



MEDI-CAL DRUG USE REVIEW (DUR) BOARD

**State of California
DEPARTMENT OF HEALTH CARE SERVICES**

Notice is hereby given that the **Medi-Cal DUR Board** will conduct a public meeting on **Tuesday, May 17, 2016**, at the following location:

Department of Health Care Services
1500 Capitol Avenue
Training Rooms B+C
Sacramento, CA 95814

Medi-Cal Drug Use Review Board
Meeting Agenda
May 17, 2016
9:30 AM-12:00 PM

Report Type*	Agenda Item	Presenter	Time
C	1. Welcome/Introduction	Pauline Chan, RPh, MBA	930-945
A	2. Call to Order/Review and Approval of Previous Minutes from February 16, 2016	Robert Mowers, PharmD	945-950
	3. Old Business		
A	a. Review of Action Items from Previous Board Meeting: i. Pricing Policy for Code Z7610 ii. Prospective DUR: New GCNs iii. Prospective DUR: LR Alert iv. Educational Outreach: MEDD Letter v. RetroDUR: Skeletal Muscle Relaxants vi. RetroDUR: Buprenorphine	Pauline Chan, RPh, MBA and Ivana Thompson, PharmD	950-1000
	4. New Business		
R/A/D	a. Board Activities	DUR Board	1000-1005
R/D	b. Managed Care Presentation by Partnership HealthPlan: "Managing Pain Safely: A plan's approach to combating the opioid epidemic"	Dina M. Haynes, BA, CPhT [Associate Director, Pharmacy Operations, Pharmacy Department], Stan Leung, Pharm.D. [Associate Director, Clinical Pharmacy Programs], and Danielle Niculescu, MPH [Project Coordinator II]	1005-1025

R/D	c. Presentation: “Comprehensive Medication Management: California Wellness Plan Implementation”	Jessica Nunez de Ybarra, MD, MPH [Chief, California Wellness Plan Implementation, CDPH]	1025-1045
R/A	d. Quarterly Report: 1Q2016 (January – March 2016) e. Review of Physician Administered Drugs (PADs): 4Q2015 f. Prospective DUR i. Review of DUR Alerts for New GCNs: 1Q2016 ii. Update on Pregnancy (PG) Alert iii. Drug-Drug Interaction (DD) Alert g. Review of DUR Educational Outreach to Providers i. Updated Outcomes: Antipsychotic Monitoring ii. Outcomes: MEDD iii. Proposal: Anticholinergic Drugs	Amanda Fingado, MPH	1045-1125
R/A/D	h. Retrospective DUR i. Review of PCSK9 Inhibitors ii. Review of Methadone i. Review of DUR Publications i. DUR Bulletin (April, 2016): Concomitant Use of Antipsychotic and Metabolic Drugs ii. DUR Alert (April, 2016): Opioids iii. DUR Alert (April, 2016): Saxagliptin and Alogliptin iv. Discussion/Recommendations for Future Bulletins	Shalini Lynch, PharmD	1125-1150
R/D	j. Pharmacy Update i. CMS DUR Annual Report 2015 Revisions ii. Antipsychotic Drug Use in Children (ADC) Affinity Group iii. Prescription Opioids Abuse Actions iv. Proposed Medicaid Managed Care Regulation v. Quality Strategy vi. Child & Adult Core Set Measures vii. Value Based Purchasing in Medicaid viii. Academic Detailing: October 21, 2016 (Sacramento)	Pauline Chan, RPh, MBA	1150-1155
C	5. Public Comments		1155-1200
	6. Consent Agenda		
I	a. Meeting feedback b. Next meeting: September 20, 2016 (9:30 AM -12:00 PM) Xerox State Healthcare, LLC 840 Stillwater Road, Monterey Room West Sacramento, CA 95605 c. Proposed DUR Board Meeting Dates for 2016/2017: Tuesday, November 15, 2016 Tuesday, February 21, 2017 Tuesday, May 16, 2017 Tuesday, September 19, 2017 Tuesday, November 21, 2017 d. Academic detailing meeting is set for October 21, 2016 in Sacramento		
	7. Adjournment		1200

* REPORT TYPE LEGEND: **A: Action; R: Report; I: Information; C: Comment; D: Discussion**

** Comments from the public are always appreciated. However, comments will be limited to five minutes per individual.

Picture identification is required to gain access into the California Department of Health Services building. However, your security information will not be provided to the DUR Board.

You can obtain the DUR Board agenda from the Medi-Cal DUR Main Menu Web site (http://files.medi-cal.ca.gov/pubsdoco/dur/dur_home.asp).



**MEDI-CAL DRUG USE REVIEW BOARD
MEETING MINUTES**

Tuesday, February 16, 2016

9:30 a.m. – 12 p.m.

Location: Department of Health Care Services
1500 Capitol Avenue
Training Rooms B+C
Sacramento, CA 95814

Topic	Discussion
<p>1) WELCOME/ INTRODUCTION</p>	<ul style="list-style-type: none"> • The meeting was called to order by the Chair of the Board, Dr. Robert Mowers. • Board members present: Drs. Andrew Wong, Randall Stafford, Robert Mowers, and Patrick Finley. • Board members absent: Drs. Timothy Albertson, Janeen McBride, and Marilyn Stebbins. • Board members and attendees introduced themselves. • Pauline Chan, RPh, James Gasper, PharmD, Teri Miller, PharmD, and Dorothy Uzoh, PharmD were present from DHCS Pharmacy Benefits Division. • Ivana Thompson, PharmD (Xerox) announced that the DUR Board meeting is being recorded and reminded everyone to sign the attendance sheet.
<p>2) CALL TO ORDER/ REVIEW AND APPROVAL OF NOVEMBER 2015 MINUTES</p>	<p>The Medi-Cal Drug Use Review Board (the “Board”) reviewed the November 17, 2015 minutes. Dr. Wong noted he had minor edits and motioned that the minutes be approved with these changes. There was no discussion. The Board voted unanimously to approve the minutes as edited by Dr. Wong.</p> <p>ACTION ITEM: Incorporate Dr. Wong’s edits into the minutes and post to the DUR website.</p>
<p>3) OLD BUSINESS</p>	<p>a. Review of Action Items from Previous Board Meeting:</p> <ul style="list-style-type: none"> i. Prospective DUR: Section 20 Cleanup – Dr. Thompson reported that the Board recommendations were approved and implemented in December 2015. ii. Prospective DUR: Pregnancy (PG) Alert – Dr. Thompson reported that the Board recommendations were approved and implemented in December 2015. iii. Physician Administered Drugs: Acetaminophen and Ibuprofen – At the DUR Board meeting in November 2015, the Board had asked how these claims are reimbursed, as the reimbursement paid to providers seemed high. Dr. Thompson explained that there is a pricing ceiling based on a combination of the HCPCS code and the diagnosis (or procedure). Providers can submit their usual and customary charge, and as long this amount is under the pricing ceiling, the claim will pay. If this charge is above the ceiling, the claim will suspend pending further review. Dr. Thompson stated that pricing for ACETAPMINOPHEN and IBUPROFEN fall under the pricing algorithm for physician-administered drugs using the HCPCS code of Z7610: “MISC DRUGS AND MED SUPPLIES, ADMIN STAT.” Dr. Thompson clarified that this code excludes any injectable drugs and applies primarily to oral dosage forms. <p>Dr. Mowers suggested the DUR Board should conduct further research into this policy, including a comparison to reimbursement paid for similar pharmacy claims that use pricing guidelines set by pharmacy policy. Dr. Thompson stated that the pricing method and table used for code Z7610 comes from medical policy, and not the Pharmacy Benefits Division. Ms. Chan suggested she could speak with someone from the medical policy side and see if they would be willing to provide the Board with more information on the pricing policy for this code at a future DUR Board meeting.</p> <p>ACTION ITEM: The DUR Board recommendation to further research the pricing policy for code Z7610 will be submitted to DHCS.</p>

4) NEW BUSINESS

- a. Board Activities:**
- i. Review of Board Goals and Objectives – Dr. Mowers presented the following DUR Board Goals for the next two years (2016-2017):
 - Conduct systematic review to identify therapeutic drug categories and establish relative cost comparisons that also comply with contractual requirements for cost confidentiality
 - Promote dialogue, collaboration, and recommend best practices in pharmacy utilization management on drugs that are commonly used in both Medi-Cal fee-for-service and managed care
 - Recommend prospective DUR alerts system design as part of new CAMMIS system
 - Conduct studies to evaluate various methods in the design of “dear doctor” letters
 - Collaborate with other agencies in the use of Morphine Equivalent Daily Dose (MEDD) to prevent opioid overdose
 - Establish DUR 5-year trending reports on selected measures
 - Collaborate with other agencies in improving psychotropic medication use for all populations
 - Establish a learning collaborative with managed care health plans and other agencies to promote best practices using academic detailing
 - Align DUR board goals with DHCS Quality Strategy
- b. Pharmacy Update:**
- i. DUR Program Review 2015
 - Antipsychotic Drug Use in Children (ADC) Affinity Group – Ms. Chan reminded the DUR Board that in early 2015 the Office of the Inspector General recommended that CMS work with state Medicaid programs to:
 - Perform utilization review of second generation antipsychotic (SGA) drugs prescribed to children
 - Conduct periodic review of medical records related to SGAs
 - Consider other methods of enhanced oversight of SGAs

One response proposed by CMS was to form the ADC Affinity Group. The ADC Affinity Group will focus on strategies to improve the quality of care for children who are prescribed antipsychotic drugs. The group also will identify and encourage strategies aimed at reporting on the 2016 Child Core Set measure for Medicaid/CHIP: Use of Multiple Concurrent Antipsychotics in Children and Adolescents. CMS plans to support states’ efforts to improve quality of care by providing learning opportunities regular meetings and communications between states. Interested state Medicaid agencies were asked to submit an expression of interest form identifying team members and indicating leadership support.

DHCS is planning to submit an interest form for participation in the ADC Affinity Group, and is including DUR team members in the application. Monthly 1:1 calls begin in March 2016 and will continue for 12 months, in addition to quarterly group calls with other states and QI experts. Activities of the ADC Affinity Group will be shared with the DUR Board at each meeting and input from the Board will be welcome.

 - A report entitled, “Comprehensive Medication Management Programs: Description, Impacts and Status in Southern California, 2015” was published on 12/23/2015. Ms. Chan commended the California Department of Public Health for making this report available and congratulated Board member Dr. Marilyn Stebbins for her contribution to this important report.
 - ii. Medicaid Drug Utilization Review State Comparison/Summary Report for FFY2014 – Ms. Chan reported that CMS has posted the FFY 2014 DUR Annual State Reports on

the CMS website at: <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/downloads/2014-dur-summary-report.pdf>. Ms. Chan encouraged attendees to read the summary report, specifically the following sections:

- Generic Policy and Utilization Data (pages 15-17)
- Program Evaluation/Cost Savings/Cost Avoidance (pages 18-20)
- Fraud, Waste, and Abuse Detection (pages 21-43)

Ms. Chan reminded the Board that this summary report was for FFY 2014, which covered October 1, 2013 through September 30, 2014.

- c. FFY2015 DUR Annual Report to CMS – Ms. Chan informed the Board that the Centers for Medicare & Medicaid Services (CMS) notified states this week about proposed revisions to the DUR Annual Report to CMS for federal fiscal year (FFY) 2015. CMS stated that revisions are being made to the report with input from a committee of members from the American Drug Utilization Review Society (ADURS). CMS provided a link to review the draft of the proposed FFY2015 survey at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-R-153.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending>. Ms. Chan stated that further information regarding the final version of the report template will be available in late March 2016 and that the submission due date has been extended from June 30, 2016 to November 30, 2016. In light of this information, the Board discussion on the draft of the FFY 2015 DUR Annual Report to CMS was postponed until September.
- d. Presentation by the Inland Empire Health Plan – Chris Chan, PharmD, the Senior Director of Pharmacy Services for the Inland Empire Health Plan (IEHP) gave a presentation entitled, “IEHP Pharmacy Pay For Performance (P4P) Program.” Dr. Chan stated that the IEHP covers over one million Medi-Cal beneficiaries residing in one of two Southern California counties (Riverside and San Bernardino). In October 2013, IEHP began the rollout of the P4P program for pharmacy providers to improve pharmacy services provided by IEHP community pharmacy providers. IEHP used financial incentives to help transition community pharmacies to an outcome-based medication therapy management model.

Dr. Chan reported that the eligibility criteria for participation in the P4P program included the following:

- Must be a Contracted IEHP (via IEHP contracted PBM) Community Pharmacy Provider
- Must be an IEHP Pharmacy Provider in good standing (free of outstanding fraud, waste and abuse investigation)
- Store location must be within San Bernardino and Riverside Counties
- Must have an annual IEHP prescription volume of greater than 1,000 (500 every 6 months)
- Pharmacy must be in business during the entire evaluation period
- Must have at least 10 members qualifying for 4 out of 7 clinical measures under the IEHP P4P Program (this criteria was new for 2015 - 2016)

Dr. Chan also summarized the scoring methodology used for the P4P program, which included three separate measures evaluating the proportion of days covered (hypertension, diabetes, and statins), the appropriate treatment of hypertension in diabetes, medication therapy for persons with asthma, use of high-risk medications in the elderly, and the generic rate. For 2015-2016, the criteria were changed to include asthma suboptimal control and statin use in diabetes. Results for each metric of the P4P program were presented, with each metric showing results trending in a promising direction.

Dr. Chan then described IEHP's Pharmacy Transformation Project that was established to assist independent pharmacy providers to evaluate their current capabilities for additional services. Assessments are made based on current pharmacy setting, demographic information, latest technologies available, and targeted/future enhancements. The goal of this project is to optimize pharmacy efficiency and to assist pharmacists to be successful in integrating other clinical services. The tentative start date for this project is June 2016 and in

order to participate, pharmacies must be high-performing (with a rating of 4 or 5 stars) and members must be a patient of an eligible pharmacy with two out of three metabolic syndrome conditions (diabetes, hypertension, hyperlipidemia, or asthma). Outcome targets include: 1) an A1C < 8 with at least two labs in the last 12 months; 2) blood pressure < 140/90; 3) LDL < 100; and 4) adherence measure (controller) and number of albuterol fills. Tentative proposed payments to successful pharmacies would be \$20 per MTM consultation (with a maximum of \$240 per patient, per year). Future outcome-based MTM payments will be adjusted based on the actual experience in the first year of the program.

Dr. Chan concluded by stating that the mission and goals of the P4P program is to disrupt the current pharmacy services delivery model by helping to craft the next-generation pharmacy model, which will include clinical services. This program will be able to evaluate the return on investment of community pharmacist-delivered services and allow payors to create a reasonable payment model for future pharmacist-run outcome-based MTM services.

e. Presentations by the California State Board of Pharmacy

- i. Naloxone Protocol for Pharmacists – Virginia Herold, the Executive Director of the California State Board of Pharmacy, presented information on the naloxone protocol for pharmacists. Effective January 28, 2016, there is now statutory authority for pharmacists to distribute naloxone, replacing an emergency regulation that took effect on April 10, 2015. This regulation appears in the California Business and Professions Code (section 4052.01) and enables pharmacists to furnish naloxone to patients to overcome opioid overdoses. It also requires pharmacists to provide education to patients about naloxone and how to use it. The screening questions for naloxone use were described and the California State Board of Pharmacy is in the process of translating these screening questions into additional languages (patient fact sheets are currently available in six languages). Distribution of naloxone will be available for any pharmacist with at least one hour of approved continued-education in the use of naloxone in all routes of administration, or the equivalent curriculum-based training program in a school of pharmacy. The naloxone protocol is not limited to advanced practice pharmacists (APP).
- ii. Drug Take Back Regulations – Ms. Herold also reported that the California State Board of Pharmacy is in the process of developing drug take-back regulations. These regulations will mirror the federal requirements put forth by the United States Drug Enforcement Administration (DEA) that allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. The federal regulations allow authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities. California will permit mailing of prescription drugs to a destruction site or placement in a mailbox collection receptacle that has the capability to track the contents, which will then be sent to a reverse distributor or to an incineration site. Finalized regulations are expected from the California State Board of Pharmacy in six-nine months.

Pauline Chan commented that James Gasper, PharmD, formerly clinical pharmacist at San Francisco Department of Public Health and now with the Department of Health Care Services, has been instrumental in developing the pharmacist protocol for naloxone.

- f. Quarterly Report – 4Q2015 (October – December 2015): Ms. Fingado reported that in 2015 Q4, all age groups except the 0-12 year age group and the 65+ age group posted decreases in total utilizing beneficiaries and total paid claims in comparison to the prior quarter. Ms. Fingado stated that among the 65+ age group this increase may be attributed to the increase in seniors and people with disabilities who are dually eligible for both Medi-Cal and Medicare opting-out of the Cal MediConnect program. On October 1, 2015, there

were a total of 117,179 beneficiaries enrolled in Cal MediConnect, with a projected December enrollment of 126,299. However, as of December 1, 2015 the enrollment actually decreased to 115,743.

In addition, Ms. Fingado reported that one year after being re-classified as a Schedule II controlled substance (effective October 6, 2014), HYDROCODONE/ACETAMINOPHEN continues to post decreases in total paid claims in comparison to the prior quarter (decreased by 8%) and to the prior-year quarter (decreased by 9%).

- g.** Review of Physician Administered Drugs (PADs) – 3Q2015 (July – September): Ms. Fingado showed a summary of paid claims for physician-administered drugs for the 3rd quarter of 2015, which includes paid claims with dates of services between July 1, 2015, and September 30, 2015. These data were presented in three tables: 1) the top 20 drugs by total reimbursement paid, 2) the top 20 drugs by utilizing beneficiaries, and 3) the top 20 drugs by reimbursement paid to pharmacies per utilizing beneficiary. Ms. Fingado reported increases in both total utilizing beneficiaries (a 19% increase) and total paid claims (a 9% increase) from 2Q2015 to 3Q2015 in the category “PHYSICIAN ADMINISTERED DRUG – NDC NOT REQUIRED,” which can be attributed to large increases in the influenza vaccine starting in September 2015. Within this same category, Ms. Fingado pointed out large decreases in both total utilizing beneficiaries (a 55% decrease) and total paid claims (a 50% decrease) from 3Q2014 to 3Q2015. Ms. Fingado stated that this decrease may be due to the migration of dually-eligible beneficiaries from the Medi-Cal Fee-for-Service Program to the MediConnect program, which occurred during this same time period.
- h.** Prospective DUR reports were presented by Amanda Fingado
- i.** Review of DUR Alerts for New GCNs in 4Q2015 (October – December 2015)
- At each DUR Board meeting, a list of new GCN additions with prospective DUR alerts turned on other than ER and DD will be provided to the DUR Board for review. For this meeting, the DUR Board reviewed the alert profiles of the following thirteen GCNs:
 - GCNs #074851 and #074853: MORPHINE SULFATE - Drug-Allergy (DA), Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
 - GCNs #074887, #074888, and #074889: ARIPIPRAZOLE - Drug-Disease (MC), Additive Toxicity (AT), Therapeutic Duplication (TD), Ingredient Duplication (ID), Underutilization (LR), High Dose (HD), Low Dose (LD)
 - GCN #063478: FLUCONAZOLE IN NAACL,ISO-OSM - High Dose (HD), Low Dose (LD)
 - GCN #075065: PSEUDOEPH/DM/ GUAIFEN/ACETAMIN - Ingredient Duplication (ID), High Dose (HD)
 - GCN #075115: NAPROXEN CAPSAICIN/MENTHOL- Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
 - GCN #075117: ELVITEG/COBI/ EMTRIC/TENOFO ALA - Ingredient Duplication (ID)
 - GCN #075135: NAPROXEN SODIUM/MENTHOL- Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
 - GCNs #075207 and #075208: MELOXICAM, SUBMICRONIZED - Drug-Pregnancy (PG)
 - GCNs #075237: DICLOFENAC SODIUM, MICRONIZED - Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
 - Due to a lack of quorum, a motion could not be made to accept these alert profile recommendations. It was agreed that the Board would be polled after the DUR

meeting to approve these recommendations. There was no further discussion.

ACTION ITEM: Survey the DUR Board members regarding alert profile recommendations for GCNs added in Q4 2015 and report these recommendations at the upcoming DUR meeting in May.

ii. Review of Prospective DUR Criteria: Late Refill (LR) Alert

- Ms. Fingado reported that in the Medi-Cal System, the LR alert is generated when a sub-therapeutic pattern of prescription drug use is detected. Specifically, alerts are generated when patients fail to renew prescriptions for selected maintenance drugs before more than 125 percent of the days' supply of the previous prescription has been used. A review of the LR alert showed the following inconsistencies between drugs that appear on the Medi-Cal LR target drug list and drugs with the LR alert turned on in the Medi-Cal prospective DUR system:
 - Some drugs appear in the DUR manual on the LR target drug list (TDL) but the LR alert is not turned on in the system
 - Some drugs that are generally not used as maintenance therapy appear on the LR target drug list and/or have the LR alert turned on in the system
- Ms. Fingado summarized the current prospective DUR criteria in a table that included the name of the drug, whether or not the drug had the LR alert on, whether or not the drug appeared on the LR TDL, and a recommended action, if any.
- Ms. Fingado recommended removing the following drugs from the LR target drug list: CELECOXIB, CIPROFLOXACIN, CLONAZEPAM, EPOETIN ALFA, FENTANYL, LEVOFLOXACIN, MEGESTROL, MORPHINE/OPIUM, NITROGLYCERIN, OXYCODONE, PHENOBARBITAL, TESTOSTERONE, TRAMADOL, and ZOLPIDEM
- Ms. Fingado also recommended turning off the LR alert for the following drugs (all GCNs): CELECOXIB, CLONAZEPAM, EPOETIN ALFA, MEGESTROL, MORPHINE/OPIUM, NITROGLYCERIN, PHENOBARBITAL, and TESTOSTERONE and turning on the LR alert for the following drugs (all GCNs): GABAPENTIN and LEVOTHYROXINE.
- Dr. Stafford wondered why we would want to turn off PHENOBARBITAL, as it can be used chronically for seizure disorders. Dr. Thompson stated that we had recommended turning off LR alerts for all scheduled drugs, but she agreed with Dr. Stafford that it would make sense to keep the LR alert on for single-ingredient PHENOBARBITAL products only. Dr. Stafford agreed the LR alert did not need to remain on for PHENOBARBITAL combination drugs. Drs. Wong and Mowers also agreed with Dr. Stafford and suggested accepting all other recommendations (besides single-ingredient PHENOBARBITAL, which will remain on). There was no further discussion.
- Due to a lack of quorum, a motion could not be made to accept these recommendations. It was agreed that the Board would be polled after the DUR meeting to approve these recommendations. There was no further discussion.

ACTION ITEM: Survey the DUR Board members regarding LR alert recommendations and report these recommendations at the upcoming DUR meeting in May.

i. Review of DUR Educational Outreach to Providers

i. Updated Proposal: MEDD Letter

- Ms. Fingado presented updated information about the target population for this intervention. She described that between July 1, 2015 and December 31, 2015 a total of 39,713 paid claims exceeded > 80 mg MEDD, representing 10,167 Medi-Cal fee-for-service beneficiaries. Ms. Fingado then stated that the following inclusion/exclusion criteria were applied in a stepwise order to these 10,167 beneficiaries, in order to determine the size of the study population:
 - A total of 5,157 beneficiaries were excluded as they were currently receiving buprenorphine as part of a narcotic withdrawal treatment plan between July 1, 2015 and December 31, 2015;

- A total of 1,848 beneficiaries had approved Treatment Authorization Requests (TARs) on file for opioid paid claims between July 1, 2015 and December 31, 2015;
- A total of 1,084 beneficiaries were not continuously-eligible in the Medi-Cal fee-for-service program since July 1, 2015 (including January 2016);
- A total of 336 beneficiaries had a primary or secondary diagnosis of cancer between January 1, 2015 and December 31, 2015;
- A total of 321 beneficiaries resided in a long-term care facility or received hospice care between January 1, 2015 and December 31, 2015.

Ms. Fingado stated that after all listed inclusion/exclusion criteria were applied there was a total study population of 1,421 beneficiaries with 3,340 paid claims that exceeded > 80 mg MEDD (for a total of 1,147 providers). As described in the prior version of the methods, which was presented to the DUR Board on November 17, 2015, Ms. Fingado reported that because the total number of provider letters for this mailing would exceed 500 letters, the MEDD threshold would be adjusted to > 120 mg MEDD and the days' supply filtered to only include those paid claims with a days' supply greater than 14 days. This brought the number of providers to 380, representing 464 beneficiaries and 1,542 paid claims. Ms. Fingado reported that only 218 of these providers had mailing addresses listed in the Medi-Cal Provider Master File (representing 276 beneficiaries and 951 paid claims).

Dr. Stafford enquired as to why the provider address is still limiting the sample so significantly. He suggested that DHCS take whatever steps necessary to fix this issue so physician addresses are not a limiting factor in the DUR program's educational outreach to providers. Ms. Chan agreed and said she would work with Xerox and UCSF to explore ways to use alternate data sources for future provider mailings.

Ms. Fingado also reported that after the materials were submitted for this meeting, it was suggested by Dr. Gasper (DHCS) that patient profiles be included with this mailing to show clinically-relevant hospitalizations and/or emergency department visits, if any. She stated he also recommended the inclusion of all opioid claims in the profile, as well as additional paid claims for high-risk concomitant medications like benzodiazepines. The Board agreed this would be very helpful to providers.

Dr. Mowers stated that he thought this educational outreach letter should move forward, although a motion could not be made to recommend this outreach due to a lack of quorum. It was agreed that the Board would be polled after the DUR meeting to approve these recommendations. There was no further discussion.

ACTION ITEM: Survey the DUR Board members regarding educational outreach to providers using the updated parameters described in the MEDD proposal and report these recommendations at the upcoming DUR meeting in May

j. Retrospective DUR presented by Dr. Shalini Lynch (UCSF):

- i. Review of Retrospective DUR Criteria: Skeletal Muscle Relaxants
 - The DUR Board had expressed an interest in finding out more information about the utilization of CARISOPRODOL and other SKELETAL MUSCLE RELAXANTS in the Medi-Cal fee-for-service population. Dr. Lynch reported that as of January 11, 2012, CARISOPRODOL is listed as a schedule IV controlled substance and currently is only available to Medi-Cal fee-for-service beneficiaries with an approved *Treatment Authorization Request (TAR)*. Dr. Lynch stated that combining prescription opioids with other drugs, such as benzodiazepines and skeletal muscle relaxants, may increase the risk of morbidity and mortality due to additive effects on the respiratory and central nervous systems and that the simultaneous use of opioids, benzodiazepines, and skeletal muscle relaxants (colloquially known as the "triple threat") may result in a feeling of euphoria similar to that produced by heroin. Dr. Lynch also reported that the combination of hydrocodone, carisoprodol, and alprazolam is also referred to in street

terms as the “holy trinity”.

- Dr. Lynch presented utilization data for all paid claims for SKELETAL MUSCLE RELAXANTS in the Medi-Cal fee-for-service program between September 1, 2014 and August 31, 2015. Dr. Lynch reported a total of 25,797 Medi-Cal fee-for-service beneficiaries had at least one paid claim for a SKELETAL MUSCLE RELAXANT during this measurement year, with the majority of beneficiaries (n=24,258; 94%) having at least one paid claim during the year for BACLOFEN. A further review of the 703 beneficiaries with at least one paid claim for CARISOPRODOL found the majority of these beneficiaries (n=647; 92%) also had at least one paid claim for an opioid and/or a benzodiazepine during the measurement year, with a total of 256 beneficiaries (36%) having at least one paid claim for both opioids and benzodiazepines. Of these 256, Dr. Lynch reported that at least seven of these beneficiaries (3%) are now deceased, and three of them all received medical care from the same small town (population less than 16,000). Further, a review of demographic characteristics for the CARISOPRODOL study population showed those beneficiaries with a paid claim for any opioid AND any benzodiazepine were predominantly female, between 18 and 39 years of age, and white/Caucasian, non-Hispanic. Finally, Dr. Lynch explained that the distribution of beneficiaries by California region of residence showed the fewest beneficiaries in the study population resided in the Bay Area and Los Angeles regions, while the more rural North and Mountain region had the greatest number of beneficiaries in the study population. Of note, Dr. Lynch stated that almost half of the study population (n=120; 47%) resided in one of two California counties: one in the Southern California without Los Angeles region (n=63; 25%) and one in the North and Mountain region (n=57; 22%).
- Dr. Lynch recommended the following to the DUR Board for their consideration:
 - Conduct a retrospective DUR outreach to prescribers for patients in the CARISOPRODOL study population who also have paid claims for opioids and benzodiazepines. The proposed outreach would include 1) patient profiles with all paid claims for these drugs, including dates of service, drug strength and quantity, and prescriber name and city and 2) information on the dangers of the triple threat.
 - Write a DUR bulletin to promote the appropriate prescribing of SKELETAL MUSCLE RELAXANTS, including 1) an overview of the safety considerations when prescribing SKELETAL MUSCLE RELAXANTS (especially drug interactions); 2) a description of the triple threat, highlighting the potential lethal consequences of concomitant use of SKELETAL MUSCLE RELAXANTS, opioids, and benzodiazepines; 3) an evaluation of concomitant use of opioids and benzodiazepines across beneficiaries with a paid claim for any SKELETAL MUSCLE RELAXANT; and 4) links to prescription drug abuse resources for prescribers and pharmacists

Dr. Stafford recommended including CYCLOBENZAPRINE in addition to CARISOPRODOL in the evaluation. Drs. Wong and Mowers stated that they agreed with these recommendations, although a motion could not be made due to a lack of quorum. It was agreed that the Board would be polled after the DUR meeting to approve these recommendations. There was no further discussion.

ACTION ITEM: Survey the DUR Board members regarding both educational outreach to providers and the writing of an educational bulletin (as outlined in the retrospective DUR review of skeletal muscle relaxants, with the addition of CYCLOBENZAPRINE) and report these recommendations at the upcoming DUR meeting in May.

- k. Review of DUR Publications presented by Dr. Shalini Lynch (UCSF)
 - i. DUR Educational Bulletin (November 2015): Anticholinergics and Antipsychotics
 - Dr. Lynch presented a summary of the DUR educational bulletin entitled, “Clinical Review: Concomitant Use of Anticholinergics and Antipsychotics.” This bulletin had the following learning objectives:
 - Understand the role of anticholinergic medications in the prevention and treatment of antipsychotic-induced extrapyramidal symptoms (EPS)

- Describe factors that should be considered when deciding to initiate and/or continue the concomitant use of anticholinergic with antipsychotic medication therapy.
- Dr. Lynch reported that while anticholinergic medications are frequently prescribed to prevent or treat EPS the long-term benefit of these drugs has not been established and the need for continued therapy is frequently not re-assessed and many patients may remain on these agents for years or decades. She described a general ranking of selected first- and second-generation antipsychotic medication by propensity for EPS and summarized current treatment guidelines.
- Dr. Lynch described utilization of anticholinergic medications in the Medi-Cal population, including a description of beneficiaries with at least one claim for an anticholinergic medication during a one-year time period. She reported that among Medi-Cal beneficiaries with a paid claim for an anticholinergic medication with ≥ 30 days supply, almost all beneficiaries (96%) also had at least one paid claim for an antipsychotic medication during the same time period and of the 34,879 beneficiaries with a paid claim for bupropion and/or trihexyphenidyl with ≥ 30 days supply, 51% had at least 6 paid claims during the measurement year and 17% had at least 12 paid claims during the measurement year.
- Dr. Lynch also reported that in the study population, clozapine had the highest rate of chronic use of anticholinergic medications (21%) among all second-generation antipsychotics even though it is generally thought to have the lowest propensity for EPS.
- The bulletin recommended that prophylactic use of anticholinergic medications is not recommended for patients taking second-generation antipsychotics and for patients taking first-generation antipsychotics, prophylactic use of anticholinergic medications to prevent extrapyramidal symptoms should be determined on a case-by-case basis, with patient-specific and medication-specific factors considered. In addition, continued use of anticholinergic medications should be re-evaluated in patients with controlled symptoms every three months and should be discontinued in older patients and/or persons with high genetic risk of cognitive disorder who use anticholinergic medications and are at increased risk of cognitive decline and dementia.

ii. DUR Educational Alert (January 2016): CURES 2.0

- Dr. Lynch summarized the educational alert entitled, “Alert: California Upgrades Prescription Drug Monitoring Program to CURES 2.0.” Dr. Lynch reported that as of January 8, 2016, California has updated their prescription drug monitoring program, the Controlled Substance Utilization Review and Evaluation System (CURES) to CURES 2.0. This upgraded database offers a significantly improved user experience and features a number of added functionalities, including the ability to delegate report queries and new practitioner-identified patient alerts. Dr. Lynch described the streamlined registration process that has been implemented for new users. Licensed health care prescribers and pharmacists can now request access to the CURES database and validate their credentials entirely online using a secure web browser (Microsoft Internet Explorer 11 or higher, Mozilla Firefox, Google Chrome, or Safari). Users attempting to access the new CURES 2.0 database with noncompliant web browsers will be redirected to the previous CURES system.
- Finally, Dr. Lynch reminded the Board that all health care practitioners authorized to prescribe or dispense Schedule II – IV controlled substances must be registered to use CURES by July 1, 2016.

iii. Discussion/Recommendations for Future Educational Bulletins

- The calendar for future DUR educational bulletins was reviewed. The Board did not have any suggested changes or additions/deletions at this time.
- Ms. Fingado advocated for moving forward the publication of a DUR educational bulletin on buprenorphine, using data presented in the retrospective DUR review at the November 2015 Board meeting. She noted that recent Medi-Cal policy changes have allowed for increased access of beneficiaries to buprenorphine and that a bulletin would be timely and could help increase awareness among providers about

	<p>the expanded access. She referred to a recent DUR publication on nicotine replacement therapy as a model for this type of bulletin. Both DHCS and CDPH have worked to expand access to buprenorphine and these efforts could be highlighted in the bulletin.</p> <ul style="list-style-type: none"> • Drs. Wong, Stafford, and Mowers stated that they agreed with the recommendation to write a DUR bulletin on buprenorphine, as outlined in the review, although a motion could not be made due to a lack of quorum. It was agreed that the Board would be polled after the DUR meeting to approve this recommendation. There was no further discussion. <p>ACTION ITEM: Survey the DUR Board members regarding a DUR educational bulletin on buprenorphine and report these recommendations at the upcoming DUR meeting in May.</p>
5) PUBLIC COMMENTS	<ul style="list-style-type: none"> • None.
6) CONSENT AGENDA	<ul style="list-style-type: none"> • The next Board meeting will be held from 9:30 a.m. to 12:00 p.m. on May 17, 2016 in in DHCS Training Rooms B+C located at 1500 Capitol Avenue, Sacramento, CA 95814.
7) ADJOURNMENT	<ul style="list-style-type: none"> • The meeting was adjourned at 12 p.m.

Action Items	Ownership
Incorporate Dr. Wong's edits into the minutes and post to the DUR website.	Ivana
The DUR Board recommendation to further research the pricing policy for code Z7610 will be submitted to DHCS.	Pauline/Ivana
Survey the DUR Board members regarding alert profile recommendations for GCNs added in Q4 2015 and report these recommendations at the upcoming DUR meeting in May.	Amanda
Survey the DUR Board members regarding LR alert recommendations and report these recommendations at the upcoming DUR meeting in May.	Amanda
Survey the DUR Board members regarding educational outreach to providers using the updated parameters described in the MEDD proposal and report these recommendations at the upcoming DUR meeting in May	Amanda
Survey the DUR Board members regarding both educational outreach to providers and the writing of an educational bulletin (as outlined in the retrospective DUR review of skeletal muscle relaxants, with the addition of CYCLOBENZAPRINE) and report these recommendations at the upcoming DUR meeting in May.	Amanda
Survey the DUR Board members regarding a DUR educational bulletin on buprenorphine and report these recommendations at the upcoming DUR meeting in May.	Amanda

**QUARTERLY SUMMARY
DRUG USE REVIEW (DUR) UTILIZATION REVIEW
REPORT PERIOD: 1st QUARTER 2016 (JANUARY - MARCH 2016)**

Executive Summary

The DUR quarterly report provides information on both prospective and retrospective drug utilization for the Medi-Cal Fee-for-Service (FFS) program. For this quarterly report, the prospective and retrospective data cover the first quarter of 2016 (2016 Q1). All tables can be found in **Appendix A** and definitions of selected terms can be found in **Appendix B**

Prospective DUR

As shown in **Table 1.1**, in comparison to the prior quarter (2015 Q4), in 2016 Q1 there was an increase in overall drug claims (increased by 5%), DUR drug claims (increased by 4%), and total DUR alerts (increased by 4%). However, in comparison to the prior-year quarter (2015 Q1), overall drug claims decreased by 5%, DUR drug claims decreased by 3%, and total DUR alerts increased by 7%.

A comparison between 2016 Q1 and 2015 Q4 showed very little change among the top 10 drugs for each of the 12 prospective DUR alerts (**Tables 2.1-2.12**) except within the drug-pregnancy (PG) alert (**Table 2.2**), in which NORETHINDRONE and SULFAMETHOXAZOLE/TRIMETHOPRIM both entered the top 10 for the first time (ranked #2 and #3, respectively).

Retrospective DUR

A comparison of 2016 Q1 to the prior-year quarter showed a 5% decrease in total utilizing beneficiaries and a 4% decrease in total paid claims (**Table 3**). However, when overall utilization from 2016 Q1 was compared to the prior quarter there was an increase in total utilizing beneficiaries and total paid claims (both increased by 5%).

In 2016 Q1, the 19-39 year age group posted across-the-board increases in total utilizing beneficiaries and total paid claims in comparison to both the prior quarter (**Table 4**) and the prior-year quarter.

As shown in **Table 5**, the following three drug therapeutic categories posted across-the-board increases in total paid claims and percent of utilizing beneficiaries with a paid claim in comparison to both the prior quarter and the prior-year quarter. While NSAIDS, CYCLOOXYGENASE INHIBITOR – TYPE may be related to cold and flu season, which peaks in California during in late Q4 and early Q1, the other two categories are related to treatment for chronic conditions: ANTIHYPERGLYCEMIC – HMG COA REDUCTASE INHIBITORS and ANTIHYPERGLYCEMIC, BIGUANIDE TYPE.

In **Table 6**, the following five drugs posted an increase (greater than 1%) of the percentage of utilizing beneficiaries with a paid claim from the prior quarter, resulting in corresponding double-digit increases in total paid claims: IBUPROFEN, AMOXICILLIN, ALBUTEROL SULFATE, AZITHROMYCIN, and PROMETHAZINE/DEXTROMETHORPHAN.

Appendix A: Prospective and Retrospective DUR Tables

Tables 1.1-1.2. Summary of Prospective DUR Alert Transactions.

Table 1.1 provides summary level data (by volume) on pharmacy claims and DUR alert activities, including data and percent change from the prior quarter. Alerts are generated after adjudication of drug claims which exceed or otherwise fall outside of certain prescribed parameters. Please see **Appendix B** for definitions of terms used in this DUR report.

Category	Current Quarter 2016 Q1 (Jan – Mar 2016)	Prior Quarter 2015 Q4 (Oct – Dec 2015)	% Change from <u>Prior</u> <u>Quarter</u>	Prior-Year Quarter 2015 Q1 (Jan – Mar 2015)	% Change from <u>Prior-Year</u> <u>Quarter</u>
Drug Claims	9,320,333	8,843,583	5.4%	9,800,080	-4.9%
DUR Drug Claims	4,764,062	4,570,055	4.2%	4,893,503	-2.6%
Total Alerts	1,068,799	1,025,190	4.3%	996,749	7.2%
Total Alert Overrides	626,134	596,651	4.9%	569,084	10.0%
Total Alert Cancels	281	269	4.5%	165	70.3%

Note: Drug claims receiving multiple alerts can be adjudicated by pharmacists by responding to only one conflict code, followed by an intervention code and outcome code. The remaining alerts on the claim cannot be tracked as they are overridden by the pharmacist's response to a single alert. For example, a single claim can generate up to eight different alerts, but the pharmacist can override all eight alerts by choosing to override only one alert. In addition, the number of cancelled alerts may be underrepresented due to the system's inability to capture claims that were not adjudicated.

Table 1.2 provides a summary of the number of drug claims and alerts generated for each therapeutic problem type (sorted by alert frequency). Total alerts not adjudicated may be overrepresented, as claims with multiple alerts that have been adjudicated under one alert will show up as not adjudicated for the remaining alerts.

Therapeutic Problem Type	Total Alerts	Total Alert Overrides	% Alert Overrides	Total Alert Cancels	% Alert Cancels	Total Alerts Not Adjudicated	% Alerts Not Adjudicated
Early Refill (ER)	336,735	102,841	30.5%	125	0.0%	233,769	69.4%
Ingredient Duplication (ID)	227,765	160,736	70.6%	41	0.0%	66,988	29.4%
Therapeutic Duplication (TD)	201,921	145,716	72.2%	55	0.0%	56,150	27.8%
Late Refill (LR)	128,748	98,101	76.2%	15	0.0%	30,632	23.8%
Total High Dose (HD)	58,379	35,957	61.6%	10	0.0%	22,412	38.4%
Additive Toxicity (AT)	45,515	36,077	79.3%	13	0.0%	9,425	20.7%
Total Low Dose (LD)	31,377	19,635	62.6%	4	0.0%	11,738	37.4%
Drug-Pregnancy (PG)	21,226	14,749	69.5%	3	0.0%	6,474	30.5%
Drug-Drug (DD)	12,043	8,814	73.2%	2	0.0%	3,227	26.8%
Drug-Disease (MC)	4,691	3,252	69.3%	0	0.0%	1,439	30.7%
Drug-Allergy (DA)	272	176	64.7%	0	0.0%	96	35.3%
Drug-Age (PA)	127	80	63.0%	0	0.0%	47	37.0%

Tables 2.1-2.12. Prospective DUR Alert Transactions by Therapeutic Problem Type.

Each of the following tables provides greater detail of each of the 12 DUR alerts with the top 10 drugs generating each respective alert. For each of the top 10 drugs, data are provided for the total number of adjudicated alerts, alert overrides, alert cancels, paid claims, and the percentage of paid claims with alert overrides. **Tables are listed in order of DUR alert priority, which is determined by the DUR Board.**

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	PHENYTOIN SODIUM EXTENDED	115	115	0	3,146	3.7%
2	PHENYTOIN	68	68	0	1,175	5.8%
3	AMOXICILLIN	13	13	0	65,969	0.0%
4	IBUPROFEN	10	10	0	121,706	0.0%
5	OXYCODONE HCL/ACETAMINOPHEN	9	9	0	8,551	0.1%
6	AMOXICILLIN/POTASSIUM CLAV	5	5	0	16,166	0.0%
7	PENICILLIN V POTASSIUM	5	5	0	5,874	0.1%
8	SULFAMETHOXAZOLE/TRIMETHOPRIM	5	5	0	22,077	0.0%
9	SOMATROPIN	3	3	0	2,155	0.1%
10	ASPIRIN	1	1	0	78,454	0.0%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	IBUPROFEN	10,186	10,185	1	121,706	8.4%
2	NORETHINDRONE	3,689	3,687	2	9,703	38.0%
3	SULFAMETHOXAZOLE/TRIMETHOPRIM	721	721	0	22,077	3.3%
4	ASPIRIN	579	579	0	78,454	0.7%
5	NAPROXEN	441	441	0	15,614	2.8%
6	DOXYCYCLINE HYCLATE	426	426	0	6,366	6.7%
7	MISOPROSTOL	367	367	0	864	42.5%
8	LORAZEPAM	220	220	0	14,635	1.5%
9	LISINAPRIL	212	212	0	39,611	0.5%
10	CLONAZEPAM	114	114	0	10,280	1.1%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	METFORMIN HCL	1,345	1,345	0	47,534	2.8%
2	POTASSIUM CHLORIDE	795	795	0	4,636	17.1%
3	HALOPERIDOL	440	440	0	21,735	2.0%
4	METOPROLOL TARTRATE	109	109	0	10,957	1.0%
5	CARBAMAZEPINE	91	91	0	4,520	2.0%
6	HALOPERIDOL DECANOATE	90	90	0	4,217	2.1%
7	METOPROLOL SUCCINATE	77	77	0	6,490	1.2%
8	ATENOLOL	62	62	0	9,146	0.7%
9	DILTIAZEM HCL	57	57	0	2,067	2.8%
10	PROPRANOLOL HCL	48	48	0	5,160	0.9%

Table 2.4: Top 10 Drugs by Therapeutic Problem Type – Drug-Drug Interaction (DD) – 2016 Q1

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	GEMFIBROZIL	710	710	0	3,897	18.2%
2	SIMVASTATIN	673	672	1	18,515	3.6%
3	ATORVASTATIN CALCIUM	493	493	0	23,925	2.1%
4	METOCLOPRAMIDE HCL	493	493	0	6,559	7.5%
5	AMLODIPINE BESYLATE	383	383	0	27,158	1.4%
6	ELVITEGR/COBICIST/EMTRIC/TENOF	285	285	0	7,757	3.7%
7	ELVITEG/COBI/EMTRIC/TENOFO ALA	260	260	0	2,243	11.6%
8	ZIPRASIDONE HCL	238	238	0	19,626	1.2%
9	LURASIDONE HCL	198	198	0	34,124	0.6%
10	DARUNAVIR ETHANOLATE	171	171	0	8,518	2.0%

Table 2.5: Top 10 Drugs by Therapeutic Problem Type – Therapeutic Duplication (TD) – 2016 Q1

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	24,071	24,066	5	136,709	17.6%
2	OLANZAPINE	16,002	15,999	3	71,704	22.3%
3	RISPERIDONE	15,355	15,348	7	90,285	17.0%
4	LURASIDONE HCL	9,179	9,178	1	34,124	26.9%
5	TRAZODONE HCL	6,169	6,167	2	13,695	45.0%
6	ZIPRASIDONE HCL	6,100	6,098	2	19,626	31.1%
7	CLOZAPINE	5,799	5,795	4	18,259	31.7%
8	ALBUTEROL SULFATE	5,669	5,669	0	73,942	7.7%
9	PALIPERIDONE PALMITATE	5,148	5,148	0	14,092	36.5%
10	PREDNISONE	4,836	4,836	0	23,333	20.7%

Table 2.6: Top 10 Drugs by Therapeutic Problem Type – Overutilization (ER) – 2016 Q1

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	9,654	9,650	4	136,709	7.1%
2	ARIPIRAZOLE	7,258	7,254	4	102,971	7.0%
3	RISPERIDONE	5,523	5,518	5	90,285	6.1%
4	OLANZAPINE	4,263	4,261	2	71,704	5.9%
5	BENZTROPINE MESYLATE	4,114	4,113	1	58,168	7.1%
6	ASPIRIN	2,527	2,525	2	78,454	3.2%
7	LURASIDONE HCL	2,487	2,485	2	34,124	7.3%
8	LITHIUM CARBONATE	2,472	2,470	2	29,344	8.4%
9	METFORMIN HCL	2,085	2,082	3	47,534	4.4%
10	ALBUTEROL SULFATE	2,045	2,044	1	73,942	2.8%

Table 2.7: Top 10 Drugs by Therapeutic Problem Type – Underutilization (LR) – 2016 Q1

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	ARIPIRAZOLE	19,109	19,108	1	102,971	18.6%
2	QUETIAPINE FUMARATE	17,989	17,987	2	136,709	13.2%
3	RISPERIDONE	12,107	12,105	2	90,285	13.4%
4	OLANZAPINE	9,055	9,055	0	71,704	12.6%
5	BENZTROPINE MESYLATE	7,247	7,247	0	58,168	12.5%
6	LURASIDONE HCL	5,184	5,184	0	34,124	15.2%
7	LITHIUM CARBONATE	4,530	4,529	1	29,344	15.4%
8	ZIPRASIDONE HCL	3,494	3,494	0	19,626	17.8%
9	ATORVASTATIN CALCIUM	3,386	3,386	0	23,925	14.2%
10	AMLODIPINE BESYLATE	2,998	2,998	0	27,158	11.0%

Table 2.8: Top 10 Drugs by Therapeutic Problem Type – Additive Toxicity (AT) – 2016 Q1

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	2,191	2,191	0	136,709	1.6%
2	ARIPIRAZOLE	2,029	2,029	0	102,971	2.0%
3	CLONAZEPAM	1,802	1,802	0	10,280	17.5%
4	LITHIUM CARBONATE	1,673	1,673	0	29,344	5.7%
5	HALOPERIDOL	1,167	1,163	4	21,735	5.4%
6	OLANZAPINE	1,097	1,096	1	71,704	1.5%
7	ZOLPIDEM TARTRATE	1,061	1,061	0	6,729	15.8%
8	RISPERIDONE	941	941	0	90,285	1.0%
9	TRAZODONE HCL	707	707	0	13,695	5.2%
10	BUPROPION HCL	582	582	0	7,897	7.4%

Table 2.9: Top 10 Drugs by Therapeutic Problem Type – Ingredient Duplication (ID) – 2016 Q1

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	QUETIAPINE FUMARATE	29,692	29,690	2	136,709	21.7%
2	OLANZAPINE	14,841	14,839	2	71,704	20.7%
3	ARIPIRAZOLE	14,300	14,300	0	102,971	13.9%
4	RISPERIDONE	13,196	13,196	0	90,285	14.6%
5	ALBUTEROL SULFATE	8,448	8,448	0	73,942	11.4%
6	CLOZAPINE	5,900	5,894	6	18,259	32.3%
7	LURASIDONE HCL	5,385	5,385	0	34,124	15.8%
8	ZIPRASIDONE HCL	4,837	4,837	0	19,626	24.6%
9	LEVOTHYROXINE SODIUM	3,720	3,719	1	31,433	11.8%
10	HALOPERIDOL	3,594	3,594	0	21,735	16.5%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	AMITRIPTYLINE HCL	35	35	0	4,371	0.8%
2	SIMVASTATIN	22	22	0	18,515	0.1%
3	DOXEPIN HCL	19	19	0	536	3.5%
4	RISPERIDONE	10	10	0	90,285	0.0%
5	ACETAMINOPHEN	6	6	0	36,255	0.0%
6	HYDROCODONE/ACETAMINOPHEN	6	6	0	51,078	0.0%
7	OLANZAPINE	4	4	0	71,704	0.0%
8	PROMETHAZINE HCL/CODEINE	4	4	0	16,932	0.0%
9	ARIPIRAZOLE	3	3	0	102,971	0.0%
10	BUDESONIDE	3	3	0	5,420	0.1%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	OLANZAPINE	8,572	8,571	1	71,704	12.0%
2	RISPERIDONE	3,146	3,146	0	90,285	3.5%
3	QUETIAPINE FUMARATE	2,602	2,602	0	136,709	1.9%
4	IBUPROFEN	2,203	2,203	0	121,706	1.8%
5	AMOXICILLIN	2,192	2,189	3	65,969	3.3%
6	AMOXICILLIN/POTASSIUM CLAV	1,687	1,687	0	16,166	10.4%
7	GABAPENTIN	1,617	1,617	0	25,197	6.4%
8	ARIPIRAZOLE	1,169	1,169	0	102,971	1.1%
9	ZIPRASIDONE HCL	1,098	1,098	0	19,626	5.6%
10	ALBUTEROL SULFATE	857	857	0	73,942	1.2%

Rank	Drug Generic Name/Ingredient Name	Total Adjudicated Alerts	Total Alert Overrides	Total Alert Cancels	Total Paid Claims	% of Paid Claims with Alert Overrides
1	LITHIUM CARBONATE	4,536	4,536	0	29,344	15.5%
2	GABAPENTIN	2,144	2,143	1	25,197	8.5%
3	ALBUTEROL SULFATE	1,428	1,428	0	73,942	1.9%
4	AZITHROMYCIN	1,214	1,214	0	46,195	2.6%
5	AMOXICILLIN	818	818	0	65,969	1.2%
6	AMOXICILLIN/POTASSIUM CLAV	760	760	0	16,166	4.7%
7	CLONIDINE HCL	702	702	0	10,763	6.5%
8	DIVALPROEX SODIUM	633	633	0	14,164	4.5%
9	ERYTHROMYCIN ETHYLSUCCINATE	543	543	0	1,682	32.3%
10	CEPHALEXIN	542	542	0	31,376	1.7%

Table 3. Summary of Medi-Cal FFS Pharmacy / Drug Utilization Measures.

This table shows pharmacy utilization for the Medi-Cal FFS population, including the percent change from the prior quarter and prior-year quarter. Please note that all retrospective data tables exclude claims from beneficiaries in the Family Planning, Access, Care, and Treatment (Family PACT) program and the California Children's Services/ Genetically Handicapped Persons Program (CCS/GHPP) because they have different guidelines concerning access to prescription drugs than other Medi-Cal FFS beneficiaries.

Table 3: Pharmacy Utilization Measures for the Medi-Cal FFS Population					
Category	Current Quarter 2016 Q1	Prior Quarter 2015 Q4	Prior-Year Quarter 2015 Q1	% Change from <u>Prior Quarter</u>	% Change from <u>Prior-Year Quarter</u>
Total Eligible FFS Beneficiaries	2,826,539	2,745,704	2,728,150	2.9%	3.6%
Total Utilizing FFS Beneficiaries	865,726	824,497	908,254	5.0%	-4.7%
Total Paid Rx Claims	3,021,024	2,887,863	3,149,512	4.6%	-4.1%
Average Paid Rx Claims per Eligible FFS Beneficiary	1.07	1.05	1.15	1.8%	-7.1%
Average Paid Rx Claims per Utilizing FFS Beneficiary	3.49	3.50	3.47	-0.3%	0.6%
Total Reimbursement Paid (\$) to Pharmacies	\$748,793,485	\$717,704,785	\$664,315,540	4.3%	12.7%
Average Reimbursement Paid (\$) per Eligible FFS Beneficiary	\$264.92	\$261.39	\$243.50	1.3%	8.8%
Average Reimbursement Paid (\$) per Utilizing FFS Beneficiary	\$864.93	\$870.48	\$731.42	-0.6%	18.3%
Average Reimbursement Paid (\$) per Paid Rx Claim	\$247.86	\$248.52	\$210.93	-0.3%	17.5%

Table 4. Pharmacy Utilization by Age Group in the Medi-Cal FFS Population.

This table presents pharmacy utilization data broken out by age group, including the percent change from the prior quarter and prior-year quarter.

Table 4: Pharmacy Utilization by Age Group in the Medi-Cal FFS Population						
Age Group (years)	Current Quarter 2016 Q1 Total Paid Claims	% Change Total Paid Claims from <u>Prior Quarter</u>	% Change Total Paid Claims from <u>Prior-Year Quarter</u>	Current Quarter 2016 Q1 Total Utilizing Beneficiaries	% Change Total Utilizing Beneficiaries from <u>Prior Quarter</u>	% Change Total Utilizing Beneficiaries from <u>Prior-Year Quarter</u>
0 – 12	337,725	15.0%	-11.2%	135,733	10.5%	-10.5%
13 – 18	150,736	5.1%	-9.7%	46,874	3.8%	-10.4%
19 – 39	894,354	5.2%	6.6%	279,720	5.3%	7.5%
40 – 64	1,315,594	2.2%	-0.8%	301,046	3.3%	1.5%
65+	301,261	2.3%	-25.3%	93,593	2.3%	-30.2%
Total*	3,021,024	4.6%	-4.1%	865,726	5.0%	-4.7%

* Unknowns represent less than 1% of total

Table 5. Top 20 Drug Therapeutic Categories in the Medi-Cal FFS Population.

This table presents utilization of the top 20 drug therapeutic categories, by **percentage of utilizing beneficiaries with a paid claim**. The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization and reimbursement dollars paid to pharmacies for these top utilized drugs. The prior-year quarter ranking of the drug therapeutic category is listed for reference.

Table 5: Top 20 Drug Therapeutic Categories by *Percentage of Utilizing Beneficiaries with a Paid Claim*

Rank	Last Year Rank	Drug Therapeutic Category Description	Current Quarter 2016 Q1 Total Paid Claims	% Change Total Paid Claims from <i>Prior Quarter</i>	% Change Total Paid Claims from <i>Prior-Year Quarter</i>	Current Quarter 2016 Q1 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change Utilizing Beneficiaries with a Paid Claim from <i>Prior Quarter</i>	% Change Utilizing Beneficiaries with a Paid Claim from <i>Prior-Year Quarter</i>
1	1	ANTIPSYCHOTICS, ATYPICAL, DOPAMINE, & SEROTONIN ANTAG	397,509	0.9%	4.0%	136,034	15.7%	-0.5%	1.2%
2	2	NSAIDS, CYCLOOXYGENASE INHIBITOR - TYPE ANALGESICS	145,085	13.5%	7.7%	124,674	14.4%	1.1%	1.5%
3	3	PENICILLINS	88,538	24.6%	-3.6%	79,920	9.2%	1.5%	0.1%
4	5	ANALGESICS, NARCOTICS	87,796	-2.8%	-4.5%	59,386	6.9%	-0.5%	0.2%
5	4	ANALGESIC/ANTIPYRETICS, SALICYLATES	77,528	-0.1%	-28.1%	51,254	5.9%	-0.2%	-1.8%
6	6	BETA-ADRENERGIC AGENTS, INHALED, SHORT ACTING	67,191	20.8%	-6.7%	50,612	5.8%	1.0%	-0.2%
7	10	ANTIPSYCHOTICS, ATYP, D2 PARTIAL AGONIST/5HT MIXED	104,000	3.0%	-0.5%	45,266	5.2%	-0.1%	0.2%
8	7	ANTIHISTAMINES - 2ND GENERATION	57,173	12.3%	-18.7%	40,132	4.6%	0.5%	-0.8%
9	8	LAXATIVES AND CATHARTICS	59,416	-2.0%	-21.0%	39,956	4.6%	-0.3%	-0.9%
10	11	MACROLIDES	42,625	36.3%	-5.0%	39,205	4.5%	1.1%	0.0%
11	9	IRON REPLACEMENT	47,188	6.1%	-24.3%	36,471	4.2%	0.1%	-1.1%
12	13	ANTICONVULSANTS	95,387	1.0%	-1.4%	36,195	4.2%	-0.1%	0.2%
13	16	ANTIHYPERTENSIVES, ACE INHIBITORS	54,124	2.4%	3.1%	34,942	4.0%	-0.1%	0.3%
14	14	ANALGESIC/ANTIPYRETICS, NON-SALICYLATE	35,766	13.0%	-8.2%	32,812	3.8%	0.3%	-0.1%
15	18	ANTIHYPERLIPIDEMIC - HMG COA REDUCTASE INHIBITORS	51,184	2.5%	5.6%	32,381	3.7%	0.0%	0.4%
16	12	NON-NARC ANTITUSSIVE-1ST GEN ANTIHISTAMINE COMB.	35,558	45.0%	-16.0%	31,373	3.6%	1.0%	-0.4%
17	15	PRENATAL VITAMIN PREPARATIONS	34,366	4.2%	-13.1%	30,307	3.5%	0.0%	-0.4%
18	24	ANTIHYPERGLYCEMIC, BIGUANIDE TYPE	45,410	5.0%	12.3%	29,832	3.4%	0.0%	0.5%
19	23	GLUCOCORTICOIDS	33,810	18.3%	-1.0%	27,932	3.2%	0.4%	0.1%
20	22	CEPHALOSPORINS - 1ST GENERATION	29,679	3.4%	-1.5%	27,817	3.2%	0.0%	0.1%

Table 6. Top 20 Drugs in the Medi-Cal FFS Population.

This table presents utilization of the top 20 drugs, by **percentage of utilizing beneficiaries with a paid claim**. The current quarter is compared to the prior quarter and prior-year quarter in order to illustrate changes in utilization for these drugs. The prior-year quarter ranking of each drug is listed for reference.

Utilization of drugs for Medi-Cal fee-for-service beneficiaries also includes carved-out drugs utilized by beneficiaries in Medi-Cal managed care plans. Carved-out drugs are listed below in bolded and italicized print.

Table 6: Top 20 Drugs by Percentage of Utilizing Beneficiaries with a Paid Claim

Rank	Last Year Rank	Drug Description	Current Quarter 2016 Q1 Total Paid Claims	% Change Total Paid Claims from <u>Prior Quarter</u>	% Change Total Paid Claims from <u>Prior-Year Quarter</u>	Current Quarter 2016 Q1 Total Utilizing Beneficiaries	% Utilizing Beneficiaries with a Paid Claim	% Change of Utilizing Beneficiaries with a Paid Claim from <u>Prior Quarter</u>	% Change of Utilizing Beneficiaries with a Paid Claim from <u>Prior-Year Quarter</u>
1	1	IBUPROFEN	121,220	15.3%	5.1%	107,312	12.4%	1.1%	1.1%
2	3	AMOXICILLIN	65,472	25.5%	-4.7%	60,527	7.0%	1.2%	0.0%
3	4	ALBUTEROL SULFATE	70,474	21.0%	-7.5%	53,376	6.2%	1.0%	-0.2%
4	5	QUETIAPINE FUMARATE	136,547	2.1%	4.6%	52,781	6.1%	-0.1%	0.5%
5	2	ASPIRIN	77,472	0.0%	-27.9%	51,210	5.9%	-0.2%	-1.8%
6	9	ARIPIRAZOLE	102,772	2.3%	-1.4%	44,806	5.2%	-0.1%	0.2%
7	10	HYDROCODONE/ACETAMINOPHEN	50,537	-1.2%	-1.4%	40,864	4.7%	-0.3%	0.2%
8	6	LORATADINE	56,576	12.5%	-18.7%	39,857	4.6%	0.5%	-0.8%
9	7	DOCUSATE SODIUM	55,694	-1.1%	-21.1%	38,233	4.4%	-0.3%	-0.8%
10	11	AZITHROMYCIN	39,604	40.2%	-4.5%	37,075	4.3%	1.1%	0.0%
11	8	FERROUS SULFATE	47,144	7.7%	-22.7%	36,455	4.2%	0.2%	-1.0%
12	12	RISPERIDONE	89,555	0.2%	-4.0%	36,134	4.2%	-0.2%	-0.1%
13	14	ACETAMINOPHEN	35,766	12.6%	-8.2%	32,812	3.8%	0.2%	-0.1%
14	24	PROMETHAZINE/DEXTROMETHORPHAN	35,558	45.0%	-16.0%	31,373	3.6%	1.0%	1.8%
15	17	METFORMIN HCL	45,410	5.3%	13.0%	29,832	3.4%	0.0%	0.5%
16	15	CEPHALEXIN	29,595	3.7%	-1.2%	27,796	3.2%	0.0%	0.1%
17	18	OLANZAPINE	71,641	2.3%	8.1%	27,132	3.1%	0.0%	0.4%
18	19	LISINAPRIL	38,610	3.7%	8.2%	25,167	2.9%	0.0%	0.3%
19	20	BENZTROPINE MESYLATE	58,151	0.5%	0.8%	23,510	2.7%	-0.1%	0.1%
20	16	FOLIC ACID	34,823	1.5%	-23.5%	20,849	2.4%	0.0%	-0.6%

APPENDIX B: Definition of terms.

Adjudicate: To pay or deny drug claims after evaluating the claim for coverage requirements

Average Reimbursement (\$): A measure of the mean value of the reimbursement in dollars; the sum of the reimbursement divided by the number measured (in dollars).

Beneficiary: A person who has been determined eligible for Medi-Cal, as according to the California Code of Regulations 50024

Eligible FFS beneficiary: A Medi-Cal FFS beneficiary that qualifies for drug benefits

Quarter: One fourth, $\frac{1}{4}$, 25% or .25 of a year measured in months.

Reimbursement: The reimbursement paid to Medi-Cal pharmacy providers for legend and nonlegend drugs dispensed to Medi-Cal Fee-for-Service (FFS) beneficiaries. Reimbursement is determined in accordance with CA Welfare and Institutions Code Section 14105.45(b)(1).

Drug therapeutic category: Drug therapeutic categories are grouping of drugs at various hierarchy levels and characteristics that may be similar in chemical structure, pharmacological effect, clinical use, indications, and/or other characteristics of drug products.

Utilizing FFS beneficiary: A Medi-Cal beneficiary with at least one FFS prescription filled during the measurement period



PHYSICIAN-ADMINISTERED DRUGS: 4th QUARTER 2015

Utilization of physician-administered drugs during the fourth quarter of 2015 (October – December 2015) is presented below, stratified by category. In order to show changes in utilization over time, **Table 1** shows the comparison to the prior quarter (2015 Q3) and **Table 2** shows the comparison to the prior-year quarter (2014 Q4).

Table 1: 2015 Q4 Physician-Administered Drugs: Change from 2015 Q3 (one quarter)						
Category	Total Utilizing Beneficiaries	% Change from 2015 Q3	Total Paid Claims	% Change from 2015 Q3	Total Reimbursement Dollars Paid	% Change from 2015 Q3
PHYSICIAN ADMINISTERED DRUG - NDC NOT REQUIRED (vaccines, hyaluronate)	27,224	22.6%	38,670	14.1%	\$875,056	7.8%
PHYSICIAN ADMINISTERED DRUG - NDC REQUIRED	271,992	-7.4%	644,007	-8.4%	\$64,386,376	-5.1%
MISCELLANEOUS PRODUCT - REPORTING REQUIRED (supplies, immune globulin, IV solutions)	119,240	-7.0%	254,532	-6.1%	\$2,906,806	-8.7%
TOTAL	418,456	-5.8%	937,209	-7.0%	\$68,168,239	-5.1%

Table 2: 2015 Q4 Physician-Administered Drugs: Change from 2014 Q4 (one year)						
Category	Total Utilizing Beneficiaries	% Change from 2014 Q4	Total Paid Claims	% Change from 2014 Q4	Total Reimbursement Dollars Paid	% Change from 2014 Q4
PHYSICIAN ADMINISTERED DRUG - NDC NOT REQUIRED (vaccines, hyaluronate)	27,224	-51.6%	38,670	-46.0%	\$875,056	-26.4%
PHYSICIAN ADMINISTERED DRUG - NDC REQUIRED	271,992	-19.6%	644,007	-20.2%	\$64,386,376	-16.3%
MISCELLANEOUS PRODUCT - REPORTING REQUIRED (supplies, immune globulin, IV solutions)	119,240	-10.6%	254,532	-8.3%	\$2,906,806	-14.3%
TOTAL	418,456	-20.8%	937,209	-19.0%	\$68,168,239	-16.3%

The following three tables show the top 20 physician-administered drugs by total utilizing beneficiaries (**Table 3**), total reimbursement dollars paid (**Table 4**), and reimbursement paid per utilizing beneficiary (**Table 5**). Each table has the comparison to the prior quarter and the prior-year quarter, for reference. In addition, the prior-year ranking is given to show changes in utilization of a drug over time.

Table 3: Top 20 Physician-Administered Drugs by Total Utilizing Beneficiaries

Rank	Last Year Rank	HCPCS Code	Drug Description	2015 Q4 Total Utilizing Beneficiaries	% Change Total Utilizing Beneficiaries from 2015 Q3	% Change Total Utilizing Beneficiaries from 2014 Q4	2015 Q4 Total Reimbursement Dollars Paid	2015 Q4 Total Paid Claims
1	1	J3490	MEDROXYPROGES TERONE ACETATE	43,156	-5.4%	-5.3%	\$2,840,899	44,084
2	2	J3490	LEVONORGESTREL	30,708	-9.2%	-15.6%	\$919,584	32,227
3	4	J3490	ULIPRISTAL ACETATE	25,233	-6.6%	0.3%	\$782,694	26,510
4	5	S4993	LEVONORGESTREL -ETHIN ESTRADIOL	22,460	-7.5%	-6.7%	\$2,687,854	22,828
5	3	J2405	ONDANSETRON HCL/PF	21,579	-9.0%	-16.3%	\$119,140	26,214
6	6	J1885	KETOROLAC TROMETHAMINE	17,078	-6.5%	-3.7%	\$99,504	18,817
7	7	X7700	0.9 % SODIUM CHLORIDE	14,027	-6.3%	-5.3%	\$339,701	22,968
8	9	J2270	MORPHINE SULFATE	12,155	-12.0%	-10.6%	\$89,822	14,612
9	8	S4993	NORGESTIMATE-ETHINYL ESTRADIOL	10,628	-13.0%	-24.2%	\$1,209,371	10,911
10	10	J0696	CEFTRIAZONE SODIUM	9,620	-9.3%	5.9%	\$61,357	10,525
11	13	Z7610	ACETAMINOPHEN	8,898	-4.6%	6.2%	\$80,847	10,480
12	16	Q0144	AZITHROMYCIN	8,752	-0.7%	-20.7%	\$69,631	9,119
13	12	J7307	ETONOGESTREL	8,673	-8.2%	-9.9%	\$5,571,814	8,673
14	18	Z7610	IBUPROFEN	8,271	-3.3%	6.1%	\$69,275	8,637
15	19	J1100	DEXAMETHASONE SOD PHOSPHATE	7,598	7.8%	-1.3%	\$52,151	10,046
16	15	J1170	HYDROMORPHONE HCL	7,405	-14.5%	-14.6%	\$63,328	10,001
17	11	J7303	ETONOGESTREL/ET HINYL ESTRADIOL	7,079	-11.4%	-32.9%	\$1,318,570	7,119
18	14	Z7610	HYDROCODONE/AC ETAMINOPHEN	7,018	-17.4%	-20.8%	\$73,822	7,764
19	17	J3010	FENTANYL CITRATE/PF	6,690	-18.0%	-20.0%	\$36,511	7,443
20	20	S5000	METRONIDAZOLE	6,345	-4.9%	-13.1%	\$49,691	6,639

Table 4: Top 20 Physician-Administered Drugs by Total Reimbursement Dollars Paid

Rank	Last Year Rank	HCPCS Code	Drug Description	2015 Q4 Total Reimbursement Dollars Paid	% Change Total Reimbursement Dollars from 2015 Q3	% Change Total Reimbursement Dollars from 2014 Q4	2015 Q4 Total Utilizing Beneficiaries	2015 Q4 Total Paid Claims
1	2	J7307	ETONOGESTREL	\$5,571,814	-7.4%	-8.8%	8,673	8,673
2	1	J7189	COAGULATION FACTOR VIIA,RECOMB (NOVOSEVEN®)	\$4,988,199	56.0%	-32.1%	21	165
3	3	J7302	LEVONORGESTREL	\$4,312,749	1.7%	-10.2%	6,159	6,190
4	7	J3490	MEDROXYPROGESTERONE ACETATE	\$2,840,899	-5.2%	-2.7%	43,156	44,084
5	8	S4993	LEVONORGESTREL-ETHIN ESTRADIOL	\$2,687,854	-10.2%	-7.0%	22,460	22,828
6	4	J9355	TRASTUZUMAB	\$2,280,378	-21.4%	-41.1%	276	901
7	9	J7300	INTRAUTERINE COPPER CONTRACEPTIVE	\$2,208,327	-10.7%	-18.8%	3,407	3,421
8	11	J9019	ASPARAGINASE (ERWINIA CHRYSAN)	\$2,056,529	11.6%	-0.6%	36	224
9	10	Q4081	EPOETIN ALFA (100 UNITS ESRD)	\$2,016,516	-6.3%	-12.7%	1,780	41,748
10	5	J7192	ANTIHEMOPH.FVIII,FULL LENGTH (INCLUDES ADVATE®, HELIXATE®, AND KOGENATE®)	\$1,994,909	-16.3%	-32.6%	64	209
11	13	J1745	INFLIXIMAB	\$1,809,237	-6.6%	2.3%	415	822
12	6	J2505	PEGFILGRASTIM	\$1,781,459	-30.2%	-39.1%	267	550
13	17	J7304	NORELGESTROMIN/ETHIN. ESTRADIOL	\$1,754,238	4.5%	19.8%	4,828	4,904
14	23	J1300	ECULIZUMAB	\$1,560,432	9.4%	94.9%	21	130
15	15	90378	PALIVIZUMAB	\$1,354,166	N/A	-17.6%	341	560
16	12	J7303	ETONOGESTREL/ETHINYL ESTRADIOL	\$1,318,570	-10.9%	-27.7%	7,079	7,119
17	14	J9035	BEVACIZUMAB	\$1,305,776	-19.8%	-20.7%	236	614
18	16	S4993	NORGESTIMATE-ETHINYL ESTRADIOL	\$1,209,371	-11.3%	-25.1%	10,628	10,911
19	18	J0886	EPOETIN ALFA (1000 UNITS ESRD)	\$1,098,002	-3.1%	-9.7%	983	17,184
20	21	J3490	LEVONORGESTREL	\$919,584	-1.6%	-9.3%	30,708	32,227

Table 5: Top 20 Physician-Administered Drugs by *Reimbursement Paid per Utilizing Beneficiary*

Rank	Last Year Rank	HCPCS Code	Drug Description	2015 Q4 Reimbursement Dollars Paid per Utilizing Beneficiary	% Change Reimbursement Dollars Paid per Utilizing Beneficiary from 2015 Q3	% Change Reimbursement Dollars Paid per Utilizing Beneficiary from 2014 Q4	2015 Q4 Total Reimbursement Dollars Paid	2015 Q4 Total Utilizing Beneficiaries
1	3	J3590	ELOSULFASE ALFA ¹	\$265,971	-16.7%	93.6%	\$265,971	1
2	1	J7189	COAGULATION FACTOR VIIA,RECOMB (NOVOSEVEN®)	\$237,533	130.3%	32.5%	\$4,988,199	21
3	17	J7190	ANTIHEMOPHILIC FACTOR, HUMAN (KOATE-DVI®)	\$147,168	-6.2%	322.2%	\$147,168	1
4	2	J7199	FACTOR IX REC, FC FUSION PROTN (ALPROLIX®)	\$139,649	12.9%	-10.0%	\$558,594	4
5	5	J1458	GALSULFASE	\$91,309	-2.0%	0.4%	\$456,547	5
6	22	J7198	ANTI-INHIBITOR COAGULANT COMP. (FEIBA NF®)	\$83,156	34.4%	200.1%	\$665,247	8
7	16	C9134	FACTOR XIII A-SUBUNIT,RECOMB (TRETEN®)	\$81,736	-28.5%	103.6%	\$163,473	2
8	7	J1743	IDURSULFASE	\$78,799	-0.6%	2.8%	\$630,395	8
9	N/A	Q2043	SIPULEUCEL-T/LACTATED RINGERS	\$76,642	199.5%	N/A	\$153,284	2
10	6	J0180	AGALSIDASE BETA	\$74,561	26.6%	-10.6%	\$298,244	4
11	10	J1300	ECULIZUMAB	\$74,306	4.2%	11.4%	\$1,560,432	21
12	80	J1322	ELOSULFASE ALFA ²	\$68,732	N/A	1731.0%	\$68,732	1
13	12	J7185	ANTIHEMOPH.FVIII,B-DOMAIN DEL (XYNTHA®)	\$61,983	41.0%	26.0%	\$185,950	3
14	9	J9019	ASPARAGINASE (ERWINIA CHRYSAN)	\$57,126	17.8%	-14.4%	\$2,056,529	36
15	14	J7199	ANTIHEMOPH.FVIII REC,FC FUSION (ELOCTATE®)	\$52,452	14.0%	23.1%	\$367,163	7
16	106	J9261	NELARABINE ³	\$50,598	N/A	3531.9%	\$50,598	1
17	29	J7193	FACTOR IX (MONONINE®, ALPHANINE® SD)	\$49,304	N/A	144.2%	\$98,608	2
18	4	J9228	IPILIMUMAB	\$47,535	86.2%	-54.8%	\$95,071	2
19	11	J0221	ALGLUCOSIDASE ALFA	\$40,866	-16.2%	-20.2%	\$163,463	4
20	8	J1786	IMIGLUCERASE	\$40,515	39.3%	-40.2%	\$202,576	5

¹In 2015 Q4, one beneficiary had 20 paid claims for this drug (for comparison, in 2014 Q4 there were 23 paid claims for two beneficiaries and in 2015 Q3 one beneficiary had 24 paid claims).

²The HCPCS code J1322 is specific to ELOSULFASE ALFA, while J3590 is a generic code for "UNCLASSIFIED BIOLOGICS." In 2014 Q4, there were two beneficiaries with one paid claim each for ELOSULFASE ALFA under this HCPCS code. However, in 2015 Q4 there was only one beneficiary with four paid claims and no paid claims in 2015 Q3.

³In 2014 Q4, as in 2015 Q4, there was only one beneficiary with a paid claim for NELARABINE. However, in 2015 Q4 the one beneficiary had nine paid claims (compared to one paid claim in 2014). There were no paid claims in 2015 Q3.



PROSPECTIVE DUR REVIEW

DATE OF REVIEW: April 12, 2016

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- GROWTH HORMONES
- TX FOR ATTENTION DEFICIT-HYPERACT(ADHD)/NARCOLEPSY
- TOPICAL ANTI-INFLAMMATORY, NSAIDS
- ANALGESIC, NON-SALICYLATE & BARBITURATE COMB.
- ANTIPSYCHOTIC-ATYPICAL,D3/D2 PARTIAL AG-5HT MIXED
- ANDROGENIC AGENTS
- ANALGESICS, NARCOTICS
- ARTV CMB NUCLEOSIDE,NUCLEOTIDE,&NON-NUCLEOSIDE RTI
- BETA-ADRENERGIC BLOCKING AGENTS
- ANTICONVULSANTS

DRUG PROBLEM TYPES: Drug-Allergy (DA), Drug-Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Underutilization (LR), Additive Toxicity (AT), Ingredient Duplication (ID), Drug-Age (PA), High Dose (HD), Low Dose (LD)

BACKGROUND: Each week new Generic Code Number (GCN) sequence numbers are added. Prospective DUR alerts for Overutilization (ER) and Severity Level 1 Drug-Drug Interactions (DD) are automatically turned on for all new GCNs.

ISSUES: New GCNs are reviewed and cross-referenced to the Medi-Cal target drug list for prospective DUR. If a GCN matches a drug on the Medi-Cal target drug list, the prospective DUR alert profile for the existing GCN is used to set the alert profile for the new GCN. A list of new GCNs with alerts turned on other than ER and DD is provided to the DUR Board for review at each DUR Board meeting.

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Review list of GCNs with prospective DUR alerts turned on between January 1, 2016 and March 31, 2016 (**Table 1**).
- Any DUR Board recommendations for additions, deletions, and/or changes will be submitted to DHCS for review. Status of recommendations will be reported to the DUR Board at DUR Board meetings, as needed.

Table 1. New GCNs for Existing DUR Target Drugs: Q1 2016 (01/01/16 – 03/31/16).

Date	GCN	Drug Description	Additional Alerts Turned on
1/13/2016	074867	SOMATROPIN	Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
1/13/2016	074870		
2/3/2016	075263	METHYLPHENIDATE HCL	High Dose (HD), Low Dose (LD)
2/3/2016	075264		
2/3/2016	075265		
2/3/2016	075439	DICLOFENAC/ BENZALKONIUM CHLOR	Drug Allergy (DA), Drug Pregnancy (PG), Drug-Disease (MC), Therapeutic Duplication (TD), Ingredient Duplication (ID), High Dose (HD)
2/24/2016	075526	BUTALBITAL/ACETAMINOPHEN	Ingredient Duplication (ID), High Dose (HD)
2/24/2016	074807	CARIPRAZINE HYDROCHLORIDE	Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD)
2/24/2016	074808		
2/24/2016	074809		
2/24/2016	074810		
2/24/2016	075566		
3/2/2016	075581	TESTOSTERONE MICRONIZED	Drug Pregnancy (PG), , Additive Toxicity (AT), High Dose (HD), Low Dose (LD)
3/9/2016	062950	FENTANYL/ROPIVACAINE/NS/PF	Drug-Allergy (DA), Drug-Disease (MC), Therapeutic Duplication (TD), Additive Toxicity (AT), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)
3/9/2106	075634	EMTRICITAB/RILPIVIRI/TENOF ALA	Ingredient Duplication (ID)
3/9/2016	075636	METOPROLOL TARTRATE	Drug-Disease (MC), Therapeutic Duplication (TD), Late Refill (LR), High Dose (HD), Low Dose (LD)
3/9/2106	075637		
3/30/2016	075703	GABAPENTIN/LIDOCAINE/MENTHOL	Drug-Allergy (DA), Late Refill (LR), Ingredient Duplication (ID), High Dose (HD), Low Dose (LD)



PROSPECTIVE DUR REVIEW

DATE OF REVIEW: September 26, 2015; April 12, 2016

AMERICAN HOSPITAL FORMULARY SERVICE (AHFS) THERAPEUTIC CATEGORY:

- Reviewed all drugs.

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- Reviewed all drugs.

DRUG PROBLEM TYPE: Drug/Pregnancy (PG)

BACKGROUND: In the current Medi-Cal DUR system, the presence of pregnancy is indicated when female recipients between 13 and 45 years of age have an active prescription for prenatal vitamins or a medical claim diagnosis code for pregnancy. The pregnancy diagnosis is removed from a beneficiary's medical profile after 240 days, or if an intervening diagnosis indicating pregnancy termination, including delivery, is received on a claim.

The Drug/Pregnancy (PG) alert is generated when a pharmacy claim for a drug that possesses a clinical significance of D, X, or 1 (as assigned by the United States Food and Drug Administration [FDA] or First DataBank, Inc.) is being processed for a beneficiary with a current pregnancy diagnosis on their profile. Codes D, X, and 1 are defined as follows:

- **D:** There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans. However, potential benefits may warrant use of the drug in pregnant women despite potential risks if the drug is needed in a life-threatening situation or for a serious disease for which safer drugs cannot be used or are ineffective. This is an FDA- assigned value.
- **X:** Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits. This is an FDA-assigned value.
- **1:** No FDA rating but is contraindicated or not recommended; may have animal and/or human studies or pre- or post-marketing information. This is a First DataBank, Inc.- assigned value.

ISSUES: A review of the DUR manual shows the reference material for the PG alert listed in Section 20 (DUR: Prospective Drug Use Review) has not been updated and does not contain a complete list of the drugs that have the PG alert turned on at this time. There are also inconsistencies in alert status within drug class, and many drugs with FDA pregnancy risk category D or X were found to not have the PG alert on.

In addition, on December 4, 2014 the United States Food and Drug Administration (FDA) published the final rule entitled, "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling, referred to as the

“Pregnancy and Lactation Labeling Rule” (PLLR, or final rule 79 FR 72064).¹ This rule creates a consistent format for providing information about the risks and benefits of drug use during pregnancy and lactation and by females and males of reproductive potential. Labeling must also include a summary of the risks of using a drug during pregnancy and lactation, a discussion of the data supporting that summary and relevant information to help health care providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. Revisions were intended to help facilitate prescribing counseling efforts in these populations.

One of the major provisions of PLLR is that it removes the existing pregnancy letter categories – A, B, C, D and X. FDA’s decision is a result of experience and feedback of stakeholders pointing out the following major inadequacies of the letter categorization system:

- Pregnancy letter categories were confusing and did not accurately and consistently communicate differences in degrees of fetal risk
- Pregnancy letter categories were heavily relied upon by clinicians but were often misinterpreted and misused in that prescribing decisions were being made based on the pregnancy category, rather than an understanding of the underlying information

The FDA stated that the new narrative structure for pregnancy labeling is considered a better way to capture and convey the potential risks of drug exposure based on animal data, human data, or both. PLLR requires the inclusion of a general statement about background risk, specifically:

"All pregnancies have a background risk of birth defect, loss, or other adverse outcome regardless of drug exposure. The fetal risk summary below describes (name of drug)'s potential to increase the risk of developmental abnormalities above the background risk."

The labeling changes took effect June 30, 2015, with all prescription drugs and biologic products submitted for approval after June 30, 2015 required to use the new format immediately. Labeling for prescription drugs approved on or after June 30, 2001, will be phased in gradually over the next five years.

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE PROSPECTIVE DUR CRITERIA:

Table 1. Recommend turning PG alert on, for consistency within drug class.

Drug Name	Pregnancy Category	DUR Alert Status	On Medi-Cal List of Contract Drugs?	On Target Drug List?	On PG Alert Target Drug List?
CELECOXIB	D		Y	Y	
DICLOFENAC	D		Y	Y	
ESTRIOL	X				
ESTRONE	X				
FLUCONAZOLE	D			Y	
INDOMETHACIN	D		Y		
KETOPROFEN	1		Y		
MELOXICAM	D		Y		
PITAVASTATIN	X		Y		
ESTROPIPATE	X	T			
FOSINOPRIL	D	T			
METHYLTESTOSTERONE	X	T	Y	Y	
MINOCYCLINE HCL	D	T			
PAROXETINE MESYLATE	X	T		Y	
TESTOSTERONES	X	T	Y	Y	
TETRACYCLINE	D	T	Y	Y	

Table 2. Recommend keeping PG alert on and updating DUR manual (as needed).

Drug Name	Pregnancy Category	DUR Alert Status	On Medi-Cal List of Contract Drugs?	On Target Drug List?	On PG Alert Target Drug List?
ALPRAZOLAM	D	Y			
ASPIRIN	D	Y	Y		
ATENOLOL	D	Y	Y	Y	Y
ATORVASTATIN	X	Y	Y	Y	Y
AZATHIOPRINE	D	Y	Y		
BENAZEPRIL	D	Y	Y	Y	Y
CAPTOPRIL	D	Y	Y	Y	Y
CARBAMAZEPINE	D	Y	Y	Y	Y
CLONAZEPAM	D	Y	Y	Y	
CYTARABINE	D	Y	Y		
DANAZOL	X	Y			
DIAZEPAM	D	Y	Y	Y	
DOXYCYCLINE	D	Y	Y		
EFAVIRENZ	D	Y	Y	Y	
ENALAPRIL	D	Y	Y	Y	Y
ESTRADIOL	X	Y	Y		
ESTROGENS	X	Y	Y	Y	Y
ETHINYL ESTRADIOL	X	Y	Y		
EXEMESTANE	X	Y	Y		
FLURAZEPAM	X	Y	Y	Y	Y
FLUVASTATIN	X	Y	Y	Y	Y
HYDROXYUREA	D	Y	Y		
IBUPROFEN	D	Y	Y	Y	Y
IMATINIB	D	Y	Y		
IRBESARTAN	D	Y			
LISINAPRIL	D	Y	Y		
LITHIUM	D	Y	Y	Y	Y
LORAZEPAM	D	Y	Y	Y	
LOSARTAN	D	Y	Y		
LOVASTATIN	X	Y	Y	Y	Y
MEDROXYPROGESTERONE	X	Y	Y		
MEGESTROL	X	Y	Y	Y	Y
MEPHOBARBITAL	D	Y			
METHIMAZOLE	D	Y	Y		
METHOTREXATE	X	Y	Y		
MISOPROSTOL	X	Y	Y		
NAPROXEN	D	Y	Y	Y	Y
NICOTINE	1	Y			
NORETHINDRONE	X	Y	Y	Y	
ORAL CONTRACEPTIVES*	X	Y	Y	Y	Y
PAROXETINE HCL	D	Y	Y	Y	
PHENOBARBITAL	D	Y	Y	Y	Y
PHENYTOIN	D	Y	Y	Y	
PRAVASTATIN	X	Y	Y	Y	Y
PROGESTERONE	D	Y	Y		
PROPYLTHIOURACIL	D	Y	Y		
RALOXIFENE	X	Y			
RAMIPRIL	D	Y	Y		
ROSUVASTATIN	X	Y	Y		
SIMVASTATIN	X	Y	Y	Y	Y
TAMOXIFEN	D	Y	Y		
TELMISARTAN	D	Y	Y		
TEMAZEPAM	X	Y	Y	Y	Y
TRIAZOLAM	X	Y	Y	Y	Y
VALPROIC ACID/DIVALPROATE	X	Y	Y	Y	Y
VALSARTAN	D	Y	Y		
WARFARIN	X	Y	Y		

***INCLUDES ALL DRUGS IN ORAL CONTRACEPTIVE DRUG CLASS**

Table 3. Recommend keeping or turning PG alert on in test-mode and evaluating the potential impact to DUR (using at least 90 days of alert data).

Drug Name	Pregnancy Category	DUR Alert Status	On Medi-Cal List of Contract Drugs?	On Target Drug List?	On PG Alert Target Drug List?
ABARELIX	X				
ABIRATERONE	X		Y		
ACETOHYDROXAMIC ACID	X	T			
ACITRETIN	X				
ADO-TRASTUZUMAB EMTANSINE	D		Y		
AFATINIB	D		Y		
ALBENDAZOLE	X				
ALIROCUMAB	1				
ALISKIREN	D				
ALITRETINOIN	D	T	Y		
ALTRETAMINE	D	T	Y		
AMBRISENTAN	X				
AMIKACIN	D	T	Y		
AMINOGLUTETHIMIDE	D				
AMIODARONE HCL	D	T	Y		
AMOBARBITAL	D				
ANASTROZOLE	X		Y		
ANDROSTENEDIONE	1				
AURANOFIN	1		Y		
AXITINIB	D		Y		
AZACITIDINE	D	T			
AZILSARTAN	D				
BELINOSTAT	D				
BENDAMUSTINE	D				
BENZPHETAMINE	X				
BEXAROTENE	X	T	Y		
BICALUTAMIDE	X	T	Y		
BLEOMYCIN	D	T	Y		
BORTEZOMIB	D	T	Y		
BOSENTAN	X	T			
BOSUTINIB	D		Y		
BRENTUXIMAB VEDOTIN	D				
BUSULFAN	D	T	Y		
BUTABARBITAL	D				
CABAZITAXEL	D		Y		
CABOZANTINIB	D				
CANDESARTAN	D	T			
CAPECITABINE	D	T	Y		
CARBOPLATIN	D	T	Y		
CARFILZOMIB	D				
CARMUSTINE	D		Y		
CERITINIB	D		Y		
CETRORELIX	X				
CHENODIOL	X				
CHLORAMBUCIL	D		Y		
CHLORDIAZEPOXIDE	1				
CHLOROTRIANISENE	X		Y		
CHORIONIC GONADOTROPIN	X	T			
CISPLATIN	D	T	Y		
CLADRIBINE	D		Y		
CLOFARABINE	D				
CLOMIPHENE	X				
CLORAZEPATE	1				
CRIZOTINIB	D				
CYCLOPHOSPHAMIDE	D	T	Y		
DABRAFENIB	D		Y		
DACTINOMYCIN	D		Y		
DASATINIB	D		Y		

Drug Name	Pregnancy Category	DUR Alert Status	On Medi-Cal List of Contract Drugs?	On Target Drug List?	On PG Alert Target Drug List?
DAUNORUBICIN	D		Y		
DECITABINE	D		Y		
DEFERIPRONE	D				
DEGARELIX	X	T	Y		
DEMECARIUM	X				
DEMECLOCYCLINE	D	T			
DENOSUMAB	D				
DEXRAZOXANE	D				
DICUMAROL	D				
DIENESTROL	X		Y		
DIETHYLSTILBESTROL	X				
DIFLUNISAL	1		Y		
DIHYDROERGOTAMINE	X	T			
DOCETAXEL	D	T	Y		
DOXORUBICIN	D	T	Y		
DRONEDARONE	X	T			
DUTASTERIDE	X	T	Y		
ENZALUTAMIDE	X		Y		
EPIRUBICIN	D	T	Y		
EPROSARTAN	D	T			
ERGONOVINE	1		Y		
ERGOTAMINE	X	T	Y		
ERIBULIN	D		Y		
ERLOTINIB HCL	D		Y		
ESTAZOLAM	X	T			
ESTRAMUSTINE	1		Y		
ETHOTOIN	D	T			
ETODOLAC	1				
ETOPOSIDE	D	T	Y		
ETRETINATE	X				
EVEROLIMUS	D	T	Y		
EVOLOCUMAB	1				
FENOPROFEN	D		Y		
FINASTERIDE	X	T			
FLOXURIDINE	D				
FLUDARABINE	D	T			
FLUOROURACIL	X/D	T	Y		
FLUOXYMESTERONE	X		Y		
FLURBIPROFEN	1		Y		
FLUTAMIDE	D	T	Y		
FOLLITROPINS	X				
FOSPHENYTOIN	D	T			
FULVESTRANT	D	T	Y		
GANIRELIX	X				
GEFITINIB	D	T	Y		
GEMCITABINE	D	T	Y		
GEMTUZUMAB OZOGAMICIN	D				
GENTAMICIN S	D	T	Y		
GOSERELIN	X	T	Y		
GRISEOFULVIN	1		Y		
HISTRELIN AC	X				
IBRITUMOMAB TIUXETAN	D				
IBRUTINIB	D				
IDARUBICIN	D				
IDELALISIB	D		Y		
IFOSFAMIDE	D		Y		
INDIUM-111 CHLOR/PENTETREOTIDE	D				
IPILIMUMAB	1		Y		
IRINOTECAN	D				
ISOFLUROPHATE	X				
ISOTRETINOIN	X				
IXABEPILONE	D				
KANAMYCIN	D				

Drug Name	Pregnancy Category	DUR Alert Status	On Medi-Cal List of Contract Drugs?	On Target Drug List?	On PG Alert Target Drug List?
KETOROLAC	D		Y		
LAPATINIB DITOSYLATE	D		Y		
LEFLUNOMIDE	X	T	Y		
LENALIDOMIDE	X	T			
LETROZOLE	X	T	Y		
LEUPROLIDE	X	T	Y		
LIRAGLUTIDE	X				
LOMITAPIDE	X				
LOMUSTINE	D	T	Y		
LORCASERIN	X				
LUTROPIN ALFA	X				
MACITENTAN	X				
MECHLORETHAMINE	D	T	Y		
MECLOFENAMATE	1				
MEFENAMIC ACID	1				
MELPHALAN	D	T	Y		
MENOTROPINS	X				
MEPROBAMATE	1	T			
MERCAPTOPYRINE	D		Y		
METHOXSALEN	D				
METHYLERGONOVINE	1		Y		
METHYSERGIDE	1				
METRONIDAZOLE	1		Y		
MIDAZOLAM	D	T			
MIFEPRISTONE	X				
MIPOMERSEN	1				
MITOMYCIN	X		Y		
MITOTANE	D		Y		
MITOXANTRONE	D	T	Y		
MOEXIPRIL HCL	D	T			
MYCOPHENOLATE	D	T			
NABUMETONE	1		Y		
NAFARELIN ACETATE	X				
NALTREXONE/BUPROPION	X				
NANDROLONE	X				
NELARABINE	D		Y		
NEOMYCIN	D	T	Y		
NILOTINIB HCL	D		Y		
NINTEDANIB	D				
NIVOLUMAB	1		Y		
NIZATIDINE	X				
OLAPARIB	D		Y		
OLMESARTAN	D	T			
OMACETAXINE	D				
ORLISTAT	X				
OSPEMIFENE	X				
OXALIPLATIN	D	T	Y		
OXANDROLONE	X		Y		
OXAPROZIN	1				
OXAZEPAM	1				
OXYMETHOLONE	X	T			
OXYTOCIN	X				
PACLITAXEL	D	T	Y		
PALBOCICLIB	1				
PAMIDRONATE	D	T			
PANOBINOSTAT	1		Y		
PAZOPANIB HCL	D		Y		
PEMBROLIZUMAB	D				
PEMETREXED	D	T	Y		
PENICILLAMINE	D	T			
PENTOBARBITAL	D				
PENTOSTATIN	D		Y		
PERINDOPRIL	D	T			
PERTUZUMAB	D		Y		

Drug Name	Pregnancy Category	DUR Alert Status	On Medi-Cal List of Contract Drugs?	On Target Drug List?	On PG Alert Target Drug List?
PHENACEMIDE	D				
PHENDIMETRAZINE	X				
PHENOL	D				
PHERTERMINE	X				
PLERIXAFOR	D				
PLICAMYCIN	X		Y		
POMALIDOMIDE	X				
PONATINIB HCL	D		Y		
PRALATREXATE	D				
PRAZEPAM	1				
PREDNISOLONE	D		Y		
PRIMAQUINE	1		Y		
PRIMIDONE	1		Y		
PROCARBAZINE	D		Y		
QUINAPRIL	D	T			
QUINESTROL	X				
QUININE	D	T			
REGORAFENIB	D		Y		
RIBAVIRIN	X	T	Y		
RIOCIGUAT	X				
ROMIDEPSIN	D				
SAMARIUM SM 153 LEXIDRONAM	D				
SECOBARBITAL	D	T			
SORAFENIB TOSYLATE	D		Y		
STANZOLOL	X				
STREPTOMYCIN	D	T			
STREPTOZOCIN	D		Y		
STRONTIUM-89	D	T			
SULFADIAZINE	1		Y		
SULFAMETHOXAZOLE	1			Y	
SULFANILAMIDE	1				
SULFISOXAZOLE	1		Y		
SULINDAC	1		Y		
SUNITINIB MALATE	D		Y		
TAZAROTENE	X	T	Y		
TEMOZOLOMIDE	D	T	Y		
TEMSIROLIMUS	D	T			
TENIPOSIDE	D		Y		
TERIFLUNOMIDE	X				
TESAMORELIN	X				
THALIDOMIDE	X	T			
THIOGUANINE	D		Y		
THIOTEPA	D		Y		
TIGECYCLINE	D				
TOBRAMYCIN	D	T	Y		
TOLMETIN	1		Y		
TOPIRAMATE	D		Y		
TOPOTECAN	D	T	Y		
TOREMIFENE	D	T			
TOSITUMOMAB IODINE-131	X				
TRAMETINIB	D		Y		
TRANDOLAPRIL	D	T	Y		
TRASTUZUMAB	D		Y		
TRETINOIN	D	T	Y		
TRIMETHADIONE	D				
TRIMETREXATE	D		Y		
TRIPTORELIN	X		Y		
ULIPRISTAL	X		Y		
UROFOLLITROPIN	X				
VALRUBICIN	1		Y		
VANDETANIB	D		Y		
VEMURAFENIB	D		Y		

Drug Name	Pregnancy Category	DUR Alert Status	On Medi-Cal List of Contract Drugs?	On Target Drug List?	On PG Alert Target Drug List?
VINBLASTINE	D	T	Y		
VINCRIStINE	D	T	Y		
VINORELBINE	D	T	Y		
VISMODEGIB	D		Y		
VORICONAZOLE	D	T			
VORINOSTAT	D		Y		
ZOLEDRONIC ACID	D	T	Y		

At the November 17, 2015 DUR Board meeting, the following recommendations were proposed to the DUR Board:

- Review the three tables of drugs with current pregnancy category D, X and significance level 1 and consider each recommendation.
- Remove the table describing drug-specific risks associated with use in pregnancy, in order to eliminate the need for frequent maintenance and updates.
- Re-evaluate the PG alert once drug compendia publish updated drug files based on the PLLR, in order to keep current data regarding risks for pregnant and lactating women.

The following recommendations were implemented in December 2015:

- The PG alert was turned on for all drugs listed in Table 1.
- The DUR manual has been updated to reflect that the PG alert is turned on for all drugs listed in Table 2. Drug-specific risks have been removed from the manual.
- All drugs listed in Table 3 had the PG alert turned on in test-mode. Of note, two drugs were removed from Table 3 for this update: CERIVASTATIN (no longer being manufactured) and UBIDECARENONE (over-the-counter). Data was collected over a ten-week period (December 25, 2015 through March 4, 2016) and 20 drugs out of the 255 drugs listed in Table 3 (8%) generated PG alerts in test mode. As a reminder, when in test-mode, PG alerts are generated for all submitted claims (not necessarily paid claims), so data summarized using alerts from test-mode typically overestimate the number of alerts that would be generated.
 - The following four drugs were the only drugs to generate greater than 10 alerts over the 10-week period:
 - METHYLERGONOVINE MALEATE (222 alerts; 361 paid claims during this period)
 - ULIPRISTAL ACETATE (52 alerts; 743 paid claims during this period)
 - TOPIRAMATE (51 alerts; 6,172 paid claims during this period)
 - METRONIDAZOLE (21 alerts; 19,115 paid claims during this period)
 - A spot check of the PG alerts showed they seemed to be working properly. The drug generating the highest percentage of alerts, METHYLERGONOVINE MALEATE has an indication specific to pregnant women (postpartum hemorrhage), which may explain the high number of alerts among paid claims.

Finally, FDB has also made modifications to the PG alert since December 2015. The following drugs have been downgraded from a clinical significance of D, X, or 1: DABRAFENIB, ERIBULIN, EVEROLIMUS, LOMUSTINE, MEDROXYPROGESTERONE ACET (INTRAMUSC), METHOXSALEN (ORAL and TOPICAL), METHYLPREDNISOLONE, NICOTINE POLACRILEX, NINTEDANIB, NORGESTIMATE, PREDNISOLONE (SYSTEMIC), and PREDNISON. If the DUR Board turns on the PG alert for all drugs in Table 3, these drugs should not have the PG alert turned on (if in current test-mode) and should have the PG alert turned off and the DUR manual updated (if currently on).

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- We recommend moving from test mode to active mode for PG alerts for all drugs listed in Table 3 due to the relatively low alert burden and the potential to prevent drug-related adverse events among women with a documented pregnancy. Exceptions to this recommendation will be drugs listed above that have since been downgraded from a clinical significance of D, X, or 1 by the FDA or FDB since December 2015.
- If PG alerts are activated for all drugs listed in Table 3, we recommend conducting periodic evaluations of alert and claims data, in order to re-assess alert burden and whether these alerts are proving to be clinically meaningful.
- We recommend an annual review of the PG alert by the DUR Board for all changes to category and severity levels (as provided by the FDA and/or FDB).

REFERENCES:

1. US Department of Health and Human Services. 21 CFR Part 201 [Docket No. FDA–2006-N-0515]. Content and format of labeling for human prescription drug and biological products; requirements for pregnancy and lactation labeling. Federal Register Volume 79, Issue 233 (4 December 2014), pp. 72064 – 72103. Available at: <http://www.gpo.gov/fdsys/pkg/FR-2014-12-04/pdf/2014-28241.pdf>. Accessed: September 25, 2015.



PROSPECTIVE DUR REVIEW

DATE OF REVIEW: April 12, 2016

AMERICAN HOSPITAL FORMULARY SERVICE (AHFS) THERAPEUTIC CATEGORY:

- Applicable to all drugs.

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- Applicable to all drugs.

DRUG PROBLEM TYPES: Drug/Drug Interaction (DD)

BACKGROUND: Medi-Cal Drug-Drug (DD) alert is active for all drug products. The current CA-MMIS System uses First Databank's (FDB) Clinical Modules to determine which claims should be flagged for DD alert. Drug-Drug Interaction alerts sent to the providers are for Severity Level 1 only, which is defined as, "drug combinations that are contraindicated and generally should not be dispensed or administered to the same patient."

Medi-Cal policy in the current DUR manual (Section 20) states that pharmacists performing DUR manually must maintain ingredient-specific patient medication records and that prior to dispensing any of the select target drugs listed in the following drug interaction table, the drug must be screened against the existing medication record to identify interacting drugs. Based on the recommendations of the DUR Board, the DUR manual says the following:

"A list of Severity Level 1 interacting drug pairs is available upon request. To make a request, see the contact information on the DUR: Board Meetings web page under the DUR Main Menu on the Medi-Cal website at www.medi-cal.ca.gov."

ISSUES: In a different location within Section 20 of the DUR manual, there is a list of 53 interacting drug pairs. This was not omitted when the new wording was added and it has not been regularly maintained, making this an incomplete and outdated resource for the providers. According to the latest list obtained from FDB, there are currently 953 drug (or drug class) pairs with a potential for a Severity Level 1 interaction.

PROPOSED INTERVENTION RECOMMENDATIONS TO THE DUR BOARD:

- Remove the existing interacting drug pairs table from Section 20 of the DUR manual.
- Add the following instructions to Section 20 of the DUR manual to encourage providers who perform DUR manually to consult up-to-date references for a possible Severity Level 1 interaction:
 - *"In the absence of a current drug information database, a manufacturer's package insert for the drug being dispensed, may be used to check possible interactions against patients' medication profile."*



**DUR EDUCATIONAL OUTREACH TO PROVIDERS
UPDATE: METABOLIC TESTING IN CHILDREN AND ADOLESCENTS LETTER**

DATE OF MAILING: AUGUST 18, 2015

DATE OF UPDATE: AUGUST 18, 2015 AND APRIL 12, 2016

OBJECTIVES

- To improve metabolic monitoring rates among children and adolescents in the Medi-Cal fee-for-service population with ≥ 4 paid claims for an antipsychotic medication between October 1, 2013 and June 30, 2015.

METHODS

The study population identified when writing the Medi-Cal DUR educational bulletin, "*Improving the Quality of Care: Antipsychotic Use in Children and Adolescents*" was used to identify Medi-Cal fee-for-service (FFS) beneficiaries in need of metabolic testing. This initial study population was comprised of a total of 2,829 children and adolescents who met the following criteria:

- Between 1 and 17 years of age (between October 1, 2013 and September 30, 2014).
- Had at least two paid claims for an antipsychotic medication between October 1, 2013 and September 30, 2014.
- Did not have a paid claim for either an HbA1C/glucose or LDL-C/cholesterol test between October 1, 2013 and September 30, 2014.

For the mailing, eligibility criteria was re-reviewed for each of these beneficiaries to ensure they remained continuously enrolled in the Medi-Cal fee-for-service program between October 1, 2014 (the day after the original data pull for the DUR educational bulletin) and June 30, 2015.

Further inclusion/exclusion criteria for beneficiaries to be included in the study population:

- Beneficiaries < 18 years of age through September 1, 2015
- Beneficiaries with ≥ 2 paid claims for an antipsychotic medication between October 1, 2014 and June 30, 2015 (so at least four total paid claims total between October 1, 2013 and June 30, 2015).
- Did not have a paid claim for either an HbA1C/glucose or LDL-C/cholesterol test between October 1, 2013 and August 17, 2015.
- The prescriber on file of the antipsychotic medication had to have address information available through the Medi-Cal Master Provider File.

A total of 548 beneficiaries from the original cohort of 2,829 met the above inclusion/exclusion criteria. In the 57 cases where a beneficiary had multiple prescribers, the most recent prescriber was usually selected to receive the letter (data were reviewed by both the DUR data analyst and the Xerox DUR Pharmacist). A total of 264 prescribers were identified for educational outreach letters, although some prescribers had more than one address listed as their physical location, so a total of 274 prescriber letters were prepared for mailing.

Prescribers were mailed a letter with a summary of clinical recommendations. The mailing also included the following:

- List of all patients (name and date of birth) from the study population linked to this prescriber
- Medi-Cal DUR article on appropriate antipsychotic medication use among children and adolescents
- Provider response survey(s); one survey per patient

Timeframe of mailing following approval of packet by DHCS:

- Prescriber Letters (n=274)
 - Friday, July 31, 2015: packet submitted to Publications
 - Thursday, August 13, 2015: final, edited packet approved by DHCS/Xerox
 - Monday, August 17, 2015: packet sent to printer
 - Tuesday, August 18, 2015: packet mailed to providers

OUTCOMES

- Direct costs associated with mailing:
 - A total of 274 letters were mailed for a total cost of \$273.75.
 - Each letter was estimated to have cost \$0.9991, which equals the cost of two envelopes and postage for two envelopes, as a self-addressed stamped envelope was included with each letter
- Rate of undeliverable letters:
 - A total of 80 providers (out of 264 unique providers) had their letters returned to sender as undeliverable, for an undeliverable rate of 30%
- Provider response rate (within 90 days):
 - A total of 75 providers (out of 264 unique providers) returned 154 patient surveys within 90 days, for a provider response rate of 28%
 - The 154 patient surveys received represent 28% of patient surveys sent to providers (a total of 548 surveys were sent)
 - If undeliverable letters are removed from the denominator, the response rate increases to 41% (75 out of 184 unique providers)

Survey responses (n=154)

- A total of 138 surveys (90%) indicated that the patient was currently under their care, with the following responses (respondents could check more than one option):
 - "I have reviewed the information and will order metabolic testing" (n=82; 53%)
 - "I have reviewed the information and will continue without change" (n=47; 31%)

- “however, has not seen me recently” (n=13; 8%)
- “I have reviewed the information and will modify drug therapy” (n=3; 2%)
- A total of 16 surveys (10%) indicated that the patient was not currently under their care, with the following responses:
 - “but has previously been a patient of mine” (n=10; 6%)
 - “however, I did prescribe medication while covering for other MD or in the ER” (n=3; 2%)
 - “and has never been a patient of mine” (n=3; 2%)
- A total of 55 patient surveys (36%) contained written comments from providers.
 - The majority of comments discussed lab testing recently completed (n=14) or ordered (n=14, with 11 of these comments stating this was being done in response to the letter).
 - Some comments described barriers to completion:
 - “[PATIENT] was scheduled for checkup on 3/13/15 and no-showed”
 - “Gets blood work done while under sedation getting teeth cleaned; BIG PROBLEM”
 - “[PATIENT] refused follow-up blood test on several occasions; “[PATIENT] is in a residential treatment setting”
 - “I ordered medication monitoring labs frequently however they were never completed by the family”
 - “I see [PATIENT] for preventive care but he is under the care of a neurologist who monitors his meds and orders lab work”
 - “Lab testing has been ordered, but due to [PATIENT’S] autism and inability to cooperate with lab testing the parent has opted not to get lab testing done”
 - “[PATIENT] difficult to get blood; will try”
 - “[PATIENT] has been violent when approached to perform lab testing. Parent has opted to continue antipsychotics without lab testing.”
 - Several comments described that the patient had not been seen for an extended period of time (n=3) or was no longer their patient (n=9)
 - There was one particularly positive response to the mailing: “[PATIENT] was given order to check labs in May 2015. They have not done this. I will show them this letter to emphasize the point that the client needs to have labs done. And thanks for sending the good practice pamphlet.”
 - There was one particularly negative response to the mailing: “Labs were done on 3/24/15. This letter is wasting my time. I would gladly let a psychiatrist take over but none will take [PATIENT’S] low paying insurance.”
 - Additional comments for review include the following:
 - “I review growth chart; doing well”
 - “Latuda was recently stopped”
 - “Other physician began the medication with which I don't agree, but the patient is dependent on it”
 - “Patient no longer on Abilify/antipsychotics”
 - “Patient was inconsistent in taking meds and many times stopped meds without MD consult”
 - “Thanks for your concern. I am aware of the benefits and many potential side effects. Patient is being monitored for these potential problems. My goal is to discontinue his antipsychotics as soon as possible. So far he does best while on his current regimen.”
 - “Weaning off risperidone”

Primary Outcome Variable

- Out of the 548 beneficiaries in the original study population, a total of 439 (80%) continue to be eligible in the Medi-Cal fee-for-service program. The letters for 147 of these beneficiaries were returned as undeliverable, leaving a total of 292 beneficiaries as the denominator.
 - 57 of these beneficiaries (20%) had at least one laboratory monitoring test done within 90 days of the mailing
 - 54 beneficiaries (18%) had both laboratory monitoring tests completed
 - 65 of these beneficiaries (22%) had at least one laboratory monitoring test done within 6 months of the mailing
 - 61 beneficiaries (21%) had both laboratory monitoring tests completed
- Among the 147 beneficiaries who had letters to their providers returned as undeliverable, only one of these beneficiaries had at least one laboratory monitoring test done within 90 days of the mailing (and only three within 6 months of the mailing), for a rate of less than 1%.

Secondary Outcome Variable

- Out of the 292 beneficiaries evaluated for the primary outcome variable, a total of 104 of these beneficiaries (36%) have not had at least two paid claims for an antipsychotic medication since the mailing (dates of service September 1, 2015 through February 29, 2016). Data are stratified by lab monitoring status in Table 1.

Table 1. Continued use of antipsychotic medications among children and adolescents, stratified by lab monitoring within 6 months of the mailing (dates of service September 1, 2015 through February 29, 2016).

	≤ 1 paid claim for antipsychotic	> 2 paid claims for antipsychotics
Had at least one lab test (n=65)	14 (22%)	51 (78%)
Did not have either lab test (n=227)	90 (40%)	137 (60%)
Total (n=292)	104 (36%)	188 (64%)

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Discuss benefit of future educational outreach to providers on this topic, including a repeat of this intervention in the future and/or patient-specific reminders for providers to order metabolic monitoring for children and adolescents in the Medi-Cal population.



**DUR EDUCATIONAL OUTREACH TO PROVIDERS
MORPHINE EQUIVALENT DAILY DOSE (MEDD) LETTER**

DATE OF MAILING: MARCH 9, 2016 AND MARCH 11, 2016

DATE OF UPDATE: APRIL 12, 2016

OBJECTIVE

- To improve the quality of pain treatment among non-cancer, non-hospice Medi-Cal fee-for-service beneficiaries at increased risk of opioid overdose.

METHODS

A morphine equivalent daily dose (MEDD) was calculated for any Medi-Cal fee-for-service beneficiary with a paid pharmacy claim for a prescription opioid medication between July 1, 2015 and December 31, 2015. A total of 39,713 paid claims exceeded > 80 mg MEDD, representing 10,167 Medi-Cal fee-for-service beneficiaries.

The following inclusion/exclusion criteria were applied in a stepwise order to these 10,167 beneficiaries to determine the size of the study population:

- A total of 5,157 beneficiaries were excluded as they were currently receiving buprenorphine as part of a narcotic withdrawal treatment plan between July 1, 2015 and December 31, 2015
- A total of 1,848 beneficiaries had approved Treatment Authorization Requests (TARs) on file for opioid paid claims between July 1, 2015 and December 31, 2015
- A total of 1,084 beneficiaries were not continuously-eligible in the Medi-Cal fee-for-service program since July 1, 2015 (including January 2016)
- A total of 336 beneficiaries had a primary or secondary diagnosis of cancer between January 1, 2015 and December 31, 2015
- A total of 321 beneficiaries resided in a long-term care facility or received hospice care between January 1, 2015 and December 31, 2015

This left a study population of 1,421 beneficiaries with 3,340 paid claims that exceeded > 80 mg MEDD, for a total of 1,147 providers. As the total number of provider letters for this mailing would exceed 500 letters, the MEDD threshold was adjusted to > 120 mg MEDD.

With the threshold adjusted to > 120 mg MEDD and the days' supply filtered to only include those paid claims with a days' supply greater than 14 days, the number of providers dropped to 380, representing 464 beneficiaries and 1,542 paid claims. We then reviewed the prescriber NPI to determine that of those 380 prescribers, a total of 218 had current

mailing addresses listed in the Medi-Cal Master Provider File (representing 259 beneficiaries and 951 paid claims).

A final review of the medical and pharmacy claims for the 259 beneficiaries was conducted and 101 beneficiaries who did not have a paid claim for an opioid after November 30, 2015 were excluded, as were two beneficiaries who were now listed as deceased, and one beneficiary who was found to have a cancer diagnosis. Patient profiles were developed for the remaining 155 beneficiaries and 134 letters were created for 132 prescribers (two prescribers had two separate practice locations listed).

Between March 9, 2016 and March 11, 2016 all 134 prescriber letters were mailed. Each letter contained the following:

- Patient name, gender, and date of birth for all patients identified for the prescriber
- Paid claims information for all opioid claims for each patient with dates of service between July 1, 2015 and February 29, 2016, including date of service, drug description, days' supply, drug quantity, calculated MEDD, prescriber, and prescriber city
- Any clinically relevant hospitalizations, emergency department visits, or clinic visits for each patient with dates of service between July 1, 2015 and February 29, 2016, including date of service, primary and secondary ICD-9-CM diagnostic codes and descriptions, provider or facility name, and provider or facility city
- Medi-Cal DUR bulletin on MEDD
- Handout with information about naloxone
- One provider response survey for each patient identified for the prescriber

Timeframe of mailing following approval of packet by DHCS:

- Prescriber Letters (n=134)
 - Monday, February 29, 2016: packet submitted to Publications
 - Wednesday, March 2, 2016: final, edited packet approved by DHCS/Xerox
 - Friday, March 4, 2016: packet sent to printer
 - Wednesday, March 9, 2016 and Friday, March 11, 2016: packet mailed to providers

OUTCOMES

- Direct costs associated with mailing:
 - A total of 134 letters were mailed for a total estimated cost of \$138.88
 - Each letter was estimated to have cost \$0.9991, which equals the cost of two envelopes and postage for two envelopes, as a self-addressed stamped envelope was included with each letter
- Rate of undeliverable letters (within 90 days):
 - Thus far, after 30 days, 33 prescribers (out of 132 unique prescribers) had their letters returned to sender as undeliverable, for an undeliverable rate of 25%
- Provider response rate (within 90 days):
 - Thus far, after 30 days, a total of 23 prescribers (out of 132 unique prescribers) returned 28 patient surveys, for a provider response rate of 17%
 - If undeliverable letters are removed from the denominator, the response rate increases to 23% (23 out of 99 unique prescribers)
 - The 28 patient surveys received thus far represent 18% of patient profiles in this mailing

As stated in the original proposal, the following outcome variables will need to be assessed at later time points, as medical claims data become available:

- The primary outcome variable will be the percentage of the continuously-eligible study population with a paid claim for an opioid medication exceeding > 120 mg MEDD in the 6-month period following the mailing of the intervention letter (April 1, 2016 through September 30, 2016)
- The following secondary outcome variables will be assessed in the 6-month period following the mailing of the intervention letter (April 1, 2016 through September 30, 2016):
 - Percentage of the continuously-eligible study population identified as receiving prescription opioid medication as part of a narcotic withdrawal treatment plan
 - Percentage of the continuously-eligible study population identified with hospital or emergency department visits due to opioid overdose
 - Percentage of the continuously-eligible study population identified as having a paid claim for naloxone in the 6-month period
 - The number of days with cumulative MEDD > 120 mg in the 6-month period prior to the mailing of the intervention letter compared to the number of days with cumulative MEDD > 120 mg 6-month period following the mailing of the intervention letter, by beneficiary (in the continuously-eligible study population)



**Medi-Cal DUR Educational Outreach to Providers:
Anticholinergic Intervention Proposal**

Background

Anticholinergic medications including benztropine and trihexyphenidyl are often prescribed to prevent or treat antipsychotic-induced extrapyramidal symptoms (EPS), including tremor, rigidity, bradykinesia, and acute dystonia.¹ However, the need for continued therapy with anticholinergics is frequently not reassessed and many patients remain on them for several years, and even decades.¹ Prescribers may be reluctant to discontinue anticholinergics, even when patients are prescribed second-generation antipsychotics, which are less likely than first-generation antipsychotics to induce EPS.¹⁻⁵

Despite the widespread use of anticholinergic medications for prophylaxis and treatment of antipsychotic-induced EPS, there is a lack of systematic reviews and meta-analyses supporting this practice and the long-term benefit of anticholinergic use has not been established.^{1,6} In fact, several adverse effects have been reported from long-term use, including cognitive impairment and worsening of tardive dyskinesia, especially among persons 65 years of age and older.^{5,7,8} The 2009 Schizophrenia Patient Outcomes Research Team Treatment Recommendations state that the prophylactic use of anticholinergics to reduce the incidence of EPS was not warranted in patients treated with second-generation antipsychotics, but should be evaluated on a case-by-case basis for patients treated with first-generation antipsychotics.^{9,10}

The consensus among the medical community is that prophylaxis of EPS with anticholinergics is generally not indicated in patients receiving antipsychotics and that anticholinergic use should be limited to when parkinsonism arises and when other measures, such as dose reduction, have failed.¹¹ As differences in the risk for EPS are correlated to the relative potency of antipsychotics, switching to antipsychotics with a lower propensity for EPS may also help limit or avoid the use of anticholinergics (see Table 1).^{9,10}

Table 1. General ranking of selected first- and second-generation antipsychotics, by propensity for EPS.^{9,10,12-14}

<ul style="list-style-type: none"> • High potency first-generation antipsychotics: fluphenazine, haloperidol, perphenazine, pimozide, thiothixene, trifluoperazine 	<p>Highest propensity for EPS</p>  <p>Lowest propensity for EPS</p>
<ul style="list-style-type: none"> • Mid potency first-generation antipsychotics: perphenazine, loxapine • Risperidone, paliperidone 	
<ul style="list-style-type: none"> • Low potency first-generation antipsychotics: chlorpromazine, thioridazine • Olanzapine, ziprasidone, aripiprazole 	
<ul style="list-style-type: none"> • Quetiapine • Clozapine 	

Results

Between September 1, 2014 and August 31, 2015, a total of 34,879 unique beneficiaries were identified with a paid claim for benztropine and/or trihexyphenidyl with a days' supply equal to or greater than 30 during this one-year period. The majority of these beneficiaries (n=32,230; 92%) had a paid claim for benztropine and 345 (1%) beneficiaries had at least one paid claim for benztropine and trihexyphenidyl.

To determine if anticholinergic use was primarily short-term, the total number of paid claims with a days' supply equal to or greater than 30 was calculated for each beneficiary. A little more than half of the study population (51%) had at least six paid claims for an anticholinergic medication during the measurement year, suggesting long-term use of at least six months of the year, and 17% had paid claims that amounted to at least a years' supply.

Among those beneficiaries with at least one paid claim for an anticholinergic medication, a total of 360 beneficiaries (1%) were age 65 years and older (191 of these beneficiaries had at least six paid claims for an anticholinergic medication during the measurement year). As stated previously, the risk of adverse events related to anticholinergic medication use is increased in this population, and both benztropine and trihexyphenidyl appear on the American Geriatrics Society updated Beers Criteria for potentially inappropriate medication use in older adults.⁸

Objective:

- To improve the quality of care among Medi-Cal fee-for-service beneficiaries age 65 years and older with concomitant use of second-generation antipsychotic and anticholinergic medications.

Methods:

A query will be done to identify any Medi-Cal fee-for-service beneficiary 65 years of age and older with regular, concomitant use of second-generation antipsychotic medications and anticholinergics. Regular use will be defined as six or more paid claims for each medication (antipsychotic and anticholinergic) during a one-year period.

All prescribers of anticholinergics to beneficiaries in the final study population will receive a letter with a summary of clinical recommendations (**Appendix A**). The mailing will also include the following:

- Patient name and date of birth (all patients identified for this prescriber)
- Medi-Cal DUR article on Anticholinergics
- One provider response survey (**Appendix B**) per patient

Outcomes:

The primary outcome variable will be the percentage of the continuously-eligible study population with two or more paid claims for an anticholinergic in the 6-month period following the mailing of the intervention letter.

In addition, prescriber response rates will be calculated, and response data and comments will be presented in aggregate in a report to DHCS and the DUR Board.

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Appendix A. Letter to Prescribers

«Date»

«Provider_Title» «Provider_First_and_Middle_Name» «Provider_Last_Name»
«Prvdr_Physical_Street_1_Address» «Prvdr_Physical_Street_2_Address»
«Prvdr_Physical_City», CA «Prvdr_Physical_Zip_Code»

RE: Retrospective Drug Utilization Review Morphine Equivalency Initiative

Dear Provider,

Despite the widespread use of anticholinergic medications such as benztropine and trihexyphenidyl for prophylaxis and treatment of antipsychotic-induced extrapyramidal symptoms (EPS), there is a lack of systematic reviews and meta-analyses supporting this practice and the long-term benefit of anticholinergic use has not been established. In fact, several adverse effects have been reported from long-term use, including cognitive impairment and worsening of tardive dyskinesia, especially among persons 65 years of age and older and both benztropine and trihexyphenidyl appear on the American Geriatrics Society updated Beers Criteria for potentially inappropriate medication use in older adults.

In addition, the 2009 Schizophrenia Patient Outcomes Research Team Treatment Recommendations state that the prophylactic use of anticholinergics to reduce the incidence of EPS was not warranted in patients treated with second-generation antipsychotics, but should be evaluated on a case-by-case basis for patients treated with first-generation antipsychotics.

A recent analysis by the Medi-Cal Drug Use Review (DUR) program found that over a one-year period, a total of 191 Medi-Cal beneficiaries 65 years of age and older had at least six paid claims for both a second-generation antipsychotic medication and at least six paid claims for benztropine and/or trihexyphenidyl. The full publication is included with this mailing for your review and can be found on the Medi-Cal DUR website at: *[website]*.

For your reference, the following Medi-Cal beneficiaries 65 years of age and older were identified in your practice as having at least six paid claims for a second-generation antipsychotic medication and at least six paid claims for an anticholinergic medication between [date] and [date]:

Patient Name	Patient Date of Birth
[BENEFICIARY NAME]	[BENEFICIARY DOB]

Please evaluate these patient(s) and consider the following recommendations:

- For patients taking second-generation antipsychotics, prophylactic anticholinergic medications are not recommended.
- Continued use of anticholinergic medications should be re-evaluated in patients with controlled symptoms every three months.
- Older patients and/or persons with high genetic risk of cognitive disorder who use anticholinergic medications are at increased risk of cognitive decline and dementia. Providers should consider discontinuation of anticholinergic medications in these populations.

The success of the Medi-Cal DUR program is enhanced by the two-way exchange of information. Therefore, we would appreciate learning of your assessment of this information. Although your participation is voluntary, we would find your feedback helpful as we expand our educational outreach efforts.

At your convenience, please complete the enclosed survey(s) and return survey(s) using the enclosed self-addressed stamped envelope. If you have any questions or concerns about this information or our request, please contact Ivana Thompson, DUR Pharmacist, at (916) 295-9488.

Thank you for your professional consideration of this information and request for response, as well as your continued participation in the Medi-Cal program.

Sincerely,

Mike Wofford

Michael Wofford, Pharm D.
Chief, Pharmacy Policy Branch



PROVIDER RESPONSE SURVEY – PATIENT PROFILE

Beneficiary First Name: FIRST NAME Beneficiary Date of Birth: MM/DD/YYYY
Beneficiary Last Name: LAST NAME Beneficiary Gender: GENDER

Provider: [PROVIDER]

Date range for claims data: [DATE] through [DATE]

All information used to generate the enclosed letter was obtained from medical and pharmacy claims data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation.

This patient **is** under my care (**select all that apply**):

- I have reviewed the information and will continue without change.
- and has an appointment to discuss drug therapy.
- however, has not seen me recently.
- I reviewed the information and will modify drug therapy.
- I have not modified drug therapy because benefits outweigh the risks.
- I have tried to modify therapy, however the patient refuses to change.
- I have tried to modify therapy, however symptoms reoccurred.

This patient **is not** under my care:

- however, I did prescribe medication while covering for other MD or in the ER.
- but has previously been a patient of mine.
- because the patient recently expired.
- and has never been under my care.

Additional comments or suggestions:

Thank you for participating in the California Medicaid Drug Utilization Review Program.

Please return within 30 days of receipt using the enclosed self-addressed stamped envelope.



RETROSPECTIVE DUR REVIEW

DATES OF REVIEW: April 12, 2016

AMERICAN HOSPITAL FORMULARY SERVICE (AHFS) THERAPEUTIC CATEGORY:

- 24:06.24 – PROPROTEIN CONVERTASE SUBTILISIN KEXIN TYPE 9 (PCSK9) INHIBITORS

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- ANTIHYPERLIPIDEMIC – PCSK9 INHIBITORS

DRUG PROBLEM TYPES: Over Utilization (OU), Therapeutic Appropriateness (O¹)

BACKGROUND: Reduction in low-density lipoprotein (LDL) cholesterol levels has proved to be highly effective in reducing rates of major cardiovascular events in numerous large outcome trials.^{1,2} Recent clinical trials showed monoclonal antibodies that inhibit proprotein convertase subtilisin–kexin type 9 (PCSK9) to be a promising new class of drugs that very effectively lowered LDL cholesterol levels by approximately 60%.³⁻⁸

The two FDA-approved PCSK9 inhibitors, evolocumab and alirocumab are approved for adjunct treatment to diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease and evolocumab also is approved for adjunct treatment to diet and other LDL cholesterol-lowering therapies in adolescents and adults with homozygous familial hypercholesterolemia.

ISSUES: Recent editorials argue that PCSK9 inhibitors are priced so high they aren't worth it, except for a tiny fraction of high-risk patients who are statin-intolerant.^{9,10} The two FDA-approved PCSK9 inhibitors, evolocumab and alirocumab, are estimated to cost between \$12,000 and \$14,000 per year.

According to the expert consensus statement published online April 1, 2016, in the *Journal of the American College of Cardiology*, the American College of Cardiology (ACC) updated their recommendations for the management of elevated LDL cholesterol levels in high-risk patients, specifically addressing the use of non-statin therapies, such as PCSK9 inhibitors and ezetimibe in patients unable to achieve sufficient LDL-cholesterol lowering. The updated guidelines recommend that high-risk patients who require additional LDL-cholesterol lowering beyond that achieved with a statin, the first second-line agent should be ezetimibe 10 mg daily and only after ezetimibe has been tried should physicians consider adding or replacing ezetimibe with one of the PCSK9 inhibitors.

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE (FFS) CRITERIA: Paid claims for PCSK9 inhibitors with dates of service between August 27, 2015 (FDA-approval date) and March 31, 2016 were reviewed for Medi-Cal fee-for-service beneficiaries. During this time period, a total of seven beneficiaries were identified as having a paid claim for evolocumab, for a total number of 17 paid claims. There were no paid claims for alirocumab identified during this time period. Of note, all seven beneficiaries had at least one prior paid claim for ezetimibe.

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Given the low utilization of these drugs in the Medi-Cal fee-for-service population and evidence that prescribing of these drugs follows updated clinical guidelines, there are no recommendations for further action regarding PCSK9 inhibitors at this time.
- Periodic monitoring of utilization of high-cost drug therapeutic categories, such as PCSK9 inhibitors, is recommended, as requested by the DUR Board.

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RETROSPECTIVE DUR REVIEW

DATE OF REVIEW: April 12, 2016

AMERICAN HOSPITAL FORMULARY SERVICE (AHFS) THERAPEUTIC CATEGORY:

- 28:08.08 – OPIATE AGONISTS

FIRST DATABANK DRUG THERAPEUTIC CATEGORIES:

- ANALGESICS, NARCOTICS

DRUG PROBLEM TYPES: Over Utilization (OU), Therapeutic Appropriateness (O¹)

BACKGROUND: For decades, methadone has been safely and effectively used in medication-assisted treatment for opioid use disorder, under strict regulation by federal, state, and local guidelines.¹ While methadone is also an effective analgesic, it is considered a second-line agent in the treatment of severe, chronic pain and is most useful in patients who have developed tolerance to other opiate agonists or intractable side effects due to opiate therapy.^{1,2}

However, methadone has been associated with disproportionate numbers of overdose deaths relative to the frequency with which it is prescribed for pain.³ While methadone represented less than 5 percent of opioid prescriptions dispensed between 2002 and 2008, it was implicated in one-third of opioid-related deaths during that time period.⁴⁻⁶ Between 2004 and 2006, the rate for methadone-related emergency department visits was approximately 23 times greater than for hydrocodone, and six times greater than for oxycodone.⁴ The CDC estimates that 30 percent of prescription opioid-related drug overdose deaths in 2009 involved methadone prescriptions for pain.⁷

ISSUES: In January 2016, the Centers for Medicare & Medicaid (CMS) distributed an informational bulletin entitled, "*Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction.*" Wherever possible, the bulletin provides examples of methods states can use to target the prescribing of methadone for pain relief, given the disproportionate share of opioid-related overdose deaths associated with methadone when used as a pain reliever. Suggestions included pharmacy benefit management strategies such as reassessing preferred drug list (PDL) placement of methadone, introducing clinical criteria, prior authorization, step therapy, quantity limits, and implementing drug utilization review (DUR) processes.

Currently, methadone appears on the Medi-Cal List of Contract Drugs. The 5 mg tablets are restricted to a maximum dispensing quantity of 120 tablets and a maximum of three (3) dispensings in any 75-day period for the 5 mg tablets only. The 10 mg tablets are restricted to a maximum dispensing quantity of 240 tablets and a maximum of three (3) dispensings in any 75-day period for the 5 mg tablets only.

A review was conducted to assess use of methadone in the Medi-Cal fee-for-service population and to determine if further action is warranted.

REVIEW OF CURRENT MEDI-CAL FEE-FOR-SERVICE (FFS) CRITERIA: All paid claims for methadone with dates of service between July 1, 2015 and December 31, 2015 were reviewed for beneficiaries in the Medi-Cal fee-for-service program.

During this six-month time period, there were a total of 1,013 Medi-Cal fee-for-service beneficiaries with a paid claim for methadone during this time period, for a total of 3,223 paid claims. As shown in Table 1, the majority of these paid claims (82%) were for 10 mg tablets of methadone.

Table 1. Methadone paid claims by strength, formulation in the Medi-Cal fee-for-service population (7/1/15-12/31/15)

	n (%)
1 mg/ml injectable	37 (1%)
2 mg/ml injectable	28 (1%)
5 mg tablet	530 (16%)
10 mg tablet	2,628 (82%)
Total	3,223 (100%)

Tables 2 (5 mg tablets) and 3 (10 mg tablets) give more details on paid claims for methadone tablets, including two separate calculations for morphine equivalency. Of note, the regular MEDD calculation uses a conversion factor of 3.0, while the CDC MEDD calculation uses the following conversion factors based on the total daily dose: 1-20 mg/day = 4, 21-40 mg/day = 8, 41-60 mg/day = 10, and 61-80 mg/day = 12. For any claims with a total daily dose of methadone > 80 mg/day, the conversion factor of 12 was used for the CDC MEDD calculation.

Table 2. Paid claims for methadone 5 mg tablets (n=530) between July 1, 2015 and December 31, 2015.

	Paid Claim Billed Quantity	Paid Claim Days' Supply	Methadone mg/day	CDC MEDD Calculation	MEDD Calculation
Mean	67	25	16	98	47
Median	60	30	11	45	34
Std. Deviation	45	9	12	138	37
Minimum	2	1	3	10	7
Maximum	360	60	102	1,224	306
Percentiles 25	30	18	10	40	30
50	60	30	11	45	34
75	90	30	15	60	45

Table 3. Paid claims for methadone 10 mg tablets (n=2,628) between July 1, 2015 and December 31, 2015.

	Paid Claim Billed Quantity	Paid Claim Days' Supply	Methadone mg/day	CDC MEDD Calculation	MEDD Calculation
Mean	132	25	58	609	175
Median	120	30	40	320	120
Std. Deviation	94	9	46	595	137
Minimum	3	1	4	16	12
Maximum	1,200	80	400	4,800	1,200
Percentiles 25	60	22	30	240	90
50	120	30	40	320	120
75	180	30	80	960	240

Methadone and Approved *Treatment Authorization Requests*

A total of 525 (16%) of paid methadone claims had an approved *Treatment Authorization Request* (TAR) on file, including all 65 claims for injectable methadone, all 16 claims for 5mg tablets with a quantity of > 120 tablets, and all 133 claims for 10mg tablets with a quantity of > 240 tablets. On average, 439 methadone claims per month do not have an approved TAR on file, representing approximately 394 beneficiaries.

PROPOSED INTERVENTION RECOMMENDATION TO THE DUR BOARD:

- Discuss implications of restricting methadone use to those beneficiaries with an approved *Treatment Authorization Request*, especially among claims for the 10 mg tablets where the average MEDD exceeds the 80 mg/day limit suggested by the Medical Board of California and the California State Board of Pharmacy.
- If policy changes are recommended and implemented, suggest a DUR educational bulletin or alert to help inform providers. The educational bulletin or alert could include a summary of the clinical practice guidelines from the American Pain Society and College on Problems of Drug Dependence, in collaboration with the Heart Rhythm Society.

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Update: DUR Publications

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May 17, 2016

DUR Publications – April 2016

DUR Educational Bulletin

- Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

DUR Educational Alerts

- Drug Safety Communication: New Safety Warnings Added to Prescription Opioids
- Drug Safety Communication: Saxagliptin, Alogliptin and Risk of Heart Failure

April 2016: DUR Educational Bulletin

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

▪ Learning Objectives

- Review the risk of adverse metabolic effects with use of atypical antipsychotics
- List monitoring parameters recommended in consensus guidelines for patients starting and continuing on atypical antipsychotics
- Describe strategies to reduce the risk of adverse metabolic effects among patients who use atypical antipsychotics.

April 2016: DUR Educational Bulletin - 1

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

- The prescribing of atypical antipsychotics for on- and off-label uses has soared in recent years
- Antipsychotics are associated with potentially serious metabolic effects
 - May increase both the 10-year risk of cardiovascular disease and mortality from cardiovascular disease

April 2016: DUR Educational Bulletin - 2

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

- Cardiovascular disease is the single largest cause of death in patients with schizophrenia
- Modifiable risk factors such as smoking, obesity, unhealthy diet and lack of physical activity are common in patients with major mental illness and should be addressed

April 2016: DUR Educational Bulletin - 3

	FDA-Approved Indications for Adults	Metabolic Adverse Effects		
		Weight gain	Risk for diabetes	Dyslipidemia
aripiprazole*	A,D,I,M,S,T	Low to none	None	None
asenapine*	M,S	Low to none	Low to none	Low to none
brexpiprazole	D,S	(Newer drugs with limited long-term data)		
cariprazine	M,S			
clozapine*	S,SA,SU	High	High	High
iloperidone*	S	Moderate	Low	Low
lurasidone*	M,S	Low	Low	Low to none
olanzapine*	D,M,S	High	High	High
paliperidone	S,SA	Low	Low	None
quetiapine*	D,M,S	Moderate	Moderate	Moderate
risperidone*	I,M,S	Moderate	Moderate	Low
ziprasidone*	A,B,M,S,T	Low to none	None	None

April 2016: DUR Educational Bulletin - 4

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

- Retrospective cohort study to assess use of atypical antipsychotics, potential metabolic adverse effects, and rates of metabolic monitoring
- All continuously-eligible FFS beneficiaries between age 18 and 64
 - With at least one paid claim for an atypical antipsychotic medication during every 4-month period between November 1, 2013 and February 29, 2016
 - Excluded if not on the same medication for ≥ 180 days

April 2016: DUR Educational Bulletin - 5

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

- Medical claims (ICD-9-CM) reviewed for prevalence of co-morbid conditions
 - Obesity, diabetes, dyslipidemia, HTN, other cardiovascular disease
- Paid pharmacy claims reviewed for ≥ 2 claims for concomitant use of statins, metformin, or ACE-I/ARBs
- Metabolic monitoring rates reviewed for the same timeframe as initial inclusion
 - LCL-C or total cholesterol, glucose or HbA1c

April 2016: DUR Educational Bulletin - 6

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

- 6,561 beneficiaries in study population
 - Documented FDA-approved indication: 65% (n = 4,237)
 - Two or more atypical antipsychotics for ≥ 90 days: 21% (n = 1,358)
- Commonly prescribed antipsychotics:
 - Risperidone (20%; n = 1,283)
 - Quetiapine (19%; n = 1,262)
 - Olanzapine (15%; n = 951)
 - Aripiprazole (15%; n = 923)

April 2016: DUR Educational Bulletin - 7

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

- Prevalence of co-morbid medical conditions
 - Overweight/obesity/weight gain (19%; n = 1,265)
 - Diabetes (29%; n = 1,893)
 - Dyslipidemia (36%; n = 2,374)
 - Hypertension (42%; n = 759)
 - Other cardiovascular disease (11%; n = 739)
- Prevalence of concomitant medications
 - Statins (15%; n = 975)
 - Metformin (8%; n = 527)
 - ACE/ARBs (11%; n = 725)

April 2016: DUR Educational Bulletin - 8

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

■ Metabolic Monitoring

- 69% (n = 4,507) of beneficiaries had both glucose and cholesterol monitoring within the past 2 years
 - Blood glucose or HbA1C (84%; n = 5,524)
 - LDL-C or cholesterol (69%; n = 4,534)
- Monitoring rates were greater among those beneficiaries with a comorbid metabolic condition (at least 82%) and among those taking concomitant statins, ACE inhibitors/ARBs, and/or metformin (at least 85%)

April 2016: DUR Educational Bulletin - 9

Clinical Review: Atypical Antipsychotics and Adverse Metabolic Effects

■ Summary and Clinical Recommendations

- A high prevalence of comorbid metabolic conditions highlights the importance of following recommended assessment and monitoring schedules
- Prescribe atypical antipsychotics for FDA-approved indications
- Address modifiable risk factors in patients with mental illness even in the absence of metabolic changes
- Follow ADA and APA consensus guidelines for baseline assessment and monitoring
- For patients with a worsening metabolic profile, especially weight gain, consider switching agents

April 2016: DUR Educational Alerts - 1

Drug Safety Communication: New Safety Warnings Added to Prescription Opioids – March 22, 2016

- Updated warnings for opioids:
 - Potential interaction with antidepressants and migraine medicines may cause serotonin syndrome
 - Rarely, adrenal insufficiency may occur in patient taking opioids
 - Long term use of opioids may be associated with decreased sex hormone levels and symptoms such as reduced interest in sex, impotence, or infertility

April 2016: DUR Educational Alerts - 2

Drug Safety Communication: Saxagliptin, Alogliptin and Risk of Heart Failure – April 5, 2016

- A safety review has found that medicines containing saxagliptin and alogliptin may increase the risk of heart failure, particularly in patients who already have heart or kidney disease
- Patients taking these medications should seek medical attention immediately if they develop signs or symptoms of heart failure
- Health care providers should consider discontinuing these medications in patients who develop heart failure

Future Topics: Bulletins

DUR Educational Bulletins:

- Promotion of appropriate prescribing of buprenorphine, including a summary of clinical guidelines and recent updates to Medi-Cal policy (submitted for publication in May 2016 Pharmacy Priority Bulletin)
- Summarize relative risk of QT interval prolongation due to adverse drug reactions (in-progress)
- Promotion of appropriate prescribing of skeletal muscle relaxants, including an evaluation of concomitant use of opioids and benzodiazepines
- Provide treatment guidelines for managing pain in population with co-morbid mental health conditions, including those with a documented history of substance abuse
- Nicotine replacement therapy – to be timed with implementation of pharmacist furnishing of NRT

Future Topics: Alerts/Prospective Reviews

DUR Educational Alerts:

- Annual vaccine alert, including any updates on current guidelines (ongoing, published each September)
- FDA drug safety communications for drugs on the Medi-Cal List of Contract Drugs (ongoing)

Prospective DUR Reviews:

- Annual review of categories for duplicate therapy (Section 25, ongoing)
- Discrepancy clean-up (Section 20, ongoing)
- Quarterly review of new GCNs (ongoing)

Future Topics: Retrospective Reviews

Retrospective DUR Reviews:

- HCV polymerase inhibitors
- Assessment of opioid use and mortality, linking death index information with medical/pharmacy claims data
 - Concomitant use of benzodiazepines
 - Gender disparities
- Use of HIV antiretrovirals (in collaboration with Medi-Cal managed care program)
- Annual review of drugs added to the Medi-Cal List of Contract Drugs (ongoing, presented each November)
- Policy impact of antipsychotic TAR requirement for children and adolescents

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Medi-Cal Drug Utilization Review Board Meeting Pharmacy Updates

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Pharmacy Policy Branch

05-17-16

Topics

- CMS DUR Annual Report 2015 Revisions
 - Antipsychotic Drug Use in Children (ADC) Affinity Group
 - Prescription Opioids Abuse Actions
 - Proposed Medicaid Managed Care Regulation – impact on DUR program
 - Quality Strategy
 - Child Core Set Measures
 - Adult Core Set Measures
 - California Department of Public Health (CDPH) Report: Comprehensive Medication Management Programs: Description, Impacts, and Status in Southern California, a report
 - Value Based Purchasing in Medicaid
-



CMS DUR Annual Report 2015 Revisions

- With input from a committee of American Drug Utilization Review Society (ADURS) members, CMS has proposed revisions to the annual DUR report. The revised DUR report is currently going through CMS clearance process
- 2015 report due to CMS on November 30, 2016
- DUR team participated in a CMS briefing conference call on 3-31-16
- [CMS DUR Annual Report 2015 Revision](#)



CMS DUR Annual Report 2015 Revisions -2

- Revisions include new or expanded questions in several areas:
 - Potential fraud or abuse of controlled and non-controlled substances
 - Prescription drug monitoring program (PDMP)
 - Morphine equivalent daily dose (MEDD) limits
 - Antipsychotic monitoring program
 - Managed care organizations (MCOs) DUR reports
 - MCOs targeted intervention programs (CMC/lock in)



Antipsychotic Drug Use in Children Affinity Group (ADC)

- Early 2015, the Office of the Inspector General recommended that CMS work with state Medicaid programs to:
 1. Perform utilization review of second generation antipsychotic (SGA) drugs prescribed to children
 2. Conduct periodic review of medical records related to SGAs
 3. Consider other methods of enhanced oversight of SGAs
- One of the responses CMS proposes is the formation of the ADC affinity group



Antipsychotic Drug Use in Children Affinity Group (ADC) -2

- **Goals:**
 - CMS plans to support state efforts to improve quality of care
- **Benefits to States:**
 - Learning opportunities
 - Regular meetings/communication with CMS
- **Participants:**
 - State Medicaid agency staff (with responsibility for fee-for-service or managed care)
- **Timeline/Commitment:**
 - Monthly 1:1 calls begins March 2016 for 12 months
 - Quarterly group calls with other states and QI experts



Actions to Combat Prescription Opioid Abuse

- [White House Fact Sheet](#) (released March 29, 2016)
 - Administration actions announced include:
 - Expanding access to treatment
 - proposed rule to increase the current patient limit for qualified physicians who prescribe buprenorphine to treat opioid use disorders from 100 to 200 patients
 - new funding (\$94 million) to 271 community health centers to increase substance use disorder treatment services
 - \$11 million funding for up to 11 states to expand medication-assisted treatment services
 - Preventing opioid overdose deaths
 - funding to purchase and distribute opioid overdose reversal drug, naloxone



Actions to Combat Prescription Opioid Abuse -2

- New Private Sector Commitments to Address the Epidemic
 - 60 medical schools will require students to take prescriber education, in line with the newly released Centers for Disease Control and Prevention Guideline for Prescribing Opioids for Chronic Pain
 - Rite Aid has trained over 8,400 pharmacists on naloxone
- Updates on Federal Actions and Private Sector Commitments
 - FDA announced safety labeling changes for all immediate-release opioid pain medications



Actions to Combat Prescription Opioid Abuse -3

- Medicaid
 - CMS released a guidance document to States identifying “Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction”:
 - Increase access to treatment
 - Increase the use of naloxone to reverse opioid overdose
 - More effective pharmacy benefit management



Proposed Medicaid Managed Care Regulations

- Medicaid Managed Care Notice of Proposed Rulemaking
 - Medicaid shifting from Fee-for-Service to Managed Care
 - Rules last updated in 2002 needs overhaul
 - Added new requirements
 - Released June 1, 2015 with final rule expected in summer 2016
- Potential impact on state DUR program
 - In FY 2014, 14 states required MCOs to monitor or report DUR activities
 - State may have a role to review DUR reports from MCOs
 - Aligning quality strategy across MCO and FFS
 - Medi-Cal DUR Board goals include coordinating and sharing best practices with MCOs



Quality Strategy

- States must develop a comprehensive quality strategy (CFR 431.502 and 431.504)
 - States have to identify specific quality metrics and performance targets for improvement
 - This requirement applies to both MCO and FFS
 - Potential impact on state DUR:
 - Quality strategy to address safe and appropriate drug use
 - DUR board role in recommending quality measures and setting improvement targets
 - Medi-Cal DUR goals align with quality strategy



2016 Child Core Set Measures

- The Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA)
 - CHIPRA required HHS to identify and publish a core measure set of children's health care quality measures for voluntary use by State Medicaid and CHIP programs.
 - Measure Applications Partnership (MAP), convened by National Quality Forum (NQF) provides input to HHS, including annual recommendations for revising measures in the Child Core Set and identifying high-priority measure gaps.
 - MAP supported the 2015 Child Core Set measures for continued use. In addition, MAP recommends consider up to six measures for phased addition.
 - New measure include Use of Multiple Concurrent Antipsychotics in Children & Adolescents (APC)
 - 2016 [Child Core Set Measures](#)



2016 Adult Core Set Measures

- The Affordable Care Act (Section 1139B) requires the Secretary of HHS to identify and publish a core set of health care quality measures for 2016 adult Medicaid enrollees.
- [2016 Adult Core Set Measures](#)
- New measures added include:
 - Diabetes Screening for People with Schizophrenia or Bipolar Disorder Who Are Using Antipsychotic Medications (SSD)
 - Use of Opioids at High Dosage (OHD)



Comprehensive Medication Management

- [Comprehensive Medication Management Programs:](#) Description, Impacts, and Status in Southern California, 2015, a report, was published on 12/23/2015
- Board member and former Board Chair, Marilyn Stebbins is one of the contributing authors.



Value-Based Purchasing in Medicaid

- [The Role of State Medicaid Programs in Improving the Value of the Health Care System](#) – a report from the National Association of Medicaid Directors (NAMd), March 2016
- Likely to continue to be top agenda for Medicaid programs to assess value of the health system by considering quality measures and cost.



Questions?

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