COLORADO DEPARTMENT OF HEALTH CARE POLICY & FINANCING

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John W. Hickenlooper, Governor • Susan E. Birch MBA, BSN, RN, Executive Director

December 1, 2012

The Honorable Pat Steadman, Chair
Joint Budget Committee
200 East 14th Avenue, Third Floor
Denver, CO 80203

Dear Senator Steadman:

Enclosed please find a legislative report to the Joint Budget Committee on the Department of Health Care Policy and Financing's (Department) Pharmacy Utilization Plan FY 12-13.

C.R.S. § 25.5-5-506(3)(b) (2006) requires the Department to provide the Pharmacy Utilization Plan on an annual basis to the General Assembly.

The Pharmacy Utilization Plan describes the drug utilization mechanisms implemented by the Department and the estimated savings generated by those mechanisms.

If you require further information or have additional questions, please contact the Department's Legislative Liaison, MaryKathryn Hurd, at MK.Hurd@state.co.us or 303-547-8494.

Sincerely,

Susan E. Birch, MBA, BSN, RN
Executive Director

SEB/jl

Enclosure(s) 2012 Pharmacy Utilization Plan

Cc: Representative Claire Levy, Vice-Chair, Joint Budget Committee
Representative Crisanta Duran, Joint Budget Committee
Representative Cheri Gerou, Joint Budget Committee
Senator Mary Hodge, Joint Budget Committee
Senator Kent Lambert, Joint Budget Committee
John Ziegler, Staff Director, JBC
Kevin Neimond, JBC Staff
Eric Kurtz, JBC Analyst
Henry Sobanet, Director, Office of State Planning and Budgeting
Erick Scheminske, Deputy Director, Office of State Planning and Budgeting
Bettina Schneider, Budget Analyst, Office of State Planning and Budgeting
Katherine Blair, Health Policy Advisor, Governor's Office
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Lorez Meinhold, Community Partnerships Office Director
Tom Massey, Policy and Communications Office Director
MaryKathryn Hurd, Legislative Liaison

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 2012-13

DECEMBER 1, 2012

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INTRODUCTION

The Pharmacy Utilization Plan FY 2012-13 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. These mechanisms include enforcing limits on specific drugs, placing prior authorization requirements on specific 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 2011-12 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.

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 2011-12. It is important to recognize that market factors the Department cannot account for 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 2011-12, the Department collected $5,006,447 in total supplemental rebates.

Typically, the majority of savings from a new PDL class are realized within the first one to two years of implementation. Each class is reviewed annually to take into consideration clinical updates and additional opportunities for cost-avoidance, but once the initial cost-avoidance has been realized through proper drug class management, significant additional savings can only occur when new rebate opportunities or new generic alternatives become available. 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 captures utilization shifts between drugs, and it compares utilization and cost differences prior to implementation to those of the class following the change in policy. This sort of comparison can be negatively influenced when new, high-cost products are introduced within an established PDL class. The demand for the product and the use of the new product may increase compared to the pre-policy utilization because of increased availability and/or marketing. If the new

product is treated as non-preferred, the utilization will be restricted by prior authorization criteria usually resulting in lower utilization. If however, the pre-policy utilization was low or non-existent, any increased utilization will result in a reported cost. 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 2012-13 the Department is continuing to expand the PDL by adding three new 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 2011-12 for PDL classes where implementation occurred more than two years ago.

PDL Classes Updated in FY 2011-12

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.

Antiplatelet Agents – This class was originally implemented January 1, 2012, achieving $27,525 in cost-avoidance for FY 2011-12.

Agents to Treat Multiple Sclerosis – This class was originally implemented April 1, 2010, achieving $159,873 in cost avoidance for FY 2009-10. It was expanded on April 1, 2011, to include three additional agents: Copaxone®, Ampyra® and Gilenya™. In FY 2011-12 this class was responsible for $493,852 in cost-avoidance.

Newer Diabetic Agents – This class was originally implemented April 1, 2010, achieving $11,627 in cost avoidance for FY 2011-12. Major changes to this class included the addition of Tradjenta® and a required prior trial of (or documented contraindication to) metformin therapy before initiation of therapy. In FY 2011-12 this class was responsible for $2,340 in cost-avoidance.

Overactive Bladder Agents – This class was originally implemented October 1, 2010. During FY 2011-12, this class was associated with an overall cost of $4,196. 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.

Stimulants – This class was changed significantly in October 2011, when Strattera® became a preferred product. The estimated cost-avoidance for the Stimulant policy was $1,454,287 during FY 2011-12.

Targeted Immune Modulators – This class was originally implemented January 1, 2011. During FY 2011-12, this class was associated with an overall cost of $21,993. There have been no major changes to this class. Further analysis on class wide cost increases is being conducted.

Topical Immunomodulators – This class was originally implemented July 1, 2011. For FY 2011-12, this class had an estimated cost of $4,456. There have been no major changes to this class.

The overall cost-avoidance savings for FY 2011-12 is $1,947,359. Similar savings are expected in FY 2012-13 for drugs currently on the PDL, as utilization after the first year is not expected to change significantly.

Prior Authorizations Previously Implemented

Synagis® (palivizumab) – The prior authorization criteria for Synagis® have remained largely the same dating back to FY 2009-10. Past estimates of cost savings have been based upon projected utilization increases found prior to the implementation of the current criteria. Considering that the criteria have been in effect for over two years, a more conservative comparison was conducted this year using utilization trends present following the implementation in FY 2009-10. In FY 2011-2012, a shift was made which required that the review of Synagis® prior authorizations for medical necessity be conducted internally by the Department's clinical staff. Under this internal review, additional cost-avoidance was created compared to the previous year expenditure under the same criteria.

FY 2011-12 estimated cost-avoidance with Synagis®: **$1,527,013**
FY 2012-13 estimated cost-avoidance with Synagis®: **$937,558**

The following criteria were added July 1, 2011:

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, 6six days gestation;
- Dose is administered by a health care professional;
- Compounded hydroxyprogesterone product is contraindicated.

FY 2011-12 estimated cost-avoidance for Makena™: **$19,484**
FY 2012-13 estimated cost-avoidance for Makena™: **$354,445**

The following criteria were added 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 positive 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.

The criteria set for these products were implemented to encourage appropriate utilization. Both products had been introduced to the market only briefly before implementation of criteria. The extremely limited utilization of these products both before and after implementation of prior authorization demonstrates successful utilization management, but it does not allow for a calculation of cost-avoidance.

The following criteria were added July 1, 2011:

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.

  FY 2011-12 estimated cost-avoidance for Protease Inhibitors (Hepatitis C): **$737,514**
  FY 2012-13 estimated cost-avoidance for Protease Inhibitors (Hepatitis C): **$2,953,184**

The following criteria were added January 15, 2012:

Low-dose quetiapine – Low-dose quetiapine (<150mg/day) is only FDA approved as part of a drug titration schedule to aid patients in getting to the target quetiapine dose. Prior authorization will be required for quetiapine doses of < 150mg per day for longer than 30

days, except for utilization (when appropriate) in clients age 65 years or older. This criteria was created to reduce off-label utilization of the antipsychotic quetiapine.

FY 2011-12 estimated cost-avoidance for low-dose quetiapine restriction: $698,900
FY 2012-13 estimated cost-avoidance for low-dose quetiapine restriction: $985,666

The following criteria were added May 1, 2012:

Pregabalin appropriate dosing – For clients with no epilepsy diagnosis in the last two years (as confirmed by SMART PA), Prior Authorization will be required for pregabalin prescriptions requiring more than 3 capsules per day or for prescriptions requiring doses greater than 600mg per day. This rule encourages appropriate dosing of pregabalin by restricting the utilization to FDA approved levels. Drug utilization review had identified an issue with dosing pregabalin six or more times daily at significant cost to the Department.

FY 2011-12 estimated cost-avoidance for pregabalin dosing restriction: $36,888
FY 2012-13 estimated cost-avoidance for pregabalin dosing restriction: $23,541

Total estimated cost-avoidance for prior authorizations implemented:

FY 2011-12: $3,019,799

FY 2012-13: $5,254,394

PLAN UTILIZATION MECHANISMS TO BE IMPLEMENTED IN FY 2012-13

The Department's focus will continue to be split between adding/managing PDL classes, educating providers regarding updates and monitoring plan utilization while implementing criteria to support safe, appropriate and cost-effective use of drug products.

The Department's DUR contractor, the University of Colorado School of Pharmacy, continues to provide high quality utilization and clinical recommendations to guide policy decisions. The claims analysis team at the School of Pharmacy provides quarterly reporting on the top drugs by claims, by cost, by provider and by therapeutic class. They also provide in-depth reports on identified problem areas for deeper analysis than currently available. In-depth analysis for FY 2011-12 included Atypical Antipsychotic utilization and Proton Pump Inhibitor utilization. The expert pharmacists offer clinical perspective and opportunities to ensure efficient utilization of the pharmacy benefit. Another focus for this group is provider education. The team has been active in creating quarterly newsletters for medical and pharmacy providers which emphasize new drugs, FDA alerts and Medicaid plan updates. In FY 2012-13, the team plans to implement active learning applications to better inform Colorado Medicaid providers.

Effective July 1, 2012

The Fibromyalgia Agents were added to the PDL July 1, 2012. At the time of this report, the estimated cost-avoidance for this class is not available. This figure will be reported in the report for FY 2013-14. Previously implemented classes were reviewed and updated including Antihistamines, Antihypertensives, Opioids, Respiratory Inhalants, Topical Immunomodulators and Skeletal Muscle Relaxants. The policies for the previously implemented classes have been stable for more than two years. Cost-avoidance for these classes has been scored in prior years, and the classes are being maintained and reviewed for significant new clinical findings or newly available agents.

Effective October 1, 2012

The Protease Inhibitors for Hepatitis C were added to the PDL October 1, 2012. At the time of this report, the estimated cost avoidance for this class is not available. This figure will be reported in the FY 2013-14. Previously implemented classes were reviewed and updated including Bisphosphonates, Diabetes Management Classes, Erythropoiesis Stimulating Agents, Overactive Bladder Agents and Stimulants and ADHD Agents. The policies for the previously implemented classes have been stable for more than two years. Cost-avoidance for these classes has been scored in prior years, and the classes are being maintained and reviewed for significant new clinical findings or newly available agents.

Effective January 1, 2013

The Department will add Pancreatic Enzymes to the PDL January 1, 2013. 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 2013-14 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, 2013. At this time, the updated PDL has not been approved. Cost-avoidance will be reported in the report for FY 2013-14.

NEW PRIOR AUTHORIZATION CRITERIA IMPLEMENTED IN FY 2012-13

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 estimate at this time. Analysis of the cost-avoidance of the following will be included in the FY 2013-14 report.

Effective July 1, 2012

Kalydeco™ (ivacaftor) will only be approved if all of the following criteria are met:

1. Client has been diagnosed with cystic fibrosis AND

2. Client is an adult or pediatric patient 6 years of age or older AND

3. Documentation has been provided to indicate a G551D mutation in the CFTR gene AND

4. Documentation has been provided that baseline ALT and AST have been accessed and are within 2x normal limits (AST and ALT should be examined every 3 months for the first year and annually after that).

Kalydeco™ will only be approved at doses no more than 150 mg twice daily. Prior authorizations need to be obtained yearly.

Kalydeco™ will not be approved for clients who are concurrently receiving rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, or St. John's Wort.

Effective October 1, 2012

Belviq® (lorcaserin HCl) and Qsymia™ (phenteramine and topiramate extended release) were added to Appendix P as non-covered medications because they are weight loss agents.

PDL Stimulant and ADHD criteria – The following criteria were added:

For beneficiaries with ADD/ADHD or narcolepsy warranting treatment with a stimulant or non-stimulant agent (either preferred or non-preferred), a diagnosis of ADD/ADHD or narcolepsy must be documented in the beneficiaries medical record at the time of diagnosis and annually thereafter.

For patients with ADD/ADHD, prior to receiving pharmacotherapy, the beneficiary must have additional documentation through a validated ADHD/ADD instrument.

For beneficiaries with ADD/ADHD who are currently receiving a stimulant or non-stimulant without a documented diagnosis of ADD/ADHD, the beneficiary will have six months to obtain a diagnosis otherwise the medication will be discontinued.

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 is listed below. Please note that cost-avoidance has been reported for relevant classes that have been recently implemented or updated. Drug classes without significant change may still contribute to overall cost-avoidance because of the Supplemental Rebate contracting process.

Total Supplemental Rebates Collected	**$5,006,447**

Table 1: Summary of Savings Achieved through Utilization Control Mechanisms

Utilization Control Mechanism	FY 2011-12	FY 2012-13
Preferred Drug List Updates	$1,947,359	Not Available
Prior Authorization Policy	$3,019,799	$5,254,394
Total	**$4,967,158**	**$5,254,394**

Table 2: Preferred Drug List Savings by Drug Class

Drug Class	FY 2011-12
Antiplatelets	$27,525
Agents to Treat Multiple Sclerosis	$493,852
Overactive Bladder Agents	($4,196)
Stimulants	$1,454,287
Targeted Immune Modulators	($21,993)
Newer Diabetic Agents	$11,627
Total Preferred Drug List Update Savings	**$1,961,102**

Table 3: Prior Authorization Policy Savings by Drug

Drug Class	FY 2011-12	FY 2012-13
Synagis	$1,527,013	$937,558
Makena	$19,484	$354,445
Protease Inhibitors for Hepatitis C	$737,514	$2,953,184
Low-dose quetiapine	$698,900	$985,666
Dose restriction pregabalin	$36,888	$23,541
Total Prior Authorization Savings	**$3,019,799**	**$5,254,394**