

Alabama Medicaid DUR Board Meeting Minutes
July 22, 2015

Members Present: Kelli Littlejohn, Robert Moon, Paula Thompson, Bernie Olin, Frank Pettyjohn, Dan McConaghy, Donald Kern, Richard Glaze, Chris Phung, Marilyn Bulloch

Also Present: Tiffany Minnifield, Clemice Hurst, Heather Vega, Lori Thomas, Kristin Marvin, Katherine Ronan, James Sloan, Suzanne Stanger

Present via Conference Call: Kristian Testerman, Amy Donaldson, Tammy Dubac, Angela Lowe

Members Absent: Denyse Thornley-Brown, P.J. Hughes, Sandra Parker, Christopher Randolph

Call to Order: The DUR meeting was called to order by P. Thompson at approximately 1:02p.m.

Review and Adoption of Minutes: The minutes of the April 22, 2015 meeting were presented and P. Thompson made a motion to update a sentence in the Cost Management Analysis section. F. Pettyjohn 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 January 2015. She reported 9,064 total manual requests. She then reported 19,174 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for January 2015, L. Thomas reported that approximately 46% of all manual PAs and 45% of all overrides were completed in less than two hours. Eighty-seven percent of all manual PAs and 88% of all overrides were completed in less than four hours. Ninety-eight percent of all manual PAs and 99% of all overrides were completed in less than eight hours. For the month of February 2015, L. Thomas reported 7,928 manual PA requests and 17,648 electronic PA requests. She reported that 50% of manual PAs and 48% of overrides were completed in less than two hours and 87-88% of all manual PAs and overrides were completed in less than four hours. Ninety-six percent of all manual PAs and overrides were responded to in less than eight hours. For the month of March 2015, L. Thomas reported 9,336 manual PA requests and 19,270 electronic PA requests. L. Thomas reported that approximately 44% of all manual PAs and 41% of all overrides were completed in less than two hours. Eighty-two percent of all requests were completed in less than four hours and approximately 94% of all requests were completed in less than eight hours.

Program Summary Review: L. Thomas briefly reviewed the Alabama Medicaid Program Summary. She reported 3,805,552 total prescriptions, 235,819 average recipients per month using pharmacy benefits and an average paid per prescription of \$87.40 for the months of October 2014 through March 2015.

Cost Management Analysis: L. Thomas reported an average cost per claim of \$91.81 for March 2015. L. Thomas reminded the Board members that the Maintenance Supply was phased in on October 1st and became mandatory on January 1, 2014. This includes 84-, 90-, and 91-day supplies. L. Thomas reported that an average cost per claim for a maintenance supply prescription was approximately \$40.00. From the 1st Quarter 2015 Drug Analysis, L. Thomas reported 79.5% generic utilization, 10.6% brand single-source, 6.4% brand multi-source (those requests which required a DAW override), and 3.5% OTC and "other". From the Top 25 Drugs Based on Number of Claims from 01/01/2015-03/31/2015, L. Thomas reported the top five drugs: amoxicillin, hydrocodone-acetaminophen, azithromycin, ProAir[®] HFA, and cetirizine. L. Thomas emphasized that the hydrocodone claims had reduced by almost 2,000 claims since

the last report at the April 2015 DUR meeting, in which claims had decreased by 11,000. She then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 01/01/2015-03/31/2015: Abilify®, Vyvanse®, Tamiflu®, Invega® Sustenna®, and Harvoni®. L. Thomas informed the Board that Abilify became available in a generic form in early May 2015 and reminded them that the generic still requires a prior authorization. B. Olin asked if there were any limitations on ADHD medications. L. Thomas explained that Vyvanse is a preferred agent and has quantity limitations in place. K. Newman explained that preferred status was determined based on financial review of the class after the P&T Committee determined all drugs in the class were comparable to each other in regards to safety and efficacy. 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, Corticosteroids (Respiratory Tract), Miscellaneous Anticonvulsants, and Respiratory and CNS Stimulants.

UPDATES

Review of Palivizumab Utilization for the 2014-2015 Season: The 2014-2015 RSV season ended March 31, 2015. L. Thomas provided an update which compared the results of the 2014-15 season to previous seasons. L. Thomas referred to Alabama RSV data from the CDC which supported Alabama Medicaid's policy of limiting the Synagis® timeframe to October 2014 – March 2015. L. Thomas briefly reviewed the updates to the American Academy of Pediatrics (AAP) recommendations for palivizumab administration. L. Thomas reminded the Board that each recipient could receive a maximum of 5 doses per season and that all policies relating to Synagis® were based on clinical literature and recommendations. For the 2014-15 season, there were 2,631 claims for 477 recipients. The average cost per claim was \$2,180 while the average cost per recipient was \$12,022. L. Thomas pointed out that there were 1,518 prior authorizations requested over the course of the season, with an approval rate of 61.0%. L. Thomas reviewed the graphs comparing the total spend of all drugs compared to the total spend of Synagis® per RSV season.

RDUR Intervention Report: L. Thomas presented the RDUR Activity Report for January 2015. She reported 719 profiles reviewed and 875 letters sent with 161 responses received as of the date of the report. She reported 86 of 124 physicians indicated that they found the RDUR letters “useful” or “extremely useful”. The criteria for the cycle of intervention letters included drug-drug interaction (SSRIs and tricyclic antidepressants; stimulants and opioids) and appropriate use (concurrent use of buprenorphine and pure opiate agonist). L. Thomas then presented the RDUR Activity Report for February 2015. She reported 645 profiles reviewed and 1,065 letters sent with 165 responses received as of the date of the report. She reported 85 of 131 physicians indicated that they found the RDUR letters “useful” or “extremely useful”. The criteria for the cycle of intervention letters included drug-drug interaction (use of narcotics with antipsychotics), therapeutic appropriateness (benzodiazepine use in fibromyalgia) and appropriate use (concurrent use of buprenorphine and pure opiate agonist). The March 2015 Activity Report indicated 680 profiles reviewed and 1,056 letters sent with 79 responses received as of the date of the report. L. Thomas reported 36 of 65 physicians indicated that they found the RDUR letters “useful” or “extremely useful”. The criteria for the cycle of intervention letters were drug-disease precaution (use of hydrocodone or oxycodone in patients with a diagnosis of fibromyalgia), inappropriate therapy (narcotic use in patients with a history of drug abuse) and appropriate use (concurrent use of buprenorphine and pure opiate agonist).

Proposed Criteria: L. Thomas presented the proposed set of 36 criteria to the Board. T. Minnifield instructed the Board members to mark their ballots. Of the 36 criteria, results from the criteria vote returned 32 approved and 4 approved as amended.

Medicaid Update: T. Minnifield began the Medicaid Update by reminding the Board members that all Medicaid information discussed is available online, as well as any new Medicaid ALERTs. T. Minnifield

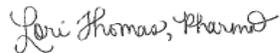
reminded the Board that the every July the Board would vote on a Vice Chair and asked the members to mark their ballots and pass them to the front.

P & T Committee Update: C. Hurst began the P & T Update by informing the Board that the last meeting was held on May 20, 2015 and covered the Anticoagulants, Cardiac Agents, and Cholesterol-lowering Agents. The next P and T meeting is scheduled for August 19, 2015, at 9am and will cover the Antihypertensive Agents and the Hepatitis C Antivirals.

New Business: P. Thompson notified the Board that the next DUR meeting will be held on October 28, 2015. K. Newman mentioned that the RCO and Health Homes were moving right along and quality measures were being developed. R. Moon informed the Board that Lock In would be included in the Health Homes and would be another approach to provide coordinated care. R. Moon also described the process of assigning Health Homes to recipients. P. Thompson made a motion to adjourn the meeting. The motion was seconded by R. Moon. A voice vote to adjourn was unanimous. The meeting was adjourned at 2:11 p.m.

Next Meeting Date: The next DUR Board meeting will be held on October 28, 2015.

Respectfully submitted,

A handwritten signature in cursive script that reads "Lori Thomas, PharmD".

Lori Thomas, PharmD

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

4. Dapagliflozin/Metformin / Insulin & Insulin Secretagogues

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Alert Message: The concurrent use of Xigduo XR (dapagliflozin/metformin extended-release) 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/metformin.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Dapagliflozin/Metformin	Insulin Chlorpropamide Tolbutamide Tolazamide Glyburide Glipizide Glimepiride	

References:
Xigduo XR Prescribing Information, Oct. 2014, AstraZeneca.

5. Dapagliflozin/Metformin / Hypotension

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Alert Message: The dapagliflozin component of Xigduo XR (dapagliflozin/metformin extended-release) 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. Monitor patients for signs and symptoms during therapy. Before initiating dapagliflozin in patients with one or more of these characteristics, volume status should be assessed and corrected.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Dapagliflozin/Metformin	Hypotension Hypovolemia CKD Stage Dehydration	

References:
Xigduo XR Prescribing Information, Oct. 2014, AstraZeneca.

6. Dapagliflozin/Metformin / Loop diuretics

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Alert Message: The dapagliflozin component of Xigduo XR (dapagliflozin/metformin extended-release) 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. Monitor patients for signs and symptoms during therapy. Before initiating dapagliflozin in patients with one or more of these characteristics, volume status should be assessed and corrected.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Dapagliflozin/Metformin	Furosemide Torsemide Ethacrynate Bumetanide	

References:
Xigduo XR Prescribing Information, Oct. 2014, AstraZeneca.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

10. Suvorexant / Overutilization

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Alert Message: The manufacturer’s recommended dose of Belsomra (suvorexant) is 10 mg taken no more than once per night, within 30 minutes of going to bed, and with at least 7 hours remaining before the planned time of awakening. If 10 mg is well-tolerated but not effective the dose can be increased to a maximum of 20 mg once daily.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A Util B Util C

Suvorexant

Max Dose: 20 mg/day

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

11. Suvorexant / Narcolepsy

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Alert Message: Belsomra (suvorexant) is contraindicated in patients with narcolepsy. Suvorexant is an orexin receptor antagonist and this mechanism of action may account for the ability of suvorexant to produce signs of narcolepsy/cataplexy.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A Util B Util C (Include)

Suvorexant Narcolepsy

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

12. Suvorexant / Respiratory Disease

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Alert Message: Caution should be exercised when prescribing Belsomra (suvorexant) to patients with compromised respiratory function due to the potential of suvorexant-induced respiratory depression.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A Util B Util C (Include)

Suvorexant Asthma
 COPD
 Emphysema
 Bronchitis
 Obstructive Sleep Apnea

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

13. Suvorexant / Depression & Suicidal Thinking

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Alert Message: Belsomra (suvorexant) should be used with caution in patients with depression or suicidal ideation. In clinical studies, a dose-dependent increase in suicidal ideation was observed in patients taking suvorexant as assessed by questionnaire. In primarily depressed patients sedative/hypnotic use has been associated with worsening depression and suicidal thoughts and actions. The lowest number of tablets that is feasible should be prescribed for the patient at any one time.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Suvorexant		Depression Suicide Suicidal Ideation

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

**14. Suvorexant / Sleep Paralysis, Hypnagogic/Hypnopompic Hallucinations
Cataplexy-like Symptoms**

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Alert Message: Sleep paralysis, hypnagogic/hypnopompic hallucinations and symptoms similar to cataplexy can occur with Belsomra (suvorexant) use and the risk of occurrence may increase with dose. Patient should be informed of the nature of these events when prescribed suvorexant.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

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

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

15. Suvorexant / CNS Depressants

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Alert Message: Concurrent use of Belsomra (suvorexant) with a CNS depressant may require dosage adjustment of suvorexant and/or the other drug due to the potential for additive depressant effects.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suvorexant	Antidepressants Opioid Agonists & Mixed Agonist/Antagonist Barbiturates Phenothiazines Anxiolytics Anticonvulsants Antipsychotics Sedating Antihistamines Muscle Relaxants Antiparkinson Agents (Dopaminergic & COMT) Sedative/Hypnotics	

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

16. Suvorexant / Strong CYP3A4 Inhibitors

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Alert Message: Concurrent use of Belsomra (suvorexant) with a strong CYP3A4 inhibitor is not recommended. Suvorexant is primarily metabolized by CYP3A4 and inhibition of this isoenzyme may significantly increase suvorexant exposure and increase the risk of suvorexant adverse effects.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suvorexant	Nefazodone	Ketoconazole
	Clarithromycin	Itraconazole
	Telithromycin	Posaconazole
	Saquinavir	Voriconazole
	Ritonavir	Boceprevir
	NelfinavirTelaprevir	
	Indinavir	

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
FDA US Food and Drug Administration: Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at:
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm>
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

17. Suvorexant / Moderate CYP3A4 Inhibitors

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Alert Message: The recommended dose of Belsomra (suvorexant) is 5 mg in patients receiving a moderate CYP3A4 inhibitor but may be increased to a maximum of 10 mg in these patients if necessary for efficacy. Suvorexant is primarily metabolized by CYP3A4 and inhibition of this isoenzyme may significantly increase suvorexant exposure and increase the risk of suvorexant-related adverse effects.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suvorexant 20 mg	Aprepitant	Fluconazole
	Atazanavir	Fosamprenavir
	Ciprofloxacin	Imatinib
	Diltiazem	Verapamil
	Erythromycin	

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
FDA US Food and Drug Administration: Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at:
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm>
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

18. Suvorexant / Strong CYP3A4 Inducer

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Alert Message: The concurrent use of Belsomra (suvorexant) and a strong CYP3A4 inducer may result in reduced suvorexant efficacy due to induction of suvorexant CYP3A4-mediated metabolism.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suvorexant	Carbamazepine Phenytoin Phenobarbital Primidone Rifampin Efavirenz	

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
FDA US Food and Drug Administration: Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Accessed: 08/230/2012.
Available at:
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm>
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

19. Suvorexant / Digoxin

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Alert Message: The concurrent use of Belsomra (suvorexant) with digoxin has been shown to slightly increase digoxin levels due to inhibition of intestinal P-glycoprotein (P-gp). Digoxin concentrations should be monitored when co-administering suvorexant with digoxin.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suvorexant	Digoxin	

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

20. Suvorexant / Pediatric Use

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

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

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

Age Range: 0-18 yoa

References:

Belsomra Prescribing Information, August 2014, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

21. Arformoterol / Overutilization

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Alert Message: Brovana (arformoterol) may be over-utilized. The manufacturer's recommended maximum dose is 30 mcg per day (15 mcg twice daily). Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. As with other inhaled beta-2 adrenergic drugs, do not use arformoterol more often at higher doses than recommended or with other long-acting beta agonists.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A

Util B

Util C

Arformoterol

Max Dose: 30 mcg/day

References:

Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

Brovana Prescribing Information, Feb. 2014, Sunovion Pharmaceuticals, Inc.

22. Arformoterol / Hepatic Impairment

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Alert Message: Brovana (arformoterol) should be used cautiously in patients with hepatic impairment. Systemic exposure (Cmax & AUC) to arformoterol increased 1.3 to 2.4-fold in subjects with hepatic impairment as compared to matched healthy control subjects. While dosage adjustment is not required it is recommended that these patients be monitored closely.

Conflict Code: MC – Drug (Actual) Disease Precaution

Drugs/Disease:

Util A

Util B

Util C

Arformoterol

Hepatic Impairment

References:

Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

Brovana Prescribing Information, Feb. 2014, Sunovion Pharmaceuticals, Inc.

23. Arformoterol / Therapeutic Appropriateness

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Alert Message: Brovana (arformoterol) should not be used in children as the safety and efficacy of arformoterol have not been established in pediatric patients.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Disease:

Util A

Util B

Util C

Arformoterol

Age Range: 0–18 yoa

References:

Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

Brovana Prescribing Information, Feb. 2014, Sunovion Pharmaceuticals, Inc.

Criteria Recommendations**Accepted Approved Rejected
As
Amended****24. Arformoterol / MOAIs & TCAs & QT Prolongation**

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Alert Message: Brovana (arformoterol), as well as other beta 2-agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval. Concurrent use of these agents may potentiate the adrenergic agonist action of arformoterol on the cardiovascular system.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Disease:

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>		
Arformoterol	Albuterol	Disopyramide	Imipramine	Pazopanib	Thioridazine
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Tizanidine
	Amantadine	Dolasetron	Isradipine	Pimozide	Tolterodine
	Amiodarone	Doxepin	Itraconazole	Posaconazole	Trazodone
	Amitriptyline	Dronedarone	Ketoconazole	Procainamide	TMP/SMZ
	Amphetamine	Droperidol	Lapatinib	Propafenone	Trimipramine
	Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline	Vandetanib
	Asenapine	Epinephrine	Levofloxacin	Quetiapine	Vardenafil
	Atazanavir	Erythromycin	Lithium	Quinidine	Venlafaxine
	Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	Ziprasidone
	Azithromycin	Felbamate	Methadone	Risperidone	Zolmitriptan
	Chloral Hydrate	Flecainide	Moexipril/HCTZ	Ritonavir	Ezogabine
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	Isocarboxazid
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	Phenelzine
	Ciprofloxacin	Foscarnet	Nilotinib	Sertraline	Tranylcypromine
	Citalopram	Fosphenytoin	Norfloxacin	Solifenacin	Linezolid
	Clarithromycin	Galantamine	Nortriptyline	Sotalol	Rasagiline
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Tacrolimus	
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen	
	Desipramine	Ibutilide	Paliperidone	Telithromycin	
	Diphenhydramine	Iloperidone	Paroxetine	Terbutaline	

References:

Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

Brovana Prescribing Information, Feb. 2014, Sunovion Pharmaceuticals, Inc.

25. Arformoterol / Beta-Blockers

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Alert Message: The concurrent use of Brovana (arformoterol) and a beta-adrenergic receptor blocker may result in antagonism. The beta blocker may block the therapeutic effect of the beta-agonist as well as produce severe bronchospasms in COPD patients.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Arformoterol	Atenolol	Metoprolol
	Betaxolol	Timolol
	Penbutolol	Sotalol
	Carteolol	Acebutolol
	Bisoprolol	Propranolol
	Pindolol	Timolol
	Carvedilol	Nebivolol
	Labetalol	

References:

Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

Brovana Prescribing Information, Feb. 2014, Sunovion Pharmaceuticals, Inc.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

26. Arformoterol / Methylxanthines & Steroids & K+ Depleting Diuretics

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Alert Message: The concurrent use of Brovana (arformoterol) with methylxanthines (theophylline, aminophylline), steroids, or potassium depleting diuretics may potentiate any hypokalemic effect of arformoterol. Monitor patients for development of hypokalemia.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Disease:

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Arformoterol	Theophylline	Budesonide	Chlorothiazide
	Aminophylline	Betamethasone	Hydrochlorothiazide
	Prednisone	Triamcinolone	Bendroflumethiazide
	Prednisolone	Furosemide	Methyclothiazide
	Hydrocortisone	Bumetanide	Indapamide
	Cortisone	Torsemide	Metolazone
	Dexamethasone	Ethacrynic Acid	Chlorthalidone
	Methylprednisolone		

References:

Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.
Brovana Prescribing Information, Feb. 2014, Sunovion Pharmaceuticals, Inc.

27. Arformoterol / Therapeutic Appropriateness (Black Box Warning)

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Alert Message: Brovana (arformoterol) is a long-acting beta-2-adrenergic agonist (LABA) and all LABAs increase the risk of asthma-related death. The safety and efficacy of arformoterol in patients with asthma have not been established. Arformoterol is not indicated for the treatment of asthma.

Conflict Code: TA - Therapeutic Appropriateness

Drugs/Diseases

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

References:

Brovana Prescribing Information, Feb. 2014, Sunovion Pharmaceuticals, Inc.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

28. Arformoterol / Non-adherence

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

Conflict Code: LR – Non-adherence

Drugs/Diseases

Util A

Util B

Util C

Arformoterol

References:

van Boven JF, Chavannes NH, van der Molen T, et al. Clinical and Economic Impact of Non-adherence in COPD: A Systematic Review. *Respir Med.* 2014 Jan;108(1):103-113.

Restrepo RD, Alvarez MT, Wittnebel LD, et al., Medication Adherence Issues in Patients Treated for COPD. *International Journal of COPD.* 2008;3(3):371-384.

Simoni-Wastila L, Wei Y, Qian J, et al., Association of Chronic Obstructive Pulmonary Disease Maintenance Medication Adherence With All-Cause Hospitalization and Spending in a Medicare Population. *Am J Geriatr Pharmacother.* 2012 Jun;10(3):201-210.

Lareau Sc, Yawn BP. Improving Adherence with Inhaler Therapy in COPD. *International Journal COPD.* 2010 Nov 24;5:401-406.

29. Olodaterol / Overutilization

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Alert Message: The manufacturer’s recommended dose of Striverdi Respimat (olodaterol) is 2 inhalations once-daily. Do not use olodaterol inhalation more than two inhalations every 24 hours. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A

Util B

Util C

Olodaterol

Max Dose: 2 inhalations per day = (5.0 mcg olodaterol/day)

References:

Clinical Pharmacology, 2014 Elsevier/Gold Standard.

Striverdi Respimat Prescribing Information, July 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

30. Olodaterol / Black Box Warning

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Alert Message: Striverdi Respimat (olodaterol) is a long-acting beta-2 adrenergic agonist (LABA) and all LABAs increase the risk of asthma-related death. The safety and efficacy of olodaterol in patients with asthma have not been established. Olodaterol is not indicated for the treatment of asthma.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A

Util B

Util C

Olodaterol

References:

Clinical Pharmacology, 2014 Elsevier/Gold Standard.

Striverdi Respimat Prescribing Information, July 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

31. Olodaterol / Cardiovascular, Convulsive Disorders, Diabetes & Thyrotoxicosis

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Alert Message: Striverdi Respimat (olodaterol) should be used with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis, or sensitivity to sympathomimetic drugs. Olodaterol is a sympathomimetic amine and can exacerbate these conditions.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Olodaterol	Hypertension Arrhythmias Heart Failure Diabetes Seizures Epilepsy	

References:

Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Striverdi Respimat Prescribing Information, July 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

32. Olodaterol / MAOIs, TCAs & Other QTc Prolonging Meds

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Alert Message: Striverdi Respimat (olodaterol) should be administered with extreme caution to patients being treated with MAOIs, TCAs, or drugs known to prolong the QTc interval because the action of the adrenergic agonist, olodaterol, on the cardiovascular system may be potentiated by these agents.

Conflict Code: DD –Drug/Drug Interactions

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>				<u>Util C</u>
Olodaterol	Albuterol	Disopyramide	Imipramine	Pazopanib	Thioridazine
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Tizanidine
	Amantadine	Dolasetron	Isradipine	Pimozide	Tolterodine
	Amiodarone	Doxepin	Itraconazole	Posaconazole	Trazodone
	Amitriptyline	Dronedarone	Ketoconazole	Procainamide	TMP/SMZ
	Amphetamine	Droperidol	Lapatinib	Propafenone	Trimipramine
	Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline	Vandetanib
	Asenapine	Epinephrine	Levofloxacin	Quetiapine	Vardenafil
	Atazanavir	Erythromycin	Lithium	Quinidine	Venlafaxine
	Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	Ziprasidone
	Azithromycin	Felbamate	Methadone	Risperidone	Zolmitriptan
	Chloral Hydrate	Flecainide	Moexipril/HCTZ	Ritonavir	Ezogabine
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	Isocarboxazid
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	Phenelzine
	Ciprofloxacin	Foscarnet	Nilotinib	Sertraline	Tranlycypromine
	Citalopram	Fosphenytoin	Norfloxacin	Solifenacin	Linezolid
	Clarithromycin	Galantamine	Nortriptyline	Sotalol	Rasagiline
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Tacrolimus	
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen	
	Desipramine	Ibutilide	Paliperidone	Telithromycin	
	Diphenhydramine	Iloperidone	Paroxetine	Terbutaline	

References:

Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Striverdi Respimat Prescribing Information, July 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

33. Olodaterol / Adrenergic Drugs

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Alert Message: Caution should be exercised when Striverdi Respimat (olodaterol) is prescribed concurrently with other adrenergic sympathomimetic agents, administered by any route, because the sympathetic effects of olodaterol may be potentiated.

Conflict Code: DD- Drug/Drug Interaction
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>			<u>Util C</u>
Olodaterol	Ephedrine	Methyldopa	Phentermine	Naphazoline
	Epinephrine	Tizanidine	Benzphetamine	Pirbuterol
	Pseudoephedrine	Amphetamine	Diethylpropion	Metaproterenol
	Phenylephrine	Dextroamphetamine	Phendimetrazine	Terbutaline
	Clonidine	Lisdexamfetamine	Apraclonidine	Albuterol
	Guanfacine	Methylphenidate	Brimonidine	Levalbuterol

References:
Clinical Pharmacology, 2014 Gold Standard.
Striverdi Respimat Prescribing Information, July 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

34. Olodaterol / Nonselective Beta-Blockers / Selective Beta-Blockers

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Alert Message: Concurrent use of a beta-adrenergic blocker with Striverdi Respimat (olodaterol) may diminish the pulmonary effect of the beta-agonist olodaterol. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in patients with asthma and COPD. If concomitant therapy cannot be avoided, consider a cardioselective beta-blocker, but administer with caution.

Conflict Code: DD- Drug/Drug Interaction
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Olodaterol	Carvedilol	Acebutolol
	Nadolol	Atenolol
	Labetalol	Betaxolol
	Penbutolol	Bisoprolol
	Pindolol	Metoprolol
	Propranolol	Nebivolol
	Sotalol	
	Timolol	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Striverdi Respimat Prescribing Information, July 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

35. Olodaterol / Xanthines Derivatives, Steroids & K+ Depleting Diuretics

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Alert Message: Caution should be exercised when Striverdi Respimat (olodaterol) is prescribed concurrently with xanthine derivatives, steroids, or non-potassium sparing diuretics because concomitant administration may potentiate the hypokalemic effect of olodaterol. The ECG changes or hypokalemia that may result from the administration of non-potassium sparing diuretics can be acutely worsened by beta-agonists.

Conflict Code: DD- Drug/Drug Interaction
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Olodaterol	Theophylline	Prednisolone	Chlorothiazide
	Aminophylline	Prednisone	Chlorthalidone
	Dyphylline	HCTZ	
	Betamethasone	Indapamide	
	Budesonide	Methyclothiazide	
	Cortisone	Metolazone	
	Dexamethasone	Furosemide	
	Hydrocortisone	Bumetanide	
	Methylprednisolone	Torsemide	

References:
Clinical Pharmacology, 2014 Gold Standard.
Striverdi Respimat Prescribing Information, July 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

36. Olodaterol / Non-adherence

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

Conflict Code: LR – Non-adherence
Drugs/Diseases

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

References:
van Boven JF, Chavannes NH, van der Molen T, et al. Clinical and Economic Impact of Non-adherence in COPD: A Systematic Review. Respir Med. 2014 Jan;108(1):103-113.
Restrepo RD, Alvarez MT, Wittnebel LD, et al., Medication Adherence Issues in Patients Treated for COPD. International Journal of COPD. 2008;3(3):371-384.
Simoni-Wastila L, Wei Y, Qian J, et al., Association of Chronic Obstructive Pulmonary Disease Maintenance Medication Adherence With All-Cause Hospitalization and Spending in a Medicare Population. Am J Geriatr Pharmacother. 2012 Jun;10(3):201-210.
Lareau Sc, Yawn BP. Improving Adherence with Inhaler Therapy in COPD. International Journal COPD. 2010 Nov 24;5:401-406.