

Alabama Medicaid DUR Board Meeting Minutes October 27, 2010

Members Present: Kevin Green, Paula Thompson, Donald Marks, Kevin Royal, Kelli Littlejohn, Bernie Olin, Dan McConaghy, Denise Thornley-Brown, Robert Moon, David Harwood

Also Present: Clemice Hurst, Tiffany Minnifield, Christina Faulkner, and V. Ellen Marable, student

Members Absent: Jimmy Jackson, Rhonda Harden, Daniel Mims, Hugh Frazer

Call to Order: Kevin Green, Chair, called the meeting to order at 1:00pm.

Review and Adoption of Minutes of July 28, 2010 meeting: Kevin Green asked if there were additions, deletions, or changes to the minutes of the July 28 meeting. No changes were suggested. Bernie Olin made a motion to approve the minutes as discussed and Paula Thompson seconded the motion. A voice vote to approve the minutes was unanimous.

Methadone Update: Christina reported to the Board that in April 2009, the DUR Board recommended that the P & T Committee reevaluate the efficacy/safety of methadone and that the Agency consider requiring a prior authorization for the generic product. Methadone was initially re-reviewed by the Committee during its November 18, 2009 meeting. At that time, the Committee elected to wait until the FDA finalized their Risk Evaluation and Mitigation Strategy (REMS) regarding methadone before making any further recommendations. The FDA released a statement in July 2010, which recommended additional provider and patient education strategies for the long-acting opioids in lieu of stronger action. During its August 2010 meeting, the P & T Committee recommended the following: 1) generic methadone maintain the current preferred status, 2) the Agency to continue to monitor methadone's utilization, 3) the DUR Board and HID to continue its physician education efforts regarding methadone, and 4) the P & T Committee to re-review methadone's utilization data. The recommended utilization of methadone will be included in the scheduled AHFS Class (opiate agonists) clinical re-review in May 2011. At that time, the P & T Committee will review the current utilization data and make a recommendation regarding generic methadone's preferred status.

Prior Authorization and Overrides Update: Christina Faulkner began the Prior Authorization and Overrides Update with the Monthly Manual Prior Authorizations and Overrides Report for the month of June. She reported 8,099 total requests and an approval rate of 59.91%. She reported 12,883 electronic requests for the same time frame. From the Prior Authorization and Override Response Time Ratio report for June 2010 she reported that between 93 and 94% of all manual PAs were responded to in less than two hours, between 97 and 98% under four hours and between 99 and 100% in less than eight hours. For the month of July, Christina reported 8,116 manual PA requests and 14,503 electronic PA requests. She reported that 94.01% of PAs were responded to in less than two hours, 97.98% in less than four hours and 98.40% in less than eight hours. For the month of August, Christina reported 8,622 manual PA requests and 14,924 electronic PA requests for the same time frame. For August, Christina reported between 86 and 87% approved in less than two hours, approximately 91% in less than four hours and between 95 and 96% approved in less than eight hours.

Program Summary Review: Christina briefly reviewed the Alabama Medicaid Program Summary on page 26. From the 6 Month Assessment, she noted 4.2 million prescriptions, average number of recipients per month of 210,000 to 211,000 and an average paid per prescription of \$59.43. Discussion included the recent 9/22/10 implementation of the pharmacy reimbursement Average Acquisition Cost (AAC) modification and the next analysis should be divided pre- and post- 9/22/10.

Cost Management Analysis: Christina reported for July 2008 an average cost per claim of \$62.28 and for June 2010 an average cost per claim of \$60.20. From the Drug Analysis 2nd Quarter 2010, Christina reported 72.84% generic utilization, 17% brand single-source, 3.64% brand multi-source and 6.49% OTC and "other". From the Top 25 Drugs Based on Total Claims from 07/01/10-07/31/10, Christina reported the top five drugs: hydrocodone-acetaminophen, Singulair[®], alprazolam, amoxicillin and omeprazole. She then reported the top five drugs from the Top 25 Drugs Based on Claims Cost from 07/01/10-07/31/10: Abilify[®], Singulair[®], Seroquel[®], Zyprexa[®] and Aciphex[®]. From the Top 15 Therapeutic Classes by Total Cost of Claims from 07/01/10-07/31/10, Christina reported the top five classes: antipsychotic agents, hemostatics, anticonvulsants, beta-adrenergic agonists and leukotriene modifiers. A request was made to compare the Alabama Medicaid pharmacy costs (per member per month) to other commercial third parties' costs. The Board also requested that HID report how many recipients with no FDA approved indication on file received one of the top five drugs from the Top 25 Drugs by Cost Report.

Anticonvulsants (Miscellaneous AHFS Class 281292): At the last DUR meeting, the Board requested that HID provide a list of drugs and number of recipients taking anticonvulsants without a diagnosis of epilepsy. Christina reported that in July 2010, the Miscellaneous Anticonvulsant class was the third leading drug class based on claims cost. There were 23,058 prescriptions reported at a cost of \$1,900,969, which averages to approximately \$82.00 paid per prescription. Christina listed the drugs included in the AHFS Class 281292 (Miscellaneous Anticonvulsants) and noted that Lyrica[®] is included in this class. She went on to inform the Board that in the month of July 2010, there were 17,393 unique recipients using drugs in this AHFS class and that 12,984 of those patients did not have an epilepsy diagnosis on file. Patients with an ICD-9 code of 345 (epilepsy and recurrent seizures) or 780.3 (convulsions) were excluded. Christina informed the Board that diagnoses are not tied to drug claims, but the top recurring diagnoses for those patients without an epilepsy diagnosis are: schizoaffective disorder, unspecified hypertension, diabetes mellitus without mention of complication, paranoid type schizophrenia, long term use other medications, lumbago, unspecified schizophrenia, benign hypertension and unspecified examination. The Board requested a breakdown, with diagnosis, for each drug. Christina will present that information at the next DUR meeting.

Aripiprazole/Quetiapine Utilization: In response to a request by the Board at the last DUR meeting, Christina presented information regarding the utilization of aripiprazole. She informed the Board that in July of 2010, aripiprazole was the leading drug based on claims cost. There were 3,279 prescriptions reported at a cost of \$1,692,538, averaging approximately \$516 per prescription for the month of July, 2010. Aripiprazole is indicated for use in the treatment of schizophrenia, bipolar disorder, as adjunctive treatment of major depressive disorder, and treatment of irritability associated with autistic disorder. The Board requested the number of patients using aripiprazole for treatment of depression rather than for its other indications. Antipsychotic use as adjunctive therapy for depression is a relatively new treatment with aripiprazole being approved in late 2007 and quetiapine XR approved in late 2009. After reviewing the data provided by HID, the DUR Board agreed to take no further action at this time.

Singulair: In response to a request by the Board at the last meeting, Christina presented information regarding the appropriate utilization of Singulair[®]. Christina reported that HID gathered utilization data for Singulair[®] through RxExplorer, which searches through paid medical and pharmacy claims. From 08/21/09 to 08/20/10, a total of 55,579 unique recipients received prescriptions for Singulair[®]. Of the total number of recipients, 47,327 were children under the age of 18. The Board requested information regarding therapies tried prior to Singulair, specifically antihistamines and steroids. Christina will provide that information to the Board at the next DUR meeting.

Alprazolam Utilization: A recommendation was made at the last DUR meeting to consider an edit that supports the clinical guidelines regarding alprazolam utilization. There was also discussion as to whether the Board had the authority to impose certain limits/edits. In response, Christina reported information from the Agency stating that it is in the DUR Board's scope of duties to impose a hard edit on alprazolam if they choose. At the last DUR meeting,

the Board requested information regarding other drugs being used with alprazolam. They also requested the dollar amount spent on clonazepam compared to alprazolam. Christina reported 135,610 prescriptions for alprazolam at a cost of \$1,223,516 (average cost per prescription of \$9.02) and 107,147 prescriptions for clonazepam at a cost of \$959,339 (average cost per prescription of \$8.95). The Board recommended that the Agency, through the Academic Detailing program, provide information to prescribers through education initiatives and RDUR letters (criteria to be presented at the next DUR meeting) for the group of recipients receiving other drugs with alprazolam.

Early Refill Policy Review: At the last DUR meeting, the Board requested information on early refills by age and drug. Christina provided this information to the Board broken down by age and drug class. Christina also provided information on refill tolerance for both controlled and non-controlled substances for other states for comparison. After discussion, the Board agreed not to impose a hard edit on the current refill tolerance levels, but to look at the number of outlier prescribers of controlled substances for educational letters.

Synagis 2009-2010 Update: Christina provided the 2009-2010 Synagis[®] data to the Board. She reported the changes that occurred for the last season. Changes included the requirement for providers to submit the hospital discharge summary from birth with each prior authorization request except in very special circumstances. Also, Alabama Medicaid modified its criteria to reflect the changes adopted by the American Academy of Pediatrics. Additional staff, including an experienced pediatric nurse, was employed by HID to better serve the provider community and manage the palivizumab PA process. New educational initiatives for providers were developed by Alabama Medicaid in conjunction with HID to include a statewide web conference in which new criteria, forms and PA requirements were discussed. Also, face-to-face visits by Medicaid Pharmacy Specialists were made with all physicians and pharmacies that prescribe and /or dispense palivizumab to Alabama Medicaid recipients. Christina reported that HID instituted a new tracking system, which allows HID to maintain a database of doses given and doses needed, which also allows clinical personnel to monitor the recipient weight to avoid waste. Finally, the prior authorization team made a commitment to call Synagis providers in the event a second denial was issued for a specific recipient to explain what was needed to complete the request. Christina reported 4093 total claims for palivizumab with a total reimbursement amount of \$7,332,802 for 959 unique recipients. Christina reported to the Board the top ten denials by reason and the top ten pharmacy providers. Christina also provided historical utilization data for the last six seasons. Dan Roach from the University of South Alabama Center for Strategic Health Innovation also presented to the Board the Realtime Medical Electronic Data Exchange (RMEDE) Synagis Hospitalization Study.

RDUR Intervention Report: Christina presented the RDUR Activity Report for July 2010. She reported 436 profiles reviewed and 354 letters sent with 72 responses received as of the date of the report. She reported 28 of 54 physicians indicated that they found the RDUR letters “useful” or “extremely useful”. The criteria for the cycle of intervention letters was underutilization, exacerbation of existing disease states, duplicate therapy and adverse events.

RDUR Criteria: Christina presented the set of 19 proposed criteria to the Board for their review. Board members were instructed to mark their ballots.

Medicaid Update: Tiffany called the board members’ attention to their Medicaid packets and reminded them to turn in their vouchers. She called the members’ attention to the Alert. Effective October 1, NDCs will be required on physician administered drug claims. The Drug Look-up System was made available to providers October 5 and will be available on the Agency’s website also. Regarding the use of social security numbers and provider numbers, as of January 7, 2011, providers will no longer be given the new recipient numbers. Claims with old recipient ID numbers will be rejected. Tiffany referred to the contents of the packet which included meeting dates, Medicaid Matters and the Provider Insider. She informed the Board that Carol Hermann Steckel would be leaving the Agency in November. Tiffany also informed the Board that new AAC pricing has been implemented. Kelli Littlejohn informed the Board that Dr. Moon is working on a pilot project currently informally named Care Networks for

which an RFP will be released soon. Kelli also informed the Board that the Agency's most recent CE program presented by Dr. Kevin Green was very successful and well received by the provider community in Mobile.

P & T Committee Update: Clemice Hurst began the P&T Update by informing the Board that at the last meeting on August 11, the Committee reviewed the Overactive Bladder Agents, Platelet Aggregation Inhibitors, Cardiac Agents and Cholesterol Agents. She stated that the next P&T meeting will be held on November 10. At the November meeting the committee will review the Antihypertensive Agents, the Antidiuretic Agents and will present an update of the Thiazolidinediones.

New Business: Kevin Green, Chair, asked the Board if there was any new business. There being no new business brought before the Board, Kevin asked for a motion to adjourn. Kevin Royal made a motion to adjourn the meeting. The motion was seconded by Denyse Thornley-Brown. A voice vote to adjourn was unanimous. The meeting was adjourned at 2:30pm.

Next Meeting Date: The next DUR Board meeting will be held on January 26, 2011.

Respectfully submitted,



Christina Faulkner, PharmD

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

Criteria Recommendations

**Accepted Approved Rejected
 As
 Amended**

1. ActoPlus Met XR /Overutilization

Alert Message: ActoPlus Met XR (extended-release pioglitazone/metformin) may be over-utilized. The manufacturer's maximum recommended daily dose is 45 mg pioglitazone / 2000 mg metformin.

_____ **x** _____ _____

Conflict Code: ER – Overutilization

Drug/Disease:

Util A Util B Util C
ActoPlus Met XR

Max Dose: 45mg pioglitazone -2000mg metformin extended-release per day

References:

Facts & Comparisons, 2010 Updates.

ActoPlus Met XR Prescribing Information, March 2009, Takeda Pharmaceuticals.

2. ActoPlus Met XR /Non-adherence

Alert Message: Non-adherence to ActoPlus Met XR (extended-release pioglitazone/metformin) therapy may result in loss of glycemic control and an increased risk of developing diabetic-related complications.

_____ **x** _____ _____

Conflict Code: LR – Non-adherence

Drug/Disease:

Util A Util B Util C
ActoPlus Met XR

References:

Facts & Comparisons, 2010 Updates.

ActoPlus Met XR Prescribing Information, March 2009, Takeda Pharmaceuticals.

3. Dutasteride/tamsulosin / Overutilization

Alert Message: Jalyn (dutasteride/tamsulosin) may be over-utilized. The manufacturer's maximum recommended daily dose is one capsule (0.5 mg dutasteride/0.4 mg tamsulosin) daily.

_____ **x** _____ _____

Conflict Code: ER - Overutilization

Drug/Disease:

Util A Util B Util C
Dutasteride/tamsulosin

Max Dose: 0.5 mg dutasteride/0.4 mg tamsulosin per day

References:

Jalyn Prescribing Information, June 2010. GlaxoSmithKline.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

4. Tamsulosin / Strong CYP 3A4 Inhibitors

Alert Message: Tamsulosin-containing products should not be co-administered with strong CYP3A4 Inhibitors (e.g. ketoconazole, itraconazole, and ritonavir). Tamsulosin is metabolized via CYP3A4 isoenzyme and concurrent use with a strong inhibitor can significantly decrease tamsulosin metabolism and increase tamsulosin exposure.

 x _____ _____

Conflict Code: DD – Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Tamsulosin-All	Ketoconazole	Ritonavir	
	Itraconazole	Saquinavir	
	Nefazodone	Indinavir	
	Clarithromycin	Nelfinavir	
	Telithromycin	Atazanavir	

References:

Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

5. Tamsulosin / CYP2D6 Inhibitors & Moderate 3A4 Inhibitors

Alert Message: Tamsulosin-containing products should be used with caution when co-administered with moderate CYP3A4 inhibitors, moderate or strong CYP2D6 inhibitors or in patients known to be poor 2D6 metabolizers. Tamsulosin is metabolized via CYP3A4 and CYP2D6 and concurrent use with Inhibitors of these isoenzymes or in poor 2D6 metabolizers may result in a significant increase in tamsulosin exposure.

 x _____ _____

Conflict Code: DD - Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Tamsulosin-All	Erythromycin	Paroxetine	Terbinafine
	Aprepitant	Bupropion	
	Fluconazole	Fluoxetine	
	Verapamil	Quinidine	
	Diltiazem	Duloxetine	

References:

Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: <http://medicine.iupui.edu/clinpharm/ddos/table.asp>.
Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

6. Tamsulosin-All / Cimetidine

Alert Message: Tamsulosin-containing products should be used with caution when co-administered with cimetidine (an inhibitor of both CYP3A4 and 2D6). Concurrent use of these agents has resulted in a moderate increase in tamsulosin AUC (44%) with a 26% decrease in tamsulosin clearance.

 x _____ _____

Conflict Code: DD - Drug/Drug Interaction

Drug/Disease:

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tamsulosin-All	Cimetidine	

References:

Jalyn Prescribing Information, June 2010. GlaxoSmithKline.

Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine.
Available at: <http://medicine.iupui.edu/clinpharm/ddos/table.asp>.
Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

7. Tamsulosin-All / Warfarin

Alert Message: Tamsulosin-containing products should be used with caution when co-administered with warfarin. Results from limited in vitro and in vivo studies are inconclusive concerning this interaction, therefore caution should be exercised with concurrent use.

 x

Conflict Code: DD - Drug/Drug Interaction

Drug/Disease:

Util A Util B Util C
Tamsulosin-All Warfarin

References:

Jalyn Prescribing Information, June 2010. GlaxoSmithKline.

Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine.

Available at: <http://medicine.iupui.edu/clinpharm/ddos/table.asp>.

Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

8. Alpha-1-Adrenergic Receptor Blockers/ Duplicate Therapy

Alert Message: Therapeutic duplication of alpha-1-adrenergic blockers may be occurring. These agents should not be used concurrently due to the increased risk of hypotension.

 x

Conflict Code: TD – Therapeutic Duplication

Drug/Disease:

Util A Util B Util C

Tamsulosin-all

Prazosin

Terazosin

Doxazosin

Alfuzosin

Silodosin

References:

Jalyn Prescribing Information, June 2010. GlaxoSmithKline.

Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

Minipress Prescribing Information, July 2009, Pfizer Labs.

9. Dutasteride / Pregnancy / Pregnancy Negating

Alert Message: Dutasteride-containing products are contraindicated during pregnancy and in women of childbearing potential due to risk for fetal harm. In animal studies dutasteride, an androgen hormone inhibitor, inhibited the normal development of external genitalia in male fetuses. Dutasteride-containing products are pregnancy category X.

 x

Conflict Code: MC – Drug/Diagnosis Precaution/Warning/Contraindication

Drug/Disease:

Util A Util B Util C (Negating)

Tamsulosin Pregnancy ICD-9s

dutasteride

Delivery
Miscarriage
Abortion

Age: 12 – 999 years of age

References:

Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Facts & Comparisons, 2010 Updates.
Avodart Prescribing Information, June 2010, GlaxoSmithKline.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

10. Leflunomide / Liver Toxicity Warning (Black Box Warning)

 x _____ _____

Alert Message: Arava (leflunomide) may be associated with severe liver injury. The risk of injury is greater in patients taking other drugs associated with liver injury and patients with liver disease. Liver enzymes should be monitored at least monthly for 3 months after beginning leflunomide and quarterly thereafter. Leflunomide therapy should be discontinued if liver enzymes rise to two times the upper limit of normal.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A

Util B

Util C

Leflunomide

References:

MedWatch: The FDA Safety Information and Adverse Event Reporting Program 2010.

11. Zocor & Vytorin / High Dose

 x _____ _____

Alert Message: The simvastatin-containing agent may be over-utilized. The manufacturer's recommended maximum daily dose is 80 mg. Exceeding the maximum dose may increase the risk of adverse effects, including the occurrence of myopathy and/or rhabdomyolysis.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A

Util B

Util C

Simvastatin

Simvastatin/Ezetimibe

Max Simvastatin Dose: 80mg/day

References:

Zocor Prescribing Information March 2010, Merck & Co., Inc.

FDA Drug Safety Communication: Ongoing Safety Review of High-Dose Zocor (simvastatin) and Increased Risk of Muscle Injury. FDA 3/19/2010.

Vytorin Prescribing Information, March 2010, Merck/Schering-Plough Pharmaceuticals.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

12. Simvastatin / Strong CYP3A4 inhibitors

Alert Message: Concurrent use of a simvastatin-containing agent and a strong CYP3A4 inhibitor may result in myopathy or rhabdomyolysis due to elevated simvastatin levels. The risk is increased when higher doses of simvastatin are involved. Discontinuation of simvastatin is advised when short-term therapy with azole antifungals or macrolides is needed.

 x _____ _____

Conflict Code: DD – Drug/Drug interaction

Drugs/Diseases

Util A

Util B

Util C

Simvastatin-All

Ketoconazole

Nefazodone

Darunavir

Fosamprenavir

Itraconazole

Ritonavir

Tipranavir

Erythromycin

Voriconazole

Saquinavir

Atazanavir

Clarithromycin

Fluconazole

Nelfinavir

Indinavir

Telithromycin

References:

Zocor Prescribing Information March 2010, Merck & Co., Inc.

FDA Drug Safety Communication: Ongoing Safety Review of High-Dose Zocor (simvastatin) and Increased Risk of Muscle Injury. FDA 3/19/2010.

Clinical Pharmacology, 2010 Gold Standard.

Vytorin Prescribing Information, March 2010, Merck/Schering-Plough Pharmaceuticals.

Simcor Prescribing Information, July 2010, Abbott Laboratories.

13. Simcor / High Dose

Alert Message: Simcor (simvastatin/niacin) may be over-utilized. The manufacturer's recommended maximum daily dose is 40/2000 mg. Exceeding the maximum dose may increase the risk of adverse effects, including the occurrence of myopathy and/or rhabdomyolysis which is simvastatin dose-related.

 x _____ _____

Conflict Code: ER – Overutilization

Drugs/Diseases

Util A

Util B

Util C

Simvastatin/Niacin

Max Simcor Dose: 40/2000mg per day

References:

Simcor Prescribing Information, July 2010, Abbott Laboratories.

Clinical Pharmacology, 2010 Gold Standard.

FDA Drug Safety Communication: Ongoing Safety Review of High-Dose Zocor (simvastatin) and Increased Risk of Muscle Injury. FDA 3/19/2010.

14. Zocor & Vytorin / Danazol

Alert Message: The dose of a simvastatin-containing agent (Zocor or Vytorin) should not exceed 10 mg/day in patients receiving danazol due to the increased risk of myopathy and/or rhabdomyolysis.

 x _____ _____

Conflict Code: DD – Drug/Drug interaction

Drugs/Diseases

Util A

Util B

Util C (Include)

Simvastatin

Danazol

Simvastatin/Ezetimibe

Max Simvastatin Dose: 10 mg/day

References:

Clinical Pharmacology, 2010 Gold Standard.
Facts & Comparisons, 2010 Updates.
Vytorin Prescribing Information, March 2010, Merck/Schering-Plough Pharmaceuticals.
Zocor Prescribing Information March 2010, Merck & Co., Inc.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

15. Simcor / Cyclosporine & Danazol

Alert Message: The concurrent use of Simcor (simvastatin/niacin) with danazol or cyclosporine should be avoided due to increased risk of myopathy and/or rhabdomyolysis. The dose of a simvastatin-containing agent should not exceed 10 mg/day in patients receiving cyclosporine or danazol. The lowest dose of simvastatin available in the combination product, Simcor, is 20mg.

 x _____ _____

Conflict Code: DD - Drug/Drug interaction

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Simvastatin/Niacin	Cyclosporine	Danazol

References:

Simcor Prescribing Information, July 2010, Abbott Laboratories.
Clinical Pharmacology, 2010 Gold Standard.
Facts & Comparisons, 2010 Updates.

16. Pramlintide / Hypoglycemia (Black Box Warning)

Alert Message: The concurrent use of Symlin (pramlintide) and insulin has been associated with increased risk of insulin-induced severe hypoglycemia, particularly with type 1 diabetes. Appropriate patient selection, careful patient instruction, and insulin dose adjustment are critical elements for reducing this risk.

 x _____ _____

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

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

References:

Facts & Comparisons, 2010 Updates.
Clinical Pharmacology, 2010 Gold Standard.
Symlin Prescribing Information, July 2008, Amylin Pharmaceuticals.

17. Rasagiline / Overutilization

Alert Message: Azilect (rasagiline) may be over-utilized. The manufacturer's recommended maximum dose (as monotherapy or adjunct to levodopa) is 1 mg per day.

 x _____ _____

Conflict Code: ER - Overutilization

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>		
Rasagiline		Hepatic Impairment	Tacrine	Zileuton
		Ciprofloxacin	Cimetidine	Fluvoxamine
		Mexiletine	Tizanidine	
		Amiodarone	Ticlopidine	

Max Dose: 1.0 mg/day

References:

Azilect Prescribing Information, Dec. 2009, Teva Neuroscience.
Facts & Comparisons, 2010 Updates.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2010.

Criteria Recommendations

**Accepted Approved Rejected
As
Amended**

18. Rasagiline / Overutilization

Alert Message: Azilect (rasagiline) may be over-utilized. The manufacturer's recommended maximum dose in patients with mild hepatic impairment is 0.5 mg per day. Rasagiline should not be used in patients with moderate or severe hepatic impairment.

 x _____ _____

Conflict Code: ER - Overutilization

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rasagiline	Hepatic Impairment	

Max Dose: 0.5 mg/day

References:

Azilect Prescribing Information, Dec. 2009, Teva Neuroscience.
Facts & Comparisons, 2010 Updates.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2010.

19. Rasagiline / Ciprofloxacin

Alert Message: Concomitant use of Azilect (rasagiline) and a CYP1A2 inhibitor (e.g. , tizanidine, mexiletine, tacrine and ciprofloxacin) may cause a 2-fold increase in rasagiline plasma concentrations resulting in increased adverse reactions. Patients taking these agents concurrently should not exceed 0.5 mg/day of rasagiline.

 x _____ _____

Conflict Code: ER - Overutilization

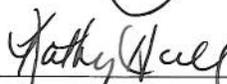
Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Rasagiline	Ciprofloxacin Mexiletine Amiodarone Tacrine Cimetidine Tizanidine Ticlopidine Zileuton Fluvoxamine	

References:

Azilect Prescribing Information, Dec. 2009, Teva Neuroscience.
Facts & Comparisons, 2010 Updates.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2010.
Clinical Pharmacology, 2010 Gold Standard.

The minutes of the October 27, 2010 DUR Board Meeting have been reviewed and approved as submitted.

 _____ Robert D. Church, Jr., CPA, Commissioner	<input checked="" type="checkbox"/> Approve () Deny	<u>12/2/10</u> Date
 _____ Kathy Hall, Deputy Commissioner	<input checked="" type="checkbox"/> Approve () Deny	<u>11/30/10</u> Date
 _____ Robert Moon, M.D., Medical Director	<input checked="" type="checkbox"/> Approve () Deny	<u>12-1-10</u> Date