Idaho Medicaid Drug Utilization Review Program

July 20, 2017
Annual DUR Report Highlights

Federal Fiscal Year 2016
Background

Section 1927(g)(3)(D) of the Social Security Act (the Act) requires each State to submit an annual report on the operation of its Medicaid Drug Utilization Review (DUR) program. Such reports are to include descriptions of:

- Nature and scope of the prospective and retrospective DUR programs
- Retrospective DUR intervention summary
- DUR Board Activities
- Assessment
  - Impact on quality of care
  - Cost savings generated by the program
Contents

• 126 Questions
• Attachments
  • Pharmacy Oral Counseling Compliance Report
  • RetroDUR Educational Outreach Summary
  • Summary of DUR Board Activities
  • Generic Drug Substitution Policies
  • Cost Savings/Cost Avoidance
  • Innovative Practices
  • E-Prescribing
  • Executive Summary
Top 10 PA Requests by Drug Name

- duloxetine
- lamotrigine
- Strattera
- topiramate
- tretinoin
- Lyrica
- Advair
- dextroamphetamine-amphetamine
- Adderall XR
- omeprazole
Top 10 PA Requests by Drug Class

- Anticonvulsants
- Psychostimulants-Antidepressants (duloxetine, Strattera, Intuniv)
- Ataractic-Tranquilizers (second generation antipsychotics)
- Narcotic Analgesics
- Bronchial Dilators (Advair, montelukast, beta agonists)
- Amphetamine Preparations
- All Other Dermatologicals
- Miscellaneous
- Anti-Ulcer Preps/Gastrointestinal Preps
- CNS Stimulants (methylphenidate, Nicoderm and Chantix)
Top 5 Claim Denial Reasons

- DUR Reject Error
- Prior Authorization Required
- Plan limitations exceeded
- Submit bill to other processor or primary payor
- Product/Service Not Covered
Top 10 Drug Names by Amount Paid/ Percent of Total spend

- Abilify $17,274,754 8.41%
- methylphenidate ER $5,303,499 2.58%
- Latuda $4,670,360 2.27%
- Invega Sustenna $4,288,156 2.09%
- Harvoni $4,102,297 2.00%
- Vyvanse $3,962,829 1.93%
- Stratterra $3,561,030 1.73%
- Adderall XR $3,503,815 1.71%
- Proair HFA $2,857,087 1.49%
- Humira $2,820,714 1.39%
Top 10 Drug Names
by Claim Count/ Percent of Total Claims

- hydrocodone-acetaminophen 3.53%
- amoxicillin 2.77%
- omeprazole 2.39%
- Proair HFA 2.15%
- sertraline 1.71%
- montelukast sodium 1.61%
- trazodone 1.58%
- levothyroxine sodium 1.57%
- fluoxetine 1.57%
- azithromycin 1.50%
Generic Drugs

- Generic Utilization Percentage 81.5%
- Generic Expenditure Percentage 20%
Cost Savings/Cost Avoidance

- ProDUR Estimated Avoided Costs $17,031,162
  - Reversed claims not resubmitted
- RetroDUR Estimated Avoided Costs $11,325,875

Grand Total Estimated Avoided Costs $28,357,037

Savings = 14% of Total Drug Expenditures
Do you have measures in place to either monitor or manage the prescribing of methadone for pain management?

YES !

√ pharmacist override
√ deny claim and require PA
√ quantity limits
√ intervention letters
√ morphine equivalent daily dose program
√ step therapy or clinical criteria
Do you have a documented program in place to either manage or monitor the appropriate use of antipsychotic drugs in children?

YES !

√ all children
√ edit for child’s age
√ edit for dosage
√ edit for polypharmacy
Retrospective Educational Outreach Summary

- **October 2015**
  - Multiple dosage forms of aripiprazole prescribed concomitantly
  - Buprenorphine patients paying cash for opioids
  - Patients receiving > 1 long-acting opioid

- **November 2015**
  - Multiple dosage forms of paliperidone prescribed concomitantly

- **February 2016**
  - Inhaled glucocorticoid PDL change

- **July 2016**
  - Foster Children case worker outreach
DUR Board Activities

- Multiple dosage forms of aripiprazole prescribed concomitantly
- Hepatitis C
- Buprenorphine and benzodiazepines concurrently
- Patients receiving > 1 long-acting opioid
- Foster children – high utilizers
- Multiple dosage forms of oral paliperidone (Invega) prescribed concomitantly
- Physician administered drugs
- Idaho Medicaid activities for improving opioid prescribing
- Synagis
- Ondansetron in < 1 year old
DUR Board Activities- 2

- Second generation antipsychotic use in children
- Narcotic prescribing improvement project – Top 150 utilizers per claim count
- Methadone utilization
- Albuterol MDI
- Glucocorticoids, inhaled
- Cystic Fibrosis – Kalydeco and Orkambi
- Ophthalmic Antibiotic/Steroid combinations
- Skeletal muscle relaxants
- CDC Guideline for prescribing opioids for chronic pain
Innovative Practices

• Buprenorphine direct to the prescriber intervention
• Pharmacist case management
  • Hepatitis C
  • Hemophilia
• Foster Children Collaborative Practice
• Oversight of physician administered drugs
• Narcotic Prescribing Improvement Project
• High Cost Drug Prediction Model
Executive Summary Highlights

- Idaho Medicaid and Magellan Partnership
- Internal PA Call Center
- DUR Outcome Studies on PDL Impact
- Lack of Legislative Restriction
- Physician Administered Drugs
- 19 RetroDUR Studies
- Narcotic Analgesics and Psychotropics in Children Emphasis
- Generic Utilization – not best measure
- > 80 Drug Classes on Preferred Drug List
Ongoing Reviews

- Buprenorphine and benzodiazepine concomitant use
- Hepatitis C Update
- Statin use in children
- Methadone
Buprenorphine and benzodiazepine concomitant use

July 20, 2017
Buprenorphine and benzodiazepine concomitant use

- Suboxone Package Insert

- Buprenorphine in combination with benzodiazepines or other CNS depressants including alcohol has been associated with significant respiratory depression and death.

- Patients should be warned of the potential of self-administration of benzodiazepines or other depressants while under treatment with Suboxone.
Buprenorphine and benzodiazepine concomitant use

- Payment block went into effect 1/6/16 requiring prior authorization for payment for either buprenorphine or benzodiazepine with overlapping days of service.
Buprenorphine and benzodiazepine concomitant use

- PMP Interconnect Search
  - Twenty-one States now on the list (must select each individual state to search) – including Idaho

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Buprenorphine and benzodiazepine concomitant use

New Federal Regulations Increase Limit Rule to 275 Buprenorphine Patients

Effective Date: 8/08/2016
Buprenorphine and benzodiazepine concomitant use

- Physicians who have prescribed buprenorphine to 100 patients for at least one year can now apply to increase their patient limits to 275 under new federal regulations.

- To be considered for the higher limit, complete the [Online Request for Patient Limit Increase](#). SAMHSA reviews applications within 45 days of receipt.

- Document Citation: 81 FR 44711
Buprenorphine and benzodiazepine concomitant use

FOR IMMEDIATE RELEASE
November 16, 2016
Contact: HHS Press Office
202-690-6343
media@hhs.gov

• HHS takes additional steps to expand access to opioid treatment
  • The U.S. Department of Health and Human Services (HHS) is taking additional steps to address the U.S. opioid epidemic by further expanding access to medication-assisted treatment (MAT) for opioid use disorders.

  • Administered by the Substance Abuse and Mental Health Services Administration (SAMHSA), today’s announcement enables nurse practitioners (NPs) and physician assistants (PAs) to immediately begin taking the 24 hours of required training to prescribe the opioid use disorder treatment, buprenorphine.
Buprenorphine and benzodiazepine concomitant use

- NPs and PAs are required to obtain no fewer than 24 hours of initial training addressing each of the topics in 21 USC 823(g)(2)(G)(ii)(IV) provided by one of the following organizations: The American Society of Addiction Medicine, American Academy of Addiction Psychiatry, American Medical Association, American Osteopathic Association, American Nurses Credentialing Center, American Psychiatric Association, American Association of Nurse Practitioners, American Academy of Physician Assistants, or any other organization that the Secretary of Health and Human Services determines is appropriate.

- NPs and PAs may take the eight-hour DATA-waiver course for treatment of opioid use disorder, designed by national experts, that physicians currently take. The course is offered for free by SAMHSA through the Providers’ Clinical Support System for Medication Assisted Treatment (PCSS-MAT) (link is external).
Buprenorphine and benzodiazepine concomitant use

- For the additional 16 hours, SAMHSA will also offer the training for free through the PCSS-MAT once it has been developed. NPs and PAs who have completed the required training and seek to become DATA-waiver for up to 30 patients will be able to apply to do so beginning in early 2017. For more information on the upcoming launch of the application and SAMHSA-sponsored training opportunities, [sign up (link is external)](link is external) for the Buprenorphine Waiver Management email list.

- SAMHSA website last updated 2/28/2017
Buprenorphine and benzodiazepine concomitant use

- Idaho’s Board of Medicine has stated that Physician Assistants can only treat and prescribe in accordance with their supervising physician’s capabilities. If the MD doesn’t have a waiver to prescribe buprenorphine for the treatment of opioid addiction, then the Physician Assistant cannot obtain a waiver.

- NPs and PAs who have completed the 24 hours of required training may seek to obtain a DATA 2000 waiver for up to 30 patients by completing the Waiver Notification Form.

- NPs and PAs may send copies of their training certificates to infobuprenorphine@samhsa.hhs.gov (link sends e-mail). These waiver applications are forwarded to the Drug Enforcement Administration (DEA), which will assign the NP or PA a special identification number. DEA regulations require this number to be included on all buprenorphine prescriptions for opioid dependency treatment, along with the NP’s or PA’s regular DEA registration number.

- SAMHSA shall review waiver applications within 45 days of receipt. If approved, NPs and PAs will receive a letter via email that confirms their waiver and includes their prescribing
Buprenorphine and benzodiazepine concomitant use

- Total # of participants on oral buprenorphine
- Participants who paid cash for an opioid while on oral buprenorphine
Buprenorphine and benzodiazepine concomitant use

- Buprenorphine patients
- Concomitant benzo while on buprenorphine
- Cash paying opioids while on buprenorphine
- Cash paying opioids AND concomitant benzo while on buprenorphine
Buprenorphine and benzodiazepine concomitant use

Buprenorphine and benzodiazepine March 2017 – May 2017

- Buprenorphine prescriber justified ongoing benzo usage
- Buprenorphine prescriber is weaning benzo or has discontinued benzo
- Patient no longer on buprenorphine but continuing benzo
- Paying cash for benzo while on buprenorphine (see detail next slide)
- Waiting for call back/need to call to discuss
Buprenorphine and benzodiazepine concomitant use

Detail on patients paying cash for benzo while on buprenorphine

- MD aware/ok with it: 4
- Patient told to discontinue benzo: 2
- No PA request received or insufficient info submitted: 5
- Prior auth request denied: 7
Buprenorphine and benzodiazepine concomitant use

- Questions/Comments ??
Hepatitis-C DUR

July 20, 2017
2nd Quarter 2017
(Calendar Year)
Hepatitis-C DUR

Hepatitis-C Requests
April-June 2017

- Total Reviewed: 51
- Approved: 18
- Denied: 27
- Pending Review: 6
Hepatitis-C DUR

Approved Patients
Mean Age: 55 (41-64 y/o)
Hepatitis-C DUR

Approved Requests
*Drugs*

Harvoni: 10
Epclusa: 8
Hepatitis-C DUR

Approved Requests
*Genotype*

- Genotype 1: 12.67%
- Genotype 2: 1.5%
- Genotype 3: 5.28%
- Genotype 4: 0.0%
Hepatitis-C DUR
Hepatitis-C DUR
Hepatitis-C DUR

Denied Patients
Mean Age: 45 (25-60 y/o)

- Male, 9, 53%
- Female, 8, 47%
Hepatitis-C DUR

Denied Requests
*Drugs*

- Harvoni: 17
- Epclusa: 6
- Voseira Pak: 4
Hepatitis-C DUR
Hepatitis-C DUR
Hepatitis-C DUR

Denied Requests

- Did Not Meet Fibrosis Criteria: 20
- No Follow-Up Response: 4
- Active Substance Abuse: 3
Hepatitis-C DUR

Total Amount Paid
April-June 2017

Total: $1,700,571
Hepatitis-C DUR

FDA approved July 18, 2017

Gilead: Triple combo agent Vosevi
(Sofosbuvir/velpatasvir/voxilaprevir)

- Vosevi is the first treatment approved for patients who have been previously treated with the direct-acting antiviral drug sofosbuvir or other drugs for HCV that inhibit a protein called NS5A
  - 12 week treatment in Genotype 1 who have failed previous regimen containing NS5Q inhibitor class. (96% to 98% SVR)
  - Appears to have pangenotypic properties in some studies.
  - Vosevi is contraindicated in patients taking the drug rifampin.
**Hepatitis-C DUR**

Pipeline agents to watch: 2017

**AbbVie**: Pangenotypic once a day dosing of NS3/4A protease inhibitor glecaprevir and the NS5A inhibitor pibrentasvir (G/P).
- 8 week treatment (95% to 99% SVR)

**Merck**: Triple regimen of MK-3682 (polymerase inhibitor), grazoprevir (protease inhibitor) plus ruzasvir (NS5A inhibitor) with or without ribavirin.
- Studies suggest 12 or 16 weeks treatment are most efficacious and 100% SVR in patients who have failed a previous course of Harvoni or Zepatier.
Hepatitis-C DUR

- Questions/Comments??
Statin Use in Children

July 20, 2017
Statin Use in Children

- Discussion at 4-21-17 Pharmacy and Therapeutics Committee on current age parameters in drug database for statins
  - Minimum age for many statins set at zero
  - Some statins set at 8 or 10 or 18
  - Inconsistent !!
Statin Use in Children

- AAP (American Academy of Pediatrics) Recommendations
  - Cholesterol screening
    - Children between 2-21 years with risk factors including obesity and family history of heart disease or high cholesterol
    - Universal screening between ages 9-11 years and again between 17-21 years
Statin Use in Children

- AAP (American Academy of Pediatrics) Recommendations
  - For patients 8 years and older with LDL $\geq 190$mg/dl
    - Or $\geq 60$mg/dl with a family history of early heart disease
    - Or $\geq 130$mg/dl and diabetic
  - Pharmacologic intervention should be considered
Statin Use in Children

- NHLBI (National Heart, Lung, and Blood Institute) Guidelines

  - All children should undergo cholesterol screening once between ages 9-11 and again between ages 17-21
    - Non-fasting total cholesterol and high density lipoprotein (HDL) should be used for initial lipid screening test
  - Clinicians may recommend low-fat or no-fat dairy at age 1 year for high risk patients
  - For patients who fail lifestyle changes and require lipid-lowering medications, pharmacologic treatment should be considered at age 10 years
Statin Use in Children

- Claims data between 10/16/16 – 4/16/17 for children less than 10 years old

Four children identified

1. 5 year old obese female with family history of hyperlipidemia and obesity
   - Family practice physician started patient on atorvastatin 80mg once daily

2. 7 year old female patient with heart disease (AV canal s/p surgical repair, pulmonary hypertension)
   - Pediatric cardiologist prescribing simvastatin 2.5mg (1/2 of 5mg tablet) daily
Statin Use in Children

- Claims data between 10/16/16 – 4/16/17 for children less than 10 years old

Four children identified

3. 7 year old male patient s/p heart transplant  
   Pediatric cardiologist prescribing atorvastatin 10mg twice weekly

4. 9 year old female patient s/p heart transplant  
   Pediatric cardiologist prescribing pravastatin 10mg once daily
Statin Use in Children

- Next Steps
  - Changed minimum age for all statins to 8 years old (prior authorization with medical necessity documentation will be required for anyone younger than 8 years old)
    - Except minimum age for atorvastatin 80mg and Livalo was set at 18 years old
  - Grandfathered current patients who are less than 8 years old
    - Discussion with family practice physician who is prescribing atorvastatin 80mg for 5 year old patient
Statin Use in Children

• Questions/Comments ??
Methadone

Growing Public Health Concern

- More than 16,500 people in the United States die each year from opioid-related prescription drug overdoses.

- Methadone is responsible for nearly 1/3 of these deaths but accounts for only 2% of opioid pain reliever prescription.

Methadone

Preferred pain reliever for most state Medicaid programs.

- Idaho Medicaid removed Methadone preferred status October 2015.

- Prior authorization required

- Informed methadone providers of implementation of methadone prior authorization and requested tapering off of methadone.
Methadone

Methadone Prior Authorization Request Forms

- Methadone, Initial Request
  - States initial criteria for review:
    - Failure of all alternative long acting narcotic agents.
    - Electrocardiogram (QTc interval documentation).
    - Pain score and functionality documentation.
    - Other active concurrent opioids (immediate release)
    - Documentation of failure/intolerance to non-opioid or opioid agents.
    - Limit to 30 mg/day maximum dose.
    - Cancer pain treatment is excluded from monitoring criteria.
Methadone

- **Methadone, Reauthorization**
  - Emphasizes monitoring and recommends dose tapering:
    - Electrocardiogram (QTc interval annual review).
    - Doses greater than 30 mg/day will require documentation of medical necessity and clinical reason why dose reduction cannot be employed.
      - Previously was at 40 mg/day.
    - History of failure/intolerance to non-opioid or other opioid agents.
    - Only prescribers who are familiar with methadone’s titration and risks, or those who are able to consult with a pain specialist or clinical pharmacist, should prescribe or make changes to methadone treatment.
    - Medicaid is monitoring active patients on methadone.
Methadone

American Society of Interventional Pain Physicians (ASIPP) Guidelines

- Recommend methadone only for use after failure of other opioid therapy and only by clinicians with specific training in its risks and uses, within FDA recommended doses. (Evidence: Level I; Strength of Recommendation: Strong)
Methadone

Review of Methadone drug utilization after changing to non-preferred agent.

Calendar Quarters Reviewed:

4th Quarter 2015 (Oct-Dec)
2nd Quarter of 2016 (Apr-Jun)
3rd Quarter of 2016 (Jul-Sept)
4th Quarter of 2016 (Oct-Dec)
1st Quarter of 2017 (Jan-Feb)
2nd Quarter of 2017 (Apr-Jun)
Methadone

Methadone

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<td>2nd Q 2017</td>
<td>114</td>
<td>141</td>
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Methadone

Percentage of Claims - Total Daily Dose

- Less than 40mg/day
- 40mg/day
- Greater than 40mg/day

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<td>30%</td>
<td>56%</td>
<td>14%</td>
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<td>1st Q 2017</td>
<td>33%</td>
<td>56%</td>
<td>11%</td>
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<td>2nd Q 2017</td>
<td>34%</td>
<td>55%</td>
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Methadone

NUMBER OF PATIENTS
MG/DAY

- Greater than 40 mg/day, 40, 28%
- 40 mg/day, 17.12%
- Less than 40 mg/day, 84, 68%
Methadone

Total Methadone Claims

324   | 309   | 303   | 271    | 265    | 289    | 268    | 257    | 236    | 279    | 234    | 217    | 204    | 182    | 176    | 164    | 147    | 145    | 132    | 78
Methadone
Methadone
Methadone

In conclusion:

- Continued decrease in Methadone claims since incorporation of prior authorization and monitoring criteria implementation.
  - Decreased utilization reporting because patients are paying cash for methadone.
- Patients taking more than 40 mg/day of methadone has not decreased.
  - Grandfathered prior authorizations require follow up reporting.
  - Continue to recommend tapering agent down to acceptable Morphine Daily Equivalents.
Methadone

- Questions/Comments??
Current Interventions/Outcomes Studies

- Opana ER
- Xyrem
- Fluoroquinolone use in children
Opana ER DUR

July 20, 2017
Opana ER DUR

June 8th, 2017 FDA requests removal of Opana ER

- This decision follows a March 2017 FDA advisory committee meeting where a group of independent experts voted 18-8 that the benefits of reformulated Opana ER no longer outweigh its risks.

- The FDA’s decision is based on a review of all available post marketing data, which demonstrated a significant shift in the route of abuse of Opana ER from nasal to injection following the product’s reformulation.
  - Abuse-deterrent properties of Opana ER turned the pill into a gel that supposedly made it hard to snort or inject when crushed.
Endo International PLS stated it will voluntarily stop selling Opana ER.

Generic versions are not reformulated and at this time have not been pulled from the market.

Opana ER and Oxymorphone ER are non-preferred agents.

- History of failure of preferred agents required before non-preferred agents will be considered for approval.

DUR to determine how much of an impact Opana ER withdrawal from the market will have on Idaho Medicaid.
Regulatory History of Opana ER

Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee
March 13-14, 2017

Ellen Fields, MD, MPH
Deputy Director, Division of Anesthesia, Analgesia and Addiction Products
Outline

• Oxymorphone
• Approval History
• Reformulated Opana ER
• Citizen petition
• General extended-release/long-acting opioid analgesic information
Oxymorphone

- Semisynthetic opioid analgesic
- Schedule II CSA
- Pure agonist, relatively selective for mu receptor
- Pharmacologic effects consistent with other mu opioid agonists
- Relatively low oral bioavailability ~ 10%
- Principally metabolized in liver
- Approximate potency (by IV route) compared to morphine is 10:1
History

• 1959–1960 Numorphan (Endo)
  • Parenteral oxymorphone 1 mg/mL
  • Immediate-release tablets
  • Rectal suppository - 5 mg
  • Relief of moderate-to-severe pain, preop medication, support of anesthesia, obstetrical analgesia, and relief of anxiety in patients with dyspnea associated with pulmonary edema due to left ventricular dysfunction
• Numorphan IR tablets voluntarily withdrawn from market 1982
  • Sponsor cited commercial reasons
  • Anecdotal reports of abuse by injection in 60’s and 70’s
History

• 2006
  • Opana (immediate-release tablets)
    • Relief of moderate-to-severe acute pain
  • Opana ER (extended-release tablets)
    • Management of moderate-to-severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time
2006 Approval

Opana
• 3 studies in post op pain, 2 orthopedic, 1 abdominal
• 5 and 10 mg tablets
• Dosing: 10-20 mg every 4-6 hours
• Food effect: increase in Cmax and AUC ~40%
  • Take on an empty stomach
2006 Approval

Original Opana ER
– 2 double-blind, controlled trials in patients with moderate-severe chronic low back pain, 1 opioid naïve, 1 opioid tolerant
– Safety data in >2000 subjects
– 5, 10, 20, 40 mg tablets
– 7.5, 15, and 30 mg dosage strengths added in 2008
– Dosing:
  • Opioid naïve- 5 mg Q 12 h
  • Opioid tolerant- convert from prior opioid
– Food effect: increase Cmax ~ 50%- take on empty stomach
– Not intended to be abuse deterrent: Swallow whole. Crushing, chewing, snorting, or injecting the dissolved product will result in uncontrolled delivery and pose significant risk that could result in overdose and death
– Approval included Risk Minimization Action Plan (RiskMAP)
Reformulated Opana ER

- Supplemental NDA (sNDA) submitted in 2010
- Designed with physicochemical properties intended to make formulation resistant to physical and chemical manipulation for abuse by intranasal (IN) and intravenous (IV) routes
- Excipients include polyethylene oxide, which is included in a number of AD formulations, and is intended to:
  - Make tablets hard, difficult to crush
  - Form a viscous gel when tablets contact liquids
Reformulated Opana ER

• Submitted in vitro and in vivo studies that assessed AD properties
  • Agency determined did not support AD labeling
• Approved December, 2011 without AD labeling
• Approval included Risk Evaluation and Mitigation Strategy (REMS)
• Replaced original Opana ER over first few months of 2012
• Generic products to original Opana ER continue to be marketed
  • Currently no generic products referencing reformulated
Citizen Petition

Submitted by Endo in 2012
• Requested FDA make determination that original Opana ER was withdrawn from market due to safety concerns
• This would result in withdrawing generic products referencing original Opana ER
• Petition denied in 2013
  • Insufficient data to conclude original Opana ER posed increased risk of abuse compared to reformulated Opana ER
  • Refer to background package for details of Agency response to petition
Reformulated Opana ER

sNDA submitted February, 2013 to request AD labeling language
• Included same studies as first sNDA plus preliminary post-marketing epidemiology data on Opana ER
• Not approved, insufficient data to support AD labeling
Reformulated Opana ER

Resubmitted January 2016 requesting labeling for AD properties for IN abuse, as well as additional epidemiologic data on abuse patterns of Opana ER.

• Concurrently, reports of serious illnesses associated with IV abuse of Opana ER
• Agency concerns regarding shift of abuse from nasal to IV
• Advisory Committee meeting planned
• Supplement withdrawn by Sponsor, August, 2016 → AC cancelled

• Subsequently, three years of postmarketing data submitted to Agency to inform discussion at this AC
• Note: Sponsor not currently seeking AD labeling
Opana ER DUR


- 19 patient with a history of Opana ER utilization.
  - 17 patients female
  - 2 patients male
- 82 claims
- Total cost of $49,680
Opana ER DUR

Opana ER Utilization
Patient with a History of Opana ER Utilization
12/13/2016 to 6/13/2017

Active
Not Active
Opana ER DUR

- Number of Medicaid patients on Opana ER is small.
- Opana ER withdraw from the market will have a minimal impact on Medicaid services.
- Generic version is available and brand name will likely switch to generic.
Opana ER DUR

• Questions/Comments??
Prior Authorization Criteria Recommendations
July 20, 2017
Xyrem DUR

Xyrem ® (Sodium Oxybate) 500 mg/ml (550 mg/3 g dose)

FDA Approved Indications

- Indicated for the treatment of excessive daytime sleepiness and cataplexy in patients with narcolepsy.
- Initial, 2.25 g orally at bedtime and 2.25 g taken 2.5 to 4 hours later (total initial dose 4.5 g/night); increase dose by 1.5 g/night (0.75 g/dose) at weekly intervals; take while in bed and lie down immediately.
- Maintenance dosage, 6 to 9 g orally per night administered in 2 equally divided doses at bedtime and 2.5 to 4 hours later; take while in bed and lie down immediately; MAX 9 g/night.
Xyrem DUR

Background:

• Xyrem® (sodium oxybate) is a central nervous system depressant that has been shown in clinical studies to reduce excessive daytime sleepiness and cataplexy in patients with narcolepsy. However, the precise mechanism by which sodium oxybate produces an effect on cataplexy is unknown.

• It’s effects are thought to be mediated through gamma-aminobutyric acid (GABA)-B actions at the noradrenergic, dopaminergic, and thalamocortical neurons.
Xyrem DUR

Background:

- Sodium oxybate is also being studied for use in chronic insomnia (from a variety of sources including PTSD, in patients with schizophrenia, and chronic fatigue syndrome), fibromyalgia, Parkinson’s disease, and obstructive sleep apnea.
Black Box Warning:

WARNING: CENTRAL NERVOUS SYSTEM (CNS) DEPRESSION and MISUSE AND ABUSE.

See full prescribing information for complete boxed warning.

• Respiratory depression can occur with Xyrem use.
• Xyrem is a Schedule III controlled substance and is the sodium salt of gamma hydroxybutyrate (GHB), a Schedule I controlled substance. Abuse or misuse of illicit GHB is associated with CNS adverse reactions, including seizure, respiratory depression, decreased consciousness, coma and death.
• Because of the risks of CNS depression, abuse, and misuse, Xyrem is available only through a restricted distribution program called the Xyrem REMS Program using the central pharmacy that is specially certified. Prescribers and patients must enroll in the program.
Due to safety concerns with Xyrem and specific diagnosis criteria, prior authorization therapeutic criteria is recommended.

- Therapeutic Criteria document
- Prior authorization form.
Xyrem DUR

Therapeutic Criteria:

Inclusion Criteria

- FDA approved indications with required documentation for diagnosis of narcolepsy with cataplexy or narcolepsy without cataplexy.
- Documented history of failure or inadequate response to amphetamines and modafinil or armodafinil.
- Documentation of other causes of sleep disorders have been ruled out or appropriately treated (refer to therapeutic criteria document).
- Must be prescribed by a neurologist, pulmonologist, or sleep specialist.
Xyrem DUR

Therapeutic Criteria:

Exclusion Criteria

- Concurrent use of alcohol, sedative hypnotic agents, or benzodiazepines.
- Diagnosis of succinic semialdehyde dehydrogenase deficiency.
- Non-FDA/Off-Label use of sodium oxybate.
- Know hypersensitivity to sodium oxybate.
- Active history of substance or alcohol abuse.
- No history of preferred agents.
Xyrem DUR

Therapeutic Criteria:

Monitoring Criteria

- Patients with or without a history of substance have been counseled regarding potential for abuse and dependence and will be closely monitored for signs of abuse and dependence.
- The prescriber must review the patient’s use of controlled substance on the Idaho Medicaid Prescription Monitoring Program (PMP) website at https://idaho.pmpaware.net/login prior to requesting prior authorizations.
- Initial approval of 3 months. Follow up required reporting improvement in the signs and symptoms of narcolepsy with or without cataplexy.
Xyrem DUR

5 patients treated by sleep specialist.

- 3 females
  - Age: 24, 33, 43
- 2 Males
  - Age: 39, 47
- Total Claims= 16
- Patients are taking a stimulant.
  - Adderall XR, modafinil, or armodafinil.
- Maximum monthly refill is 540 ml or 9 g/day
  - 2 patients at 9 g/day
  - 1 (7.5 g/day), 1 (4.5 g/day) and 1 (6 g/day)
Xyrem

• Questions/Comments??
Fluoroquinolone use in children

July 20, 2017
Fluoroquinolone use in children

Idaho Medicaid’s Preferred Drug List

Preferred: ciprofloxacin tablet, Cipro suspension, levofloxacin tablets

Non-Preferred: ciprofloxacin ER, levofloxacin suspension, moxifloxacin, ofloxacin

- Note: Applies to patients of all ages, not just children.
Fluoroquinolone use in children


The U.S. Food and Drug Administration (FDA) approved changes to the labels of fluoroquinolone antibacterial drugs for systemic use (i.e., taken by mouth or by injection). These medicines are associated with disabling and potentially permanent side effects of the tendons, muscles, joints, nerves, and central nervous system that can occur together in the same patient. As a result, we revised the Boxed Warning, FDA’s strongest warning, to address these serious safety issues. We also added a new warning and updated other parts of the drug label, including the patient Medication Guide.
We have determined that fluoroquinolones should be reserved for use in patients who have no other treatment options for acute bacterial sinusitis, (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) because the risk of these serious side effects generally outweighs the benefits in these patients. For some serious bacterial infections the benefits of fluoroquinolones outweigh the risks, and it is appropriate for them to remain available as a therapeutic option.
Fluoroquinolone use in children

• FDA Drug Safety Communication – July 26, 2016 (continued)

Health care professionals should not prescribe systemic fluoroquinolones to patients who have other treatment options for acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and uncomplicated urinary tract infections (UTI) because the risks outweigh the benefits in these patients. Stop fluoroquinolone treatment immediately if a patient reports serious side effects, and switch to a non-fluoroquinolone antibacterial drug to complete the patient’s treatment course.
Fluoroquinolone use in children

- FDA Update on 5-10-17

As part of our ongoing review of fluoroquinolone antibiotics, FDA is informing the public that patient cases identified by the FDA and findings from published studies currently do not support reports that these medicines may result in detachment of the retina in the eyes, or bulges or tears in the aorta blood vessel called aortic aneurysm and aortic dissection. We will continue to assess safety issues with fluoroquinolones and will update the public if additional actions are needed.
Fluoroquinolone use in children

- Current age parameters in Idaho drug database
  - Ciprofloxacin set at zero
    - Per prior DUR that found that the majority of patients prescribed these medications had CF, cancer, or other chronic lung diseases
    - FDA approved for ages 18 and older
  - Package insert: Although effective in clinical trials, CIPRO is not a drug of first choice in the pediatric population due to an increased incidence of adverse reactions compared to controls. Quinolones, including CIPRO, cause arthropathy in juvenile animals [see Warnings and Precautions (5.12) and Nonclinical Toxicology (13.2)].
Fluoroquinolone use in children

- Current age parameters in Idaho drug database
  - Levofloxacin set at zero
    - Per prior DUR that found that the majority of patients prescribed these medications had CF, cancer, or other chronic lung diseases
  - FDA approved for ages 18 and older
  - Package insert: Quinolones, including levofloxacin, cause arthropathy and osteochondrosis in juvenile animals of several species. [see Warnings and Precautions (5.11) and Animal Toxicology and/or Pharmacology (13.2)].
Fluoroquinolone use in children

- Current age parameters in Idaho drug database
  - Moxifloxacin set at 16 years
    - FDA approved for ages 18 and older
    - Package insert: Effectiveness in pediatric patients and adolescents less than 18 years of age has not been established. AVELOX causes arthropathy in juvenile animals. Limited information on the safety of AVELOX in 301 pediatric patients is available from the cIAI trial [see Boxed Warning, Warnings and Precautions (5.9) and Nonclinical Toxicology (13.2)].
Fluoroquinolone use in children

- Current age parameters in Idaho drug database
  - Ofloxacin set at 16 years
    - FDA approved for ages 18 and older
    - Package insert: safety and efficacy in children less than 18 years of age have not been established.
Fluoroquinolone use in children

- Baxdela (delafloxacin)
  - Not commercially available yet and not yet in First Databank drug file.
  - Will be available as tablets and injection.
  - Approved for treatment of acute bacterial skin and skin structure infections caused by susceptible bacteria.
Fluoroquinolone use in children

- Baxdela (delafloxacin)

Use in patients under 18 years of age is not recommended. Safety and effectiveness in pediatric patients below the age of 18 years have not been established. Pediatric studies were not conducted because risk-benefit considerations do not support the use of BAXDELA for ABSSSI in this population. Fluoroquinolones cause arthropathy in juvenile animals.
Fluoroquinolone use in children

- Paid claims between 12-1-16 and 5-31-17 for children less than 16 years old
- 148 unique recipients
Fluoroquinolone use in children

Breakdown of paid claims by age

CLAIMS

AGE

< 1 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

10 7 6 5 2 3 8 5 8 10 12 16 17 31

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 31

0 5 10 15 20 25 30 35

121
Fluoroquinolone use in children

Breakdown by taxonomy

- NP: 36 claims
- Family Practice: 35 claims
- Pediatricians: 32 claims
- Physician Assistants: 20 claims
- Urology: 5 claims
- ER: 5 claims
- Pulmonology: 4 claims
Fluoroquinolone use in children

Breakdown by taxonomy

- Dentist: 2 claims
- Internal Medicine: 2 claims
- Oncology: 2 claims
- Surgery: 2 claims
- Allergy: 1 claim
- Nephrology: 1 claim
- Otolaryngology: 1 claim
Fluoroquinolone use in children

Breakdown by age and taxonomy for prescriber groups with > 10 claims
Fluoroquinolone use in children

Discussion Points

1. Do we want to change any of the age parameters in the drug database?
2. Do we want to add any more clinical criteria?
Idaho Opioid Equivalent Dosing Project

DUR Presentation

July 20, 2017
Idaho Opioid Equivalent Dosing Project

Today IDHW’s Pharmacy Unit is managing Opioid utilization in various ways, such as
  • Quantity Limits on all drugs
  • PA on specific State Drug Classes
  • Profile review and educational outreach

MME (Morphine Milligram Equivalence) of 90 is now the recommended goal, a point to understand is that there is not just one MME Calculator:
  • CMS MME Calculator (calculator we are going to utilize)
  • Other MME Calculators
  • Customized MME Calculator
Idaho Opioid Equivalent Dosing Project

• Prior Authorization

• First Rx

• First Trax

• First IQ

• Reporting
Prior Authorization

**Goal:** require a prior authorization if a patient exceeds the >90 Morphine Milligram Equivalence (MME) per day combined Short and Long acting narcotic agents*

- According to the CDC, clinicians should avoid increasing dosage to >90 MME or carefully justify a decision to go above that threshold.

*Report will be run to determine those recipients who have had an MME of >90 in the past 90 days and Prior Authorizations will be entered for those recipients for 1 year.

**Criteria to approve override of quantity limit >90 MME**
First Rx - capable of supporting standard and custom MME cumulative dosing limits, conversion factors, and drug lists

- Recommend using the CMS standard conversion factor and drug list
  - Allows for a one time entry and QC
  - Conversion factor layout (First Rx team) is already defined and approved
  - Maintenance of the standard drug list
First Trax – MME display and calculator

1. **FirstTrax enhancement to allow IDHW Clinical Pharmacists to view:**
   - MME of the incoming claim that exceeded the MME Quantity Limit
   - MME of each claim that contributed to the incoming claim to exceed the limit
   - Total Combined MME of all claims that contributed to the incoming claim to exceed the limit

2. **Calculator:**
   - First Trax has a Calculator functionality installed
     - *Pulls information from relevant opioid claims only*
     - *Auto-populates calculator with necessary claims data*
     - *Enables the Clinical Pharmacist to change the value of some fields*
First Trax – MME display and calculator, continued

Calculator (continued):
  • Calculator functionality
    – Targeted opioids
    – Conversion factors
    – MME limit

Status:
  • First Trax development is complete
  • Training and rollout this week for IDHW Staff
First IQ - RDUR

FIQ can be used for
- Member identification only, or
- FIQ can used to generate letters for to:
  - members, prescribers and/or pharmacies

FIQ is highly flexible
- Drug groups for criterion are defined within the application
- Criterion and output can be customized
### OPIOID OVERUTILIZATION

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<td>4/1/2017 - 6/30/2017</td>
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#### TABLE 1: # of Members Filling Opioids, by Quarters

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<th>6/30/2017</th>
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<td>Members on Opioids</td>
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#### TABLE 2: Opioid Members by MED/Day (mg) > 90 mg MED

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<th>Duration of MED &gt; 90 MED</th>
<th>4/1/2017</th>
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<tr>
<td>&gt;= 0 Days</td>
<td>3,669</td>
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<td>&lt; 90 Days</td>
<td>1,602</td>
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<td>&gt;= 90 Days</td>
<td>2,067</td>
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<tr>
<td>Total</td>
<td>3,669</td>
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### TABLE 3: All Opioid Members by # of Prescribers and Pharmacies

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<tr>
<th>n of prescribers</th>
<th>n of pharmacies</th>
<th>4/1/2017</th>
<th>6/30/2017</th>
<th>% of Total Opioid</th>
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<tr>
<td>≥ 4</td>
<td>≥ 4</td>
<td>36</td>
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<tr>
<td>≥ 4</td>
<td>3</td>
<td>48</td>
<td></td>
<td>0%</td>
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<td>≥ 4</td>
<td>&lt; 3</td>
<td>179</td>
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<td>&lt; 3</td>
<td>567</td>
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<td></td>
<td>≥ 3</td>
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<td>&lt; 3</td>
<td>&lt; 3</td>
<td>13,082</td>
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</table>

### TABLE 4: Opioid Members with > 90 mg MED, by # of Prescribers and Pharmacies

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<th>n of prescribers</th>
<th>n of pharmacies</th>
<th>4/1/2017</th>
<th>6/30/2017</th>
<th>% of ≥ 90 consecutive days &gt; 90 MED Members</th>
<th>% of Total Opioid Members</th>
</tr>
</thead>
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<tr>
<td>≥ 4</td>
<td>≥ 4</td>
<td>10</td>
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<td>0.48%</td>
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<td>≥ 4</td>
<td>3</td>
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<td>0.73%</td>
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<tr>
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<td>&lt; 3</td>
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<td>2.56%</td>
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<tr>
<td>3</td>
<td>≥ 3</td>
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<td>1.11%</td>
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<td>3</td>
<td>&lt; 3</td>
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<td>7.01%</td>
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<td>&lt; 3</td>
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<td>&lt; 3</td>
<td>&lt; 3</td>
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<td>Label Name</td>
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<tr>
<td>HYDROCODON-ACETAMINOPHEN</td>
<td>5</td>
<td>47430</td>
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<td>HYDROCODON-ACETAMINOPHIN</td>
<td>10MG-325MG</td>
<td>30623</td>
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<td>TRAMADOL</td>
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<tr>
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<td>OXYCODONE-ACETAMINOPHEN</td>
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<td>4222</td>
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<td>ACETAMINOPHEN-COD</td>
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TABLE 6: Top 20 Pharmacies Dispensing Opioids

<table>
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<tr>
<th>Pharmacy Name</th>
<th>Pharmacy NPI</th>
<th>Total</th>
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<tr>
<td>WALGREENS</td>
<td>1417962531</td>
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<td>WALGREENS</td>
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<td>WALGREENS</td>
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<td>683</td>
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<td>WALGREENS</td>
<td>1881609907</td>
<td>643</td>
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<td>WALGREENS</td>
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</tr>
<tr>
<td>DICK'S</td>
<td>1295832574</td>
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<td>WALGREENS</td>
<td>1871508994</td>
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<td>RITE</td>
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<td>387</td>
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<tr>
<td>WALGREENS</td>
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<tr>
<td>ALBERTSONS,</td>
<td>1295781110</td>
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### TABLE 7: Top 20 Members with Highest Daily MME

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Next steps

The edit went into production on July 19, 2017.
Study Proposals for Upcoming Quarters:
Prospective DUR Report

- History Errors:
  - DD – drug-to-drug
  - PG – drug to pregnancy
  - TD – therapeutic duplication
  - ER – early refill
  - MC – drug-to-disease

- Non-History Errors:
  - PA – drug-to-age
  - HD – high dose
  - LD – low dose
  - SX – drug-to-gender
# Prospective DUR Report

## Idaho Medicaid Program

### ProDUR Message Report

**June 2017**

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<th>ProDUR Message</th>
<th>ProDUR Severity</th>
<th>Message Count</th>
<th>Message Amount</th>
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</table>

- **Total Number of Claims with Messages**: 237,404
- **Average ProDUR Message Per Claim**: 4.50
Medicaid Update

DUR Board Meeting July 20, 2017
Idaho Medicaid Drug Utilization Review Program

Next Meeting October 19, 2017

Holiday Inn Boise Airport

2970 West Elder Street
Boise, Idaho
83705
United States