Patient Safety Analysis

PDP/MA-PD Contracts
Overutilization Monitoring System User Guide

Web Portal

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Technical Support

If you need help accessing the Overutilization Monitoring System (OMS) or have questions about the content of the reports, please contact the Acumen, LLC help desk at:

Email	Phone
PatientSafety@AcumenLLC.com	(650) 558-8006

If you have questions related to the Medicare Part D drug management program requirements, send an email with "DMP" in the subject line to CMS at:

Email

PartD_OM@cms.hhs.gov

If you have questions related to MARx Drug management program reporting, send an email with "MARx" in the subject line to CMS at:

Email

PartD_OM@cms.hhs.gov

1 Introduction

Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Part D sponsors to establish Drug Management Programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). CMS published a final rule (CMS-4182-F) on April 16, 2018 ("final rule") that established the framework under which Part D plan sponsors may establish a DMP. This rule codified the many aspects of the retrospective Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS), with adjustments as needed to comply with CARA, by integrating them into the DMP provisions at 42 CFR § 423.153(f).

Starting January 2019, sponsors that adopt a DMP must engage in the case management of each Potential At-Risk Beneficiary (PARB) reported through OMS and provide information related to their review within 30 days. In addition, sponsors must also report through OMS any sponsor-identified PARBs, newly enrolled PARBs or At-Risk Beneficiaries (ARBs) for which a sponsor received a transaction reply code (TRC) of '376' (New Enrollee CARA Status Notification) from the daily transaction reply report (DTRR).

Additional DMP guidance is available on the CMS Part D Overutilization website at: https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/RxUtilization.html

Information about navigating the Patient Safety Analysis web portal can be found in the Patient Safety Web Portal User Guide, located on the Help Documents page of the Patient Safety Analysis web portal.

1.1 Report Access

To access the OMS reports (within the Overutilization Monitoring Packages), an authorized user must be added to the Patient Safety Analysis web portal. Current authorized users of the Patient Safety Analysis web portal will automatically be granted comparable access to OMS functionality.

All authorized users can navigate the web portal and receive email notifications regarding report releases. A user's access to the OMS is limited to one of two levels:

- Summary Report Only: User can access the OMS contract-level rate reports with summary information. Users with Summary Report Only permissions will not be able to access beneficiary-level data.

    o The Summary OMS report is titled:
    *ContractID*_Summary_Overutilization_Monitoring_Report_*MMDDYY*.xlsx.

- Summary and Confidential Beneficiary Reports: User can access confidential beneficiary-level information in the Detail OMS report and the Summary OMS report.

    o The Detail OMS report is titled:
    *ContractID*_Detail_Overutilization_Monitoring_Report_*MMDDYY*.xlsx.

A contract's Medicare Compliance Officer determines the access level of each individual associated with a given contract and can authorize "Summary and Confidential Beneficiary Reports" access for up to five users (including her/himself) per contract. Authorization must be completed through Acumen's User Security web portal at https://partd.programinfo.us/User_Security.

At least one user from each contract must have access to Summary and Confidential Beneficiary Reports in order to view and respond to beneficiary-level reports and forms.

Users should request changes to their permission level through their contract's Medicare Compliance Officer.

Authorized users can download the Overutilization Monitoring Package through the Download Files page. For more information about downloading reports, see the Patient Safety Web Portal User Guide on the Help Documents page of the Patient Safety Analysis web portal.

1.2 Report and Response Process

The contract-level Overutilization Monitoring Package is provided once each quarter. Sponsors will receive an email when the quarterly package is available for download. Each PARB identified by OMS is assigned a case number and is referred to in OMS as either a case or PARB. The case number is specific to the beneficiary and contract.

Once the package is available, sponsors should complete the following steps:

1. **Download the Overutilization Monitoring Package(s)**. The Overutilization Monitoring Package(s) is available for download on the Download Files page of the Patient Safety Analysis web portal on the last business day of the given quarter. Please see the Submission Schedule document on the Help Documents page of the Patient Safety web portal for exact report release dates. Only contracts with a DMP will receive an Overutilization Monitoring Package.

   - **The Summary OMS Package includes the following files:**

     i. Summary OMS Report (.xlsx)

     ii. Sponsor Report Form (SRF) (.xlsx)

     iii. OMS User Guide (.pdf)

     iv. ORF and SRF Information Workbook (.xlsx)

   - **The Detail OMS Package includes the following files:**

     i. Detail OMS Report (.xlsx)

     ii. OMS Response Form (ORF) – if the contract has open cases for review (.xlsx)

     iii. Sponsor Report Form (SRF)

     iv. OMS User Guide (.pdf)

v. ORF and SRF Information Workbook (.xlsx)

2. **Review closed cases (Detail Report only).** Cases are closed each quarterly report cycle dependent on sponsors' prior submitted responses or changes to a beneficiary's status.

3. **Review open cases (Detail Report only).** Open cases are reported each quarter and require sponsor responses (see Step 4). Sponsors should use the beneficiary-level information provided in the Detail Overutilization Monitoring Report to assist in performing case management. Unless the sponsor determines that the beneficiary is exempt from DMPs or does not meet the Minimum OMS criteria based on plan information, the sponsor must engage in case management through clinical contact with the prescribers to determine if the beneficiary is at-risk and if a coverage limitation(s) is necessary.

4. **Complete OMS Response Form (ORF) - if available.** Use the ORF to select the appropriate responses for each case. **Note**: this form will only be made available to contracts that have open cases in the given quarter. See Section 4.2 for more information about the ORF, including instructions for completing the form.

5. **Complete Sponsor Report Form (SRF).** Sponsors must use the SRF to report any sponsor-identified PARBs or newly enrolled PARBs or ARBs for which a sponsor received a TRC of '376' (New Enrollee CARA Status Notification) from the DTRR and after requesting the prior contract's case management information. See Section 4.3 for more information about the SRF, including instructions for completing the form.

   - Sponsor-reported cases meet either the Minimum OMS criteria or the Supplemental OMS criteria. See Section 2.1 for more details regarding the criteria.

   - **Note:** Unlike the ORF, the SRF is made available to sponsors each quarter. The SRF is expected to be completed by sponsors each quarter. If there are no cases to report in a given quarter, please indicate so in the form.

6. **Submit ORF (if available) and SRF through the web portal.** Once the responses are complete, upload the ORF and SRF to the Patient Safety Analysis web portal.

   - All forms must be submitted as an .xlsx or .zip file via the secure Upload Files feature of the Patient Safety Analysis web portal in order to be considered for submission. Forms will not be accepted via any other means.

   - Only completed forms will be accepted by the Patient Safety Analysis web portal. Sponsors can confirm whether a form is completed by checking the "Overall Form Status" cell at the top of each form (See Table 5), and the "Response Status" column (See Table 7) for every applicable case.

   - Sponsors must provide responses for open ORF cases and sponsor-identified (SRF) cases within 30 days of the OMS report release date. The submission deadline is provided in the email notification and in the Submission Schedule document on the Help Documents page of the Patient Safety web portal.

Sponsors who do not submit by the deadline may be subject to compliance action by CMS. Once the submission deadline passes for that report cycle, sponsors may no longer update the responses for that quarter.

- Contact Acumen for assistance if an incorrect ORF or SRF was submitted.

7. **Confirm upload was successful.** After uploading the forms, view the Process Status on the Upload File History page to confirm the upload was successful. The Process Status will read "Form(s) processed" if the upload was successful.

8. **Confirm case response status.** Use the Case Tracking (Table 13) page to confirm that responses were submitted for each case identified in the ORF. The status of the case must be "Submitted".

9. **Review ORF and SRF Validation Reports**. After the submission deadline, contracts will receive an OMS Response Validation Package that will include reports detailing the validation status of each submitted ORF and SRF cases' responses. The Case Tracking page can also be used to confirm the validation status of each case. The status of the case must be "Valid" for the responses to be accepted. Please see Section 4.5 for more information regarding the response validation process.

- **The OMS Response Validation Package includes the following files:**

  i. ORF Validation Report (.xlsx)

  ii. SRF Validation Report (.xlsx)

Additional information about completing each of these steps is provided in the following sections of this guide.

2 Methodology

This section describes the current methodology used to identify cases monitored through the OMS.

2.1 OMS Identification Criteria

- **Minimum OMS Criteria**: Use of opioids with an average daily morphine milligram equivalent (MME) equal to or exceeding 90 mg for any duration during the most recent 6 months and either: 3 or more opioid prescribers and 3 or more opioid dispensing pharmacies OR 5 or more opioid prescribers, regardless of the number of opioid dispensing pharmacies. These cases are identified through OMS or by sponsors.

- **Supplemental OMS Criteria:** Use of opioids (regardless of average daily MME) during the most recent 6 months with 7 or more opioid prescribers OR 7 or more opioid dispensing pharmacies. These cases are identified by sponsors.

2.1.1 Measurement Period and Data Sources

Measurement Period:	The 6 months previous to the month of a given quarterly report release. This includes Prescription Drug Event (PDE) data from all contracts that a beneficiary is (or was) enrolled with a date of service during the 6 month period.
Data Sources:	Prescription Drug Event (PDE) – used for opioid claims and resident code
	Common Medicare Environment (CME) – used for enrollment, Low Income Subsidy (LIS) status, and demographic information
	Medicare Enrollment Database (EDB) – used for hospice enrollment
	Common Working File (CWF) – used for cancer and other exclusion diagnosis information
	Risk Adjustment Processing System (RAPS) – used for RxHCC cancer diagnoses
	First DataBank (FDB) – used for medication list information
	Medi-Span – used for medication list information
	Centers for Disease Control and Prevention (CDC) MME Conversion Factors (CF) – used to calculate the MME of an opioid prescription
	Medicare Provider Enrollment, Chain, and Ownership System (PECOS) – used for prescriber information

Health Plan Management System (HPMS) Data – used for contract information

Medicare Advantage Prescription Drug (MARx) System – used to identify cases with an active CARA Status (i.e. an open Point of Sale (POS) Edit, Prescriber Limitation, and/or Pharmacy Limitation period)

CY 20YY Opioid Safety Edit Template – used to identify contracts with a DMP.

2.1.2 Medication and Code Workbook

This workbook includes the applicable medication lists and additional codes used to identify exclusions. The medication lists include the characteristics (i.e., product name, strength, strength units, route of administration, dosage form and the opioid CFs) for opioids, benzodiazepines, gabapentin, and pregabalin. The exclusion code list includes RxHCC and International Classification of Diseases -10th Revision - Clinical Modification (ICD-10-CM) for cancer diagnoses and palliative care as well as PDE codes used to identify long-term care (LTC) or intermediate care facility (ICF) residents.

The specific National Drug Codes (NDCs) included in the analysis are maintained by Acumen and are created from Medi-Span and First DataBank (FDB) databases. Due to Medi-Span and FDB licensing restrictions, the medication NDCs are not provided. The medication lists are created using the following methodology:

Opioid Medication List:

- All opioid products with the same opioid ingredient, dosage form, and route of administration included on the Center for Disease Control and Prevention Oral MME List (CDC MME List) are identified from the Medi-Span and FDB databases.
- The CDC MME List contains specific exclusions: opium tinctures, cough/cold products, powders, topical and all opioids administered via injection, intravenous, intrathecal or epidural routes. These products are excluded from calculation of both the average MME and provider counts.
- Opioid products containing buprenorphine are excluded from the average MME calculations but are included when determining prescriber and pharmacy counts.
- Opioid products containing methadone do not have a static MME CF, but instead utilize a graduated MME CFs based upon the daily MME dose. An overview of the steps used to calculate MME can be reviewed in Section 2.1.3 below.

When the 'quantity dispensed' on PDE claims is counted as 'each', such as transdermal patches and nasal sprays, the MME CF is adjusted to reflect the units and doses billed.[1]

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[1] See CDC Analyzing Prescription Data and Morphine Milligram Equivalents (MME) https://www.cdc.gov/drugoverdose/resources/data.html or the Opioid Morphine EQ CF document found here; https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

Benzodiazepine Medication List:

- All benzodiazepine products with the same benzodiazepine ingredient, dosage form, and route of administration included on the Patient Safety Concurrent Use of Opioids and Benzodiazepines Measure NDC list.

Gabapentin and Pregabalin Medication List:

- All products with 'gabapentin' or 'pregabalin' as an active ingredient and the route of administration as 'oral'.

Exclusion Code List:

- Cancer ICD-10-CM and RXHCC codes
- Palliative Care ICD-10-CM code
- LTC and ICF PDE resident codes

The OMS medication and code workbook is available on the Help Documents page of the Patient Safety Analysis web portal.

2.1.3 Opioid MME Calculation

The steps below detail the average MME calculation process.

- To calculate the daily MME for each non-methadone opioid claim, use the following equations:
  - Opioid dosage units per day = (opioid claim quantity) / (opioid claim's days supply)
  - MME daily dose (mg) per claim = (number of opioid dosage units per day) × (opioid strength per unit) × (MME CF[2])
  - Daily MME = each claim's MME is assigned to each calendar day spanning the date of service (DOS) plus the days supply value minus one day.
- For Methadone claims, use the following equations:
  - Methadone dosage units per day = (methadone claim quantity) / (methadone claim's days supply)
  - Methadone daily dose (mg) per claim = (methadone dosage units per day) × (methadone strength per unit)
  - Methadone daily dose per day = each Methadone claim's daily dose is assigned to each calendar day spanning the DOS plus the days supply value minus one day.
- To calculate a beneficiary's MME for each day of the measurement period, use the following equations:

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[2] Opioid MME CFs are on the Opioid Medication List available on the Help Documents page of the Patient Safety Analysis web portal.

- o Non-methadone total daily MME = for a given day, sum the daily MME across all claims to get the total MME for that day. Repeat for each day of the measurement period.
  - o Methadone total daily MME = for a given day, sum the daily dose across all claims to get the total mg dose for that day. Repeat for each day of the measurement period. Then, depending on the total daily dose for each day, multiply by the appropriate graduated methadone MME CF[3].
  - o Total daily MME = (non-methadone total daily MME) + (methadone total daily MME) for each given day of utilization
- The following equations are used to calculate the average MME for each opioid user:
  - o Total MME = sum of total daily MME within the measurement period[4]
  - o Duration of opioid usage = number of days between first and last day of opioid use within the measurement period (inclusive of first and last days of utilization)
  - o Average MME = Total MME / Duration of opioid usage

A detailed example of the MME calculation can be found in Appendix A.

2.1.4 Opioid Provider Count Methodology

- Buprenorphine PDE claims contribute towards a beneficiary's opioid prescriber and opioid dispensing pharmacy counts.
- To count the number of unique opioid prescribers, the prescriber National Provider ID (NPI) is taken from the 'prescriber ID' on the PDE data. The PDE NPIs are then matched with the NPIs found in the PECOS database, where relationships between individuals and organizations can be established. Individual prescribers with the same single organizational Tax Identification Number (TIN) are grouped and counted as one prescriber. No grouping will take place if a relationship cannot be established or if the PDE does not contain an NPI.
- To count the number of unique opioid dispensing pharmacies, the pharmacy NPI is taken from the 'service provider' and 'alternate service provider' IDs on the PDE data. If only the National Council for Prescription Drug Programs (NCPDP) pharmacy ID is available, an attempt will be made to crosswalk the NCPDP to a NPI ID. Otherwise, the pharmacy ID found in the 'service provider' field is used.

2.1.5 OMS Report Exceptions

Beneficiaries that meet any of the following criteria are not reported:

- Beneficiaries with a long-term care (LTC) or intermediate care facility (ICF) resident code ("03" and "09" respectively) on the last PDE of the 6 month measurement period.

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[3] Methadone MME CFs are on the Opioid Medication List available on the Help Documents page of the Patient Safety Analysis web portal.

[4] By calculating a daily MME and limiting the total MME to days within the measurement period, any days supply or quantity dispensed beyond the measurement period is excluded.

- Beneficiaries with a cancer diagnosis in the CWF during the 12 months prior to the end of the measurement period or identified with a cancer RxHCC in the RAPS.
- Beneficiaries enrolled in hospice, according to EDB, at any point during the 6 month measurement period.
- Beneficiaries with at least 1 inpatient or at least 2 outpatient claims with a Z51.5 ("Encounter for palliative care") diagnosis code in the CWF during the 6 month measurement period.
- Beneficiaries with a death date in the CME.
- Beneficiaries who are not Part D enrolled as of the OMS report date.
- Beneficiaries with an active CARA Status as of the end of the measurement period i.e., an open period for a POS Edit, Prescriber Limitation, and/or Pharmacy Limitation in MARx for any FAD.
- Beneficiaries suppressed due to an active ORF or SRF exception or sponsor response. See Sections 4.3 and 4.4 for more details regarding ORF and SRF exceptions and sponsor responses that suppress beneficiaries from OMS reporting.
- Beneficiaries identified through OMS in 2018 with an unexpired reported exception who are still enrolled in the reporting contract.

2.1.6 Informational Report Metrics

The OMS reports include several metrics for Part D sponsors as supplemental information, including:

- **High Opioid Daily Dose (90 MME) Rate:** Calculated as the total number of opioid utilization days equal to or exceeding 90 MME per 1,000 opioid utilization days for all Part D enrolled beneficiaries within the contract during the 6-month measurement period.
- **Total Open ORF Cases with Concurrent Potentiator Drug and Opioid Use:** Concurrent use is defined as at least 1 day of overlapping days supply of both the opioid and potentiator drug claim during the 6 month measurement period. The concurrent opioid-potentiator drug metrics are calculated for the following drugs: benzodiazepine, high dose gabapentin (>2,400 mg), and pregabalin.

3 OMS Report Structure

All Part D sponsors with a Medicare Part D DMP will receive a Summary Overutilization Monitoring Report with contract-level information regarding the contract's enrollees and their opioid utilization. Sponsors with open cases will also receive a Detail Overutilization Monitoring Report which contains the same summary overview, along with beneficiary-level information for all open and closed cases identified through OMS (ORF cases).

3.1 OMS Reports

This section outlines the levels of analysis included in the Detail Overutilization Monitoring Report Package. Each sub-section contains a description of each metric, any related notes, and a table of key elements that are found in the corresponding worksheets.

3.1.1 Contract Summary

Worksheet Description: Presents a summary of open and closed cases reported through OMS at the contract-level. The Contract Summary worksheet provides two tables: a summary of the sponsor's current enrollees and open cases, as well as an historical (overall) summary of ORF and SRF cases reported. These summary metrics are broken out at the following beneficiary group levels: All Enrollees, Non-LIS Beneficiaries, and LIS Beneficiaries.

Key Elements:

Table 1: Current Summary Key Elements

Key Element	Definition
Total Part D Enrollees	Total number of Part D beneficiaries enrolled in contract during the period measured.
Total Opioid Utilizers	Total number of beneficiaries with at least one prescription fill for an opioid.
% of Enrollees who are Opioid Utilizers	Calculated as Total Opioid Utilizers / Total Part D Enrollees
Total Open ORF Cases	Total number of beneficiaries identified as a case (PARBs) by meeting the Minimum OMS criteria. This number may include beneficiaries who were identified as a case in a previous OMS report and do not meet the exception criteria.
% of Opioid Users that are Open ORF Cases	Calculated as Total Open ORF Cases / Total Opioid Utilizers
Total Open ORF Cases with Concurrent Benzodiazepine and Opioid Use	Total number of open ORF cases where the beneficiary has at least one day of concurrent benzodiazepine and opioid use.
Total Open ORF Cases with Concurrent High Dose Gabapentin (>2400 mg) and Opioid Use	Total number of open ORF cases where the beneficiary has at least one day of concurrent high dose gabapentin (> 2,400 mg) and opioid use.

Key Element	Definition
Total Open ORF Cases with Concurrent Pregabalin and Opioid Use	Total number of open ORF cases where the beneficiary has at least one day of concurrent pregabalin and opioid use.
High Opioid Daily Dose (90 MME) Rate	Total number of opioid utilization days with at least a 90 MME daily dose per 1,000 opioid utilization days for all opioid utilizers.
Total Open SRF Cases	Total number of beneficiaries identified as open SRF cases.

Table 2: Overall Summary Key Elements

Key Element	Definition
Open ORF Cases - Response Expected	Total number of beneficiaries identified as a case (PARBs) by meeting the Minimum OMS criteria. This number may include beneficiaries who were identified as a case in a previous OMS report and do not meet the exception criteria.
Total ORF Cases Reported Since Mon-YYYY	Total number of beneficiaries ever identified as a case (PARB) according to the Minimum OMS criteria. This number includes all open and closed cases.
Total Closed ORF Cases Since Mon-YYYY	Total number of beneficiaries previously identified as a case (PARB) by meeting the Minimum OMS criteria, but currently closed.
Total SRF Cases since Mon-YYYY	Total number of beneficiaries ever identified by sponsors via SRF. This number may include closed, as well as open SRF cases.

3.1.2 Open ORF Cases

Worksheet Description: Presents a list of all currently open ORF cases requiring a response along with opioid utilization information for each case.

Key Elements:

Table 3: Open ORF Cases Key Elements

Key Element	Definition
Case Number	The unique identifier assigned to a beneficiary for the given contract.
HICN	The beneficiary's Health Insurance Claim Number.
MBI	The beneficiary's Medicare Beneficiary Identifier.
DOB	The beneficiary's date of birth.
PBP ID	The beneficiary's plan benefit package (PBP) ID number.
LIS Status	The beneficiary's low-income subsidy (LIS) status. "Y" indicates the beneficiary ever had LIS status and "N" indicates the beneficiary never had LIS status during their Part D enrollment within the measurement period.
Date First Reported	Indicates the date that the beneficiary was first reported to the sponsor.
Measurement Period	Indicates the period in which the beneficiary was identified as a case (PARB).
Prior Contracts Contributing to Utilization	List of beneficiary's prior contracts from PDE data that contributed to the beneficiary's utilization. If this field is empty, all claims contributing to the beneficiary's utilization were filled through the contract on the report.
Duration of Opioid Use	Number of days between first and last opioid use during the measurement period (calculated as days from the first opioid fill date of service to the last day of opioid use during the measurement period)

Key Element	Definition
Total MME	Total MME utilized by the beneficiary during the measurement period.
Average Daily MME	The average daily MME, calculated as 'Total MME' divided by 'Duration of Opioid Use'.
Concurrent Benzodiazepine and Opioid Use	Concurrent usage of a benzodiazepine and an opioid for at least one day. (N = No and Y = Yes)
Concurrent High Dose Gabapentin (>2400 mg) and Opioid Use	Concurrent usage of high dose gabapentin (> 2,400 mg) and an opioid for at least one day. (N = No and Y = Yes)
Concurrent Pregabalin and Opioid Use	Concurrent usage of pregabalin and an opioid for at least one day. (N = No and Y = Yes)
Number of Pharmacies Contributing to Opioid Claims	Total number of distinct pharmacies that filled opioid claims.
Number of Prescribers Contributing to Opioid Claims	Total number of distinct prescribers with different Tax IDs that were attributed to opioid prescriptions.
Prior Submitted Review Status	The last review status reported by the contract for a case (PARB) reported to the contract through OMS. See Table 7. Element E. Review Status Codes (R1-R3). New cases will have a review status "NA".

3.1.3 Closed ORF Cases

Worksheet Description: Presents a list of all previously identified but currently closed cases along with the reason for the closed status.

Key Elements:

Table 4: Closed Cases Key Elements

Key Element	Definition
Case Number	The unique identifier assigned to a beneficiary for the given contract.
HICN	The beneficiary's Health Insurance Claim Number.
MBI	The beneficiary's Medicare Beneficiary Identifier.
DOB	The beneficiary's date of birth.
LIS Status	The beneficiary's low-income subsidy (LIS) status. "Y" indicates the beneficiary ever had LIS status and "N" indicates the beneficiary never had LIS status during their Part D enrollment within the measurement period.
PBP ID	The beneficiary's plan benefit package (PBP) ID number.
Date Closed	Indicates the report date that the case was closed.
Current Exclusion: Death or Lacks Part D Eligibility	Case closed due to death, Part D disenrollment, or disenrollment from contract associated with case number.
Current Exemption: Cancer, Hospice, Palliative Care, or Facility	Case closed due to cancer diagnosis, hospice enrollment, palliative care diagnosis, or residence in an exempt facility.
Does Not Meet Minimum OMS Criteria	Case closed as beneficiary does not meet Minimum OMS criteria at the time of the report.

Key Element	Definition
Suppressed from OMS due to Sponsor Prior Response	Case closed due to sponsor provided response in the ORF.
Active CARA Status in MARx	Case closed due to active CARA Status in MARx (i.e., FAD notification or implementation of a coverage limitation).
Prior Submitted Review Status	The last review status reported by the contract for a case previously reported to the contract through OMS. See Table 7. Element E. Review Status Codes (R1-R3).

Note: Cases with an 'Initial Review Complete' or 'Update' status will be closed when the beneficiary's drug utilization no longer meets the Minimum OMS criteria, regardless if the Part D contract previously reported that the beneficiary had an OMS exception (Table 9). Cases with an 'Initial Review in Progress' status who meet the exemption criteria per OMS during the current measurement period will not be re-reported. However, if the case does not meet the exemption criteria in the current measurement period it will be re-reported regardless of the drug utilization (i.e. MME, number of prescribers or pharmacies).

4 Contract Responses

Sponsors must respond to each case identified by OMS using the OMS Response Form (ORF) included in the downloadable Detail Overutilization Monitoring Report Package. Additionally, sponsors must report internally identified cases using the Sponsor Report Form (SRF). This section describes the process and requirements for completing and submitting both the ORF and the SRF. Table 5 provides an overview of the key status definitions within the ORF and SRF.

Table 5: ORF and SRF Status Definitions

Key Element	Definition
Overall Form Status	**Incomplete** = The responder information portion of the form is incomplete, one or more response elements are missing, or an unacceptable response code is present for any case in the response form. **Note**: All acceptable response codes are provided in the drop-down menus within the response forms. Incomplete forms will not be accepted by the web portal. **Complete** = All response elements are populated and acceptable response codes are present for each case in the response form. **Note:** A 'Complete' status only indicates that the form is fully populated and does not necessarily mean that the response combinations are valid.
# of Cases	Number of cases requiring a response in the given form.
# of Complete Cases	Number of cases with a complete status in the given form.

Additional information, including flowcharts that provide a visual illustration for completing the response form(s), response form layouts with descriptions and formats for each data element, and full descriptions of the response codes, can be found in the ORF and SRF Information workbook included in the report packages, and on the Help Documents page of the Patient Safety web portal, and on CMS.gov at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html

4.1 ORF and SRF Information

Before responding to each case identified by OMS in the ORF or internally identified cases in the SRF, it is recommended that sponsors review the 'ORF and SRF Information Workbook'. This workbook helps sponsors ensure that the ORF and SRF forms are populated completely and with valid response combinations for each case. This workbook contains the following information:

Table 6. ORF and SRF Information Workbook Layout

Workbook Tab	Description
ORF Flowchart	This tab depicts the logic tree for the ORF reporting process and all response codes.
SRF Flowchart	This tab depicts the logic tree for the SRF reporting process and all response codes.

Workbook Tab	Description
Response File Layouts	This tab lists the detailed descriptions of each data element, as well as each data element's format and possible values.
Response Codes	This tab lists detailed descriptions of all ORF and SRF response codes.
ORF Valid Cases	This tab lists all expected valid response code combinations for ORF cases.
SRF Valid Cases	This tab lists all expected valid response code combinations for a SRF cases.
Error Code Hierarchy	This tab outlines the hierarchy used for all 10 of the error codes and messages for invalid responses. (See Section 4.5 for more information on invalid responses)

Following the flowcharts, response file layouts, response codes descriptions, and the list of case valid response code combinations as described in the ORF and SRF Information workbook will ensure that your submitted responses will be processed and receive a Validation Status of 'Valid'.

4.2 OMS Response Form (ORF)

Sponsors with a DMP and open ORF cases will receive an ORF within the Detail Overutilization Monitoring Package that has been prepopulated with the case number, MBI, HICN, and DOB for each case. If there are no open cases, an ORF will not be provided.

Sponsors must use the current ORF to respond to all open cases. That is, respond to new cases or update pending cases (i.e., where previous response was 'Initial Review in Progress'). **Note:** If the ORF is submitted multiple times during the 30 day submission period, only the responses in the most recent ORF will be used.

4.2.1 Completing the ORF

Table 7 and the accompanying notes provide an overview of the response codes that must be selected in the ORF for a given case for elements E through K. **If a response code is not applicable to a particular aspect of a given case, 'NA' must be selected in the field to have a valid response. Only one 'Final Response' code, as indicated in the Response Description column below, can be selected for each case number, except for element K. Multiple 'Y' or 'N' responses are acceptable for 'K.1-9 Exceptions' (see Table 9).**

Table 7: ORF Response Codes

Table Element. Response Category	Response Code	Response Name	Response Description
A. Case Number	–	–	CMS-assigned case number at the beneficiary-contract level.
B. HICN	–	–	Health Insurance Claim Number
C. MBI	–	–	Medicare Beneficiary Identifier
D. DOB	–	–	Date of Birth

Table Element. Response Category	Response Code	Response Name	Response Description
E. Review Status	**R1**	Initial Review in Progress	Sponsor's review is pending. All subsequent element responses should be NA. **Final Response***
	R2	Initial Review Complete	Sponsor's review of a newly identified or an in-progress case from the prior report is complete. **Proceed to 'F. Clinical Contact Status'**
	R3	Update	Update to a previously reported and reviewed case. **Proceed to 'F. Clinical Contact Status'**
F. Clinical Contact Status	**C1**	Clinical Contact - Only Written Report Sent to Prescriber(s)	Only written information and a Prescriber Inquiry Letter sent to prescriber(s). **Proceed to 'G. Prescriber Verification'**
	C2	Further Clinical Contact Attempted	Further clinical contact attempted with prescribers, such as a phone call. **Proceed to 'G. Prescriber Verification'**
	C3	Other - No Clinical Contact Due to Exception(s)	No clinical contact is made with prescribers because the sponsor identified from internal data that the beneficiary has an exception(s). **Proceed to 'K. Exceptions'**
	NA	Not Applicable	If 'E. Review Status' = 'R1'
G. Prescriber Verification	**Y**	Yes	Prescriber(s) verified that the beneficiary is at-risk. **Proceed to 'H. Coverage Limitation Necessary'**
	N	No	Prescriber(s) verified that the beneficiary is NOT at-risk. **Proceed to 'H. Coverage Limitation Necessary'**
	NR	No Response	No response from prescriber(s). **Proceed to 'H. Coverage Limitation Necessary'**
	NA	Not Applicable	If 'F. Clinical Contact Status' = 'C3' or 'NA'
H. Coverage Limitation Necessary	**Y**	Yes	Sponsor decided that a coverage limitation(s) is necessary. **Proceed to 'I. Prescriber Agreed to Coverage Limitation'**
	N	No	Sponsor does not intend to implement a coverage limitation(s). **Proceed to 'J. Reason Coverage Limitation Unnecessary'**
	NA	Not Applicable	If G. Prescriber Verification = 'NA'
I. Prescriber Agreed to Coverage Limitation	**Y**	Yes	Prescriber agreed that a coverage limitation(s) was necessary. **Final Response***
	N	No	Prescriber did not agree that a coverage limitation was necessary. **Final Response***
	NR	No Response	No response from prescriber(s). **Final Response***
	NA	Not Applicable	'H. Coverage Limitation Necessary' = 'N' or 'NA'
J. Reason Coverage Limitation Unnecessary	**O1**	Wait and See	Sponsor is monitoring beneficiary's FAD use to see if the prescribers adjust their care of their patient such that the beneficiary no longer meets the OMS criteria. **Final Response***

Table Element. Response Category	Response Code	Response Name	Response Description
J. Reason Coverage Limitation Unnecessary *(continued)*	O2	Prescriber(s) Agreed During Clinical Contact to Manage/Coordinate Care	Coverage limitation is not necessary, prescriber will manage/coordinate the beneficiary's FAD use. **Final Response***
	O3	Prescriber(s) Attested During Clinical Contact that the Medication Regimen is Appropriate	Coverage limitation is not necessary, prescriber verified that the **total** FAD regimen is medically necessary. **Final Response***
	O4	Clinical Contact Determined has a Beneficiary Exception(s)	During case management it was determined the beneficiary has an exception. **Proceed to K. 'Exceptions'**
	NA	Not applicable	If 'H. Coverage Limitation Necessary' = 'Y' or 'NA'
K. 1-9 Exceptions (see Table 9)	Y	Yes	The beneficiary has an exception. **Final Response(s)****
	N	No	The beneficiary did not meet an exception. **Final Response(s)****
	NA	Not Applicable	If 'J. Reason Coverage Limitation Unnecessary' is NOT 'O4' AND 'F. Clinical Contact Status' is NOT 'C3'
Response Status	Complete		Checks that acceptable response codes are populated for each element. Only the responses in the drop-down box are accepted for each element. A correctly populated row will have a 'Complete' status while a row with any missing or unacceptable responses will have an 'Incomplete Response' status. **Note:** this check only determines whether an acceptable and non-missing response is populated in each individual element, not if the responses meet the current validation logic (see Section 4.5 for additional response validation information).

*Only one 'Final Response' code, as indicated in the Response Description column, can be selected for each case number except for element K.

**Multiple 'Y' or 'N' responses are acceptable for 'K. 1-9 Exceptions' (see Table 9).

Notes:

- If the Overall Form Status is "Incomplete" the form will not be processed and the responses will not be recorded.
- If multiple ORFs are received for a given case number, the most recent complete response received by the close of the submission period will be used. An incomplete response uploaded after a complete response will not replace the latest complete response for that case.
- If an ORF from a previous reporting cycle is submitted during a current cycle, responses for the cases will not be processed.

4.3 Sponsor Report Form (SRF)

Sponsors must also report to CMS beneficiaries who meet either the Minimum OMS criteria or the Supplemental OMS criteria identified by the sponsor. These cases should be reported only after case management and the reported review status is complete. Sponsors must also report newly enrolled beneficiaries for which a sponsor received a TRC of '376' (New Enrollee CARA Status Notification) from the daily transaction reply report (DTRR). Sponsors may report these cases as in progress or complete depending on when they received the enrollment request and when the OMS report is due. In addition, if the sponsor determines that a currently closed ORF case's status requires updating in OMS (e.g. a coverage limitation is deemed necessary), the sponsor should report the beneficiary and responses in the SRF using the MBI/HICN. When updating a case, sponsors should select 'R3' for the review status to indicate that the case was previously reported and is being updated after further review.

Note: the SRF is independent of the ORF, and the two forms cannot be used interchangeably. The SRF that is provided in a given quarter must be used in that quarter (i.e., previous versions of the SRF from different quarters will not be processed by the web portal). If the SRF is submitted multiple times during a given quarter, only the most recent responses will be used.

4.3.1 Completing the SRF

This section details the data elements and response codes that are specific to the SRF. All other data elements and response codes from the ORF section apply to SRF in the same manner.

First, after completing the responder information portion of the form, answer the question in Cell B13: 'Has the sponsor internally identified any cases?'

- **If 'N'**, then leave the remainder of the SRF blank, save the form to your desktop, and upload the form to the Patient Safety Analysis web portal using the Upload Files page
- **If 'Y'**, then populate the form with the SRF cases that have been identified using the remainder of this section as a guide

For each SRF case, the MBI and/or the HICN, and the DOB fields must be populated by the sponsor. If one of these elements is not available to the sponsor, please populate the element with "NA". The SRF includes all the elements in the ORF (see Table 7) plus Elements **S. Method of Identification** and **T. Prior Sponsor Beneficiary CARA Status**. Some responses in the SRF are not valid in the ORF. Key differences in elements are noted below:

Table 8: SRF Response Codes

Table Element / Response Category	Response Code	Response Name	Response Description
S. Method of Identification	**M1**	Met Minimum OMS Criteria	The beneficiary met the Minimum OMS criteria. **Proceed to 'E. Review Status'.**

Table Element / Response Category	Response Code	Response Name	Response Description
S. Method of Identification *(continued)*	**M2**	Met Supplemental OMS Criteria	The beneficiary met the Supplemental OMS criteria. **Proceed to 'E. Review Status'.**
	M3	Notice Upon Enrollment – Active CARA Status	The sponsor received an active CARA Status notification for the beneficiary. **Proceed to 'T. Prior Sponsor Beneficiary CARA Status'.**
T. Prior Sponsor Beneficiary CARA Status *Only applies if the response to S. = M3*	**P1**	At-Risk Beneficiary with a Coverage Limitation Implemented	Indicates that successful communication was established with the prior Part D sponsor and the beneficiary had an implemented coverage limitation(s) under the prior contract. **Proceed to 'E. Review Status'.**
	P2	No Response from Prior Plan	Indicates that attempted contact with the prior Part D sponsor was unsuccessful. **Proceed to 'E. Review Status'.**
	P3	Potential At-Risk Beneficiary with No Coverage Limitation Implemented	Indicates successful communication was established with the prior Part D sponsor and the beneficiary coverage limitation(s) were pending. **Proceed to 'E. Review Status'.**
	NA	Not Applicable	If 'S. Method of Identification' = 'M1' or 'M2'.
E. Review Status		See Table 7 for response codes and definitions	
F. Clinical Contact Status	**C1**	Clinical Contact - Only Written Report Sent to Prescriber(s)	Only written information and a Prescriber Inquiry Letter sent to the prescriber(s). **Proceed to 'G. Prescriber Verification'.**
	C2	Further Clinical Contact Attempted	Further clinical contact attempted with prescribers, such as phone call. **Proceed to 'G. Prescriber Verification'.**
	C3	Other - No Clinical Contact due to Exception(s)	No clinical contact is made with prescribers because the sponsor identified from internal data that the beneficiary has an exception(s). **Proceed to 'K. Exceptions'.**
	C4[5]	Exempt from Case Management	Sponsor obtained case management information from the previous sponsor and such information is still clinically adequate and up to date. **Proceed to 'H. Coverage Limitation Necessary'.**

[5] Note: A response of 'F. Clinical Contact Status' = 'C4' (Exempt from Case Management) can only be selected if 'S. Method of Identification' = 'M3' (Notice Upon Enrollment - Active CARA Status).

Table Element / Response Category	Response Code	Response Name	Response Description
F. Clinical Contact Status *(continued)*	NA	Not Applicable	If 'E. Review Status' = 'R1'
G. Prescriber Verification	Y	Yes	If 'F. Clinical Contact Status' = 'C1' or 'C2' AND Prescriber(s) verified that the beneficiary is at-risk. **Proceed to 'H. Coverage Limitation Necessary'.**
	N	No	If 'F. Clinical Contact Status' = 'C1' or 'C2' AND Prescriber(s) verified that the beneficiary is NOT at-risk. **Proceed to 'H. Coverage Limitation Necessary'**
	NR	No Response	If 'F. Clinical Contact Status' = 'C1' or 'C2' AND No response from prescriber(s). **Proceed to 'H. Coverage Limitation Necessary'.**
	NA	Not Applicable	If 'F. Clinical Contact Status' = 'C3', 'C4', or 'NA'
Complete remaining elements in Table 7 and Table 9.			

Once the form is complete, save the form to your desktop, and upload the file to the Patient Safety Analysis web portal using the Upload Files page. For detailed information about the using the Upload Files and Upload File History pages, see the Patient Safety Web Portal User Guide on the Help Documents page of the Patient Safety Analysis web portal.

4.4 Suppression Rules

The following is the list of potential exceptions that a sponsor may identify for a particular case based on internal data or through case management. Select "Y" for all the exceptions that apply to the case. The list also includes the maximum time that a case is suppressed from OMS reporting while the beneficiary is enrolled in the contract. If the sponsor's response to **'F. Clinical Contact Status'** = 'C3' or **'J. Reason Coverage Limitation Unnecessary'** = **'O4'**, sponsors respond to the '**K. Exception'** elements 1-9 with 'Y' or 'N'. Otherwise, sponsors should populate the **'K. Exceptions'** elements with 'NA'. In addition, if the Supplemental OMS criteria was used by the sponsor to identify a case, a response of 'NA' would be appropriate for K8 and K9 since MME is not applicable. **Note:** this table applies to both the ORF and SRF. It includes the OMS exemptions, plus additional exceptions that can only be identified by the Part D sponsor.

Table 9. List of OMS Report Exceptions and Suppression Rules

Element	Exception	Description	Suppression Rule
K1.	Exemption: Resident of an Exempt Facility	Beneficiary is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another	If last PDE Patient Resident Code is 3 or 9.

Element	Exception	Description	Suppression Rule
K1. *(cont.)*	Exemption: Resident of an Exempt Facility *(continued)*	facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy.	If last PDE Patient Resident Code is 3 or 9. *(cont.)*
K2.	Exemption: Active Cancer-Related Pain	Beneficiary is being treated for active cancer-related pain.	Y=Suppressed up to 1 year, DOD or disenrollment.
K3.	Exemption: Hospice, Palliative or End-of-Life Care	Beneficiary has elected to receive hospice care or is receiving palliative or end-of-life care.	Y=Suppressed up to 1 year, DOD or disenrollment.
K4.	Administrative Exclusion: Deceased	Beneficiary is deceased.	Exclude from OMS reporting based on CME.
K5.	Administrative Exclusion: Disenrolled or Lacks Part D Eligibility	Beneficiary disenrolled or lacks Part D enrollment.	Exclude from OMS reporting based on CME.
K6.	OMS Criteria Not Met: Prescriber(s) in a Group Practice	OMS Prescriber criterion not met because prescribers within the same group practice are treated as one prescriber	Y=Suppressed up to 1 year, DOD or disenrollment.
K7.	OMS Criteria Not Met: Pharmacies share Real-Time Electronic Data	OMS Pharmacy criterion not met because pharmacies with multiple locations that share real-time electronic data treated as one pharmacy	Y=Suppressed up to 1 year, DOD or disenrollment.
K8.	OMS Criteria Not Met: MME Approved Due to Favorable Coverage Determination or Appeal	OMS MME criterion not met because of a favorable coverage determination or appeal	Y=Suppressed up to 1 year, DOD or disenrollment.
K9.	OMS Criteria Not Met: MME for Other Reasons	OMS MME criterion not met (e.g., MME is due to appropriate prescription fill overlap, data entry error, an acute/temporary short-term use that has resolved or dosage was reduced)	None

4.4.1 Additional Sponsor Responses and Suppression Rules

Other sponsor responses that result in the case being suppressed from OMS include the following:

Table 10. Additional Sponsor Responses and Suppression Rules

Element	Final Response	Description	Suppression Rule
H. Coverage Limitation Necessary	Yes	Sponsor intends to implement a coverage limitation(s).	The beneficiary has an active CARA Status (i.e., coverage limitation notification or implementation period for a FAD) in MARx as of the last day in the measurement period.

Element	Final Response	Description	Suppression Rule
J. Reason Coverage Limitation Unnecessary	O2	Prescriber(s) agreed during clinical contact to manage/coordinate care.	Y=Suppressed up to 1 year, DOD or disenrollment.
	O3	Prescriber(s) attested during clinical contact that the medication regimen is appropriate.	Y=Suppressed up to 1 year, DOD or disenrollment.
	O4 and at least one K.1-9 response is Yes	Clinical contact determined beneficiary exception: exemption, OMS criteria not met, or administrative exclusion identified.	Y=Suppressed up to 1 year, DOD or disenrollment.

4.5 ORF and SRF Response Validation Package

After the submission deadline, each ORF and SRF case's response combination with a Response Status of 'Complete' will be validated based on the logic outlined in the ORF and SRF Information workbook. Each case will receive a Validation Status on the Case Tracking page of the Patient Safety web portal of 'Invalid' or 'Valid' approximately a week after the submission deadline, and each sponsor will receive a OMS Response Validation Package. This section describes the OMS Response Validation Report Package. Each sub-section contains a description of the workbook, any related notes, and a table of key elements that are found in the corresponding workbook.

4.5.1 ORF and SRF Validation Reports

Within the OMS Response Validation Package, sponsors will receive a separate validation report for responses submitted via the ORF and the SRF. The validation reports will include all of the fields that are included in the form, along with several unique fields that are described below.

Workbook Description: Includes report instructions, and the validation status for each case with a complete status, and if deemed invalid, the error code and error message.

Key Elements:

Table 11: ORF and SRF Validation Report Key Elements

Data Element	Element Description
Validation Status	Indicates whether a submitted response is considered 'Valid' or 'Invalid'.
Error Code	If the case status is 'Invalid', the hierarchy error code associated with the submission error.
Error Message	The hierarchical reason why a case submission was identified as invalid.

4.5.2 Invalid Responses

The ORF or SRF Validation Report will include the error code and error message for all completed cases with a status of 'Invalid'. The fields that pertain to the error code and message will be highlighted. **Only the highest hierarchy error and message code will be displayed.** In the event that multiple errors exist, correcting only the highlighted error code may still result in an 'Invalid' status.

A list of all error codes and messages as well as the list of valid response combinations are listed on the "Error Code Hierarchy" tab of in the ORF and SRF Information workbook, located on the Help Documents page of the Patient Safety Analysis web portal. CMS expects sponsors to compare their case responses to the list of valid response combinations prior to OMS submission. Table 12 lists the possible error codes that may appear in the validation reports invalid case.

Table 12. Validation Error Code Hierarchy

Hierarchy	Error Code	Error Message
1	E1	Both element B (MBI) and C (HICN) are invalid.
2	E2	Prior Sponsor Beneficiary CARA Status (element T) **is not** populated with 'NA' when Method of Identification (element S) is populated with 'M1' or 'M2'.
3	E3	Prior Sponsor Beneficiary CARA Status (element T) **is** populated with 'NA' when Method of Identification (element S) is populated with 'M3'.
4	E4	Multiple final response elements populated with non-'NA' responses.
5	E5	All final response elements populated with 'NA'.
6	E6	At least one element is not populated with 'NA' when Review Status (element E) is populated with 'R1'.
7	E7	Elements leading to final response populated incorrectly.
8	E8	At least one exception (elements K.1-9) is populated with 'Y' or 'N' when Clinical Contact Status (element F) is not populated with 'C4' and Reason Coverage Limitation Unnecessary (element J) is not populated with 'O4'.
9	E9	No exceptions (elements K.1-9) are populated with 'Y' when Clinical Contact Status (element F) is populated with 'C3' or Reason Coverage Limitation Unnecessary (element J) is populated with 'O4'.
10	E10	Review Status (element E) is populated with 'R3' for a newly identified case.

Sponsors must submit the ORF responses within 30 days or may be subject to a compliance action. It is possible that a sponsor's response may not appear to meet the expected valid response algorithm, which may necessitate a discussion with CMS on how to rectify. CMS will evaluate the necessity for an additional re-submission period via the Patient Safety Analysis web portal on a case by case basis for corrections only, and additional instructions will be available at that time.

5 Summary and Case Tracking

In addition to downloading reports and uploading forms, sponsors can use the OMS to track ORF cases over time. The following sections provide an overview of the Summary Tracking and Case Tracking pages, and describe how to use these pages to monitor the contract's progress in responding to OMS.

For more information about the using the Summary Tracking and Case Tracking pages, see the Patient Safety Web Portal User Guide on the Help Documents page of the Patient Safety Analysis web portal.

5.1 Summary Tracking Page

The Summary Tracking page provides sponsors with an overview of the number of unique ORF cases requiring a response for a given report date, by contract. If a contract did not have any ORF cases requiring a response in the given reporting period, all fields will be populated with zero.

5.2 Case Tracking Page

The Case Tracking page allows sponsors to view status information for ORF cases and the submitted responses. The Case Tracking Page includes three status fields that are described below:

- Submission Status – This status indicates whether a response was successfully 'Submitted' or 'Not Submitted' for the given case.
- Review Status – If the 'Submission Status' is 'Submitted', then the 'Review Status' will be populated with the Review Status value from the submitted ORF. This value can be 'R1', 'R2', or 'R3'. See Section 4.2 for more information regarding these response codes.
- Validation Status – After the Response Validation Reports are sent out to sponsors, the 'Validation Status' will be updated to indicate whether a submitted response is considered 'Valid' or 'Invalid'. See Section 4.5 for more information regarding the validation process.

Note: Before the ORF is submitted, the three statuses fields will default to "Not Submitted". After the ORF is submitted and processed successfully, the Validation Status will be "Pending" until the validation process is complete. Table 13 provides more information about the information displayed on the Case Tracking page.

Table 13. Case Tracking

Data Element	Element Description
Contract	CNNNN
Case Number	CNNNN_NNNNNNN
Submission Status	Not Submitted / Submitted
Review Status	Not Submitted / R1 / R2 / R3
Validation Status	Not Submitted / Pending / Valid / Invalid
Date Reported	mm/dd/yyyy

Data Element	Element Description
Deadline	mm/dd/yyyy
Last Update	mm/dd/yyyy

Appendix A: Average MME Calculation:

This appendix outlines the steps that are used to calculate the average MME for one beneficiary example. For the purposes of this appendix, the beneficiary example that is referenced throughout the remaining sections is assumed to have received three methadone claims and four non-methadone claims.

A.1 Step 1: Calculate Dosage Units per Day and Daily Dose per Claim

First, the dosage units per day are calculated for both non-methadone and methadone claims. Dosage units per day is calculated by dividing quantity supplied by days supply. Second, the MME or daily dose per claim is calculated as the dosage units per day multiplied by the strength and MME CF, if applicable. For non-Methadone claims, the MME CF is used in the daily dose per claim calculation. Methadone claims use a graduated MME CF that is implemented in Step 2, thus the methadone MME CF is left out of the daily dose per claim calculation.

A.1.1 Non-Methadone Claims:

In the first row of Table 14, the quantity supplied is 10, the days supply is 2, the strength is 30, and the MME CF is 1. The dosage units per day and MME daily dose per claim for this row is calculated as follows:

Dosage units per day: (10/2) = **5**

MME daily dose per claim: (5x30x1) = **150**

Table 14: Non-Methadone Dosage Units per Day and Daily Dose per Claim Examples

Claim	Fill Date	Days Supply	Quantity Supplied	Strength	MME CF	Dosage Units per Day	MME Daily Dose (mg) per Claim
Morphine #1	01/01/2019	2	10	30	1	**5**	**150**
Morphine #2	01/03/2019	2	20	10	1	**10**	**100**
Morphine #3	01/03/2019	1	4	10	1	**4**	**40**
Morphine #4	01/06/2019	1	16	10	1	**16**	**160**

A.1.2 Methadone Claims:

In the first row of Table 15, the quantity supplied is 8, the days supply is 4, and the strength is 10. The dosage units per day and daily dose per claim for this row is calculated as follows:

Dosage units per day: (8/4) = **2**

Daily dose per claim: (2 x10) = **20**

Table 15: Methadone Dosage Units per Day and Daily Dose per Claim Examples

Claim	Fill Date	Days Supply	Quantity Supplied	Strength	Dosage Units per Day	Daily Dose (mg) per Claim
Methadone #1	01/01/2019	4	8	10	**2**	**20**
Methadone #2	01/04/2019	1	3	5	**3**	**15**
Methadone #3	01/06/2019	2	4	10	**2**	**20**

A.2 Step 2: Calculate Daily MME

Next, the daily dose for both the methadone and non-methadone claims are assigned across each calendar day with utilization as described below:

- Start Day = Fill Date
- End Day = Fill Date + Days Supply - 1
- Utilization Days = Start Day to End Day

A total daily MME is then calculated by summing up the daily dose for all claims for each day in the measurement period. A graduated MME conversions factor is applied to calculate the total daily MME for methadone claims in this step.

A.2.1 Daily Non-Methadone MME Calculation:

The Morphine #2 and Morphine #3 claims have one day of overlap. This means that the beneficiary filled their third Morphine prescription before their second Morphine claim's day supply ended. The Morphine #1 and Morphine #4 claims do not overlap with any other non-methadone prescriptions.

Table 16 assigns MME daily dose per claim (mg) across the usage days. The total daily MME is calculated by summing up the MME daily dose for all claims for each day in the measurement period.

Table 16: Daily MME for Non-Methadone Claims Examples

Claim	Metric	1/1/2019	1/2/2019	1/3/2019	1/4/2019	1/5/2019	1/6/2019	1/7/2019
Morphine #1	MME daily dose	150	150	-	-	-	-	-
Morphine #2	MME daily dose	-	-	100	100	-	-	-
Morphine #3	MME daily dose	-	-	40	-	-	-	-
Morphine #4	MME daily dose	-	-	-	-	-	160	-
Non-Methadone	**Total Daily MME**	**150**	**150**	**140**	**100**	**-**	**160**	**-**

In Table 16, rows 2 and 3 contain Morphine #2 and Morphine #3 prescriptions that have a 1 day overlap on 1/3/2019. The total Daily MME for 1/3/2019 is calculated by summing the MME daily dose for each claim (100+40=140).

A.2.2 Daily Methadone MME Calculation:

The beneficiary also has two methadone claims that have 1 day of overlap. This means that the beneficiary filled the second methadone claim before the first methadone supply expired. The third claim does not overlap with the first two claims.

Table 16 assigns the daily dose per claim (mg) across the usage days. Rows 1 and 2 contain Methadone #1 and Methadone #2 claims that have a day of overlap on 1/4/2019. Similar to what is done for non-methadone claims in Table 15, the total daily dose is calculated by summing up the daily dose per claim (mg) for each day within the measurement period.

An additional step is used for methadone claims, in which the total daily MME is calculated by multiplying the total daily dose with the appropriate graduated methadone CF. The graduated methadone CF that is used is determined by the total daily dose. The graduated methadone CFs can be found in the OMS Medication List that is made available on the Help Documents page of the Patient Safety Analysis web portal.

For example, on 1/1/2019 in Table 17, a daily dose of 20 is associated with a graduated methadone CF of 4. As a result, the total daily MME for 1/1/2019 is: 20 x 4 = 80. On 1/4/2019, the methadone daily dose falls in the range that is associated with a CF of 8.

Table 17: Daily MME for Methadone Claims Examples

Claim	Metric	1/1/2019	1/2/2019	1/3/2019	1/4/2019	1/5/2019	1/6/2019	1/7/2019
Methadone #1	Daily Dose	20	20	20	20	-	-	-
Methadone #2	Daily Dose	-	-	-	15			-
Methadone #3	Daily Dose	-	-	-	-	-	20	20
Methadone	**Total Daily Dose**	**20**	**20**	**20**	**35**	**-**	**20**	**20**
Methadone	**Total Daily MME**	20*4 = 80	20*4 = 80	20*4= 80	35*8 = 280	**-**	20*4 = 80	20*4 = 80

A.2.3 Daily MME Calculation:

Finally, the daily MME for both methadone and non-methadone claims for each day in the measurement period is summed to calculate the total daily MME. Table 18 calculates the total daily MME for each day by summing up the methadone and non-methadone rows.

Table 18: Total Daily MME Examples

Claim	Metric	1/1/2019	1/2/2019	1/3/2019	1/4/2019	1/5/2019	1/6/2019	1/7/2019
Methadone	Total Daily MME	80	80	80	280	-	80	80
Non-Methadone	Total Daily MME	150	150	140	100	-	160	-
All	**Total Daily MME**	**230**	**230**	**220**	**380**	**0**	**240**	**80**

A.3 Step 3: Calculate Average MME

After calculating the total daily MME for the beneficiary on each day of the measurement period, the average MME is calculated by totaling the MME dispensed within the measurement period and dividing it by the duration of opioid usage. The duration of opioid usage is calculated by counting the number of days from the first and last day of opioid usage, including the first and last days. Despite not having any opioid utilization on 1/5/2019, this day is still included in duration of opioid usage.

The average MME calculation for the example beneficiary is as follows:

Total MME: (230 + 230 + 220 + 380 + 0 + 240 + 80) = **1,380**

Duration of Opioid Usage: **7**

Average MME: (1,300/7) = **197.14**