Members Present: Kelli Littlejohn Newman, Robert Moon, Marilyn Bulloch, Rachel Seaman, Paula Thompson, Denyse Thornley-Brown, Kenny Murray, P.J. Hughes

Also Present: Tiffany Minnifield, Lori Thomas, Heather Vega, Whitney Hughley

Present via Conference Call: Kristian Testerman, Samir Hadid, Amy Donaldson, Joshua Lee, Allana Alexander, Lydia Rather

Members Absent: Dan McConaghy, Donald Kern, Chris Phung, Bernie Olin

Call to Order: The DUR meeting was called to order by M. Bulloch at approximately 1:01 p.m.

Review and Adoption of Minutes: The minutes of the April 26, 2018 meeting were presented and D. Thornley-Brown made a motion to approve the minutes. K. Murray 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 Prior Authorization and Overrides Report for the month of January 2018. She reported 10,811 total manual requests and 18,437 total electronic requests. From the Prior Authorization and Override Response Time Ratio report for January 2018, L. Thomas reported that approximately 84% of all manual PAs and 86% of all overrides were completed in less than two hours. Ninety-one percent of all manual PAs and 93% of all overrides were completed in less than four hours. Ninety-four percent of all manual PAs and 95% of all overrides were completed in less than eight hours. For the month of February 2018, L. Thomas reported 11,180 manual PA requests and 20,180 electronic PA requests were received. She reported that 71% of all manual PAs and 69% of all overrides were completed in less than two hours. Eighty-nine percent of all manual PAs and 88% of all overrides were completed in less than four hours. Ninety-one percent of all manual PAs and 89% of all overrides were completed in less than eight hours. For the month of March 2018, L. Thomas reported 12,874 manual PA requests and 23,782 electronic PA requests. L. Thomas reported that approximately 68% of all manual PAs and 66% of all overrides were completed in less than two hours. Eighty-seven percent of all manual PA requests and all overrides were completed in less than four hours. Eighty-nine percent of all manual PA requests and 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 July 2017 – December 2017. She reported 3,605,286 total prescriptions, 218,277 average recipients per month using pharmacy benefits, and an average paid per prescription of $105.08.

Cost Management Analysis: L. Thomas reported an average cost per claim of $104.23 for December 2017 and emphasized that the table contained the average cost per claim over the past two years. From the 4th Quarter 2016 Drug Analysis, L. Thomas reported 79.3% generic utilization, 8.9% brand single-source, 8% brand multi-source (those requests which required a DAW override), and 3.8% OTC and “other”. From the Top 25 Drugs Based on Number of Claims from 10/01/2017 – 12/31/2017, L. Thomas reported the top five drugs: amoxicillin, cetirizine, ProAir® HFA, hydrocodone-acetaminophen, and azithromycin. L. Thomas then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 10/01/2017 – 12/31/2017: Vyvanse®, Focalin XR®, Invega® Sustenna®, Concerta®, and ProAir® HFA. She reminded the Board that Vyvanse® and Focalin XR® are preferred agents. 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, Amphetamines, Respiratory and CNS Stimulants, Miscellaneous Anticonvulsants, and Insulins.
Opioid Overview: K. Newman reviewed the status of the Agency’s work of upcoming opioid edits. The Agency is working toward a phase-in approach beginning later this year. Discussion from the group segued into the opioid refill tolerance proposal.

Review of Alabama Medicaid Refill Tolerance Policy: K. Newman began the review of Alabama Medicaid’s Administrative Code pertaining to the Refill Tolerance Policy. She introduced a proposed change to the timely refill policy surrounding controlled substances. The recommendation would allow pharmacies to dispense refill medication to recipients once the patient has used at least 85% of the original supply of the controlled substances. P. Thompson recommended that the policy be modified to pertain to only full and partial agonist opioids. The Board approved the changes for the refill tolerance threshold as amended. R. Seaman seconded the motion and the motion was approved unanimously.

RDUR Intervention Report: L. Thomas presented the RDUR Activity Report for January 2018. She reported 533 profiles reviewed and 490 letters sent with 48 responses received as of the date of the report. She reported 24 of 38 physicians indicated that they found the RDUR letters “useful” or “extremely useful”. The criteria for the cycle of intervention letters included Therapeutic Dupslication of atypical antipsychotics and Appropriate Use (concurrent use of buprenorphine and pure opiate agonists). L. Thomas then presented the RDUR Activity Report for April 2018. She reported 551 profiles reviewed and 594 letters sent with 66 responses received as of the date of the report. She reported 32 of 67 physicians indicated that they found the RDUR letters “useful” or “extremely useful”. The criteria for the cycle of intervention letters included Overuse Precaution (appropriate use of immediate-release opioids) and Appropriate Use (concurrent use of buprenorphine and pure opiate agonists).

Proposed Criteria: L. Thomas presented the proposed set of 53 criteria to the Board. T. Minnifield instructed the Board members to mark their ballots. Of the 53 criteria, results from the criteria vote returned 50 approved and 3 approved as amended.

Medicaid Update: T. Minnifield reminded the Board members that all updated Medicaid drug lists provided are also available online and that the next DUR Meeting would be October 24th. T. Minnifield reminded the Board that every July the Board would vote on a Vice Chair and asked the members to mark their ballots and pass them to the front. Results of the vote elected Paula Thompson as Vice Chair. The current Vice Chair, Dr. Denyse Thornley-Brown will begin her term as Chairman of the board beginning with the October 2018 meeting.

P & T Committee Update: K. Newman began the P & T Update by informing the Board that the last meeting was held on May 9, 2018, and covered Skeletal Muscle Relaxants; Opiate Agonists; Opiate Partial Agonists; Antiemetics; Proton Pump Inhibitors; and EENT agents. The next P & T meeting is scheduled for August 8, 2018, at 9 a.m. and will cover the Alzheimer’s Agents; Antidepressants; Cerebral Stimulants; Anxiolytics, Sedatives, and Hypnotics; Genitourinary Smooth Muscle Relaxants; and Disease-Modifying Antirheumatic Agents.

Next Meeting Date: A motion to adjourn the meeting was made by K. Murray. D. Thornley-Brown seconded the motion and the meeting was adjourned at 2:48 p.m.

Respectfully submitted,

[Signature]

Lori Thomas, PharmD.
# ALABAMA MEDICAID
**RETROSPECTIVE DRUG UTILIZATION REVIEW**
**CRITERIA RECOMMENDATIONS**

<table>
<thead>
<tr>
<th>Criteria Recommendations</th>
<th>Accepted</th>
<th>Approved</th>
<th>Rejected</th>
<th>As Amended</th>
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### 1. Dapagliflozin-Saxagliptin / Overutilization

Alert Message: Qtern (dapagliflozin-saxagliptin) may be over-utilized. The manufacturer's recommended maximum daily dose of dapagliflozin/saxagliptin is 10 mg dapagliflozin/5 mg saxagliptin once daily.

Conflict Code: ER - Overutilization

<table>
<thead>
<tr>
<th>Drugs/Diseases</th>
<th>Util A</th>
<th>Util B</th>
<th>Util C (Negate)</th>
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<tr>
<td>Dapagliflozin/Saxagliptin</td>
<td>CKD Stage 3, 4 &amp; 5</td>
<td>ESRD</td>
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</tbody>
</table>

Max Dose: 10 mg/5 mg per day

References:

### 2. Dapagliflozin-Saxagliptin / CKD Stage 3, 4 & 5 & ESRD

Alert Message: Qtern (dapagliflozin/saxagliptin) use is contraindicated in patients with moderate to severe renal impairment, end-stage renal disease or on dialysis. The dapagliflozin component of the combo product causes intravascular volume contraction and can cause renal impairment.

Conflict Code: TA - Therapeutic Appropriateness

<table>
<thead>
<tr>
<th>Drugs/Diseases</th>
<th>Util A</th>
<th>Util B</th>
<th>Util C (Include)</th>
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<td>Dapagliflozin/Saxagliptin</td>
<td>CKD Stage 3, 4 &amp; 5</td>
<td>ESRD</td>
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</tr>
</tbody>
</table>

References:

### 3. Dapagliflozin-Saxagliptin / Therapeutic Appropriateness

Alert Message: Assessment of renal function is recommended prior to initiation of Qtern (dapagliflozin/saxagliptin) therapy and periodically thereafter. Discontinue dapagliflozin/saxagliptin if estimated glomerular filtration rate (eGFR) falls persistently below 60 mL/min/1.73 m2. Do not initiate dapagliflozin/saxagliptin in patients with an eGFR below 60 mL/min/1.73 m2.

Conflict Code: TA - Therapeutic Appropriateness

<table>
<thead>
<tr>
<th>Drugs/Diseases</th>
<th>Util A</th>
<th>Util B</th>
<th>Util C</th>
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<tbody>
<tr>
<td>Dapagliflozin/Saxagliptin</td>
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</table>

References:
4. Dapagliflozin-Saxagliptin / Strong CYP3A4/5 Inhibitors

Alert Message: Do not co-administer Qtern (dapagliflozin/saxagliptin) with strong CYP3A4/5 inhibitors (e.g., ketoconazole, atazanavir, nefazodone, ritonavir, and clarithromycin). The saxagliptin component of the combo product is a CYP3A4/5 substrate and use with a strong CYP3A4/5 inhibitor is expected to significantly increase saxagliptin plasma concentrations.

Conflict Code: DD – Drug/Drug Interaction

<table>
<thead>
<tr>
<th>Drugs/Diseases</th>
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<th>Util B</th>
<th>Util C</th>
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<td>Nelfinavir</td>
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<td>Atazanavir</td>
<td>Telithromycin</td>
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<td></td>
<td>Clarithromycin</td>
<td>Nefazodone</td>
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<td>Saquinavir</td>
<td>Cobicistat</td>
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<td></td>
<td>Ritonavir</td>
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</table>

References:
Qtern Prescribing Information, February 2017, AstraZeneca.

5. Dapagliflozin-Saxagliptin / Insulin & Insulin Secretagogues

Alert Message: The concurrent use of Qtern (dapagliflozin/saxagliptin) with insulin or an insulin secretagogue 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 dapagliflozin/saxagliptin.

Conflict Code: DD – Drug/Drug Interaction

<table>
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<th>Util C</th>
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<td>Chlorpropamide</td>
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<td>Tolazamide</td>
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<td>Glyburide</td>
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<td>Glipizide</td>
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<td>Glimepiride</td>
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</tbody>
</table>

References:
Qtern Prescribing Information, February 2017, AstraZeneca.
Criteria Recommendations

6. **Dapagliflozin-Saxagliptin / Bladder Cancer**
   Alert Message: In clinical trials an increased occurrence of bladder cancer was observed in subjects receiving dapagliflozin (0.17%) as compared to placebo (0.03%). Qtern (dapagliflozin/saxagliptin) should not be used in patients with active bladder cancer and used with caution in patients with a prior history of bladder cancer.

   Conflict Code: TA – Therapeutic Appropriateness
   Drugs/Diseases
   Util A Util B Util C (Include)
   Dapagliflozin/Saxagliptin Neoplasm of Bladder History of Malignant Neoplasm of Bladder

   References:
   Qtern Prescribing Information, February 2017, AstraZeneca.

7. **Dapagliflozin-Saxagliptin / Hypotension (Loop Diuretics)**
   Alert Message: The dapagliflozin component of Qtern (dapagliflozin/saxagliptin) can cause osmotic diuresis which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients, or patients on loop diuretics. Before initiating a dapagliflozin-containing agent in patients with one or more of these characteristics, volume status should be assessed and corrected. Patients should be monitored for signs and symptoms during therapy.

   Conflict Code: DD – Drug/Drug Interaction
   Drugs/Diseases
   Util A Util B Util C
   Dapagliflozin/Saxagliptin Furosemide Torsemide Ethacrycine Bumetanide

   References:
   Qtern Prescribing Information, February 2017, AstraZeneca.

8. **Dapagliflozin-Saxagliptin / Therapeutic Appropriateness (Pediatric)**
   Alert Message: Safety and effectiveness of Qtern (dapagliflozin/saxagliptin) in patients under 18 years of age have not been established.

   Conflict Code: TA – Therapeutic Appropriateness
   Drugs/Diseases
   Util A Util B Util C
   Dapagliflozin/Saxagliptin

   Age Range: 0 - 17 yoa

   References:
   Qtern Prescribing Information, February 2017, AstraZeneca.
Criteria Recommendations

9. Dapagliflozin-Saxagliptin / Therapeutic Appropriateness

Alert Message: The use of Qttern (dapagliflozin/saxagliptin) can cause an increase in LDL-C levels. Patients treated with dapagliflozin/saxagliptin demonstrated a mean percent increase from baseline LDL-cholesterol ranging from 2.1% to 6.9%. Patients receiving dapagliflozin/saxagliptin should have their LDL-C monitored and treated per standard of care.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

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<thead>
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<th>Util B</th>
<th>Util C (Include)</th>
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<tbody>
<tr>
<td>Dapagliflozin/Saxagliptin</td>
<td>Hypercholesterolemia</td>
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</table>

References:
Qttern Prescribing Information, February 2017, AstraZeneca.

10. Dapagliflozin-Saxagliptin / Nonadherence

Alert Message: Based on refill history, your patient may be under-utilizing Qttern (dapagliflozin/saxagliptin). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence

Drugs/Diseases

<table>
<thead>
<tr>
<th>Util A</th>
<th>Util B</th>
<th>Util C</th>
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</thead>
<tbody>
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<td></td>
</tr>
</tbody>
</table>

References:
Qttern Prescribing Information, February 2017, AstraZeneca.
11. Dapagliflozin-Saxagliptin / Pregnancy / Pregnancy Negating

Alert Message: Based on animal data showing renal effects from dapagliflozin, Qtern (dapagliflozin/saxagliptin) is not recommended during the second and third trimesters of pregnancy. The limited available data with dapagliflozin and saxagliptin in pregnant women are not sufficient to determine a drug-associated risk for major birth defects or miscarriage. During pregnancy, consider appropriate alternative therapies.

Conflict Code: MC – Drug (Actual) Disease Precaution

<table>
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<tr>
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<th>Util C (Negating)</th>
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<tbody>
<tr>
<td>Dapagliflozin/Saxagliptin</td>
<td>Pregnancy</td>
<td>Delivery</td>
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<td></td>
<td>Abortion</td>
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<td></td>
<td></td>
<td>Miscarriage</td>
</tr>
</tbody>
</table>

References:
Qtern Prescribing Information, February 2017, AstraZeneca.

12. Deutetrabenazine / Depression & Suicidality

Alert Message: Austedo (deutetrabenazine) is contraindicated in patients who are actively suicidal or who have depression which is untreated or undertreated.

Conflict Code: MC – Drug (Actual) Disease Warning

<table>
<thead>
<tr>
<th>Util A</th>
<th>Util B</th>
<th>Util C</th>
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<tbody>
<tr>
<td>Deutetrabenazine</td>
<td>Depression – in partial or unspecified remission</td>
<td>Suicidal Ideation</td>
</tr>
</tbody>
</table>

References:
Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.
13. **Deutetrabenazine / Depression**

Alert Message: Caution should be exercised when prescribing Austedo (deutetrabenazine) to patients with a history of depression or prior suicide attempts or ideation. Patients with Huntington's disease are at increased risk for depression, suicidal ideation, or behavior. Deutetrabenazine use is associated with risk of or worsening of depression and suicidality.

**Conflict Code:** MC – Drug (Actual) Disease Warning

**Drugs/Diseases**

<table>
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<tr>
<th>Util A</th>
<th>Util B</th>
<th>Util C (Include)</th>
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<tbody>
<tr>
<td>Deutetrabenazine</td>
<td></td>
<td>Depression In Remission</td>
</tr>
</tbody>
</table>

**References:**
- Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

14. **Deutetrabenazine / Hepatic Impairment**

Alert Message: Austedo (deutetrabenazine) use is contraindicated in patients with impaired hepatic function due to the potential for increased deutetrabenazine exposure and greater risk for serious adverse reactions. The effect of hepatic impairment on the pharmacokinetics of deutetrabenazine has not been studied; however in a clinical study conducted with tetrabenazine, a closely related VMAT2 inhibitor, there was a large increase in exposure to tetrabenazine and its active metabolites in patients with hepatic impairment.

**Conflict Code:** MC – Drug (Actual) Disease Warning

**Drugs/Diseases**

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<tr>
<th>Util A</th>
<th>Util B</th>
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<tbody>
<tr>
<td>Deutetrabenazine</td>
<td></td>
<td>Hepatic Impairment</td>
</tr>
</tbody>
</table>

**References:**
- Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.
15. Deutetrapenazine / MAOIs
Alert Message: Austedo (deutetrapenazine) is contraindicated in patients taking MAOIs. Deutetrapenazine should not be used in combination with or within a minimum of 14 days of discontinuing therapy with an MAOI. Concurrent use may result in hypertensive crisis due to depletion of monoamines (dopamine, serotonin, norepinephrine, and histamine) from nerve terminals.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Deutetrapenazine Isocarboxazid
Phenelzine Tranlycypromine
Linezolid Selegiline
Rasagiline

References:
AUSTEDO Prescribing Information, April 2017, Teva Pharmaceuticals.

16. Deutetrapenazine / Reserpine
Alert Message: Concurrent use of Austedo (deutetrapenazine) with reserpine is contraindicated due to the potential for significant depletion of serotonin and norepinephrine in the CNS. At least 20 days should elapse after stopping reserpine before starting deutetrapenazine.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Deutetrapenazine Reserpine

References:
AUSTEDO Prescribing Information, April 2017, Teva Pharmaceuticals.

17. Deutetrapenazine / Tetrabenazine
Alert Message: Concurrent use of Austedo (deutetrapenazine) with tetrabenazine is contraindicated. Deutetrapenazine therapy may be initiated the day following discontinuation of tetrabenazine. Both deutetrapenazine and tetrabenazine are VMAT2 inhibitors and concomitant use may cause synergistic or additive toxicity.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Deutetrapenazine Tetrabenazine

References:
AUSTEDO Prescribing Information, April 2017, Teva Pharmaceuticals.
18. Deutetrabenazine / Strong CYP2D6 Inhibitor
Alert Message: The concurrent use of Austedo (deutetrabenazine) with a strong CYP2D6 inhibitor (e.g., fluoxetine, paroxetine, and quinidine) may markedly increase the exposure to the active metabolites of deutetrabenazine (approximately 3-fold). The total dose of deutetrabenazine should not exceed 36 mg per day in these patients. The maximum single dose should not exceed 18 mg.

Conflict Code: HD – High Dose
Drugs/Diseases
Util A Util B Util C (Include)
Deutetrabenazine Paroxetine
Fluoxetine
Quinidine
Bupropion

Max Dose: 36 mg/day

References:
Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

19. Deutetrabenazine / CNS Depressants
Alert Message: The concurrent use of Austedo (deutetrabenazine) with CNS depressants including alcohol may have additive effects and worsen sedation and somnolence.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Deutetrabenazine Sedatives/Hypnotics Benzodiazepines Narcotics

References:
Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.

20. Deutetrabenazine / Dopamine Antagonists
Alert Message: The concurrent use of Austedo (deutetrabenazine), a dopamine depleting agent, with dopamine antagonists may result in increased risk for parkinsonism, neuroleptic malignant syndrome (NMS), and akathisia.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Deutetrabenazine Antipsychotics Metoclopramide Amoxapine

References:
Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.
21. Deutetrabenazine / QTc Prolongation, Arrhythmias, Bradycardia

Hypokalemia & Hypomagnesemia

Alert Message: Austedo (deutetrabenazine) use should be avoided in patients with congenital long QT syndrome, cardiac arrhythmias, or history of hypokalemia or hypomagnesemia. At 24 mg, deutetrabenazine has been shown to cause an approximate 4.5 msec mean increase in the QTc.

Conflict Code: MC – Drug (Actual) Disease Warning

Drugs/Diseases

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<tr>
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</table>

References:
Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.
22. Deutetrabenazine / Medications Causing QT Prolongation

Alert Message: The concurrent use of Austedo (deutetrabenazine) with medications that are known to prolong QTc should be avoided. At 24 mg, deutetrabenazine has been shown to cause an approximate 4.5 msec mean increase in the QTc.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<table>
<thead>
<tr>
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<th>Util B</th>
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<td>Diphenhydramine</td>
<td>Iloperidone</td>
<td>Paroxetine</td>
</tr>
</tbody>
</table>

References:
Austedo Prescribing Information, April 2017, Teva Pharmaceuticals.
23. Deutetrabenazine / Overutilization
Alert Message: The manufacturer's recommended maximum total daily dose of Austedo (deutetrabenazine) is 48 mg (24 mg twice daily). The maximum daily dose in patients who are poor CYP2D6 metabolizers is 36 mg (18 mg twice daily). Administer total daily dosages of 12 mg or above in two divided doses.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
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<td>Quinidine</td>
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<td></td>
<td>Bupropion</td>
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</table>

Max Dose: 48 mg/day

References:

24. Valbenazine / Overutilization
Alert Message: Ingrezza (valbenazine) may be over-utilized. The manufacturer’s recommended maximum daily dose of valbenazine is 80 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases
<table>
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Max Dose: 80 mg/day

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.
25. Valbenazine / Overutilization – Hepatic Impairment

Alert Message: Ingrezza (valbenazine) may be over-utilized. The manufacturer’s recommended maximum daily dose of valbenazine in patients with moderate to severe hepatic impairment (Child Pugh score 7 to 15) is 40 mg once daily.

Conflict Code: ER – Overutilization
Drugs/Diseases
Util A Util B Util C (Include)
Valbenazine Hepatic Impairment

Max Dose: 40 mg/day

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

26. Valbenazine / Severe Renal Impairment

Alert Message: Ingrezza (valbenazine) use is not recommended in patients with severe renal impairment (CrCl < 30 mL/min). Dosage adjustment is not necessary for patients with mild to moderate renal impairment (CrCl 30 to 90 mL/min).

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C (Include)
Valbenazine CKD Stage 4, 5, & ESRD

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

27. Valbenazine / CYP3A4 Inducers

Alert Message: Concurrent use of Ingrezza (valbenazine) with strong CYP3A4 inducers is not recommended. Valbenazine is a CYP3A4 substrate and co-administration with a strong CYP3A4 inducer may result in decreased exposure to valbenazine and its active metabolite reducing efficacy.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Valbenazine Carbamazepine Rifampin
Phenytoin Rifabutin
Phenobarbital Rifaxentine
Primidone Enzalutamide

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.
28. Valbenazine / MAO Inhibitors

Alert Message: Concurrent use of Ingrezza (valbenazine), a VMAT2 inhibitor, with a MAO inhibitor should be avoided. Co-administration of these agents may result in increased concentrations of monoamine neurotransmitters in synapses, potentially leading to increased risk of adverse reactions such as serotonin syndrome or attenuated treatment effect of valbenazine.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A Util B Util C
Valbenazine Isocarboxazid Phenelzine
Tranylcypromine Selegiline
Linezolid Rasagiline

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

29. Valbenazine / Strong CYP3A4 Inhibitors

Alert Message: Concurrent use of Ingrezza (valbenazine), a CYP3A4 substrate, with a strong CYP3A4 inhibitor may result in increased exposure to valbenazine and its active metabolite. Concomitant use may put the patient at risk for valbenazine exposure-related adverse reactions. The manufacturer recommends reducing the dose of valbenazine to 40 mg once daily when valbenazine is co-administered with a strong CYP3A4 inhibitor.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A Util B Util C (Include)
Valbenazine Nefazodone Saquinavir
Clarithromycin Ritonavir
Telithromycin Indinavir
Ketoconazole Nelfinavir
Itraconazole Cobicistat
Voriconazole Posaconazole

Max Dose: 40 mg/day

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.
30. Valbenazine / Strong CYP2D6 Inhibitors

Alert Message: Concurrent use of Ingrezza (valbenazine), a CYP2D6 substrate, with a strong CYP2D6 inhibitor may result in increased exposure to valbenazine and its active metabolite. Concomitant use may put the patient at risk for valbenazine exposure-related adverse reactions. Consider reducing the valbenazine dose based on tolerability when valbenazine is co-administered with a strong CYP2D6 inhibitor.

Conflict Code: DD – Drug/Drug Interaction

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<th>Util C</th>
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<td>Paroxetine</td>
<td>Fluoxetine</td>
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</table>

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

31. Valbenazine / Digoxin

Alert Message: Concurrent use of Ingrezza (valbenazine) with digoxin, a P-gp substrate, may result in increased digoxin levels due to valbenazine inhibition of digoxin P-gp mediated transport. Digoxin concentrations should be monitored when co-administering these agents. Dosage adjustment of digoxin may be necessary.

Conflict Code: DD – Drug/Drug Interaction

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References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

32. Valbenazine / QT Prolongation, Arrhythmias, Bradycardia

Alert Message: Ingrezza (valbenazine) use should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval.

Conflict Code: TA – Therapeutic Appropriateness

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<th>Drugs/Diseases</th>
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<td>Arrhythmias</td>
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</table>

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.
33. **Valbenazine / Medications Causing QT Prolongation**

Alert Message: The concurrent use of Ingrezza (valbenazine) with medications that are known to prolong QTc should be avoided. Valbenazine may cause an increase in the QT interval and use with other agents that also prolong the interval may have an additive effect.

**Conflict Code:** DD – Drug/Drug Interaction

**Drugs/Diseases**

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<td>Iloperidone</td>
<td>Paroxetine</td>
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</table>

**References:**


Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.
34. Valbenazine / Pregnancy / Pregnancy Negating

Alert Message: The limited available data on Ingrezza (valbenazine) use in pregnant women is insufficient to inform a drug-associated risk. In animal studies no malformations were observed when valbenazine was administered to rats and rabbits during the period of organogenesis at doses up to 24 times the maximum recommended human dose. However, administration of valbenazine to pregnant rats during organogenesis through lactation produced an increase in the number of stillborn pups and postnatal pup mortalities. Advise pregnant females of potential risk to fetus.

Conflict Code: MC – Drug (Actual) Disease Warning

Drugs/Diseases

Util A      Util B      Util C (Negating)

Valbenazine  Pregnancy  Delivery
             Miscarriage
             Abortion

Gender: F
Age Range: 11 – 55 yoa

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.

35. Valbenazine / Lactation & Disorders of Lactation

Alert Message: There is no information regarding the presence of Ingrezza (valbenazine) or its active metabolites in human milk. Valbenazine and its metabolites have been detected in rat milk. Based on animal findings of increased perinatal mortality in exposed fetuses and pups, advise a woman to not breastfeed during treatment with valbenazine and for 5 days after the final dose.

Conflict Code: MC – Drug (Actual) Disease Warning

Drugs/Diseases

Util A      Util B      Util C

Valbenazine  Lactation  Disorder of Lactation

Gender: Female
Age Range: 11 – 55 yoa

References:
Ingrezza Prescribing Information, April 2017, Neurocrine Biosciences, Inc.
36. Safinamide / Overutilization
Alert Message: Xadago (safinamide) may be over-utilized. The manufacturer's recommended maximum dose of safinamide is 100 mg once daily. Daily dosages of safinamide above 100 mg have not been shown to provide additional benefit, and higher dosages increase the risk for adverse reactions. Selectivity for MAO-B inhibition decreased in a dose-related manner above the highest recommended daily dosage.

daily dosage. Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C (Negate)
Safinamide Hepatic Impairment

Max Dose: 100 mg/day

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.

37. Safinamide / Hepatic Impairment
Alert Message: The recommended maximum daily dose of Xadago (safinamide) in patients with moderate hepatic impairment (Child-Pugh B score 7-9) is 50 mg once daily. Safinamide use is contraindicated in patients with severe hepatic impairment (Child-Pugh C score 10-15). As a patient taking 50 mg safinamide progresses from moderate to severe hepatic impairment, discontinue safinamide.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C (Include)
Safinamide Hepatic Impairment

Max Dose: 50 mg/day

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.
38. Safinamide / Severe Hepatic Impairment
Alert Message: Xadago (safinamide) use is contraindicated in patients with severe hepatic impairment (Child-Pugh C score 10-15). In clinical studies subjects with moderate hepatic impairment (Child-Pugh B) receiving safinamide had an approximate 80% increase in safinamide exposure.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C [Include]
Safinamide Severe Hepatic Impairment

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.

39. Safinamide / Levodopa/Carbidopa
Alert Message: A review of the patient’s drug history does not show a concurrent prescription for levodopa/carbidopa. Xadago (safinamide) is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson’s disease (PD) experiencing “off” episodes. Safinamide has not been shown to be effective as monotherapy for the treatment of PD.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C [Negate]
Safinamide Levodopa/Carbidopa

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.

40. Safinamide / MAO Inhibitors
Alert Message: Xadago (safinamide) is contraindicated for use with other drugs in the MAO inhibitor class or other drugs that are potent inhibitors of monoamine oxidase. Co-administration increases the risk of nonselective MAO inhibition, which may lead to hypertensive crisis. At least 14 days should elapse between discontinuation of safinamide and initiation of treatment of other MAOIs.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Safinamide Isocarboxazid Phenelzine Tranlylcypromine Linezolid Rasagiline

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.
Criteria Recommendations

41. Safinamide / Opioids

Alert Message: Concurrent use of Xadago (safinamide), a MAO-B inhibitor, with opioid drugs is contraindicated. Serious, sometimes fatal reactions have been precipitated with concomitant use of MAOIs and opioids. At least 14 days should elapse between discontinuation of safinamide and initiation of treatment with an opioid.

Conflict Code: DD – Drug/Drug Interaction

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</table>

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.

42. Safinamide / Dextromethorphan

Alert Message: The concurrent use of Xadago (safinamide), a MAO-B inhibitor, with a dextromethorphan-containing agent is contraindicated. The co-administration of dextromethorphan and MAOIs has been shown to cause episodes of psychosis or bizarre behavior.

Conflict Code: DD – Drug/Drug Interaction

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<td>Dextromethorphan</td>
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References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.
43. Safinamide / Serotonergic Agents
Alert Message: The concurrent use of Xadago (safinamide), a MAO-B inhibitor, with a serotonergic drug is contraindicated. The co-administration of MAOIs and a serotonergic agent may result in potentially life-threatening serotonin syndrome. At least 14 days should elapse between discontinuation of safinamide and initiation of treatment with these drugs.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Safinamide SNRIs TCAs
Tetracyclic Antidepressants Trazodone
Cyclobenzaprine

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.

44. Safinamide / Sympathomimetic Agents
Alert Message: The concurrent use of Xadago (safinamide), a MAO-B inhibitor, with a sympathomimetic agent is contraindicated. Hypertensive crisis has been reported in patients taking the recommended doses of selective MAO-B inhibitors and sympathomimetic medications.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Safinamide Methylphenidate
Dexmethylphenidate Amphetamine
Dextroamphetamine Methamphetamine
Lisdexamfetamine

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.
45. Safinamide / SSRIS
Alert Message: Caution should be exercised when Xadago (safinamide), a MAO-B inhibitor, is co-administered with selective serotonin re-uptake inhibitors (SSRIs). In clinical trials, serotonin syndrome was reported in a patient treated with safinamide and an SSRI. In a patient treated with concomitant safinamide and an SSRI, use the lowest effective dose of the SSRI and monitor the patient for symptoms of serotonin syndrome.

Conflict Code: DD – Drug/Drug Interaction

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</table>

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.

46. Safinamide / BCRP Substrates
Alert Message: Concurrent use of Xadago (safinamide) with a drug that is a BCRP substrate may result in increased plasma concentrations of the BCRP substrate. Safinamide and its major metabolite inhibit BCRP transport. If co-administration with safinamide and the BCRP substrate is warranted monitor the patient for increased pharmacologic or adverse effect of the BCRP substrate.

Conflict Code: DD – Drug/Drug Interaction

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</table>

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.
47. Safinamide / Dopamine Antagonists
Alert Message: Concomitant use of Xadago (safinamide) with a dopamine antagonist may decrease the effectiveness of safinamide and exacerbate the symptoms of Parkinson's disease.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Safinamide Antipsychotics Metoclopramide

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.

48. Safinamide / Nonadherence
Alert Message: Based on refill history, your patient may be under-utilizing Xadago (safinamide). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Conflict Code: LR – Nonadherence
Drugs/Diseases
Util A Util B Util C
Safinamide

References:
Xadago Prescribing Information, June 2017, US WorldMeds LLC.

49. Voriconazole / Ergot Alkaloids
Alert Message: Concurrent use of Vfend (voriconazole) with ergot alkaloids is contraindicated due to the risk of ergotism. Voriconazole is a strong CYP3A4 inhibitor and co-administration with an ergot alkaloid which is a CYP3A4 substrate can result in elevated substrate concentrations.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Voriconazole Ergotamine Dihydroergotamine Methylergonovine

References:
50. Voriconazole / Vinca Alkaloids

Alert Message: Concurrent use of Vfend (voriconazole) with vinca alkaloids should be avoided due to the risk if increased vinca alkaloid plasma concentrations which may lead to vinca alkaloid-related neurotoxicity. Voriconazole is a strong CYP3A4 inhibitor and co-administration with a vinca alkaloid which is a CYP3A4 substrate can result in elevated substrate concentrations.

Conflict Code: DD – Drug/Drug Interaction

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References:

51. Voriconazole / Atazanavir / Ritonavir

Alert Message: The use of Vfend (voriconazole) in patients receiving atazanavir/rtv is not recommended unless an assessment of the benefit/risk to the patient justified the use of voriconazole. If concomitant therapy cannot be avoided patients should be carefully monitored for voriconazole associated adverse reactions and loss of either voriconazole or atazanavir efficacy. Co-administration of voriconazole with atazanavir (without ritonavir) may affect atazanavir concentrations; however, no data are available.

Conflict Code: DD – Drug/Drug Interaction

<table>
<thead>
<tr>
<th>Drugs/Diseases</th>
<th>Util A</th>
<th>Util B</th>
<th>Util C (Include)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voriconazole</td>
<td></td>
<td>Atazanavir</td>
<td>Ritonavir</td>
</tr>
</tbody>
</table>

References:
52. Armonair Respiclick / Nonadherence
Alert Message: Based on refill history, your patient may be under-utilizing Armonair Respiclick (fluticasone). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Conflict Code: LR - Nonadherence
Drugs/Diseases
Util A Util B Util C
Fluticasone Inhalation Powder

References:

53. Rivaroxaban / SSRIs & SNRIs
Alert Message: Concomitant use of Xarelto (rivaroxaban) with SSRIs or SNRIs may enhance the anticoagulant effect of rivaroxaban and increases the risk of bleeding. SSRIs and SNRIs can inhibit serotonin uptake by platelets causing platelet dysfunction and risk of bleeding. Promptly evaluate any signs or symptoms of blood loss if the patient is treated concurrently with these agents.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A Util B Util C
Rivaroxaban
Fluoxetine
Venlafaxine
Fluvoxamine
Desvenlafaxine
Paroxetine
Milnacipran
Citalopram
Levomilnacipran
Escitalopram
Duloxetine
Sertraline
Vortioxetine

References:
Xarelto Prescribing Information, Aug. 2016, Janssen Pharmaceuticals.
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July 25, 2018
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Stephanie McGee Azar, Commissioner

☑ Approve ☐ Deny 8-27-18

Date

Robert Moon, M.D., Deputy Commissioner and Medical Director

☐ Approve ☐ Deny 8/23/18

Date

Kathy Hall, Deputy Commissioner

☑ Approve ☐ Deny 8/23/18

Date