STATE OF COLORADO

DEPARTMENT OF HEALTH CARE POLICY & FINANCING

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Karen Reinertson
Executive Director

December 1, 2003

The Honorable Steve Johnson, Chairman
Senate HEWI Committee
State Capitol Building
200 E. Colfax Avenue, Room 346
Denver, CO 80203

Dear Senator Johnson:

Enclosed please find a legislative report to the Health, Environment, Welfare, and Institutions Committees for The House of Representatives and The Senate and The Joint Budget Committee on Health Care Policy and Financing's Pharmacy Utilization Plan FY 03-04.

Section 26-4-408(3)(b), C.R.S.(2003) requires the Department to provide the Pharmacy Utilization Plan FY 03-04 by December 1, 2003.

The Pharmacy Utilization Plan FY 03-04 is the process identified for implementing pharmaceutical changes by the Department for FY 03-04. This plan is comprised of two phases. Phase I will limit quantities for some existing covered pharmaceuticals per FDA guidelines. This phase is scheduled for implementation December 15, 2003. Phase II will require system changes so the dispensing criteria will adhere to the FDA recommendations of the drugs. The computer system will require significant programming to allow Phase II to pay claims correctly. This phase is scheduled for implementation in January 2004.

Questions regarding the Pharmacy Utilization Plan FY 03-04 can be addressed to Martha Warner, Pharmacy Unit Supervisor, at Martha.Warner@state.co.us. Her telephone number is 303-866-3176.

Sincerely,

Karen Reinertson
Executive Director

MW:KR/sq

Enclosure(6)

Pharmacy Utilization Plan
FY 03-04

INTRODUCTION

The Pharmacy Utilization Plan FY 03-04 is required by Section 26-4-408(3)(b), C.R.S. (2003) as stated below.

> (b) The state department shall report to the health, environment, welfare, and institutions committees for the house of representatives and the senate 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, environment, welfare, and institutions committees or the joint budget committee.

The Department will achieve the savings outlined in SB03-294 and SB03-011 using the Pharmacy Utilization Plan. In the implementation of the plan, Phase II will require Prior Authorizations (PAs). The MMIS/Fiscal Agent PA costs come from the appropriations for administrative costs. Drug Utilization Reviews will provide information to optimize drug use. The information from the report and the DUR Board findings will be used for pharmaceutical savings and drug reviews. The Department will continue to monitor monthly drug expenditures and provider/client utilization patterns.

The Generic Mandate went into effect on July 29, 2003. Since the inception of the Generic Mandate, the total amount of prescriptions written for generic drugs has increased by 0.6%

The Department of Health Care Policy and Financing (the Department) identified certain drugs to lower the State's drug expenditures. The Pharmacy Utilization Plan FY 03-04 has been separated into two phases. Phase I includes the drugs that are to be limited in quantity for a 30-day time frame. The reason for the limits are as stated for the individual drugs below. Phase I will be implemented December 15, 2003. Phase II will require system changes so the dispensing criteria will adhere to the Food and Drug Administration (FDA) recommendations of the drugs. The computer system will require significant programming to allow Phase II to pay claims correctly. The implementation of Phase II will be in January 2004.

PHASE I: Scheduled Date of Implementation - December 15, 2003

Sleeping Agents: Ambien 5mg & 10mg, Sonata 5mg & 10mg

Because of the risk associated with prolonged therapy, these sleeping agents are to be used for short-term use only. Currently, the Department has no restrictions on these drugs, and they are being over utilized by not following the FDA-approved dosing guideline.

Limits will be--

Ambien 5mg & 10mg	14 tablets/30 days
Sonata 5mg & 10mg	14 tablets/30 days

Savings Expected: $445,198.32

Toradol (Ketorolac) Tablets

Ketorolac is indicated for short-term (up to 5 days) management of moderately severe acute pain only. Increasing the dose beyond the label recommendations will not provide better efficacy but will result in increasing the risk of developing serious side effects, and possible hospitalization. Ketorolac is not covered for maintenance usage.

Limits will be-

Toradol (ketorolac) Tablets	Limit to 5 days of therapy every 30 days = 20 tablets per 30 days.

Savings Expected: $4,033.11

Anti-Migraine: Amerge, Axert, Frova, Imitrex, Maxalt, Relpax, Zomig

These agents are used for the management of acute migraine pain and associated symptoms. The entire class will not have tablet limits. Only the agents mentioned will have limits. Currently, some clients are using these agents for prophylactic use rather than for treatment of migraines only.

Limits will be-

Amerge 1mg and 2.5mg	9 tablets / 30 days
Axert 6.25mg and 12.5mg	6 tablets/ 30 days
Frova 2.5mg	9 tablets / 30 days
Imitrex 25mg, 50mg and 100mg Imitrex Nasal spray Imitrex Injection	9 tablets / 30 days 6 inhalers / 30 days 4 injections/ 30 days
Maxalt 5mg & 10mg	9 tablets / 30 days

MLT 5mg & 10mg	9 tablets / 30 days
Relpax 20mg & 40mg	6 tablets / 30 days
Zomig 2.5mg & 5mg ZMT 2.5mg & ZMT 5mg Zomig 5mg Nasal Inhaler	9 tablets / 30 days 9 tablets / 30 days 6 inhalers/30 days

Savings Expected: $26,768.71

Anti-emetics: Anzemet, Emend, Kytril, Zofran

Anti-emetics are becoming increasingly expensive; the newest agent Emend is $110.00 per tablet. While the use of these drugs is common for chemotherapy patients, a limit will allow a chemotherapy patient to get the drugs during the time of chemotherapy use and step down to a less expensive drug during non-chemotherapy times.

Limits will be-

Anzemet 50mg tablet 100mg tablet	10 tablets/30day 5 tablets /30 days
Emend 125mg 80mg tablet Tripak	5 tablets/30 days 10 tablets/30 days 5 paks /30 days
Kytril 1mg Oral suspension 2mg/10ml	8 tablets /30 days 40ml /30 days
Zofran 4mg 8mg tablet 24mg tablet Oral solution 4mg/5ml	48 tablets /30 days 28 tablets /30 days 8 tablets /30 days 240ml /30 days

Savings Expected: $206,775.57

PHASE II: Scheduled date of implementation - January 2004 (no exact date set yet due to extensive programming)

The following products will be prior authorized for clients having medical necessity other than stated criteria but meeting FDA indications.

Atypicals: Zyprexa, Risperdal and Abilify

These agents are FDA approved for **once daily dosing**. The half-life ranges from 20-70 hours with a mean of 30 hours. Once daily dosing has been shown to be safe and effective when compared to multiple-daily dosing. Also, once daily dosing significantly reduces cost by using the highest tablet strength rather than multiple low-dose tablets. Currently, these atypical antipsychotics are dosed at more than once a day.

Limits will be-

Zyprexa	Limit to once daily dosing for all strengths of Zyprexa, except for the 20 mg tablet.
Risperdal	Limit to once-daily dosing for all strengths of Risperdal except for the 3 mg and 4 mg dosages. The 3 mg dose will be limited to 2 tablets per day, and the 4 mg dose will be exempt from limitation. Due to titration purposes, the Department is proposing to limit to 2 GCN per month usage.
Abilify	Limit to once daily dosing for all strengths of Abilify, except 30mg

Savings Expected: $692,078.33

Fentanyl: Actiq and Duragesic Fentanyl Patches

Actiq is indicated only for the management of breakthrough cancer pain in patients with malignancies who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain. The drug is contraindicated in the management of acute or postoperative pain. It is also contraindicated in use in opioid non-tolerant patients. The maximum dose is 4 units per day.

Duragesic Fentanyl Patches are strong analgesic narcotics used preoperatively and postoperatively. Most patients are maintained adequately with the patch when it is applied at 72-

hour intervals, however, some patients may require application of the patch at 48-hour intervals to maintain adequate analgesia.

Limits will be-

Fentanyl:	
Actiq	4 units per day and for use in cancer clients only.
Duragesic patches	Every 48 hour intervals (or every 2 days) for one fentanyl patch use

Savings Expected: $202,260.87

Cox-2 Inhibitors: Celebrex, Vioxx and Bextra

Cox-2 Inhibitor Non-Steroidal Anti-inflammatory Drugs (NSAIDS) came out in 1999 consisting of Celebrex and Vioxx with efficacy similar to the conventional NSAIDS. Studies report a lower incidence of bleeding; however, the clinical significance of this difference in patients without a coexisting risk factor for GI bleed is questionable. The daily cost of Cox-2 inhibitors is 5-10 times the cost of the older NSAIDS. These agents have been growing in expenditures since introduced to the market.

This class of drugs will require a prior authorization for clients under the age of 65. Use of the Cox-2 inhibitors are limited to FDA approved indications and dosing guidelines.

Drug	Approved Indications	Dose
Vioxx	Osteoarthritis Rheumatoid Arthritis Acute pain and Dysmenorrhea	12.5-25 mg daily 25mg daily 50mg daily for 5 days
Celebrex	Osteoarthritis Rheumatoid Arthritis Familial Adenamatous Polyposis Acute pain and Dysmenorrhea	200mg daily; 100mg BID 100mg – 200mg BID 400mg BID for 6 months 400mg day 1; 200mg BID
Bextra	Osteoarthritis Rheumatoid Arthritis Primary dysmenorrhea	10mg daily 20mg daily 20mg BID prn

Cox-2 Inhibitors Prior Authorization (PA) Criteria:

1. PA is required for clients under 65 years of age and will be approved for the above diagnosis and meets the following criteria. Clients over the age of 65 do not require a PA.
    a. FDA approved indication,
    b. Must be 18 years of age or older,
    c. Concurrent oral anticoagulant use,
    d. Concurrent use of corticosteroids,
    e. History of platelet dysfunction or coagulopathy,
    f. Prior history (within 5 years) of and/or current GI bleed/ulcers, and
    g. History of gastric or duodenal ulcer while on conventional NSAIDS therapy with documentation.

Savings Expected: $107,077.20

CONCLUSION

The savings from the Department's Pharmacy Utilization Plan FY 03-04 will total $1,684,192. These are partial year savings due to the time it will take to implement the system controls needed for the drug limitations and conducting meetings with stakeholders. Phase I savings are calculated using a duration of 6.5 months and Phase II savings are calculated using a duration of 5 months. The annualized total savings are $3,109,277.