DRUG USE REVIEW (DUR) BOARD

Minutes
October 28, 2010

Grant Sawyer Office Building
555 E. Washington Avenue Room 4412E
Las Vegas, Nevada 89416

Nevada State Legislature Building
401 So. Carson Street, Room 3137
Carson City, Nevada 89701

Committee Members Present:
Las Vegas: Paul Oesterman, Pharm.D.; James Marx, MD,
Carson City: Keith Macdonald, R.Ph., Steven Rubin, MD; Chris Shea, Pharm.D
Call-In: David England, Pharm.D
Absent: William Evans, MD;

Others Present:
DHCFP:
Las Vegas: Gabriel Lither; Deputy Attorney General
Carson City: Coleen Lawrence, Chief, Program Services; Jennifer Matus, Pharmacy Program Specialist

Magellan Medicaid Administration:
Las Vegas: Rob Coppola Pharm.D, Program Director; Paula Townsend Pharm.D; Clinical Manager; Shirley Hunting
Carson City: Dave Wuest R.Ph., Clinical Manager

Others:
Las Vegas: Chase Freeman-Pfizer; Tracy Lawyer-Pfizer; Sabrina Avery-Bristol Myers Squibb; Jennifer Lauper-Bristol Myers Squibb; Larry Hinson-Astra Zeneca; Brad Bu(illegible); Ronnie DePue-Forest; Jerry Hester-Forest; Mike Pinocer-Pfizer
Carson City: Sarah Day-VCG & Associates

i. Call to Order and Roll Call

Chairman Paul Oesterman called the meeting to order at 1:03 p.m.

ii. Discussion and Approval of July 22, 2010 Minutes

MOTION: **James Marx motioned to accept the July 22, 2010, minutes as presented.**
SECOND: **David England**
VOTES: **Unanimous**
MOTION CARRIED

iii. Status Update by DHCFP

a. Program Updates

Coleen Lawrence stated that the agency budget has been released and is posted on the DHCFP website.

Healthcare Reform has impacted the smoking cessation benefit which is administered through the pharmacy program. Currently, two ninety-day treatment regimens are allowed per year. The Healthcare Reform federal regulations requires that women who are pregnant have unlimited access to tobacco cessation products. A programming change in the pharmacy system will be made to allow an override of the two ninety-day limit per year if the physician has indicted that the treatment is for a pregnant woman. Ms. Lawrence stated that DHCFP is partnering with the Nevada American Lung Association to provide outreach and education.

Dr. Oesterman commented that in the state of New Mexico, pharmacists have prescriptive authority for prescribing over-the-counter and legend tobacco cessation products. He recommended that the DUR Board and DHCFP in conjunction with the State Board of Pharmacy consider this practice for Nevada. This item will be agendized on a future agenda.

iv. Review of Prescribing/Program Trends

a. Top 10 Therapeutic Classes (by Payment and by Claims)

Dr. Townsend reviewed the report by payment amount noting that the increase in the insulin payment amount is primarily due to pricing increases. The highest product cost increase is Lantus®. The number of claims for this product remains stable; however, the average cost per claim has increased approximately 15%. NovoLog® products ranked second in pricing increases resulting in a drug spend of $105,000 per quarter and Apidra® has risen from $140/claim to $212/claim. The loss of generic insulin products has also driven an increase in cost.

Dr. Oesterman asked if there is data on the number of diabetic patients that are being hospitalized. More money may be spent on the treatment of diabetic patients but if the results are saving hospitalizations, therapeutically, patients' lives are being enhanced.

Dr. Townsend replied that a report will be provided which looks at the number of patients with diabetes and trend over time if they were admitted. The reporting system will not be able to determine if the admitting diagnosis is for diabetes.

Dr. Townsend stated that there was a 65% increase in antihemophilic factors during the third quarter; she noted that there was a decrease in drug spend for this class during the second quarter. Payment in this class continually changes depending on the number of patients and events they experience. There are currently six patients that account for the fluctuation.

Dr. Townsend reviewed the report by claims volume. A claims query on skeletal muscle relaxants indicates that the number one drug accounting for the dollar volume in this class is carisoprodol (Soma®). The number of carisoprodol claims has increased by 600 since the first quarter of this year. The second highest drug spend in this class is cyclobenzaprine products with an average cost per claim currently at $291 compared to $134/claim in the first quarter.

Dr. Marx stated that Soma® has limited value, little efficacy and has a fair amount of diversion potential and he supports some type of edit.

Mr. Wuest suggested that a recommendation by this Board can be made to the Pharmacy and Therapeutics Committee (P&T) to non-prefer this drug or Magellan can further review the data and bring back recommendations to the DUR Board.

Mr. Lither stated that if formal direction is being asked of the Board, the item should be agendized on a future agenda and presented to the Board.

This item will be agendized for the next meeting.

b. Top 50 Drugs (by Payment and by Claims)

Paula - this report was not reviewed/discussed.

c. Program Trends

Dr. Townsend reported that total recipients continue to slowly increase. The current count is 85,767 versus 80,067 for this time period last year. Total utilizing recipients remain stable at 40%. Total claims indicate an increase of 116,671from 109,000 last year. The generic utilization rate remains steady at 75.3%.

v. Concurrent Drug Utilization Review (ProDUR)

a. Review of Q3 2010

Dr. Townsend reported that the number of alerts remain consistent with therapeutic duplication continuing to occupy the number one position in the number of alerts sent to pharmacies; drug to age edits second; drug-to-drug third. A report on drug to gender edits will be presented to the Board at the next meeting.

Dr. Steven Rubin joined the meeting at 1:22 p.m.
Keith Macdonald joined the meeting at 1:24 p.m.

vi. Retrospective Drug Utilization Review (RetroDUR) UPDATE

a. Review of Responses

Dr. Townsend reviewed the RetroDUR Letter Response Report by Response Code for second quarter 2010.

b. Status of Previous Quarter

Dr. Townsend reviewed the RetroDUR Summary Report of new reviews and re-review profile criteria and the number of profiles lettered for the second quarter of 2010.

c. Status of Current Quarter

Dr. Townsend reviewed the RetroDUR Summary Report of new reviews and re-review profile criteria for third quarter 2010 noting that this quarter is still in data collection mode.

d. Public Comment

No comment.

e. Discussion and Action by Board for Future Criterion Selection

Dr. Townsend asked if the Board has recommendations of criteria to run for future reporting.

Dr. Oesterman requested that with the new cautions regarding Avandia®, a report on the transition from the Avandia® product to the Actos® products. Dr. Townsend will provide a utilization report of the products with market shift data.

Dr. Oesterman suggested compliance with hypoglycemic regimens. He asked if there is access to information for patients with a diagnosis of diabetes getting annual medical exams and if there are preventative and prophylactic measures in place for these patients.

He felt that in addition to drug therapy, the overall health and welfare of the patients need to be taken into account. Dr. England and Dr. Marx agreed.

Mr. Wuest stated that the information is available and a report can be presented at a future meeting. He said that the diagnoses are inferred by other drugs that the patient is receiving. Criteria can be created through the RetroDUR process with lettering to the physician, however, the diagnosis in this process is through the pharmacy system and not the medical claims. He suggested that in terms of the carisoprodol, there are two criteria available 6402 (carisoprodol interacts with opioid analgesics) and 6396 (carisoprodol interacts with benzodiazepines) which the Board might consider for RetroDUR. The Board agreed. The criteria will be scheduled for the next two RetroDUR profile runs.

Mr. Lither stated that the board chairman can request reports or presentations at any time and asked why this agenda item is being presented as an action item to the Board. If specific guidance is needed from the Board, that needs to be an action item; a request to the chairman for what reports to run does not require Board action. The chairman can request information from the Division at any time; he controls the flow of information from the Division to the Board. Ms. Lawrence stated that this is not an action item.

vii. Presentation of Requested Report on Use of Anticonvulsants for Pain

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Use of Anticonvulsants for Pain

Dr. Townsend presented a report of claims with and without an ICD-9 for seizure disorder in the past year. Two queries were run to include patients with a diagnosis of seizure disorder and patients on a concomitant analgesic. 41% of claims were for patients with a diagnosis of epilepsy or convulsive disorder. 59% did not have an ICD-9 for seizure disorder. She presented a breakdown of the each drug within this class indicating the percentage of claims with or without a diagnosis. The listed drugs for the majority of claims were for recipients with no epilepsy or convulsive disorder to include gabapentin, topiramate, oxcarbazepine, pregabalin, lamotrigine, clonazepam and divalproex sodium. The total number of recipients taking an anticonvulsant with no seizure diagnosis was 6,034; 69% had at least one analgesic claim; 25% with concomitant use of analgesics (at least 60 day continuous use of analgesic with at least ten days of overlap with anticonvulsant). The report included all age groups.

Ms. Lawrence reminded the Board that a prior authorization is currently required for use of these medications in children under the age of 21. She suggested separating the report by age (21 and older).

Dr. Oesterman requested that the next report include Phenobarbital and data on recipients 21 and older versus under the age of 21.

Board action is not required.

viii. Presentation of Requested Report on Concomitant Use of Two Norepinephrine Serotonin Reuptake Inhibitor (NSRI) Drugs

a. Public Comment

Ronnie DePue, Forest Research Institute, stated that Forest supports the Savella® package insert. Co-administration of Savella® with other inhibitors of serotonin reuptake may result in hypertension and coronary artery vasoconstriction through additive serotonergic effects. Concomitant use of use of Savella® with other SSRIs, SNRIs or tryptophan is not recommended.

Dave England asked if there is peer supported literature available indicating these should be used together. Mr. DePue replied that he is not aware of any literature that supports the use of two SNRIs together.

b. Discussion and Action by Board on the Concomitant Use of Two Norepinephrine Serotonin Reuptake Inhibitor (NSRI) Drugs

Dr. Townsend reviewed the report presented to the Board of recipients with claims for more than one NSRI (reporting period 9/09 through 9/10). There were 1,535 recipients with claims for more than one NSRI. Eighteen of the recipients had overlap of greater than ten days. She presented data which indicates that no recipient received more than two NSRIs at the same time.

Dr. Oesterman asked if there is a flag in the pharmacy system when a second prescription is entered. Dr. Townsend stated the drug interaction database sends a message to the pharmacy. Dr. Coppola added that the messaging is part of the ProDUR process. The pharmacy can override the edit by entering an intervention code and the claim will process.

Dr. England felt that there is no rationale for concomitant use other than for transition; Dr. Rubin concurred. Dr. Rubin added that he has reservations why Savella®, Cymbalta® and Pristiq® are being utilized versus the generic version and why are they available on the formulary.

Ms. Lawrence stated that per federal law, drugs within the rebate program must be made available. She suggested that a duplicate edit can be put in place which allows for only one drug at a time or lettering to the physicians.

Dr. Rubin stated that there is no justification for dual agent use other than transition. He recommended lettering the physician if there is dual therapy and a database in Nevada to find out who the physicians are and if they have any affiliations with the manufacturers and incentives to prescribe these medications.

Dr. Rubin was excused from the meeting at 1:39 p.m.

Dr. Shea asked how the patients arrive at both drugs through the current system. Dave Wuest stated that this is a Severity Level 1 ProDUR edit which messages the pharmacy and can be overridden at the pharmacy level. The Board has approved use of two antidepressants when used for different indications by allowing an ICD-9 override or by the call center. An edit can be placed in the system to allow the first fill for transition and deny subsequent claims.

Dr. Oesterman stated that when a patient is prescribed one product and is switched to another, there's no issue. If there is ongoing concomitant therapy, have a system edit to flag that for prior authorization (PA).

Dr. Townsend clarified that this report does not include the diagnosis. It looks at claims where the recipient has received two drugs. The requirement for the ICD-9 to bypass the PA was not in effect during the reporting period. At the last meeting, the Board approved the PA criteria which require the ICD-9 on the prescription or a PA in order to obtain the drugs for their approved indication.

Ms. Lawrence stated that the Board could require a denial of the claim for prior authorization applying criteria for approval that transitional therapy will be approved; for non-transitional therapy, provide the diagnosis for each drug.

MOTION: **David England motioned that prior authorization will be required for use of two or more NSRIs. Approval will be given for**

transitional therapy; for ongoing use of two or more NSRI's, the prescriber will be required to provide a diagnosis for each drug.

Keith Macdonald asked to specify a time that transitional therapy should occur.
Dr. England stated thirty days and Dr. Oesterman concurred.
Dr. England accepted the amendment to the motion that transitional therapy will be thirty days.
SECOND: James Marx offered a second to the motion as amended.
Mr. Wuest expressed concern that the pharmacist and/or patient may not understand the denial when they attempt another fill thirty days following the initial fill of the transitional medication. A dialog will need to occur between the call center and prescriber that after the thirty day period, the transitional drug should be discontinued.
Dr. England asked if the ProDUR edit can send a message to the pharmacist asking if this is transition of therapy or additional therapy. Based on the pharmacist's response, if it's transitional, allow the thirty day leeway; if it's add-on therapy, deny the claim for a PA.
Mr. Wuest stated that research is needed to determine if the system is capable of that type of messaging and response.
Ms. Lawrence stated that the intent of the Board is clear; however, more research is needed regarding system limitations, etc., and offered to propose potential solutions at the next meeting.
The Board agreed.
Dave England rescinded the motion; James Marx accepted.

Dr. Oesterman stated that the proposal on how this process can be implemented will be on the agenda for the next meeting.

Dr. Rubin re-joined the meeting at 1:55 p.m.

ix. Presentation of Requested Report on Early Refill Requests for Controlled Drugs

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Early Refill Requests for Controlled Drugs

Dr. Townsend presented a report on early refill requests for controlled drugs. There were a total of 409 calls during the reporting period; 388 were approved. Increase in dose/titration was the number one reason for an early refill. The number of unique pharmacy providers was 167 indicating that there is no particular pharmacy requesting an early refill override. There was no evidence of repeated use of early refill for any one recipient.

Dr. Oesterman felt that a three month time span is relatively short and would like to expand the reporting period to at least six months in order to determine if there are repeat offenders and consider incorporating those recipients into the lock-in program.

Dr. Marx agreed and recommended reporting on an ongoing basis versus an interim review.

MOTION: James Marx motioned that early refill requests for controlled substances be reported on an ongoing basis.
SECOND: David England
VOTES: Unanimous
MOTION CARRIED

x. Proposed Quantity per Fill Limit Override Criteria for 5-HT3 Anti-Emetics

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of the Quantity per Fill Limit Override Criteria for 5-HT3 Anti-Emetics

Dr. Townsend stated that the serotonin receptor antagonists (5-HT3) drugs under antiemetics being considered today. The drugs in this class currently have a per fill quantity limit as outlined in the table presented. Two new products, granisetron transdermal patch and ondansetron dissolving film are not currently coded with a quantity limit. The proposed quantity limits for the new products are consistent with the quantity limits within the class (granisetron patch: 1 patch/fill = 7 day supply; ondansetron dissolving film 4mg = 12 films, 8mg = 6 films). The Call Center currently does not have criteria allowing a quantity limit override. Proposed criteria to approve additional medication beyond the quantity limits were presented. A PA to override the quantity limit will be effective for six months; the 34 maximum day supply will apply.

MOTION: James Marx motioned to accept the proposed criteria as presented.
SECOND: David England
VOTES: Unanimous
MOTION CARRIED

xi. Review of Existing Prior Approval Criteria for Proton Pump Inhibitors (PPIs)

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of Clinical Prior Authorization Criteria for Proton Pump Inhibitors (PPIs)

Dr. Townsend stated that at the last meeting, the COX-2 criteria were updated to include concomitant use of a PPI when COX-2s were used with aspirin including low-dose aspirin. The proposed PPI criteria presented has been updated to allow for that approval. The proposed criteria are consistent with the consensus document on reducing risk of antiplatelet therapy and non-steroidal anti-inflammatory (NSAID) use published in *Circulation* in 2008. The proposed criteria allows a PPI in patients that require both an NSAID (traditional or COX-2) and a cardio-protective dose of aspirin and in patients on anticoagulants (heparin, low-molecular weight heparin or warfarin) and aspirin.

MOTION: David England motioned to accept the proposed criteria as presented.
Dr. Marx offered a friendly amendment to move Barrett's Esophagus, which is listed under 1.c., Hypersecretory Conditions, to 1.e, Healing or Maintenance of Erosive Esophagitis which is more appropriate.
Dr. England accepted the friendly amendment.
SECOND: Keith Macdonald
Dr. Shea stated that data indicates that 82% of PA requests for PPIs are approved. Omeprazole and Nexium® are approved for approximately the same number of prescriptions for each drug (2,500). Both agents are on the Preferred Drug List (PDL). The drug spend for the last quarter for omeprazole was $8,000 and Nexium® was $250,000. There is a tremendous amount of labor and productivity lost in pursuing a PA when 82% are being approved. The cost is not only related to the drug, but the labor costs of the physician, pharmacist, call center, etc. He suggested removing the PA requirement for omeprazole and putting in step-therapy if there is a failure of omeprazole.
Dr. Oesterman reminded the Board that the PDL is outside of the DUR Board's jurisdiction.
Ms. Lawrence offered options for Board consideration. The DUR Board has the authority to implement step-therapy based upon clinical decisions not cost. The Board can request

a review of the overall cost which can be considered to improve the cost efficiency of the program. The Board has the option of modifying criteria to exclude certain drugs. Dr. Oesterman recommended that the Board take action on the proposed criteria and requested additional cost data and step-therapy recommendations be presented at the next meeting.

YEAS: England, Macdonald, Shea, Marx, Oesterman
NAYES: None
ABSTAIN: Rubin
MOTION CARRIED

Keith Macdonald stated that he agreed with Dr. Shea and the issue applies to other products as well. The concern about creating a bureaucratic type of criteria that creates a lot of work for people when there is only a 10%-15% result is worthwhile to consider and requested it be addressed at a future meeting.

Ms. Lawrence stated that a report will be presented at the next meeting.

xii. Proposed Prior Authorization Criteria for Colcrys® (colchicine)

a. Public Comment

Sarah Day, VCG & Associates, stated that she represents URL Pharma as a consultant speaking in support of Colcrys®. Prior to July, 2009, colchicine, as a single agent, had never been reviewed nor approved for marketing by the FDA. Colchicine was not reviewed under the drug efficacy study implementation or DESI program. It is not a grandfathered product or generic drug. In October, 2010, the Federal Register published that the FDA states that the manufacturer of an unapproved colchicine product must stop by 11/15/10 and distribution stopped by 12/31/10. Colcrys® is the only FDA-approved single agent colchicine. She referred to the AGREE trial (Acute Gout Flare Receiving Colchicine Evaluation) which demonstrated the efficacy and safety of Colcrys® and presented clinical information on the product. She asked the Board to consider Colcrys® for the PDL based on proven evidence of clinical safety and efficacy versus an unapproved drug with no evidence of safety or efficacy.

b. Discussion and Action by Board on the Review of Clinical Prior authorization Criteria for Colcrys® (colchicine)

Dr. Townsend clarified that proposed PA criteria for Colcrys® is being presented; Colcrys® is not being considered for the PDL at this time. Colchicine is an alkaloid indicated for acute gout flairs and familial Mediterranean fever (FMF). There are many single-use colchicine products that have been used for decades which physicians are familiar with. Between time of the FDA approval of Colcrys® and the FDA's ordering of the stop to marketing of the unapproved single ingredient oral colchicine, there has been pushback by various professional organizations; e.g., American Association of Rheumatology, etc., due to the extraordinary pricing of the branded colchicine compared to the older, unapproved colchicine product. The FDA decided that colchicine will be removed from the market and Colcrys® will be the only agent available. The approved dosing for acute gout is 1.2mg or two tablets at the first sign of a flair followed by 0.6mg or one tablet one hour later for a total of three 0.6mg tablets per course or treatment. Higher doses do not result in improved efficacy. There is no data comparing Colcrys® to other types of therapies for the treatment of acute gout. The proposed criteria are consistent with the product label. Authorization will be given 1) if there is a diagnosis of acute gout and the recipient has failed NSAID therapy or corticosteroids in the last 90 days, or 2) the recipient has a diagnosis of FMF. The proposed quantity limit for acute gout is six tablets which allows for two courses of therapy per month. Preventative therapy may be appropriate if there are more than two cases of acute gout per month. The proposed quantity limit for recipients with FMF is 120 tablets per 30 days. Claims data from the last quarter indicates a total of 143 claims and 83 recipients receiving colchicine with only one prescription for branded Colcrys® (#60) to date.

Mr. Wuest clarified that if a recipient presents at an emergency room, Colcrys® will be available without PA; criteria only applies to the products dispensed at a pharmacy.

Dr. Marx asked why approval is for one year other than for FMF. He felt an interval type approval is more appropriate. Dr. Townsend replied that one year is the standard PA length of approval which can be modified by the Board.

Dr. Oesterman referred to the package insert which states that for patients with renal impairment, the dose should not be used more than once every two weeks and for patients with hepatic impairment, it should not be used.

Ms. Lawrence suggested that the Board could consider a quantity limit versus a clinical PA.

Dr. Oesterman recommended that the Board take action on the proposed criteria. In the absence of any action, there is the risk of inappropriate quantity limits since the directions for the approved product, Colcrys®, are significantly different from the unapproved colchicine products used in the past.

MOTION: **Keith Macdonald motioned to accept the proposed criteria as presented.**
SECOND: **David England**
YEAS: **England, Macdonald, Shea, Marx, Oesterman**
NAYES: **Rubin**
MOTION CARRIED

Per the Board's request, additional data will be collected and presented for re-evaluation of the criteria at the April meeting.

xiii. Public Comment

No comment.

xiv. Date and Location of Next Meeting

The next meeting is scheduled for January 27, 2011, at the Las Vegas Chamber of Commerce with videoconferencing to the Magellan office in Reno.

xv. Adjourn

Chairman Oesterman adjourned the meeting at 3:16 p.m.