyre (pemigatinib). 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 |
|---|---|---|
| Pemigatinib | | |

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.

**13. Roflumilast / Therapeutic Appropriateness** _____ ___√____ _____

Alert Message: The safety and effectiveness of Zoryve (roflumilast cream) in pediatric patients below the age of 6 years have not been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Roflumilast Cream | | |

Age Range: 0 – 5 yoa

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zoryve Prescribing Information, October 2023, Arcutis Biotherapeutics, Inc.

**14. Roflumilast / Moderate to Severe Hepatic Impairment** ___√____ _____ _____

Alert Message: Zoryve (roflumilast cream) is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). Topical roflumilast has not been studied in patients with hepatic impairment. In clinical studies with oral roflumilast, patients with mild to moderate hepatic impairment had significant increases in the AUC and Cmax of roflumilast as compared to healthy patients.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Roflumilast Cream | Hepatic Impairment | |

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Zoryve Prescribing Information, August 2022, Arcutis Biotherapeutics, Inc.

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

**15. Roflumilast / CYP3A4 Inhibitors & Dual 3A4 & 1A2 Inhibitors** ___√___ _____ _____

Alert Message: The coadministration of Zoryve (roflumilast cream) with systemic CYP3A4 inhibitors or dual inhibitors that inhibit both CYP3A4 and CYP1A2 simultaneously (e.g., erythromycin, ketoconazole, fluvoxamine, cimetidine) may increase roflumilast systemic exposure and may result in increased adverse reactions. The risk of such concurrent use should be weighed carefully against the benefit.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Roflumilast Cream | Ciprofloxacin | Itraconazole |
| | Cimetidine | Ketoconazole |
| | Clarithromycin | Nefazodone |
| | Cobicistat | Nelfinavir |
| | Delavirdine | Posaconazole |
| | Erythromycin | Ritonavir |
| | Fluvoxamine | Saquinavir |
| | Indinavir | Voriconazole |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Zoryve Prescribing Information, August 2022, Arcutis Biotherapeutics, Inc.

**16. Roflumilast / Therapeutic Appropriateness** ___√___ _____ _____

Alert Message: There is no information regarding the presence of Zoryve (roflumilast cream) in human milk, the effects on the breastfed infant, or the effects on milk production. Roflumilast and its metabolites are excreted into the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for roflumilast cream and any potential adverse effects on the breastfed infant from roflumilast cream or the underlying maternal condition. To minimize potential exposure to the breastfed infant via breast milk, use roflumilast cream on the smallest area of skin (avoiding the nipple and areola) and for the shortest duration possible while breastfeeding.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Roflumilast | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

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

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

**17. Alogliptin/Metformin / Therapeutic Appropriateness** ___√___ _____ _____

Alert Message: Kazano (alogliptin/metformin) is contraindicated in patients with severe renal impairment (eGFR < 30 mL/min/1.73m2). The metformin component of the combination product is substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of renal impairment.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Alogliptin/Metformin | | CKD Stage 4 |
| | | CKD Stage 5 |
| | | ESRD |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Kazano Prescribing Information, March 2022, Takeda Pharmaceuticals America, Inc.

**18. Dupilumab / Therapeutic Appropriateness** ___√___ _____ _____

Alert Message: The safety and efficacy of Dupixent (dupilumab) for the treatment of prurigo nodularis in pediatric patients have not been established.

Drugs/Diseases

| Util A | Util B | Util C (Negate) |
|---|---|---|
| Dupilumab | Prurigo Nodularis | Asthma |
| | | Atopic Dermatitis |
| | | Eosinophilic Esophagitis |

Age Range: 0 – 17 yoa

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

**19. Vonoprazan/Amoxicillin/Clarithromycin / Therapeutic Appropriateness** ___√___ _____ _____

Alert Message: The safety and effectiveness of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) in pediatric patients have not been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | | |

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

**20. Vonoprazan/Amoxicillin/Clarithromycin / Rilpivirine-Containing Drugs** ___√___ _____ _____

Alert Message: Concurrent use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with rilpivirine-containing products is contraindicated. Vonoprazan reduces intragastric acidity, which may alter the absorption of rilpivirine, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Rilpivirine | |
| | Rilpivirine/Cabotegravir | |
| | Rilpivirine/Dolutegravir | |
| | Rilpivirine/Emtricitabine/Tenofovir ala | |
| | Rilpivirine/Emtricitabine/Tenofovir dis | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**21. Vonoprazan/Amoxicillin/Clarithromycin / Atazanavir-Containing Drugs** ___√___ _____ _____

Alert Message: Concurrent use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with an atazanavir-containing product should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of atazanavir, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Atazanavir | |
| | Atazanavir/Cobicistat | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**22. Vonoprazan/Amoxicillin/Clarithromycin / Nelfinavir** ___√___ _____ _____

Alert Message: Concurrent use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with nelfinavir should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of nelfinavir, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Nelfinavir | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

**23. Vonoprazan/Amoxicillin/Clarithromycin / Strong & Moderate 3A Inducers** ___V___ _____ _____

Alert Message: The vonoprazan and clarithromycin components of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) are CYP3A substrates. Strong or moderate CYP3A inducers may decrease the exposure of vonoprazan and clarithromycin, which may reduce the effectiveness of the CYP3A substrates.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Apalutamide<br>Bosentan<br>Carbamazepine<br>Efavirenz<br>Etravirine<br>Phenobarbital<br>Phenytoin<br>Primidone<br>Rifabutin<br>Rifampin<br>Rifapentine | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**24. Vonoprazan/Amoxicillin/Clarithromycin / CYP3A4 Substrates w/ NTI** ___V___ _____ _____

Alert Message: The vonoprazan and clarithromycin components of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) are CYP3A inhibitors. Concurrent use of clarithromycin and vonoprazan with CYP3A substrates where minimal concentration changes may lead to serious toxicities should be done with caution. Frequent monitoring of substrate concentrations and/or adverse reactions related to the substrate drugs is recommended when used with vonoprazan and clarithromycin.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Cyclosporine<br>Sirolimus<br>Tacrolimus | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**25. Vonoprazan/Amoxicillin/Clarithromycin / Clopidogrel** ___V___ _____ _____

Alert Message: The vonoprazan component of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with clopidogrel, a CYP2C19 substrate, may result in reduced clopidogrel efficacy. Vonoprazan may reduce plasma concentrations of the active metabolite of clopidogrel and may cause a reduction in platelet inhibition. Carefully monitor the efficacy of clopidogrel and consider alternative anti-platelet therapy.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Clopidogrel | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

**26. Vonoprazan/Amoxicillin/Clarithromycin / Citalopram** ___√___ _____ _____

Alert Message: The vonoprazan component of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with citalopram, a CYP2C19 substrate, may result in increased citalopram exposure, increasing the risk for citalopram adverse reactions. The dose of citalopram should be limited to 20 mg/day when co-administered with vonoprazan.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Citalopram | |

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**27. Vonoprazan/Amoxicillin/Clarithromycin / Cilostazol** ___√___ _____ _____

Alert Message: The vonoprazan component of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with cilostazol, a CYP2C19 substrate, may result in increased cilostazol exposure, increasing the risk of cilostazol-related adverse reactions. The dose of cilostazol should be limited to 50 mg twice daily when co-administered with vonoprazan.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Cilostazol | |

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**28. Vonoprazan/Amoxicillin/Clarithromycin / Severe Renal Impairment** ___√___ _____ _____

Alert Message: Avoid the use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) in patients with severe renal impairment (eGFR less than 30 mL/minute) or renal failure. The pack does not allow for appropriate dosage adjustments needed for these patients. In pharmacokinetic studies, patients with severe renal impairment exhibited increased systemic exposure to vonoprazan (2.4-times greater) compared to subjects with normal renal function.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | CKD Stage 4<br>CKD Stage 5<br>ESRD | |

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

**29. Vonoprazan/Amoxicillin/Clarithromycin / Mod-Sev Hepatic Impairment** __√____ _____ _____

Alert Message: Avoid the use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) in patients with moderate to severe hepatic impairment (Child-Pugh Class B or C). The pack does not allow for appropriate dosage adjustments needed for these patients. In pharmacokinetic studies, patients with severe hepatic impairment exhibited increased systemic exposure to vonoprazan (2.6-times greater) compared to subjects with normal renal function.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Hepatic Impairment | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**30. Vonoprazan/Amoxicillin/Clarithromycin / Pregnancy / Negating** ___√____ _____ _____

Alert Message: There are no adequate and well-controlled studies of Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin) in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. The use of the triple pack is not recommended in pregnant women except in clinical circumstances where no alternative therapy is appropriate.

Drugs/Diseases

| Util A | Util B | Util C (Negate) |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Pregnancy<br>Delivery<br>Miscarriage | Abortion |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

**31. Vonoprazan/Amoxicillin/Clarithromycin / Lactation** ___√___ _____ _____

Alert Message: There are no data regarding the presence of the vonoprazan component of the Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) in human milk, the effects on the breastfed infant, or the effects on milk production. Vonoprazan and its metabolites are present in rat milk. Liver injury occurred in offspring from pregnant and lactating rats administered oral vonoprazan. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, a woman should pump and discard human milk for the duration of vonoprazan therapy, and for 2 days after therapy ends, and feed her infant stored human milk (collected prior to therapy) or formula.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Lactation | |

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**32. Vonoprazan/Amoxicillin/Clarithromycin / Colchicine** ___√___ _____ _____

Alert Message: Life-threatening and fatal drug interactions have been reported in patients treated with clarithromycin, a component of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin), and colchicine. If co-administration of Voquezna Triple Pak and colchicine is necessary for patients with normal renal and hepatic function, reduce the dose of colchicine. Monitor patients for clinical symptoms of colchicine toxicity. Concomitant administration of Voquezna Triple Pak and colchicine is contraindicated in patients with renal or hepatic impairment.

Drugs/Diseases

| Util A | Util B | Util C (Negating) |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Colchicine | Hepatic Impairment<br>Renal Impairment |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**33. Vonoprazan/Amoxicillin/Clarithromycin / Omeprazole** ___√___ _____ _____

Alert Message: Avoid concomitant use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with omeprazole. In clinical studies, clarithromycin concentrations in the gastric tissue and mucus were increased by concomitant administration of omeprazole. Coadministration may result in clarithromycin-related adverse effects.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Omeprazole | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

**34. Vonoprazan/Amoxicillin/Clarithromycin / Itraconazole** ___√___ _____ _____

Alert Message: The concurrent use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with itraconazole may result in elevated clarithromycin and itraconazole exposure. Both clarithromycin and itraconazole are substrates and inhibitors of CYP3A, potentially leading to a bi-directional drug interaction when administered concomitantly. Patients taking itraconazole with Voquezna Triple Pak should be monitored closely for signs or symptoms of increased or prolonged adverse reactions associated with itraconazole and clarithromycin.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Vonoprazan/Amoxicillin/Clarithromycin | Itraconazole | |

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

**35. Tenofovir Alafenamide / Overutilization** ___√___ _____ _____

Alert Message: The safety and efficacy of Vemlidy (tenofovir alafenamide) have not been established in pediatric patients with chronic HBV infection who are less than 12 years of age.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Tenofovir Alafenamide | | |

Age Range 0 – 11 yoa

References:
Vemlidy Prescribing Information, Oct. 2022, Gilead Sciences, Inc.

**36. Venlafaxine Besylate Tablets / Overuse** ___√___ _____ _____

Alert Message: Venlafaxine besylate extended-release may be over-utilized. The maximum recommended dose is 225 mg once daily.

Drugs/Diseases

| Util A | Util B | Util C (Negating) |
|---|---|---|
| Venlafaxine besylate ER | | CKD Stage 1, 2, 3, 4, & 5<br>ESRD<br>Hemodialysis<br>Hepatic Impairment |

Max Dose: 225 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Venlafaxine Besylate Tablets, Extended-Release, June 2022, Almatica Pharma, LLC.

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

**37. Venlafaxine Besylate Tablets / Therapeutic Appropriateness** ___√___ _____ _____

Alert Message: The safety and effectiveness of venlafaxine besylate extended-release in pediatric patients have not been established.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Venlafaxine besylate ER | | |

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Venlafaxine Besylate Tablets, Extended-Release, June 2022, Almatica Pharma, LLC.

**38. Venlafaxine Besylate Tablets / Renal Impairment** ___√___ _____ _____

Alert Message: Venlafaxine besylate extended-release should be used with caution in patients with renal impairment. Renal elimination of venlafaxine is the primary route of excretion. Reduce the total daily dose of venlafaxine by 25% to 50% in patients with mild (CLcr = 60-89 mL/min) or moderate (CLcr = 30-59 mL/min) renal impairment. In patients undergoing hemodialysis or with severe renal impairment (CLcr < 30 mL/min), the total daily dose should be reduced by 50% or more. Switch to another venlafaxine extended-release product if doses lower than 112.5 mg are needed.

Drugs/Diseases

| Util A | Util B | Util C (Include) |
|---|---|---|
| Venlafaxine besylate ER | | CKD Stage 1, 2, 3, 4, and 5<br>ESRD<br>Hemodialysis |

Max Dose: 112.5 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Venlafaxine Besylate Tablets, Extended-Release, June 2022, Almatica Pharma, LLC.

**39. Venlafaxine Besylate Tablets / Hepatic Impairment** ___√___ _____ _____

Alert Message: Venlafaxine besylate extended-release should be used with caution in patients with hepatic impairment. Reduce the total daily dose of venlafaxine by 50% in patients with mild (Child-Pugh Class A) to moderate (Child-Pugh Class B) hepatic impairment. In patients with severe hepatic impairment (Child-Pugh Class C) or hepatic cirrhosis, it may be necessary to reduce the dose by 50% or more. Switch to another venlafaxine extended-release product if doses lower than 112.5 mg are needed.

Drugs/Diseases

| Util A | Util B | Util C (Include) |
|---|---|---|
| Venlafaxine besylate ER | | Hepatic Impairment |

Max Dose: 112.5 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Venlafaxine Besylate Tablets, Extended-Release, June 2022, Almatica Pharma, LLC.

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

**40. Venlafaxine Besylate Tablets / Nonadherence** ___√___ _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing venlafaxine besylate 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 |
|---|---|---|
| Venlafaxine besylate ER | | |

References:


Iuga AO, McGuire MJ. Adherence and Health Care Costs. Risk Manag Healthc Policy. 2014 Feb 20;7:35-44.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
Keene MS. Confusion and Complaints: The True Cost of Noncompliance in Antidepressant Therapy. Medscape Psychiatry & Mental Health. 2005;10(2). Available at: http://www.medscape.com/viewarticle/518273
Woldu H, Porta G, Goldstein T, et al. Pharmacokinetically and Clinician- Determined Adherence to an Antidepressant Regimen and Clinical Outcome in the TORDIA Trial. J Am Acad Child Adol Psy, 50;5:490-98. May 2011.
Chong WW, Aslani P, Chen TF. Effectiveness of Interventions to Improve Antidepressant Medication Adherence: A Systematic Review. Int J Clin Pract. 2011 Sep;65(9)954-975.


**41. Upadacitinib 30 mg / Overutilization - Atopic Dermatitis** ___√___ _____ _____

Alert Message: Rinvoq (upadacitinib) may be over-utilized. The recommended dose of upadacitinib for maintenance treatment of atopic dermatitis in adults 65 years of age and older is 15 mg once daily. No differences in effectiveness were observed between these patients and younger patients; however, there was a higher rate of serious infections and malignancies in those patients 65 years of age or older in the 30 mg dosing group in the long-term trials.

Drugs/Diseases

| Util A | Util B | Util C (Required) |
|---|---|---|
| Upadacitinib 30mg | Atopic Dermatitis | |

Age Range: ≥ 65 yoa
Max Dose: 30 mg
Day Supply: 90 days

References:


Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, Oct. 2022, AbbVie Inc.


**42. SGLT2 Inhibitors / Lithium** ___√___ _____ _____

Alert Message: Concomitant use of an SGLT2 inhibitor with lithium may decrease serum lithium concentrations. Monitor serum lithium concentration more frequently during SGLT2 inhibitor initiation and dosage changes.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Canagliflozin | Lithium | |
| Dapagliflozin | | |
| Empagliflozin | | |
| Ertugliflozin | | |

References:


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

| *Criteria Recommendations* | *Accepted* | *Approved As Amended* | *Rejected* |
|---|---|---|---|
| **43. Triumeq PD / Non-adherence**<br>Alert Message: Based on the refill history, your patient may be underutilizing Triumeq PD (abacavir/dolutegravir/lamivudine). Nonadherence to antiretroviral therapy may result in insufficient plasma levels and partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.<br><br>Drugs/Diseases<br>Util A<br>Abacavir/dolutegravir/lamivudine PD<br><br>Util B<br><br>Util C | ___√___ | _____ | _____ |

References:
Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. January 20, 2022. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf. Accessed January 25, 2022.
Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Updated December 30, 2021. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf. Accessed Jan. 5, 2022.
Panel on Treatment of Pregnant Women with HIV and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Intervention to Reduce Perinatal Transmission in the United States. Dec. 30, 2021. Available at: http://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf. Accessed Jan. 5, 2022.
Schaecher KL. The Importance of Treatment Adherence in HIV. Am J Manag Care. 2013 Sep;19(12 Suppl):231-7.

| | | | |
|---|---|---|---|
| **44. Triumeq PD / Overutilization**<br>Alert Message: Triumeq PD (abacavir/dolutegravir/lamivudine tablets for oral suspension) may be over-utilized. The manufacturer's maximum recommended dose of abacavir/dolutegravir/lamivudine tablets for oral suspension in children weighing 20 to < 25 kg is 6 tablets once daily, 14 to < 20 kg is 5 tablets once daily, and 10 to < 14 kg is 4 tablets once daily. Triumeq PD is not recommended in pediatric patients weighing 25 kg or more.<br><br>Drugs/Diseases<br>Util A<br>Abacavir/dolutegravir/lamivudine PD<br><br>Util B<br><br>Util C<br><br>Max Dose: 6 tablets per day<br>Age Range: 0 – 8 yoa | ___√___ | _____ | _____ |

References:
Triumeq & Triumeq PD Prescribing Information, Oct. 2022, ViiV Healthcare.
Clinical Pharmacology, 2022 Elsevier/Gold Standard.

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

**45. Triumeq PD / UGT1A1 & CYP3A4 Inducers / Dolutegravir (Negating)** __√_____ _____ _____

Alert Message: Concurrent use of Triumeq PD (abacavir/dolutegravir/lamivudine tablets for oral suspension) with an efavirenz-containing agent, fosamprenavir/rtv, tipranavir/rtv, carbamazepine, or rifampin may result in decreased plasma concentrations of the dolutegravir component of the antiretroviral and loss of efficacy. If co-administration is necessary for pediatric patients weighing 10 kg to < 25 kg, it is recommended that an additional weight-based dose of dolutegravir be given. Refer to the official prescribing information for the recommended dose for specific weight ranges.

Drugs/Diseases

| Util A | Util B | Util C (Negating) |
|---|---|---|
| Abacavir/dolutegravir/lamivudine PD | Carbamazepine<br>Efavirenz<br>Fosamprenavir/ritonavir<br>Tipranavir/ritonavir<br>Rifampin | Dolutegravir |

Age Range: 0 – 8 yoa

References:
Triumeq & Triumeq PD Prescribing Information, Oct. 2022, ViiV Healthcare.
Clinical Pharmacology, 2022 Elsevier/Gold Standard.

**46. Triumeq PD / Therapeutic Appropriateness** ___√_____ _____ _____

Alert Message: Triumeq PD (abacavir/dolutegravir/lamivudine oral tablets for oral suspension) is not recommended in patients weighing 25 kg or more. Triumeq PD (abacavir/dolutegravir/lamivudine) is a fixed-dose tablet, and the dosage of individual components cannot be adjusted and may lead to suboptimal dosing for patients weighing 25 kg or more.

Drugs/Diseases

| Util A | Util B | Util C |
|---|---|---|
| Abacavir/dolutegravir/lamivudine PD | | |

Age Range: > 8 yoa

References:
Triumeq & Triumeq PD Prescribing Information, Oct. 2022, ViiV Healthcare.
Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Stephanie A — (√) Approve ( ) Deny — 2/22/24
Stephanie McGee Azar, Commissioner — Date

M Rowe, MD — (√) Approve ( ) Deny — 2/15/2024
Melinda Rowe, MD, — Date
Medical Director

Gr Carmack — (X) Approve ( ) Deny — _____
Ginger Carmack, Deputy Commissioner — Date