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, 2013

The Honorable Irene Aguilar, Chair
Health and Human Services Committee
200 E. Colfax Avenue
Denver, CO 80203

Dear Senator Aguilar:

Enclosed please find a legislative report to the Senate Health and Human Services Committee on the Department of Health Care Policy and Financing's (Department) Pharmacy Utilization Plan FY 13-14.

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 mkhurd@hcpf.state.co.us or 303-866-2620.

Sincerely,

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

SEB/rl

Enclosure(s)

Cc: Senator Linda Newell, Vice-Chair, Health and Human Services Committee
Senator Jeanne Nicholson, Health and Human Services Committee
Senator John Kefalas, Health and Human Services Committee
Senator Owen Hill, Health and Human Services Committee
Senator Kevin Lundberg, Health and Human Services Committee
Senator Larry Crowder, Health and Human Services Committee
Dave De Novellis, Health and Human Services Committee Staff
Bettina Schneider, Budget Analyst, Office of State Planning and Budgeting
Katherine Blair, Health Policy Advisor, Governor's Office
Legislative Council Library
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Susan E. Birch, MBA, BSN, RN, Executive Director
John Bartholomew, Finance Office Director
Suzanne Brennan, Health Programs Office Director
Antoinette Taranto, Acting Client Services Eligibility & Enrollment Office Director
Lorez Meinhold, Community Partnerships Office Director
Tom Massey, Policy and Communications Office Director
MaryKathryn Hurd, Legislative Liaison
Rachel Reiter, Communications Director

COLORADO DEPARTMENT OF HEALTH CARE POLICY AND FINANCING

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

ON

PHARMACY UTILIZATION PLAN FY 2013-14

DECEMBER 1, 2013

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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 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 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 2012-13 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 2012-13. 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 2012-13, the Department collected $8,220,188 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 evaluate 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 2013-14 the Department is continuing to expand the PDL by adding several 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 2012-13 for PDL classes where implementation occurred more than two years ago.

PDL Classes Updated in FY 2012-13

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. The estimated savings for FY 2012-13 totals $280,876.

Agents to Treat Multiple Sclerosis – This class was originally implemented April 1, 2010. It was expanded on April 1, 2011, to include three additional agents: Copaxone, Ampyra and Gilenya. During FY 2012-13 the agent Tecfidera was added. This class is always updated on the first of April, and so the estimated savings for the majority of FY 2012-13 total $1,286,837. The period from 4/1/2013 through 6/30/2013 showed an increase in spending. Upon further analysis, the cost increase seen in our figures reflects the high cost of select non-preferred products to our program. Due to the nature of this disease and the increasingly high demand for newer oral therapies, this is a class that will continue to grow. The total costs for FY 2012-13 for this class have been calculated to show estimated savings of $1,182,455.

Stimulants – This class was not changed significantly, however our criteria is shifting patients away from the more expensive products. The estimated cost savings from the stimulant class for FY 2012-13 was $1,889,367.

Fibromyalgia Agents – This class was originally implemented July 1, 2012. This class is slightly harder to assess the savings of the addition to the PDL. The reason is that some of these agents are used in multiple areas of medicine. Nonetheless, the estimated savings for FY 2012-13 was $88,654.

Topical Immunomodulators – This class was originally implemented July 1, 2011. For FY 2011-12, this class had an estimated cost of $4,456. Both agents in this class have been limited in terms of utilization and our estimated cost savings for FY 2012-13 was $32,406.

Pancreatic Enzymes – This class was originally implemented January 1, 2013. This class in FY 2012-13 had an estimated cost of $17,345. Since this class was only added to the PDL at the beginning of 2013, we anticipate more cost savings for FY 2013-14.

Protease Inhibitors for Hepatitis C – This class was originally implemented October 1, 2012. The estimated cost savings for FY 2012-13 was $578,095.

The overall cost avoidance savings for FY 2012-13 is $4,034,509.

Prior Authorizations Previously Implemented

Synagis® (palivizumab) – The prior authorization criteria for Synagis® have remained largely the same dating back to 2009-2010. 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 three years, a more conservative comparison was conducted this year using utilization trends. Having this criteria in place for this extremely expensive drug continues to save money.

FY 2012-13 estimated cost avoidance with Synagis®: **$800,247**
FY 2013-14 estimated cost avoidance with Synagis®: **$904,688**

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

There continues to be a lot of controversy about the compounded form of this medication. There is still not any available data to show benefit of this product when compared to the compounded hydroxyprogesterone. Due to the fact that this criteria directs patients towards the compounded product that is much less expensive, we continue to see savings.

FY 2012-13 estimated cost avoidance for Makena™: **$609,980**
FY 2013-14 estimated cost avoidance for Makena™: **$1,746,913**

The following criteria were added October 1, 2012:

Belviq™ and Qysmia™ are both weight loss agents that we have chosen to not cover. We placed criteria on these agents to not cover them. 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 October 1, 2012:

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.
- Incivek® (telaprevir) will only be approved for a patient who has a contraindication to Victrelis™ (boceprevir).

FY 2012-13 estimated cost avoidance for Protease Inhibitors: $1,945,231
FY 2013-14 estimated cost avoidance for Protease Inhibitors: $2,725,668

The following criteria were added April 1, 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 2012-13 estimated cost avoidance for low-dose quetiapine restriction: $450,333
FY 2013-14 estimated cost avoidance for low-dose quetiapine restriction: $52,441

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 LYRICA prescriptions requiring more than 3 capsules per day or for prescriptions requiring doses greater than 600mg per day. This was implemented at the very end of FY 2011-12, and so the cost was tracked for FY 2012-2013. The cost for this medication has gone up over the past year without a definitive explanation. Utilization of this drug has increased for the Medicaid clients.

FY 2011-12 estimated cost for pregabalin: $142,572
FY 2012-13 estimated cost for pregabalin: $467,905

The following criteria were added January 1, 2013:

Quantity limits were placed on several asthma medications at this time. Specific agents that were determined to need limits as per the DUR board are as follows: Asmanex, Flovent, Rhinocort and Veramyst inhalers.

FY 2012-13 estimated cost avoidance for asthma quantity limits: $240,690
FY 2013-14 estimated cost avoidance for asthma quantity limits: $178,794

The following criteria were added January 1, 2013:

Beginning January 1, 2013, benzodiazepines will no longer be a benefit for Medicare-Medicaid enrollees (dual-eligible clients). The drug is no longer excluded from Medicare part D coverage, and thus must be billed to Medicare part D.

FY 2012-13 estimated cost avoidance for benzodiazepine restriction: $269,156
FY 2013-14 estimated cost avoidance for benzodiazepine restriction: $299,835

The following criteria were added April 1, 2013:

Beginning January 1, 2013, criteria was implemented to make sure that atypical antipsychotics for patients under the age of 18 are being used appropriately. The criteria is specific to keep children and adolescents only using appropriate medications that have been FDA approved for what is being treated.

FY 2012-13 estimated cost avoidance for antipsychotic age limits: $26,246
FY 2013-14 estimated cost avoidance for antipsychotic age limits: $756,370

The following criteria were added April 1, 2013:

A new oral agent for Multiple Sclerosis (MS) was given prior authorization criteria, and this agent was Tecfidera. Since this agent has been released, utilization has been increasing. This is showing an increase in spending on MS therapies. There is no cost avoidance in this area due to the fact that the new oral therapies available are much more expensive than the agents that have historically been used to treat MS. The Department is looking into ways to manage the costs for MS.

FY 2012-13 estimated cost for MS agents: $101,154
FY 2013-14 estimated cost for MS agents: $1,179,218

Total estimated cost avoidance for prior authorizations implemented:

FY 2011-12: $2,847,556

FY 2012-13: $4,112,898

PLAN UTILIZATION MECHANISMS TO BE IMPLEMENTED IN FY 2013-14

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 FY2012-13 included Atypical Antipsychotic utilization for mood disorders and depression, Proton Pump Inhibitor utilization, Psychotropic medication use in foster care children and some cost savings analyses. The expert pharmacists offer clinical perspective and opportunities to ensure efficient utilization of the pharmacy benefit. Another focus for this group is provider education, which the group is working more on putting out educational pieces that correspond with each in depth analysis. 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 2013-14, the team plans to implement active learning applications to better inform Colorado Medicaid providers. The Department is also working with the School of Pharmacy to get some practicing physicians and psychiatrists to help with consults to other providers with difficult prescribing cases.

Effective July 1, 2013

There were not any new classes added to the PDL at this time. Many of the previously implemented classes were reviewed and updated including Antihistamines, Antihypertensives, Opioids, Respiratory Inhalants, Topical Immunomodulators and Skeletal Muscle Relaxants. The policy for the previously implemented classes has 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. At this time, the Department and the School of Pharmacy are working on interventions to implement in the Opioid classes. This will help to decrease the overutilization of the opioid classes in the State of Colorado. The cost savings will be reportable in the report next year.

Effective October 1, 2013

The Oral Anticoagulants were added to the PDL on October 1, 2013. At the time of this report, the estimated cost avoidance for this class is not available. This figure will be reported in the FY 2014-2015. 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. The policy for the previously implemented classes has 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. The Protease Inhibitors for Hepatitis C were reviewed for a second time this year, and the criteria was the same. The cost avoidance is reported previously in this report.

Effective January 1, 2014

The Department will add Oral Fluoroquinolones and Oral Antiherpetic Agents to the PDL January 1, 2014. 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 2014-15 report. In addition, Pancreatic Enzymes, Antidepressants, Targeted Immune Modulators, Antiemetics, Proton Pump Inhibitors, Pulmonary Arteriole Hypertension Therapies and Triptans were reviewed again for implementation on January 1, 2014. At this time, the updated PDL has not been approved. Cost avoidance will be reported in the FY 2014-15 report.

NEW PRIOR AUTHORIZATION CRITERIA IMPLEMENTED IN FY 2013-14

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 2014-15 report.

Effective July 1, 2013

Raviciti (glycerol phenylbutyrate) will only be approved for clients meeting the following criteria:

- Client must be 2 years of age or older
- Client must have a documented diagnosis of urea cycle disorder (UCD)
- Client must be on a dietary protein restriction (verified by supporting documentation)
- Client must have tried and failed Buphenyl as evidenced by uncontrolled hyperammonia over the past 365 days
- Medication must be prescribed by a physician experienced in the management of UCD (e.g., geneticist)

Quantity Limits for Colcrys (colchicine):

- Chronic hyperuricemia/gout prophylaxis: 60 tables per 30 days
- Familial Mediterranean Fever: 120 tablets per 30 days

Effective October 1, 2013

Provigil (modafinil):

- Provigil will only be approved for the following diagnoses: narcolepsy, obstructive sleep apnea/hypopnea syndrome, shift work sleep disorder, multiple sclerosis related fatigue, ADHD and traumatic brain injury

Zubsolv (buprenorphine and naloxone sublingual tablet) will be approved if all the following criteria are met:

- Approval will be granted if prescriber meets the qualification criteria under Drug Additional Treatment Act (DATA) of 2000 and has been issued a unique DEA identification number by the DEA, indicating that he or she is qualified under the DATA to prescribe Subutex or Suboxone **AND**
- The client has a diagnosis of opioid dependence **AND**
- The client is 16 years of age or older **AND**
- No claims data show concomitant use of opiates in the preceding 30 days **AND**
- The client must have tried and failed, intolerant to, or has a contraindication to generic buprenorphine/naloxone SL tablets.

Procysbi (cysteamine bitatrate) will be approved if all the following criteria are met:

- Approval will be granted if the client is 6 years of age or older **AND**
- Has a diagnosis of neuropathic cystinosis **AND**
- Documentation is provided to the Department that treatment with cysteamine IR (Cystagon®) was ineffective, not tolerated, or is contraindicated.

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. The methodology for calculating the PDL associated savings has changed in FY 2012-13, and this has made it more difficult to calculate the projected cost avoidance for the future; therefore, the tables do not show estimated PDL cost avoidance for FY 2013-14.

Total Supplemental Rebates Collected	**$8,220,188**

Table 1: Summary of Savings Achieved through Utilization Control Mechanisms

Utilization Control Mechanism	**FY 2012-13**	**FY 2013-14**
Preferred Drug List Updates	$4,034,509	Not Available
Prior Authorization Policy	$2,847,556	$4,112,898
Total	**$6,882,065**	**$4,112,898**

Table 2: Preferred Drug List Savings by Drug Class		
Drug Class	**FY 2012-13**	**FY 2013-14**
Antiplatelets	$280,876	N/A
Agents to Treat Multiple Sclerosis	$1,182,455	N/A
Fibromyalgia Agents	$88,654	N/A
Stimulants	$1,889,367	N/A
Pancreatic Enzymes	-$17,345	N/A
Protease Inhibitors for Hep C	$578,095	N/A
Topical Immunomodulators	$32,406	N/A
Total Preferred Drug List Update Savings	**$4,034,509**	N/A

Table 3: Prior Authorization Policy Savings by Drug		
Drug Class	**FY 2012-13**	**FY 2013-14**
Synagis	$800,247	$904,688
Makena	$609,980	$1,746,913
Protease Inhibitors for Hepatitis C	$1,945,231	$2,725,668
Low-dose quetiapine	$450,333	$52,441
Dose restriction pregabalin	-$142,572	-$467,905
Belviq & Qysmia	N/A	N/A
Asthma Medication Limits	$240,690	$178,794
Benzodiazepine restrictions	$269,136	$299,835
Antipsychotic age limits	$26,246	$756,370
MS Agents (Tecfidera)	-$101,154	-$1,179,218
Total Prior Authorization Savings	**$ 2,847,556**	**$ 4,112,898**