

Alabama Medicaid DUR Board Meeting Minutes
January 21, 2026

Members Present: Dr. Jack Wanschek, Dr. Melinda Rowe, Dr. Darlene Traffanstedt, Dr. Marilyn Bulloch, Dan McConaghy, Dr. Crystal Deas, Dr. Danielle Powell, Dr. Janaki Nimmagadda, Mary Stallworth, Dr. Kristi Kelley, Dr. Craig Oliver, Dr. Luke Engeriser, Dr. Zach McLeod

Also Present: Dr. Lori Thomas, Julie Jordan, Heather Vega, Amanda Singletary, ACHN Pharmacists

Members Absent: none

Call to Order: The DUR Meeting was called to order by Dr. Bulloch at approximately 1:01 p.m. Dr. Bulloch called roll and Dr. Wanschek welcomed new Board members.

Review and Adoption of Minutes: The minutes of the October 22, 2025, meeting were presented, and Dr. Wanschek made a motion to approve the minutes. Dr. Traffanstedt 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 July 2025. She reported 13,417 manual PAs and overrides. Dr. Thomas reported 35,838 total electronic requests for the month of July 2025. Dr. Thomas reviewed the electronic PA criteria volume and pointed out PDL changes that impacted the electronic PA volume. From the Prior Authorization and Override Response Time Ratio report for July 2025, Dr. Thomas reported that approximately 74% of all manual PAs and 73% of all overrides were completed in less than two hours. Ninety percent of all manual PAs and 89% of all overrides were completed in less than four hours. Ninety-two percent of all manual PAs and 91% of all overrides were completed in less than eight hours. Dr. Thomas explained that 75% of all PAs and overrides must be completed in under eight 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 August 2025, Dr. Thomas reported 12,567 manual PA requests and 30,334 electronic PA requests. She reported that 72% of all manual PAs and 70% of all overrides were completed in less than two hours. Eighty-nine percent of all manual PAs and 89% of all overrides were completed in less than four hours. Ninety-three percent of all manual PAs and 92% of all overrides were completed in less than eight hours. For the month of September 2025, Dr. Thomas reported 13,406 manual PA requests and 29,763 electronic PA requests. Dr. Thomas reported that approximately 67% of all manual PAs and overrides were completed in less than two hours. Eighty-eight percent of all manual PA requests and 87% of all overrides were completed in less than four hours. Ninety-one percent of all manual PAs and 90% 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 April 1, 2025, through September 30, 2025. She reported 186,856 average recipients per month using pharmacy benefits, and an average paid per prescription of \$181.02.

Cost Management Analysis: Dr. Thomas reviewed the Cost Management Analysis chart highlighting the number of recipients per month over the past two years. Dr. Thomas reported an average cost per claim of \$180.08 for September 2025, and compared previous months contained in the table. From the 3rd Quarter 2025 Drug Analysis, Dr. Thomas reported 85.4% generic utilization, 7% brand single-source, 4.3% brand multi-source (those requests which required a DAW-1 override), and 3.4% OTC and "other." From the Top 25 Drugs Based on Number of Claims from 07/01/2025 - 09/30/2025, Dr. Thomas reported the top five drugs: cetirizine, amoxicillin, albuterol sulfate HFA, fluticasone propionate, and ibuprofen. Dr. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 07/01/2025 - 09/30/2025: Dupixent[®] Pen, Trikafta[®], Humira[®] Citrate-free Pen, Ozempic[®], and Invega Sustenna[®]. 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.

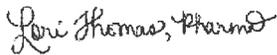
Proposed Criteria: Dr. Thomas presented a proposed set of 38 criteria to the Board and instructed Board members to mark their ballots. Of the 38 proposed criteria, results from the criteria vote returned 38 approved as amended.

Medicaid Update: Dr. Wanschek reminded the Board Members that all updated Medicaid drug lists and ALERTs were provided to them electronically and are also available online. He reviewed the January 1, 2026, PDL update.

P & T Committee Update: Dr. Wanschek began the P & T Update by informing the Board that the last P & T meeting was held on November 5, 2025, and covered the antidiabetic agents, first generation antihistamines, multiple sclerosis agents, antigout agents, estrogens, and prenatal vitamins. The next meeting is scheduled for February 4, 2026, and will cover the anticoagulants, antidepressants, and antilipemic agents.

Next Meeting Date: Dr. Bulloch informed the Board that the next DUR Meeting will be held on April 22, 2026. A motion to adjourn the meeting was made by Dr. Jack Wanschek and Dan McConaghy seconded the motion. The meeting was adjourned at 2:10 p.m.

Respectfully submitted,



Lori Thomas, PharmD.

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

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

1. Aripiprazole Tablets / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of aripiprazole tablets. Aripiprazole tablets are approved for the treatment of schizophrenia in patients 13 years of age and older, bipolar mania in patients 10 years and older, major depressive disorder in adults, irritability associated with autistic disorder in patients 6 to 17 years of age, and Tourette’s disorder in patients 6 to 18 years. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A Util B
Aripiprazole Tabs

Util C (Negate)
Schizophrenia
Manic and Mixed Episodes Bipolar I Disorder
Major Depressive Disorder
Irritability w/ Autistic Disorder
Tourette’s Disorder

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2025.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

2. Aripiprazole Asimtufii Injection / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Abilify Asimtufii (aripiprazole extended-release injectable suspension). Aripiprazole ER injectable suspension is approved for the treatment of adults with schizophrenia or bipolar I disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A Util B
Aripiprazole ER Susp

Util C (Negate)
Schizophrenia
Bipolar 1 Disorder

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

3. Aripiprazole Maintena Injection / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Abilify Maintena (aripiprazole extended-release injectable suspension). Aripiprazole extended-release injection is approved for the treatment of adults with schizophrenia or bipolar I disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|----------------------|---------------|-------------------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Aripiprazole ER Susp | | Schizophrenia Bipolar 1 Disorder |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

4. Aripiprazole Lauroxil Injection / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Aristada (aripiprazole lauroxil extended-release injectable suspension). Aripiprazole lauroxil extended-release injectable suspension is approved for the treatment of adults with schizophrenia. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|-----------------------|---------------|------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Aripiprazole Lauroxil | | Schizophrenia |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

5. Aripiprazole Film / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Opipza (aripiprazole oral film). Aripiprazole oral films are approved for the treatment of schizophrenia in patients 13 years of age and older, adjunctive treatment of major depressive disorder in adults, irritability associated with autistic disorder in patients 6 and older, and Tourette’s disorder in patients 6 and older. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A

Util B

Util C (Negate)

Aripiprazole Films

Schizophrenia
Major Depressive Disorder
Irritability w/ Autistic Disorder
Tourette’s Disorder

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

6. Aripiprazole Oral Solution / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of aripiprazole oral solution. Aripiprazole oral solution is approved for the treatment of schizophrenia in patients 13 years of age and older, acute treatment of manic and mixed episodes in bipolar 1 disorder in patients 10 years and older, irritability associated with autistic disorder in pediatric patients 6 to 17 years of age, and Tourette’s disorder in patients 6 to 18 years. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A

Util B

Util C (Negate)

Aripiprazole Oral Solution

Schizophrenia
Manic and Mixed Episodes Bipolar I Disorder
Major Depressive Disorder
Irritability w/ Autistic Disorder
Tourette’s Disorder

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Aripiprazole Oral Solution, Jan. 2025, Atlantic Biologicals Corp.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

7. Aripiprazole Mycrite Tablets / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Abilify Mycrite (aripiprazole tablets with sensor). Aripiprazole sensor tablets are approved for the treatment of adults with schizophrenia, adults with bipolar I disorder, and as adjunctive treatment for adults with major depressive disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------------------|---------------|--|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Aripiprazole Mycrite Tabs | | Schizophrenia Bipolar I Disorder Major Depressive Disorder |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

8. Asenapine Tablets / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of asenapine sublingual tablets. Asenapine sublingual tablets are approved for the treatment of schizophrenia in adults, bipolar I disorder in adults, and acute monotherapy of manic and mixed episodes in adults and pediatric patients (10 to 17 years). Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|----------------|---------------|-------------------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Asenapine Tabs | | Schizophrenia Bipolar I Disorder |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

9. Asenapine Transdermal / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of asenapine transdermal. Asenapine transdermal patches are approved for the treatment of schizophrenia in adults. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|-----------------------|---------------|------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Asenapine Transdermal | | Schizophrenia |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
 Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
 Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

10. Brexpiprazole / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Rexulti (brexpiprazole). Brexpiprazole is approved for the treatment of schizophrenia in adults and pediatric patients (13 years and older), agitation associated with dementia due to Alzheimer's disease, and adjunctive treatment of major depressive disorder in adults. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------|---------------|---|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Brexpiprazole | | Schizophrenia Dementia due to Alzheimer's Disease Major Depressive Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
 Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
 Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

11. Cariprazine / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Vraylar (cariprazine). Cariprazine is approved for the treatment of adults with schizophrenia, bipolar I disorder, or major depressive disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------|---------------|--|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Cariprazine | | Schizophrenia Bipolar I Disorder Major Depressive Disorder |

Age Range: 19 - 999

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024

12. Clozapine Tablets / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of clozapine tablets. Clozapine tablets are approved for the treatment of treatment-resistant schizophrenia and for reducing the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|----------------|---------------|----------------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Clozapine Tabs | | Schizophrenia Schizoaffective |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Clozapine Tablet, July 2025, Aurobindo Pharma Limited.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

13. Clozapine ODT / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of clozapine oral disintegrating tablets (ODT). Clozapine ODT is approved for the treatment of treatment-resistant schizophrenia and reducing the risk of recurrent suicidal behavior in schizophrenia or schizoaffective disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------|---------------|----------------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Clozapine ODT | | Schizophrenia Schizoaffective |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Clozapine Tablet, Orally Disintegrating, June 2025, Aurobindo Pharma Limited.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

14. Iloperidone / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of iloperidone. Iloperidone is approved for the treatment of adults with schizophrenia or acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------|---------------|-------------------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Iloperidone | | Schizophrenia Bipolar I Disorder |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

15. Lumateperone / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Caplyta (lumateperone). Lumateperone is approved for the treatment of adults with schizophrenia, depressive episodes associated with bipolar I or II disorder (bipolar depression), and major depressive disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|---------------|---------------|---|
| Lumateperone | | Schizophrenia Bipolar I Disorder, Depressed Bipolar II Disorder, Depressed Major Depressive Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
 Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
 Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

16. Lurasidone / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Latuda (lurasidone). Lurasidone is approved for the treatment of schizophrenia in adults and adolescents (ages 13 to 17), monotherapy for depressive episodes associated with bipolar I disorder (bipolar depression) in adults and pediatric patients (ages 10 to 17), and for adjunctive therapy in adults with major depressive episodes associated with bipolar I disorder (bipolar depression). Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|---------------|---------------|--|
| Lurasidone | | Schizophrenia Bipolar I Disorder, Depressed |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
 Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
 Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

17. Olanzapine Tabs / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of olanzapine tablets. Olanzapine tablets are approved for the treatment of schizophrenia in adults and adolescents (ages 13 to 17), for acute treatment of manic or mixed episodes associated with bipolar disorder in adults and adolescents (ages 13 to 17), as adjunct treatment of manic or mixed episodes associated with bipolar disorder in adults, for the adjunct treatment of depressive episodes associated with bipolar I disorder, bipolar depression in combination with fluoxetine in adults and children (ages 10 to 17), and for the use in combination with fluoxetine for treatment-resistant depression in adults. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Util A
Olanzapine Tabs

Util B

Util C (Negate)
Schizophrenia
Bipolar I Disorder, Manic & Mixed
Bipolar I Disorder, Depressed
Major Depressive Disorder

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

18. Olanzapine IR Injection / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of olanzapine injection. Olanzapine injection is approved for the treatment of acute agitation associated with schizophrenia and bipolar I mania in adults. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Util A
Olanzapine IR Inj

Util B

Util C (Negate)
Schizophrenia
Bipolar I Disorder Mania

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

19. Olanzapine ODT / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Zyprexa Zydys (olanzapine oral disintegrating tablets (ODT)). Olanzapine ODTs are approved for the treatment of schizophrenia in adults and adolescents (ages 13 to 17), for acute treatment of manic or mixed episodes associated with bipolar disorder in adults and adolescents (ages 13 to 17), as adjunct treatment of manic or mixed episodes associated with bipolar disorder in adults, for the adjunct treatment of depressive episodes associated with bipolar I disorder, bipolar depression in combination with fluoxetine in adults and children (ages 10 to 17), and for the use in combination with fluoxetine for treatment-resistant depression in adults. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

| | | |
|----------------|---------------|--|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Olanzapine ODT | | Schizophrenia Bipolar I Disorder, Manic & Mixed Bipolar I Disorder, Depressed Major Depressive Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

20. Olanzapine ER Injection / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Zyprexa Relprevv (olanzapine extended-release injection). Olanzapine ER injection is approved for the treatment of schizophrenia. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

| | | |
|-------------------|---------------|------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Olanzapine ER Inj | Schizophrenia | |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

21. Olanzapine/Fluoxetine / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of olanzapine/fluoxetine tablets. Olanzapine/fluoxetine tablets are approved for the treatment of treatment-resistant depression in adults and depressive episodes associated with bipolar I disorder in adults and children 10 years and older. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Util A

Olanzapine /Fluoxetine

Util B

Util C (Negate)

Bipolar I Disorder, Depressed
Treatment Resistant Depression

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

22. Olanzapine/Samidorphan Tabs / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Lybalvi (olanzapine/samidorphan). Olanzapine/samidorphan is approved for the treatment of schizophrenia and bipolar I disorder in adults. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Util A

Olanzapine/Samidorphan

Util B

Util C (Negate)

Schizophrenia
Bipolar I Disorder

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

23. Paliperidone Oral / Therapeutic Appropriateness _____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for paliperidone. Paliperidone is approved for the treatment of schizophrenia in patients 12 years and older and schizoaffective disorder in adults. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|---------------|---------------|---|
| Paliperidone | | Schizophrenia Schizoaffective Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

24. Paliperidone ER Injection / Therapeutic Appropriateness _____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Erzofri (paliperidone extended-release injection). Paliperidone extended-release injection is approved for the treatment of adults with schizophrenia or schizoaffective disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|---------------------------|---------------|---|
| Paliperidone ER Injection | | Schizophrenia Schizoaffective Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

25. Paliperidone Palmitate ER Injection / Therapeutic Appropriateness _____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Invega Sustenna (paliperidone palmitate extended-release injection). Paliperidone palmitate extended-release injection is approved for the treatment of adults with schizophrenia or schizoaffective disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------------------|---------------|---|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Paliperidone ER Injection | | Schizophrenia Schizoaffective Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

26. Paliperidone Palmitate ER Injection 3 mo / Therapeutic Appropriateness _____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Invega Trinza (paliperidone palmitate extended-release injection suspension). Paliperidone palmitate extended-release suspension injection is approved for the treatment of schizophrenia in patients after they have been adequately treated with Invega Sustenna (1-month paliperidone ER injection) for at least 4 months. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------------------|---------------|------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Paliperidone ER Injection | | Schizophrenia |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

27. Paliperidone Palmitate Gluteal IM ER Injection 6 mo / FDA Indications

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Invega Hafyera (paliperidone palmitate extended-release injection). The once-every-six-month paliperidone palmitate extended-release injection is approved for the treatment of adults with schizophrenia after the patients have been adequately treated with once-a-month paliperidone ER injectable for at least 4 months or every-three-month paliperidone ER injection for at least one three-month cycle. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------------------|---------------|------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Paliperidone ER Injection | | Schizophrenia |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
 Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
 Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

28. Pimavanserin / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Nuplazid (pimavanserin). Pimavanserin is approved for the treatment of hallucinations and delusions associated with Parkinson’s disease psychosis. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------|---------------|------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Pimavanserin | | Parkinsons Disease |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
 Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
 Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

29. Pimozide / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of pimozide. Pimozide is approved for the treatment of motor and phonic tics in patients Tourette’s disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A

Util B

Util C (Negate)

Pimozide

Tourette’s Disorder

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

30. Quetiapine / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for quetiapine. Quetiapine is approved for the treatment of schizophrenia and bipolar I disorder, manic episodes, and bipolar disorder, depressive episodes. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A

Util B

Util C (Negate)

Quetiapine

Schizophrenia

Bipolar I Disorder, Manic

Bipolar Disorder, Depressive

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

31. Quetiapine XR / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for quetiapine extended-release. Quetiapine extended-release is approved for the treatment of schizophrenia, bipolar I disorder manic or mixed episodes, bipolar disorder, depressive episodes, and major depressive disorder. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|---------------|---------------|---|
| Quetiapine | | Schizophrenia Bipolar I Disorder, Manic Bipolar Disorder, Depressive Major Depressive Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

32. Risperidone Oral / Therapeutic Appropriateness

_____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for risperidone. Risperidone is approved for the treatment of schizophrenia in patients 13 years and older, acute manic or mixed episodes associated with bipolar I disorder in patients 10 years of age and older, and irritability associated with autistic disorder in patients 5 years of age and older. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|------------------|---------------|---|
| Risperidone Oral | | Schizophrenia Bipolar I Disorder, Manic & Mixed Episodes Irritability Autistic Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

33. Risperidone LA Injection / Therapeutic Appropriateness

_____ ✓ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Risperdal Consta (risperidone long-acting injection). Risperidone long-acting injection is approved for the treatment of schizophrenia and bipolar I disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|--------------------|---------------|-------------------------------------|
| Risperidone LA Inj | | Schizophrenia Bipolar I Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

34. Risperidone ER Suspension Injection / Therapeutic Appropriateness

_____ ✓ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Rykindo (risperidone extended-release injectable suspension). Risperidone extended-release injectable suspension is approved for the treatment of adults with schizophrenia and bipolar I disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|-------------------------------|---------------|-------------------------------------|
| Risperidone ER Suspension Inj | | Schizophrenia Bipolar I Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

35. Risperidone ER Subcutaneous Injection / Therapeutic Appropriateness _____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Uzedy (risperidone extended-release subcutaneous injectable suspension). Risperidone ER subcutaneous injectable suspension is approved in adults for the treatment of schizophrenia and bipolar I disorder. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|--------------------------|---------------|-------------------------------------|
| Risperidone ER SubQ Inj. | | Schizophrenia Bipolar I Disorder |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

36. Risperidone ER Subcutaneous Injection / Therapeutic Appropriateness _____ v _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of Perseris (risperidone extended-release subcutaneous injectable suspension). Risperidone ER subcutaneous injectable suspension is approved for the treatment of schizophrenia in adults. Long-term safety and efficacy of this agent for the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
|--------------------------|---------------|------------------------|
| Risperidone ER SubQ Inj. | | Schizophrenia |

Age Range: 19 – 999 yoa

References:

- Clinical Pharmacology, 2025 Elsevier/Gold Standard.
- Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
- Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

37. Ziprasidone Oral / Therapeutic Appropriateness

_____ ✓ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of oral ziprasidone. Ziprasidone oral capsules are approved for the treatment of adults with schizophrenia, acute treatment of adults with manic or mixed episodes associated with bipolar I disorder, and as adjunct to lithium or valproate for the maintenance treatment of bipolar I disorder in adults. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|------------------|---------------|-------------------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Ziprasidone Caps | | Schizophrenia Bipolar I Disorder |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.

38. Ziprasidone Injection / Therapeutic Appropriateness

_____ ✓ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for the use of ziprasidone injection. Ziprasidone injection is approved for the treatment of acute agitation in schizophrenia in adults. Long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

| | | |
|---------------|---------------|------------------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C (Negate)</u> |
| Ziprasidone | | Schizophrenia |

Age Range: 19 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Consolidated Appropriations Act, 2024. PL No. 118-42, Sec. 203 and Sec 208. 08 March 2024.



Timothy "Bo" A. Offord, Jr.
Alabama Medicaid Commissioner

Approve

Deny

2/23/26
Date

F. Darlene Traffanstedt, MD
F. Darlene Traffanstedt, MD (Feb 19, 2026 14:35:19 CST)

F. Darlene Traffanstedt, MD
Medical Director

Approve

Deny

02/19/2026
Date