Effective Strategies for Addressing Overutilization and Abuse of Prescription Drugs in Medicare Part D

CMS’ Drug Utilization Review Requirements and Initiatives

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Overview

• Background
• Formulary Review Process
• Improving Drug Utilization Review Controls in Part D
• Formulary Management Strategies
• Opioid Overutilization Policy Development
• The Overutilization Monitoring System
• Impact of CMS Policy
• Compliance Outreach
As described in section 1860D-11(i)(2) of the Act, CMS cannot mandate a national formulary. However, CMS has exercised its antidiscrimination authority under section 1860D-11(e)(2)(D)(i) to ensure that Part D plan formularies do not substantially discourage enrollment by certain Part D eligible individuals.

Part D formulary submissions must be reviewed and approved prior to bid approval.
Part D Formulary Review Process

• CMS Formulary Reference File (FRF)
  – The FRF includes RXCUIs, adopted from NLM’s RxNorm system, to represent distinct brand names, generic names, strengths, routes of administration, and dosage forms of drugs
  – The FRF serves as a pick-list of drugs for formulary inclusion that streamlines the submission and review process, and results in improved synchronization of CMS and plan sponsor files
  – Not a “coverage” list for Part D drugs
Part D Formulary Review Process (continued)

- Formularies are submitted and reviewed via the Health Plan Management System (HPMS)
- Submissions are based on the FRF
- One formulary (FID) can be used across multiple plans
- The drug list, associated utilization management requirements, and tiering are reviewed in 3 stages
- During each review stage, Part D sponsors can provide clinical justifications, revised submissions, or both
- The final stage of the review involves addressing any unresolved issues, formulary negotiations, and conditional approvals
Level One: Improved Use of Concurrent Claim Edits (Safety Controls at Point of Sale
 – Early Refill Edits
 – Therapeutic Duplication Edits
 – Age/Gender Edits
 – Quantity Limits At or Above FDA Max Dose

Reference: CY 2013 Final Call Letter
Improving Drug Utilization Review Controls in Part D – Level Two

• Level Two: Improved Use of Formulary Management Designs
  – Quantity Limits where no clear FDA Max Dose
  – Quantity Limits Below FDA Max Dose
  – Prior Authorization Criteria
  – Step Therapy Criteria

Reference: CY 2013 Final Call Letter
Level Three: Improved Retrospective DUR Programming & Case Management

- Retrospective review of claims data to identify egregious patterns of inappropriate use of specific drugs or groups of drugs among Part D enrollees
- DUR programming and case management to detect and prevent inappropriate overutilization should events go undetected despite claim level controls

Reference: CY 2013 Final Call Letter
Formulary Management
Strategies in Practice

• Quantity Limits
• Prior Authorization
• Step Therapy
QL Rates for Opioid Class, CY 2012 – CY 2016

Source: CY12-16 HPMS approved formulary data

1. CY 2013 Final Call Letter
## QL Rate Changes

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Dose Form</th>
<th>% with QL 2012</th>
<th>% with QL 2016</th>
<th>Absolute Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROXICET</td>
<td>OXYCODONE HCL/ACETAMINOPHEN</td>
<td>ORAL SOLUTION</td>
<td>15.8%</td>
<td>92.9%</td>
<td>77.1%</td>
</tr>
<tr>
<td>ROXICODONE</td>
<td>OXYCODONE HYDROCHLORIDE</td>
<td>ORAL TABLET</td>
<td>10.5%</td>
<td>86.8%</td>
<td>76.3%</td>
</tr>
<tr>
<td>ROXICODONE</td>
<td>OXYCODONE HCL</td>
<td>ORAL TABLET</td>
<td>11.8%</td>
<td>85.5%</td>
<td>73.7%</td>
</tr>
<tr>
<td>ROXICODONE</td>
<td>OXYCODONE HCL</td>
<td>ORAL TABLET</td>
<td>13.9%</td>
<td>87.4%</td>
<td>73.5%</td>
</tr>
<tr>
<td>ROXICODONE</td>
<td>OXYCODONE HCL</td>
<td>ORAL CAPSULE</td>
<td>10.0%</td>
<td>83.2%</td>
<td>73.2%</td>
</tr>
<tr>
<td>ROXICODONE</td>
<td>MORPHINE SULFATE</td>
<td>ORAL TABLET</td>
<td>12.0%</td>
<td>84.7%</td>
<td>72.7%</td>
</tr>
<tr>
<td>ROXICODONE</td>
<td>HYDROMORPHONE HCL</td>
<td>ORAL TABLET</td>
<td>13.3%</td>
<td>85.6%</td>
<td>72.3%</td>
</tr>
<tr>
<td>DILAUDID</td>
<td>HYDROMORPHONE HCL</td>
<td>ORAL TABLET</td>
<td>10.0%</td>
<td>81.6%</td>
<td>71.6%</td>
</tr>
<tr>
<td>DILAUDID</td>
<td>LEVORPHANOL TARTRATE</td>
<td>ORAL TABLET</td>
<td>8.2%</td>
<td>79.8%</td>
<td>71.6%</td>
</tr>
<tr>
<td>DILAUDID</td>
<td>CODEINE SULFATE</td>
<td>ORAL TABLET</td>
<td>8.9%</td>
<td>79.4%</td>
<td>70.5%</td>
</tr>
</tbody>
</table>

Source: CY12-16 HPMS approved formulary data
In the CY 2014 Call Letter, CMS strongly encouraged sponsors to develop the ability to implement plan-level POS edits based upon cumulative MED across the opioid class.

The CY 2016 Call Letter continued to urge sponsors to implement a soft edit and build the capacity for a more sophisticated POS edit.
Cumulative MED POS Edit Requirements

• Submit the lesser of either the plan-approved QL for the individual opioids or the QL that is equivalent to the cumulative MED level to be applied across the opioid class

• Submit details to Part D mailbox
  – MED level
  – Written description of the program (e.g., days in excess of accumulated level that triggers edit)
  – Mechanism to resolve the edits
## Cumulative MED POS edit
### CY 2014 – CY 2016

<table>
<thead>
<tr>
<th>Year</th>
<th># of Cumulative MED POS Edits</th>
<th># of FIDs</th>
<th>% of FIDs with a Cumulative POS Edit</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>0</td>
<td>437</td>
<td>0%</td>
</tr>
<tr>
<td>2015</td>
<td>36</td>
<td>467</td>
<td>7.7%</td>
</tr>
<tr>
<td>2016</td>
<td>108</td>
<td>456</td>
<td>23.7%</td>
</tr>
</tbody>
</table>
PA Rates for Opioid Class, CY 2012 – CY 2016

Source: CY12-16 HPMS approved formulary data

1. CY 2013 Final Call Letter
2. CY 2015 Final Call Letter
As outlined in the CY 2015 Call Letter, CMS established criteria for scenarios where plan sponsors are expected to implement POS edits for PA on drugs that have the highest risk of non-Part D covered uses:

- High likelihood of coverage under Parts A or B
- High likelihood that the drug is Part D excluded as defined in section 1927(d)(2) of the Act
- High likelihood of use for non-medically accepted indications as defined in section 1860D-2(e)(4) of the Act

Examples include Transmucosal Immediate Release Fentanyl (TIRF) drugs and Cialis (tadalafil)
# PA Rate Changes

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
<th>Dose Form</th>
<th>% with PA 2012</th>
<th>% with PA 2016</th>
<th>Absolute Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>CODEINE/CARISOPRODOL/ASPIRIN</td>
<td>ORAL TABLET</td>
<td>26.8%</td>
<td>100%</td>
<td></td>
<td>73.2%</td>
</tr>
<tr>
<td>ACETAMINOPHEN / BUTALBITAL / C</td>
<td>ORAL CAPSULE</td>
<td>0.0%</td>
<td>69.9%</td>
<td></td>
<td>69.9%</td>
</tr>
<tr>
<td>PENTAZOCINE HCL/NALOXONE HCL</td>
<td>ORAL TABLET</td>
<td>9.8%</td>
<td>63.0%</td>
<td></td>
<td>53.2%</td>
</tr>
<tr>
<td>MEPERIDINE HYDROCHLORIDE</td>
<td>ORAL TABLET</td>
<td>17.4%</td>
<td>59.7%</td>
<td></td>
<td>42.3%</td>
</tr>
<tr>
<td>MEPERIDINE HCL</td>
<td>ORAL TABLET</td>
<td>17.4%</td>
<td>59.5%</td>
<td></td>
<td>42.1%</td>
</tr>
<tr>
<td>SUBSYS</td>
<td>FENTANYL</td>
<td>MUCOSAL SPRAY</td>
<td>65.3%</td>
<td>100%</td>
<td>34.7%</td>
</tr>
<tr>
<td>MEPERIDINE HCL</td>
<td>ORAL SOLUTION</td>
<td>18.5%</td>
<td>51.5%</td>
<td></td>
<td>33.0%</td>
</tr>
<tr>
<td>DEMEROL</td>
<td>MEPERIDINE HYDROCHLORIDE</td>
<td>ORAL TABLET</td>
<td>28.6%</td>
<td>55.6%</td>
<td>27.0%</td>
</tr>
<tr>
<td>LAZANDA</td>
<td>FENTANYL CITRATE</td>
<td>NASAL SPRAY</td>
<td>79.0%</td>
<td>100%</td>
<td>21.0%</td>
</tr>
<tr>
<td>ABSTRAL</td>
<td>FENTANYL CITRATE</td>
<td>SUBLINGUAL TABLET</td>
<td>79.3%</td>
<td>100%</td>
<td>20.7%</td>
</tr>
</tbody>
</table>

Source: CY12-16 HPMS approved formulary data
ST Rates for Opioid Class, CY 2012 – CY 2016

Source: CY12-16 HPMS approved formulary data
Effective January 1, 2013, CMS implemented new policy in Medicare Part D requiring sponsors to better address potential overutilization of opioids in their prescription drug benefit plans through improved drug utilization controls and case management.

Comprehensive policy was set forth in the final Call Letter (April 2, 2012) for CY 2013 and in more detail in final supplemental guidance (September 6, 2012).
Overutilization Policy Development, 2014 Call Letter

• CMS strongly encourages all sponsors to develop the ability to implement plan-level POS edits based upon cumulative morphine equivalent dose (MED) across the opioid class as soon as possible.

• Sponsors may voluntarily expand the Part D Policy on Improving Utilization Review Controls to other drugs or classes of drugs, which would include notifying CMS and the affected beneficiaries of any beneficiary-level claim edits that will be implemented.
CMS expects Part D sponsors to implement soft formulary-level safety edits at POS at a minimum to further reduce cumulative acetaminophen (APAP) overutilization among their enrollees.

Part D sponsors should lower their internal opioid criteria for retrospective identification of opioid overutilization and subsequent case management to be no less restrictive than 120 mg MED daily dose over at least 90 consecutive days as used by CMS.
Overutilization Policy Development, 2016 Call Letter

• CMS encouraged sponsors to implement a soft, formulary-level cumulative MED POS edit and prepare for a more sophisticated POS edit in 2017

• New opioid and APAP Daily Dose rates will be added to the Overutilization Monitoring System for informational purposes only

• CMS will investigate the concurrent use of buprenorphine and opioids in Part D
The OMS was implemented in July 2013 to oversee sponsors’ compliance with CMS’ new opioid overutilization policy.

Part D sponsors are provided quarterly reports on high risk beneficiaries, and submit the outcome of their review of each case.

The OMS also accepts sponsor-identified opioid overutilization cases.
Overutilization of Opioid Drugs:

- Use of opioids with cumulative daily morphine equivalent dose (MED) exceeding 120 mg for at least 90 consecutive days with more than 3 prescribers and more than 3 pharmacies contributing to their opioid claims
- Drug list and conversion factors supported by the Centers for Disease Control and Prevention
• Overutilization of APAP:
  – Use of APAP with daily dose exceeding 4 g for a total of 30 days or more within any six-month period with at least one day exceeding 4 g within the most recent calendar quarter
Methodology Updates

• **Diagnosis Data:** Cancer diagnoses are identified via RxHCCs from the Risk Adjustment Processing System dataset, and supplemented with current diagnoses from the Common Working File.

• **Opioid Methodology:** Revised opioid drug list and conversion factors based upon CDC recommendations.
OMS Functionality Updates

• January 2014: The OMS was enhanced to collect potential opioid overutilization issues that were identified through Part D sponsors’ own internal criteria and reviewed, but not previously identified by CMS

• February 2014: The Medicare Advantage and Prescription Drug System (MARx) collects opioid POS edit data from sponsors and notifies sponsors when a targeted beneficiary changes plans
  – As of October 5, 2015, sponsors submitted 2,020 beneficiary-level opioid POS edits to MARx
## Impact of CMS Policy
### 2011 through 2014 - Opioids

### Part D Opioid Overutilization Rates, 2011–2014

<table>
<thead>
<tr>
<th>Year</th>
<th>Part D Enrollees</th>
<th>Enrollees Using Opioids</th>
<th>% Enrollees Using Opioids</th>
<th>Beneficiaries Exceeding Opioid Outlier Threshold</th>
<th>Change Year-to-Year</th>
<th>Opioid Users Flagged as Outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>31,483,841</td>
<td>10,049,914</td>
<td>31.9%</td>
<td>29,404</td>
<td>-</td>
<td>0.29%</td>
</tr>
<tr>
<td>2013</td>
<td>37,842,632</td>
<td>11,794,908</td>
<td>31.2%</td>
<td>25,347</td>
<td>-4,057</td>
<td>0.22%</td>
</tr>
<tr>
<td>2014</td>
<td>39,982,962</td>
<td>12,308,735</td>
<td>30.8%</td>
<td>21,838</td>
<td>-3,509</td>
<td>0.18%</td>
</tr>
</tbody>
</table>

For this comparison, CMS applied the revised opioid methodology, including the expanded drug list from CDC.
Impact of CMS Policy
2011 through 2014 - APAP


<table>
<thead>
<tr>
<th>Year</th>
<th>Part D Enrollees</th>
<th>Enrollees Using APAP</th>
<th>% Enrollees Using APAP</th>
<th>Beneficiaries Exceeding APAP Outlier Threshold</th>
<th>Change Year-to-Year</th>
<th>APAP Users Flagged as Outliers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>31,483,841</td>
<td>9,449,693</td>
<td>30.0%</td>
<td>76,581</td>
<td>-</td>
<td>0.81%</td>
</tr>
<tr>
<td>2013</td>
<td>37,842,632</td>
<td>10,591,651</td>
<td>28.0%</td>
<td>26,122</td>
<td>−50,549</td>
<td>0.25%</td>
</tr>
<tr>
<td>2014</td>
<td>39,982,962</td>
<td>10,845,499</td>
<td>27.1%</td>
<td>6,286</td>
<td>−19,836</td>
<td>0.06%</td>
</tr>
</tbody>
</table>

For this comparison, CMS applied the 2014 OMS APAP methodology to all years of service.
## Impact of CMS Policy
### “First-Time” Overutilizers

### New Potential Overutilizers, Quarterly OMS Cycles

<table>
<thead>
<tr>
<th>OMS Cycle</th>
<th>New Opioid Outliers</th>
<th>±</th>
<th>% ±</th>
<th>New APAP Outliers</th>
<th>±</th>
<th>% ±</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013 Q4</td>
<td>13,393</td>
<td>-</td>
<td>-</td>
<td>9,758</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>2014 Q1</td>
<td>11,279</td>
<td>(2,114)</td>
<td>-15.8%</td>
<td>5,079</td>
<td>(4,679)</td>
<td>-48.0%</td>
</tr>
<tr>
<td>2014 Q2</td>
<td>8,369</td>
<td>(2,910)</td>
<td>-25.8%</td>
<td>2,666</td>
<td>(2,413)</td>
<td>-47.5%</td>
</tr>
<tr>
<td>2014 Q3</td>
<td>9,002</td>
<td>633</td>
<td>7.6%</td>
<td>2,343</td>
<td>(323)</td>
<td>-12.1%</td>
</tr>
<tr>
<td>2014 Q4</td>
<td>7,038</td>
<td>(1,964)</td>
<td>-21.8%</td>
<td>2,302</td>
<td>(41)</td>
<td>-1.7%</td>
</tr>
<tr>
<td>2015 Q1</td>
<td>6,128</td>
<td>(910)</td>
<td>-12.9%</td>
<td>1,807</td>
<td>(495)</td>
<td>-21.5%</td>
</tr>
<tr>
<td>2015 Q2</td>
<td>4,954</td>
<td>(1,174)</td>
<td>-19.2%</td>
<td>1,009</td>
<td>(798)</td>
<td>-44.2%</td>
</tr>
</tbody>
</table>
Impact of CMS Policy

OMS Quarterly Opioid Tickets

![Bar chart showing the impact of CMS Policy on OMS Quarterly Opioid Tickets from 2013 Q4 to 2015 Q2. The chart includes bars for New Outliers and Repeat Outliers.]
Impact of CMS Policy
OMS Quarterly APAP Tickets
Compliance Outreach

- CMS is performing additional outreach to Part D sponsors who are identified to be outliers based on their responses to the OMS to assess their compliance with CMS guidance
- Sponsors provide additional information about their DUM processes, rationale for their responses submitted to the OMS, and their interventions to prevent overutilization of medications
- Sponsors submit additional information for specific OMS tickets previously processed through the OMS
Summary

• Part D sponsors are in a unique position to identify potential drug overutilization

• Components of improved formulary management
  – POS Safety Edits (Level One)
  – Formulary Management Designs and concurrent DUR (Level Two)
  – Retrospective DUR and Case Management (Level Three)

• Improved drug utilization controls are helping to reduce opioid overutilization in Medicare Part D
Additional Information Resources

• **Improving Drug Utilization Controls in Part D** (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html)

• **Formulary Guidance** (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxContracting_FormularyGuidance.html)
Resources

Questions related to Formulary Management should be directed to:  PartDFormularies@cms.hhs.gov

Questions related to general PartD Policy or Opioid Overutilization / OMS should be directed to: PartD_OM@cms.hhs.gov

Questions related to technical concerns for the OMS or Patient Safety Analysis website should be directed to: PatientSafety@AcumenLLC.com