COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

REPORT TO THE HOUSE HEALTH AND ENVIRONMENT COMMITTEE, THE SENATE HEALTH AND HUMAN SERVICES COMMITTEE AND THE JOINT BUDGET COMMITTEE

ON

PHARMACY UTILIZATION PLAN FY 2011-12

DECEMBER 1, 2011

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INTRODUCTION

The Pharmacy Utilization Plan FY 2011-12 is required by 25.5-5-506(3)(b), C.R.S. (2011) as stated below.

> (b) The state department shall report to the Health and Human Services Committees for the House of Representatives and the Senate, or any successor committees, and the Joint Budget Committee no later than December 1, 2003, and each December 1 thereafter, on plan utilization mechanisms that have been implemented or that will be implemented by the state department, the time frames for implementation, the expected savings associated with each utilization mechanism, and any other information deemed appropriate by the health and human services committees, or any successor committees, or the Joint Budget Committee.

The Department of Health Care Policy and Financing (Department) continues to pursue reductions in pharmaceutical expenditures. The Department has implemented several utilization mechanisms to control costs while ensuring access to medications for clients who need them. These mechanisms include enforcing limits on certain drugs, placing prior authorization requirements on certain drugs, and selecting drug classes for the Preferred Drug List (PDL). The Department is also considering other utilization mechanisms to determine if they would result in cost avoidance.

The Drug Utilization Review (DUR) Board, established by the Department, reviews drug utilization issues and makes recommendations to the Department to ensure utilization of prescription drugs is appropriate and cost effective. The Department evaluates the issues identified by the DUR Board and implements utilization policies that are appropriate and will achieve cost savings. In addition, the Department has recently contracted with the University of Colorado School of Pharmacy to provide additional DUR analysis and make recommendations to the Department and the DUR Board. The Department will also continue to monitor monthly drug expenditures and provider/client utilization patterns.

In most cases, the Department analyzes the fiscal impact of the utilization control mechanisms by examining expenditure trends at the therapeutic class level. This captures substitution effects within drug classes, but does not always capture substitution effects between drug classes. The cost avoidance from the implementation of a prior authorization on specified drugs in a drug class may cause clients to shift to a substitute drug from a different therapeutic class instead of another drug in the same therapeutic class. The increase in the utilization for drugs in other therapeutic classes is not always measurable. This is seen with drug products having multiple approved uses, or in the instance of drugs which are prescribed off-label (for indications which are not approved by the Food and Drug Administration).

The savings and cost avoidance identified in this report that reduced FY 2010-11 expenditures are already reflected in the Department's forecasts and per capita trends for Medical Services

Premiums. Any further reduction to the Department's appropriation would double-count the impact of the pharmacy utilization plan.

DRUG REBATE DEVELOPMENTS

The Patient Protection and Affordable Care Act (PPACA), P.L. 111-148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, enacted on March 30, 2010, included changes to certain Medicaid drug rebate provisions. The changes required the Centers for Medicare and Medicaid Services (CMS) to modify their drug rebate systems. As a result, the CMS was not able to provide states with rebate data which the Department uses to calculate cost savings from January 1, 2010 to March 31, 2011. This had considerable impact on the Department's cost modeling for the pharmacy benefit during this timeframe. Going forward, this information has been made available and the ability to accurately measure cost avoidance has been restored.

In addition, the collection of supplemental drug rebates has decreased. The new rebate provisions of the PPACA have increased both the federally mandated rebate for many drugs and the federal share of collected rebates, such that the state does not benefit from the higher base rebate requirements. The formula for calculating supplemental rebates includes the federally mandated rebate. Consequently, as the amount of federal rebate for a drug increases, the amount of supplemental rebate owed to the Department decreases. Additionally, as drug manufacturers are required to pay additional federally mandated rebate (minimum of 23.1% for most branded products), they are less willing to extend additional rebate to states in supplemental rebate contracts. This development has shown an impact on the Department's overall PDL savings. As a result, the supplemental rebates collected by the Department for 2010-11 showed a decrease of 29% relative to FY 2009-10.

PLAN UTILIZATION MECHANISMS PREVIOUSLY IMPLEMENTED

In the sections that follow, the Department describes its estimates of the fiscal impact of utilization control mechanisms implemented in or prior to FY 2010-11. It is important to recognize that market factors the Department cannot account for in its analysis likely influence the fiscal impact achieved by the implementation of utilization control mechanisms. Factors may include the introduction of new drugs in the drug class, withdrawal of drugs from the market, new drugs in different drug classes that treat the same condition, or new studies regarding the effectiveness of the drug. This is particularly true for prior authorizations that were implemented more than a year ago. The Department does not believe it is possible to accurately predict the potential cost avoidance after a prior authorization has been implemented for more than a year.

Preferred Drug List

Governor Ritter signed Executive Order D 004 07 in January 2007 establishing a preferred drug list (PDL) program for Colorado Medicaid. The purpose of this program is to provide clinically appropriate medications to Medicaid clients while decreasing expenditures on pharmaceuticals. This involves selecting drugs based on safety, cost-effectiveness and clinical outcomes from classes of medications where there are multiple drug alternatives available. Since implementation

of the PDL, the majority of the Department's Pharmacy Utilization Plan has switched from individual drug prior authorization mechanisms to implementing drug classes on the PDL.

The PDL achieves savings by designating preferred drugs for which migration to a more cost-effective drug and/or collection of supplemental rebates from pharmaceutical manufacturers is possible. Supplemental rebates are rebates above the federally required minimum rebate level, which manufacturers offer to the Department in exchange for preferred status on the PDL. It is difficult to determine the exact amount of savings from the PDL that comes from supplemental rebates versus migration to preferred drugs for each drug class; however, the Department is able to provide aggregate level information. For FY 2010-11, the Department collected $3,322,507 in total supplemental rebates.

In some cases, the analysis indicates that supplemental rebates have not been enough to offset the increased utilization and price of the preferred drug. In these cases, the savings estimates are listed as negative values, indicating that the switch to a preferred drug has generated additional costs. For these few cases, the Department continues to evalutate utilization trends to determine the cause of the increase in utilization for the drugs. The method of analysis applied does not normalize for increases in caseload. It does, however, capture utilization shifts to other drugs, including higher cost newly released agents within the same drug class. It is important to note that the PDL is not a formulary. Any drug that meets the Federal requirements for a covered outpatient drug must have coverage available, and this coverage is included in the analysis.

The Department adds new drug classes to the PDL on a quarterly basis. Existing drug classes are re-evaluated yearly. In FY 2011-12 the Department is continuing to expand the PDL by adding two drug classes. For the purposes of this report, analysis has been done to determine the impact of PDL implementations on the following two years of utilization and expenditure. For the section that follows, cost avoidance has not been included beyond FY 2010-11 for PDL classes where implementation occurred more than two years ago.

PDL Classes Updated in FY 2010-11

With the maturity of the PDL, many classes have stabilized, thus limiting their capacity for additional savings. For the purpose of this report, PDL reporting will be limited to those classes which have been added or changed significantly, offering opportunity for cost avoidance.

Antidepressants – This class was implemented on January 1, 2010, achieving $372,133 in cost avoidance for FY 2009-10. Continued cost avoidance for FY 2010-11 is an estimated $390,282. Effective January 1, 2011, Lexapro and bupropion XL were no longer preferred agents. This generated an additional $426,503 in cost avoidance for a total of $816,785 in FY 2010-11. The estimated cost avoidance for FY 2011-12 for this class is $780,565.

Agents to Treat Multiple Sclerosis – This class was originally implemented April 1, 2010, achieving $159,873 in cost avoidance for FY 2009-10. The class was expanded on April 1, 2011, to include three additional agents: Copaxone, Ampyra and Gilenya. Costs for FY 2010-11 for this class increased by an estimated $153,726 between the original implementation and the class expansion. Consideration is being given to the Department's upcoming review of this class

to determine whether the change in cost avoidance is attributed to the policy change, or is due to increased utilization from caseload expansion. In addition, capturing the costs for three additional agents that were previously not considered part of this drug class may have had an impact on the cost avoidance analysis causing an underestimation of savings. Estimated costs for FY 2011-12 for this class under the current policy are $491,332.

Overactive Bladder Agents – This class was originally implemented October 1, 2010, achieving $121,178 in cost avoidance for FY 2010-11. The class was recently updated to include one branded product, Toviaz, as a preferred agent, and require trial of two preferred agents (previously only one trial was required) before the approval of a non-preferred agent. Estimated cost avoidance for this class is $181,766 in FY 2011-12.

Proton Pump Inhibitors (PPI) – This class has been part of the PDL since the initiation of the PDL. Effective April 2010, generic omeprazole capsules were added to the preferred products for this class. This change in policy was made possible by the Department's creation of a State Maximum Allowable Cost list, which bases costs of selected multiple source products on reported Colorado pharmacy acquisition costs. The cost avoidance of this policy for FY 2009-10 has been calculated at $527,571. Additionally, this change was responsible for $3,149,786 in cost avoidance for the PPI class in FY 2010-11. This cost avoidance resulted from a large migration of clients to generic omeprazole. Going forward, we expect this migration to keep expenditure down for this therapeutic class, however, future cost avoidance is unpredictable because it is unknown to what extent additional migration is possible.

Sedative Hypnotics – This class changed significantly in April 2010, when Ambien CR and Rozerem became non-preferred products. The estimated cost avoidance of this policy for FY 2009-10 is $97,830. Additionally, this class was responsible for $218,017 in cost avoidance for FY 2010-11.

Stimulants – This class was changed significantly in October 2010, when Vyvanse became a non-preferred product. The estimated cost avoidance of the Stimulant policy was $230,447 for FY 2010-11. Estimated cost avoidance for FY 2011-12 is $284,993.

Triptans – This class was most recently updated on January 1, 2010, when Maxalt tablets and generic sumatriptan nasal spray and injectable became non-preferred agents. The calculated cost avoidance for this class in FY 2009-10 was $178,357. An additional $101,790 was calculated as cost avoidance for FY 2010-11.

Growth Hormones – This class was most recently updated on April 1, 2010, when Omnitrope and Saizen became preferred products and Genotropin and Tev-Tropin were removed from the PDL. The estimated increase in costs for this class in FY 2009-10 was $145,282. An additional $1,021,176 in costs was estimated for FY 2010-11. Consideration is being given to our upcoming review of this class to determine whether the change in cost avoidance has been impacted by the policy change, or is due to increased utilization from caseload expansion. Additional analysis has shown that the cost per utilizer gross of rebate has remained constant since FY 2008-09 despite differences in acquisition cost. This indicates that the primary driver for the experienced increase in expenditure is caseload expansion.

Prior Authorizations Previously Implemented

The following approval criteria were maintained for Synagis:

A prior authorization can be approved if:

The medication will be administered in the client's home; the client must be under age 2 at the start of the current RSV season (as determined by the CDC); and the client must meet one of the following:

- Diagnosis of Chronic Lung Disease (CLD) and having one for more of the following clinical needs during the previous 6 months:
    - Supplemental oxygen;
    - Regular use of inhaled or oral bronchodilators;
    - Recent use of corticosteroid therapy; or
    - Regular or intermittent use of diuretics to treat pulmonary disease.

    **Up to five (5) monthly doses will be approved.*
- Diagnosis of Interstitial Lung Disease and/or Neuromuscular disease which impacts pulmonary function

    ** Up to five (5) monthly doses will be approved.*
- Any infant or child under the age of 2 who has a diagnosis of congenital heart disease and meets any of the following criteria:
    - Receiving medication to control congestive heart failure (diuretics, antihypertensives);
    - Suffer moderate to severe pulmonary hypertension; or
    - Suffer Cyanotic Heart Disease.

    ** Up to five (5) monthly doses will be approved.*
- Any infant up to 6 months of age, born 29 to less than 32 weeks gestation

    ** Up to five (5) monthly doses will be approved.*
- Any infant up to 12 months of age, born at 28 weeks or less gestation

    ** Up to five (5) monthly doses will be approved.*
- Any infant younger than 3 months of age at the start of the RSV season, born at 32 to less than 35 weeks gestation and meets one of the following risk factors:
    - Currently attends day care;
    - Has a sibling younger than 5 years of age;
    - Congenital abnormalities of the airway; or
    - A neuromuscular condition that compromises handling of respiratory secretions.

    **Up to three (3) monthly doses will be approved or until the child reaches 3 months of age.*
- Infants up to 2 years of age with hemodynamically significant heart disease defined as having one or more of the following:
    - Infants receiving medication to control congestive heart failure;
    - Infants with moderate to severe pulmonary hypertension; or
    - Infants with cyanotic heart disease.

** Up to five (5) monthly doses will be approved.*

FY 2010-11 estimated cost avoidance within this drug class: **$7,145,136**
FY 2011-12 estimated cost avoidance within this drug class: **$6,783,683**

The following criteria were added January 1, 2010, for Ultram ER:

A prior authorization will only be approved if a client has tried and failed on the maximum dose of tramadol (400mg per day) for a period of 3 or more months in the last six months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

The following criteria were added January 1, 2010, for Ryzolt:

A prior authorization will only be approved if a client has tried and failed on the maximum dose of tramadol (400mg per day) for a period of 3 or more months in the last six months. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

FY 2010-11 estimated cost avoidance for Ultram ER and Ryzolt: **$113,660**
FY 2011-12 estimated cost avoidance for Ultram ER and Ryzolt: **$101,434**

The following criteria were added January 1, 2010, for Veripred:

A prior authorization will only be approved if a client has tried and failed on a generic prednisolone drug. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

FY 2010-11 estimated cost avoidance for Veripred: **$154,914**
FY 2011-12 estimated cost avoidance for Veripred: **$247,435**

The following criteria were added January 1, 2010, for Flector Patch:

A prior authorization will only be approved if a client has tried and failed on VOLTAREN GEL. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

FY 2010-11 estimated cost avoidance for Flector Patch: **$448,011**
FY 2011-12 estimated cost avoidance for Flector Patch: **$854,142**

The following criteria were added January 1, 2010, for Vusion ointment:

A prior authorization will only be approved if a client has failed on an OTC antifungal and a generic prescription antifungal. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

FY 2010-11 estimated cost avoidance for Vusion ointment: **$39,910**
FY 2011-12 estimated cost avoidance for Vusion ointment: **$18,248**

The following criteria were added January 1, 2010, added for Requip XL:

A prior authorization will only be approved if a client has tried and failed on generic immediate-release ropinirole for a period of 3 or more months in the last 6 months and the client has a diagnosis of Parkinson's disease. (Failure is defined as: lack of efficacy, allergy, intolerable side effects or significant drug-drug interactions)

Grandfathering: Clients who have been previously stabilized on Requip XL can receive approval to continue on the medication for one year if medically necessary.

FY 2010-11 estimated cost avoidance for Requip XL: **$98,663**
FY 2011-12 estimated cost avoidance for Requip XL: **$100,512**

The following criteria were added January 1, 2011, for Infused Targeted Immune Modulators (TIMS):

Remicade (infliximab) will be approved for clients who are receiving the infusion in their home or in long-term care and who meet one of the following:

- clients with ulcerative colitis
- clients with rheumatoid arthritis who have tried and failed therapy with both Enbrel and Humira
- clients with psoriatic arthritis
- clients with ankylosing spondylitis
- clients with juvenile idiopathic arthritis
- clients with plaque psoriasis
- clients with Crohn's Disease

Orencia (abatacept) – will be approved for clients who are receiving the infusion in their home or in long-term care and who meet one of the following:

- Clients with moderate to severe rheumatoid arthritis who have failed therapy with both Enbrel and Humira
- Clients with moderate to severe juvenile idiopathic arthritis

Rituxan (rituximab) - will be approved for clients who are receiving the infusion in their home or in long-term care and who meet one of the following:

- Clients with moderate to severe rheumatoid arthritis who have tried and failed both Enbrel and Humira
- Clients with Chronic Lymphocytic Leukemia
- Clients with Non-Hodgkins Lymphoma

FY 2010-11 estimated cost avoidance for Infused TIMs: **$3,947**
FY 2011-12 estimated cost avoidance for Infused TIMs: **$16,470**

Total estimated cost avoidance for prior authorizations implemented:

FY 2010-11: **$8,000,293**

FY 2011-12: **$8,105,454**

PLAN UTILIZATION MECHANISMS TO BE IMPLEMENTED IN FY 2011-12

The Department's main focus will continue to be on adding classes and managing existing classes on the PDL. In addition, the Department will continue to monitor drug utilization, trends and safety information to determine if additional drugs should be placed on prior authorization.

The Department has contracted with the University of Colorado School of Pharmacy to provide utilization reporting, utilization analysis and DUR Board support. The claims analysis team at the School of Pharmacy will provide quarterly reporting on the top drugs by claims, by cost, by provider and by therapeutic class. They also will provide in-depth reports on identified problem areas for deeper analysis than currently available. The expert pharmacists offer clinical perspective and opportunities to ensure efficient utilization of the pharmacy benefit. The additional analysis will result in a marked increase in cost avoidance due to appropriate utilization prior authorization criteria.

Effective July 1, 2011

No new classes were added to the PDL this quarter; many of the previously implemented classes were reviewed and updated including Antihistamines, Antihypertensives, Opioids, Respiratory Inhalants, and Skeletal Muscle Relaxants. The cost avoidance for these classes is reflected in the previous section titled, "Plan Utilization Mechanisms Previously Implemented."

Effective October 1, 2011

No new classes were added to the PDL this quarter; many of the previously implemented classes were reviewed and updated including Bisphosphonates, Diabetes Management Classes, Erythropoiesis Stimulating Agents, Overactive Bladder Agents and Stimulants and ADHD Agents.

Effective January 1, 2012

The Department will add Antiplatelet Agents to the PDL January 1, 2012. Since this class has not been implemented with its selected preferred drugs at the time of this report, the estimated cost avoidance will be reported in the FY 2012-13 report. In addition, Antidepressants, Targeted Immune Modulators, Antiemetics, Proton Pump Inhibitors, Pulmonary Arteriole Hypertension

Therapies and Triptans were reviewed again for implementation on January 1, 2012. At this time, the updated PDL has not been approved. Cost avoidance will be reported in the FY 2012-13 report.

NEW PRIOR AUTHORIZATION CRITERIA IMPLEMENTED IN FY 2011-12

The following policies have been implemented to reduce future expenditures and ensure appropriate billing of services. Due to the lack of information available, we are unable to calculate a cost avoidance figure at this time. Analysis of the cost avoidance of the following will be included in the FY 2012-13 report.

Effective July 1, 2011

Benlysta (belimumab) - A prior authorization may be approved only when documentation has been received indicating that the drug is being administered in the client's home or long-term care facility. The client must also meet all of the following criteria:

- Diagnosis of autoantibody postitive SLE with organ involvement;
- Incomplete response to standard therapy from at least two of the following therapeutic classes: antimalarials, immunosuppressants and glucocorticoids;
- Maintenance of standard therapy while on Benlysta.

Horizant (gabapentin enacarbil) - A maximum of one tablet per day may be prior authorized for clients meeting all of the following criteria:

- Diagnosis of Restless Leg Syndrome;
- Therapy failure on at least a one month trial of Mirapex (pramipexole) and Requip (ropirinole);
- Incomplete therapeutic response to generic gabapentin.

Makena (hydroxyprogesterone caproate) - Makena will be approved for clients that meet all of the following criteria:

- The drug is being administered in the home or in long-term care setting;
- Client has a Singleton pregnancy and a history of singleton spontaneous preterm birth;
- Therapy is being initiated between 16 weeks gestation and 20 weeks, 6 days gestation;;
- Dose is administered by a healthcare professional; Compounded hydroxyprogesterone product is contraindicated.

Protease inhibitors for Hepatitis C - Protease inhibitors used to treat chronic hepatitis C will only be approved for clients meeting all of the following criteria:

- Age of 18 years or older;
- With confirmed Genotype 1A or 1B Chronic Hepatitis C with compensated liver disease (including cirrhosis);
- Concurrently taking both ribavirin and pegylated interferon compliant with product labeling;
  Following a negative pregnancy test (for women under 45 years);
  Not currently taking inducers of CYP 3A4/5 such as rifampin, rifabutin, phenytoin, carbamazepine or phenobarbital;

Manufacturer guidelines for response-guided therapy and treatment futility shall be followed. Viral loads must be taken per manufacturer guidelines and reported to the Colorado Medicaid manual PA review team.. Therapy will be limited to 12 weeks for Incivek ® (telaprevir) and 44 weeks for Victrelis ® (boceprevir). Failure to follow manufacturer guidelines or maintain compliance will result in discontinuation of prior authorization.

Newly Approved Products - Newly marketed drugs may be subject to prior authorization for a minimum of nine months following FDA marketing approval. Initial approval criteria will include non-preferred criteria (for drugs within a reviewed PDL class); or FDA approved indications, dose, age and place in therapy. For drugs in PDL classes, the next class annual review will include the new agent. For non-PDL drugs, criteria shall be reviewed at the quarterly DUR meeting closest to the nine month minimum.

Physician Administered Drugs - Medications given in a hospital, doctor's office or dialysis unit are only to be billed directly by those facilities as a medical item. IV Fluids, meds, etc. may be billed by the pharmacy when given in a long-term care facility or by home infusion following prior authorization approval. Prior authorizations will be approved based upon documentation of the location for administration.

CONCLUSION

The Department has implemented a number of drug utilization mechanisms to control costs such as adding classes to the PDL and requiring prior authorizations for drugs. In most sections of this report, the Department identifies the utilization mechanisms that have been implemented to generate cost avoidances to a specific prescription drug class, rather than attempting to identify a savings to the overall Department's pharmaceutical budget. Some mechanisms to control costs involve certain restrictions on drugs while others involve obtaining supplemental rebates from manufacturers for individual drugs. A summary of the estimated cost avoidances by drug class realized from these mechanisms is listed below. Please note that cost avoidance has been reported for classes that have been recently implemented or updated. Drug classes without significant change may still contribute to cost avoidance through Supplemental Rebate.

Table 1: Summary of Savings Achieved through Utilization Control Mechanisms

Utilization Control Mechanism	FY 2010-11	FY 2011-12
Preferred Drug List Updates	$3,505,625	$424,528
Prior Authorization Policy	$8,004,241	$8,105,454
Total	**$11,509,866**	**$8,529,982**

Table 2: Preferred Drug List Savings by Drug Class

Drug Class	FY 2010-11	FY 2011-12[(1)]
Antidepressants	$816,785	$780,565
Agents to Treat Multiple Sclerosis	($153,726)	($491,332)
Overactive Bladder Agents	$121,178	$181,766
Proton Pump Inhibitors	$3,149,786	N/A
Sedative Hypnotics	$218,017	N/A
Stimulants	$230,447	$284,993
Triptans	$101,790	N/A
Growth Hormones	($1,021,176)	N/A
Atypical Antipsychotics	$32,563	($331,464)
Alzheimer's Agents	$9,961	N/A
Total Preferred Drug List Update Savings	**$3,505,625**	**$424,528**

Note: Totals in parenthesis indicate increased costs.
1) N/A is listed for policy that is unchanged for greater than 2 years.

Table 3: Prior Authorization Policy Savings by Drug

Drug Class	FY 2010-11	FY 2011-12[(1)]
Synagis	$7,145,136	$6,783,683
Ultram ER and Ryzolt	$113,660	$101,434
Veripred	$154,914	$247,435
Flector 1.3% Patch	$448,011	$854,142
Vusion Ointment	$39,910	$18,248
Requip XL	$98,663	$100,512
Infused Targeted Immune Modulators	$3,947	N/A
Total Prior Authorization Savings	**$8,004,241**	**$8,105,454**

1) N/A is listed for policy that is unchanged for greater than 2 years.