
CBE ID

3558

Title

Initial Opioid Prescribing for Long Duration (IOP-LD)

Project

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

Endorsement Status

Endorsed with Conditions

E&M Committee Rationale/Justification

When the measure returns for maintenance (5 years), the measure developer should have explored how to address nuances based on the complexity of certain medical procedures (e.g., through stratification or exclusions).

Is Under Review

No

Next Maintenance Cycle

Spring 2030

Previous Endorsement Cycle

Spring 2025

Initial Endorsement

Fri, 11/20/2020 - 08:17

Steward

PQA, Inc.

1.0 New or Maintenance

Maintenance

1.1 Measure Structure

Single Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

The percentage of individuals ≥ 18 years of age with ≥ 1 initial opioid prescriptions for >7 cumulative days' supply during the measurement year.

1.7 Measure Type

Process

1.8 Level of Analysis

Health Plan

1.9 Care Setting

Other

1.9b Other Care Setting

Health Plan

1.10 Measure Rationale

Opioid misuse, addiction, and overdose remain a public health crisis affecting social and economic welfare in the United States. Drug overdoses involving an opioid accounted for 79,358 deaths in 2023, resulting in an age-adjusted drug overdose death rate that has more than tripled since 2013 and increased five-fold since 2003.(1) While synthetic opioids such as fentanyl are a substantial driver of increased mortality, the prescription opioid epidemic has not abated: nearly 8.6 million Americans reported misusing prescription opioids in 2023.(2) Prescription opioid safety remains an important priority, and quality measures serve as valuable tools to promote opioid safety and improve the quality of care for patients.

A large body of scientific evidence, described in detail in section 2.2 Evidence of Measure Importance, has established an association between greater duration of initial opioid exposure and significant risks, including increased likelihood for long-term opioid use, misuse, and overdose. To highlight, a retrospective cohort study by Shah et al. published in the CDC Morbidity and Mortality Weekly Report found that the probability of long-term opioid use increased with each additional day supplied past the third day when initiating opioid therapy; the probability of long-term use was more than twice as high for individuals who received greater than 7 days' supply.

Based on this evidence, regulatory bodies have issued recommendations and instituted policies regarding the duration of therapy for initial opioid prescribing. In its 2022 Clinical Practice Guideline for Prescribing Opioids for Pain, the Centers for Disease Control and Prevention (CDC) provided updated recommendations regarding duration of initial opioid prescriptions.(3) The recommendations state that "when opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids." This recommendation is category A (applies to all persons; most patients should receive the recommended course of action) and evidence type 4 (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations).

Additionally, federal regulatory requirements and published guidance from the Centers for Medicare & Medicaid Services (CMS) note that Medicare plan sponsors are expected to implement real-time opioid safety edits at the point of sale, including an edit to limit initial opioid prescription fills for opioid naïve beneficiaries to no more than a 7 days' supply.(4) An internal analysis of Part D data from 2018 to 2023 conducted by CMS showed that the percentage of Part D claims for opioids (excluding medications used for opioid use disorder) with 7 days' supply or less increased from 18.4% in 2018 to 27.7% in 2023 after the implementation of enhanced opioid safety edits at the point of sale in 2019.(5) This measure serves as a retrospective complement to these edits.

To help ensure consistent application of these clinical recommendations and efforts to ensure safe initial opioid prescribing, measurement serves as a critical tool. The PQA Initial Opioid Prescribing for Long Duration measure evaluates initial opioid prescriptions for greater than 7 days' supply, which are associated with increased risk of long-term opioid use, misuse, and overdose. Use of this measure to evaluate the performance of health plans is intended to reduce these risks, in turn leading to reduced health care resource utilization and improved quality of life. Because the measure only captures initial opioid prescriptions in individuals with no opioid history in the preceding 90 days, and does not penalize subsequent prescriptions for ongoing pain, it is not anticipated to result in unintended consequences related to access, discontinuation, or abrupt tapering in patients currently undergoing long-term opioid therapy.

References

1. Garnett MF, Minino AM. Drug overdose deaths in the United States, 2003-2023. NCHS Data Brief, No. 522. National Center for Health Statistics. Updated December 2024. Accessed April 18, 2025. <https://www.cdc.gov/nchs/data/databriefs/db522.pdf>
2. Substance Abuse and Mental Health Services Administration. *Key substance use and mental health indicators in the United States: Results from the 2023 National Survey on Drug Use and Health*. Vol. NSDUH Series H-59. 2024. Accessed April 18, 2025. <https://www.samhsa.gov/data/report/2023-nsduh-annual-national-report>
3. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. *MMWR Recomm Rep*. Nov 4 2022;71(3):1-95. doi:10.15585/mmwr.rr7103a1
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5. Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. 2024. p. 427.

1.13 Data Dictionary

Attached

1.13a Attach Data Dictionary

[s_pqa_meas_yr_2024_iop-ld_value_sets_20250117.xlsx](#)

1.14 Numerator

The number of individuals from the denominator with >7 cumulative days' supply for all opioid prescription claims within any opioid initiation period.

1.14a Numerator Details

The numerator includes individuals from the denominator with >7 cumulative days' supply for all opioid prescription claims within any opioid initiation period.

Use the steps below to identify the numerator population.

Step 1: For each individual in the denominator population, identify all initial opioid prescriptions and corresponding opioid initiation periods, defined as the date of service of the initial opioid prescription plus two days (since individuals may have multiple initial opioid prescription dates with a negative medication history, there may be multiple opioid initiation periods).

Step 2: For each individual, starting with each initial opioid prescription, sum the days' supply of all opioid prescription claims within each opioid initiation period (i.e., date of service for the initial opioid prescription + 2 days).

For example, if the date of service for an initial opioid prescription is March 15, identify any opioid prescription claims from March 15 through March 17.

Note:

- The prescription claims can be for the same or different opioids.
- For multiple opioid claims with the same date of service, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- For multiple opioid claims with different dates of service, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- If the opioid initiation period extends beyond the end of the measurement year, the opioid initiation period is truncated to the last day of the measurement year.

Step 3: Count the unique individuals with >7 cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year.

1.15 Denominator

The denominator includes individuals ≥ 18 years of age, who are continuously enrolled during the measurement period and lookback period, with ≥ 1 prescription claims for an opioid and a negative medication history for any opioid medication during the 90-day lookback period.

1.15a Denominator Details

The denominator includes individuals ≥ 18 years of age as of the first day of the measurement year (MY) with ≥ 1 prescription claims for an opioid during the MY, with continuous enrollment during the MY and 90 days prior to the index prescription start date (IPSD) and a negative medication history for any opioid medication during the 90-day lookback period. IPSD is defined as the earliest date of service for an opioid medication during the measurement year.

Individuals in hospice or palliative care at any time during the MY or 90 days prior to the IPSD, individuals with a cancer or sickle cell disease diagnosis during the MY or 90 days prior to the IPSD, and individuals receiving treatment for cancer-related pain during the MY or 90 days prior to the IPSD are excluded from the measure.

Complete the steps below to determine the denominator population.

Step 1: Identify individuals ≥ 18 years of age as of the first day of the measurement year.

Step 2: Identify individuals with ≥ 1 prescription claims for an opioid (Medication Table, OPIOIDS: Opioids) during the measurement year.

Step 3: Identify individuals continuously enrolled during the measurement year and the 90 days prior to the IPSD.

Step 4: Identify individuals with a negative medication history, defined as individuals with no prescription claims for opioids with a date of service for any opioid medication during the lookback period (a period of 90 days prior to each opioid prescription claim).

For example, an individual has opioid prescription claims on August 1, September 15 and December 20. For each of these dates of service, use the lookback period of 90 days to determine if the individual had no prescription claims for opioids. For example, for August 1, determine whether the individual had no prescription claims for opioids from May 3 – July 31. Repeat for the September 15 and December 20 opioid prescription claims.

Note:

- The prescription claims can be for the same or different opioids.
- Count the unique individuals (i.e., if an individual has multiple lookback periods, count the individual only once in the denominator).

Step 5: Exclude individuals who met at least one of the following during the measurement year or the 90 days prior to the IPSD:

- Hospice
- Cancer diagnosis
- Sickle cell disease
- Palliative care
- Cancer-related pain

Medication Table OPIOIDS: Opioids

Benzhydrocodone, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(Note: Includes combination products. Excludes the following: injectable formulations; opioid cough and cold products; sublingual sufentanil [used in a supervised setting]; and all buprenorphine products, as buprenorphine, a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.)

1.15b Denominator Exclusions

Individuals with cancer, sickle cell disease, in hospice or palliative care, or receiving cancer-related pain treatment at any point during the measurement year or the 90 days prior to the index prescription start date (IPSD) are excluded from the denominator.

1.15c Denominator Exclusions Details

Hospice exclusion: Exclude any individuals in hospice care at any time during the measurement year or 90 days prior to the IPSD.

- Hospice indicator from the enrollment database, if available (e.g., Medicare); or
- ≥ 1 claim, encounter, or medical record. See Value Set, Hospice Encounter; and Value Set, Hospice Intervention (e.g., Medicaid, commercial).

Cancer diagnosis exclusion: Exclude any individual with cancer during the measurement year or 90 days prior to the IPSD.

- ≥ 1 claim with cancer in the primary diagnosis or any other diagnosis fields. See Value Set, Cancer.

Sickle cell disease exclusion: Any individual with sickle cell disease during the measurement year or 90 days prior to the IPSD.

- ≥ 1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields. See Value Set, Sickle Cell Disease.

Palliative care exclusion: Exclude any individual in palliative care during the measurement year or 90 days prior to the IPSD.

- ≥ 1 claim with palliative care in the primary diagnosis or any other diagnosis fields during the measurement year. See Value Set, Palliative Care.

Cancer-related pain exclusion: Exclude any individual receiving treatment for cancer-related pain during the measurement year or 90 days prior to the IPSD.

- ≥ 1 claim with cancer-related pain in the primary diagnosis or any other diagnosis fields. See Value Set, Cancer-Related Pain.

1.15d Age Group

Adults (18-64 years), Older Adults (65 years and older)

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

Denominator:

Step 1: Identify individuals ≥ 18 years of age as of the first day of the measurement year.

Step 2: Identify individuals with ≥ 1 prescription claims for an opioid (Medication Table, OPIOIDS: Opioids) during the measurement year.

Step 3. Identify individuals continuously enrolled during the measurement year and the 90 days prior to the IPSD.

Step 4: Identify individuals with a negative medication history for any opioid medication during the lookback period.

- For example, an individual has opioid prescription claims on August 1, September 15 and December 20. For each of these dates of service, use the lookback period of 90 days to determine if the individual had no prescription claims for opioids. For example, for August 1, determine whether the individual had no prescription claims for opioids from May 3 – July 31. Repeat for the September 15 and December 20 opioid prescription claims.

Note:

- The prescription claims can be for the same or different opioids.
- Count the unique individuals (i.e., if an individual has multiple lookback periods, count the individual only once in the denominator).

Step 5: Identify individuals who met at least one of the following during the measurement year or the 90 days prior to the IPSD: hospice, cancer, sickle cell disease, palliative care, or cancer-related pain.

To identify individuals in hospice:

- Use the hospice indicator from the enrollment database, if available (e.g., Medicare); or
- ≥ 1 claim, encounter, or medical record. See Value Set, Hospice Encounter; and Value Set, Hospice Intervention (e.g., Medicaid, commercial).

To identify individuals with cancer:

- ≥ 1 claim with cancer in the primary diagnosis or any other diagnosis fields. See Value Set, Cancer.

To identify individuals with sickle cell disease:

- ≥ 1 claim with sickle cell disease (SCD) in the primary diagnosis or any other diagnosis fields. See Value Set, Sickle Cell Disease.

To identify individuals with palliative care:

- ≥ 1 claim with palliative care in the primary diagnosis or any other diagnosis fields. See

Value Set, Palliative Care.

To identify individuals with cancer-related pain:

- ≥ 1 claim with cancer-related pain in the primary diagnosis or any other diagnosis fields. See Value Set, Cancer-Related Pain.

Medication Table OPIOIDS: Opioids

Benzhydrocodone, butorphanol, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol

(Note: Includes combination products. Excludes the following: injectable formulations; opioid cough and cold products; sublingual sufentanil [used in a supervised setting]; and all buprenorphine products, as buprenorphine, a partial opioid agonist, is not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids.)

Step 6: Subtract the individuals identified in Step 5 (exclusions) from the population identified through Steps 1-4. The remaining individuals represent the denominator.

Numerator Population

Step 7: For each individual in the denominator population, identify all initial opioid prescriptions and corresponding opioid initiation periods.

Step 8: For each individual, starting with each initial opioid prescription, sum the days' supply of all opioid prescription claims within each opioid initiation period (i.e., date of service for the initial opioid prescription + 2 days).

For example, if the date of service for an initial opioid prescription is March 15, identify any opioid prescription claims from March 15 through March 17.

Note:

- The prescription claims can be for the same or different opioids.
- For multiple opioid claims with the same date of service, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply.
- For multiple opioid claims with different dates of service, sum the days' supply for all the prescription claims regardless of overlapping days' supply.
- If the opioid initiation period extends beyond the end of the measurement year, the opioid initiation period is truncated to the last day of the measurement year.

Step 9: Count the unique individuals with >7 cumulative days' supply for all opioid prescription claims during any opioid initiation period in the measurement year. This is the numerator.

Measure Rate

Step 10: Divide the number of individuals in the numerator (Step 9) by the denominator (Step 6) and multiply by 100. This the measure rate reported as a percentage.

- Note: Report the rates separately by line of business (e.g., Medicare, Medicaid, Commercial). For Medicare, report rates for low-income subsidy (LIS) and non-LIS populations separately.

1.19 Measure Stratification Details

The measure is stratified by the following lines of business for the health plan:

- Commercial
- Medicare
- Medicaid

PQA also recommends stratification of Medicare plans by Low-Income Subsidy status.

Definition: Medicare Low-Income Subsidy (LIS) - A subsidy paid by the Federal government to the drug plan for Medicare beneficiaries who need extra help with their prescription drug costs due to limited income and resources. Medicare beneficiaries apply for the LIS with the Social Security Administration or their State Medicaid agency.(1)

The Medicare Master Beneficiary Summary file contains the Cost Share Group variable used to identify LIS status.(2) There are 12 monthly variables - 01 through 12 at the end of the variable name corresponds with the month (e.g., 01 is January and 12 is December). CMS identifies beneficiaries with fully-subsidized Part D coverage by looking for individuals that have values of 01, 02, or 03 for the month. Other beneficiaries who are eligible for the LIS but do not receive a full subsidy have values of 04, 05, 06, 07, or 08. The remaining values indicate that the individual is not eligible for subsidized Part D coverage.

Within the Part D program, performance rates are also stratified by the contract type: Medicare Advantage Prescription Drug Plan (MAPD) contracts and standalone prescription drug plan (PDP) contracts. In this program, the term “contract” is synonymous with “health plan.”

References

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2. Chronic Conditions Warehouse Virtual Research Data Center. *Medicare Beneficiary Summary File (MBSF) Base with Medicare Part A, B, C, and D Codebook. Version 1.8*. 2025. Accessed April 18, 2025. <https://www2.ccwdata.org/documents/10280/19022436/codebook-mbsf-abcd.pd...>;

1.20 Types of Data Sources

Administrative Data, Claims Data

1.21a Data Collection Tool URL(s)

<http://example.com>

1.25 Data Source Details

This measure is calculated using standard data from medical claims, prescription claims, and health plan administrative enrollment data. These data fields are highly standardized across the healthcare industry and are a common data source for quality measures. The attached value sets include the full universe of codes required to calculate the measure.

1.26 Minimum Sample Size

If the denominator used to calculate the measure is less than 30, the organization should note in performance reports an insufficient sample size for measurement purposes on that measure and should not report the rate.

Depending on the nature of the quality program, this minimum denominator may not be applied. For example, the Medicare Part D Patient Safety Reports are provided confidentially to health plans for quality improvement; within this program, no minimum denominators are applied to ensure maximum transparency for health plans, even those with small populations.

2.1 Attach Logic Model

[IOP-LD_LogicModel_CBE.pdf](#)

2.2 Evidence of Measure Importance

As this measure is being submitted for maintenance review, a literature review was conducted to identify new evidence that has emerged since initial endorsement. This new evidence, along with the results of the literature review supporting initial endorsement, is synthesized below starting with the relevant clinical guidelines and then providing the published literature in chronological order of publication date.

In its 2022 Clinical Practice Guideline for Prescribing Opioids for Pain, the Centers for Disease Control and Prevention (CDC) provided updated recommendations regarding duration of initial opioid prescriptions.(1) The recommendations state that “when opioids are needed for acute pain, clinicians should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.” This recommendation is category A (applies to all persons; most patients should receive the recommended course of action) and evidence type 4 (clinical experience and observations, observational studies with important limitations, or randomized clinical trials with several major limitations).

Additionally, in April 2023, the Food and Drug Administration (FDA) announced required updates to the prescribing information for all opioid pain medicines to provide additional guidance for safe use. In this Drug Safety Communication,(2) the FDA stated, “Data also suggest that many acute pain conditions treated in the outpatient setting require no more than a few days of an opioid pain medicine, although the dose and duration of treatment needed to adequately manage pain will vary based on the underlying cause and individual patient factors.” These newly implemented updates reflect continued emphasis on appropriate use with a particular focus on duration.

The CDC guideline recommendation, and the IOP-LD measure’s threshold of a 7 days’ supply, is supported by the following body of epidemiologic evidence.

A retrospective analysis by Tehrani et al. published in 2017 used Medicaid claims from 2005-2014, including approximately 6 million Medicaid enrollees ages 18-64 without a cancer diagnosis, to explore trends in prescribed days’ supply for opioids.(3) The authors found that over the course of the study, the average days’ supply of opioids increased considerably for all opioids except for

morphine. Oxycodone days' supply increased 4.5 days (a 37% increase) during the study period, while hydrocodone, hydromorphone, oxymorphone, and tapentadol increased by 4, 2.5, 3, and 5 days, respectively. Notably, there was no observed decline in median days' supplied for any opioid after 2013, when the opioid epidemic gained national attention. Further evaluation of a commercial cohort during the same timeframe exhibited similar, but even steeper increases in days' supply for opioids.

In research published in 2018, Shah et al. performed a retrospective cohort study using a random sample from a nationally representative database of the commercially insured population in the United States from 2006-2015 to explore relationships between initial opioid prescription characteristics and likelihood of long-term use.⁽⁴⁾ The study examined 1,294,247 patients aged 18 years or older who met inclusion criteria and received initial opioid prescriptions, defined as those with no opioid prescriptions in the preceding 6 months of continuous enrollment. The study found that the probability of long-term opioid use increased with each additional day supplied when initiating opioid therapy, following the third day supplied. Specifically, the probability of long-term use was more than twice as high for individuals who received greater than 7 days' supply, when compared to those with at least one days' supply (13.5% vs. 6.0%). In conclusion, the authors expressly note that their findings are consistent with CDC recommendations and suggest that limiting initial opioid prescriptions to 7 or fewer days' supply (and ideally no greater than 3 days' supply) reduces the risk of unintentional long-term opioid use.

Additional research published by Shah et al. in 2018 provided further evidence that greater days' supply for initial opioid prescriptions is associated with a lower likelihood of opioid discontinuation.⁽⁵⁾ In a retrospective cohort study examining a total of 1,353,902 opioid naïve individuals (defined as individuals with at least 12 months without an opioid prescription prior to their initial prescription) from 2006-2015 who met inclusion criteria, the authors examined the relationship between initial opioid prescription characteristics and probability of opioid discontinuation among opioid naïve patients, controlling for patient level factors. The authors reported that even controlling for patient factors and underlying pain etiologies, the results are consistent with earlier findings suggesting a dose-response relationship between days' supply and likelihood of discontinuation (see citation 4), with hazard ratios for discontinuation of 0.70 (95% CI 0.70-0.71) for a 3-4 day supply, 0.48 (95% CI 0.47-0.48) for a 5-7 day supply, 0.37 (95% CI 0.37-0.38) for an 8-10 day supply, and 0.32 for an 11-14 day supply of opioids (95% CI 0.31-33), where a 1-2 day supply is the reference group.

In 2018, Zhang et al. conducted a retrospective cohort study of 403,664 privately insured patients and 107,509 Medicare Advantage patients who initiated opioid therapy between 2011 and 2013, to determine how characteristics of these initial prescriptions, including days' supply, affect risk for high-risk opioid use in the following 18 months.⁽⁶⁾ Initial opioid prescriptions were defined as opioid prescriptions among patients who did not have any opioid prescriptions within a lookback period of six months. The authors found that an initial opioid prescription consisting of greater than 7 days' supply, versus a 3 or fewer days' supply reference group, was associated with a

significant ($p < 0.001$) increase in high-risk opioid use, including overlapping opioid prescriptions (7% increase, 95% CI 6.2%-7%), concurrent use of opioids and benzodiazepines (8.7% increase, 95% CI 8.2%-9.2%), receiving opioids with a daily average dosage of 120 or more morphine milligram equivalents (MME) in the long term (4.8% increase, 95% CI 4.5%-5.2%), and use of opioids in each quarter of the 18 months following the index prescription (15% increase, 95% CI 15.0%-15.6%).

Brat et al. conducted a retrospective cohort study in 2018 that explored opioid prescribing patterns after surgery and found additional evidence regarding initial opioid prescribing and opioid misuse, defined as a composite of diagnosis codes for opioid abuse, dependence, or overdose.⁽⁷⁾ The study used surgical claims from a linked medical and pharmacy administrative database from 2008-2016, and included 568,612 opioid naïve patients, defined as patients who had used 7 or fewer days of opioids in the 60 days preceding the surgery, and who received a postsurgical opioid. The authors note that duration of use, rather than dosage, was most strongly associated with opioid misuse, with an estimated increase rate of 20% of opioid misuse per each week of an opioid prescription after adjusting for covariates (95% CI 18.5%-21.4%). These findings remained consistent after sensitivity analyses, including removing the most common ICD code for opioid dependence and relying entirely on specific abuse and overdose codes.

A 2018 comparative study by Mojtabai analyzed trends in prescription opioid use among U.S. adults from 1999-2000 and 2013-2014.⁽⁸⁾ Results showed a significant increase in the prevalence of prescription opioid use among the study population, with approximately 80 percent of use being characterized as long-term in 2013-2014. This increased prevalence of long-term prescription opioid use has significant implications, as such use was associated with poorer physical health status, concurrent use of benzodiazepines, and a history of heroin use.

A 2019 study by Durand et al. of 46,399 opioid-naïve injured workers, defined as individuals with no opioid prescriptions in the 60 days prior to injury, from 2013-2015 examined the relationship between initial opioid prescription characteristics and long-term opioid use.⁽⁹⁾ The authors found that initial prescription length, rather than demographic or injury characteristics, was the strongest predictor of long-term opioid use, which was defined as having an opioid supplied for 45 or more days in the 90 days after the injury. The study found that in comparison to a reference group of <5 days' supply, a 5-9 day supply was associated with a significant increase in the odds of long-term use (adjusted OR 1.83, 95% CI 1.56-2.14). This dose-response trend between days' supply and odds of long-term opioid use continued with greater days' supply, including 10-19 days (adjusted OR 4.73, 95% CI 3.90-5.75) and 20 days or more (OR 28.94, 95% CI 23.44-35.72).

A 2019 study performed by Hadlandsmayth et al. replicated Shah's methodology to examine the relationship between initial opioid exposures and long-term use. The study examined 19,600 patients in the Veteran's Health Administration who received an initial opioid prescription

(defined as prescriptions with no opioid prescriptions in the preceding year) and met criteria for long-term opioid use within one year of follow-up. The authors corroborated Shah's findings, with initial opioid prescriptions for 7 days or fewer serving as a reference group, and greater days' supply associated with increased risk of long-term opioid use, including 8-14 days (adjusted OR 1.44, 95% CI 1.38-1.51), 15-21 days (adjusted OR 2.43, 95% CI 2.30-2.56), 22-30 days (adjusted OR 7.35, 95% CI 8.09-7.62), and greater than 30 days (adjusted OR 15.5, 95% CI 14.7-16.4).(10)

In a 2019 study, Mundkur et al. conducted a retrospective cohort study using 2014 data, examining the frequency of refills among adults who filled an opioid analgesic prescription within 7 days of an initial outpatient visit for 10 acute pain conditions (n=176,607).(11) For adults who received an initial prescription of 7 days' supply, the adjusted probability of refill ranged from 0.11 (95% CI 0.09-0.14) for headache to 0.41 (0.19-0.68) for musculoskeletal injury. Using a lack of refill as a surrogate for adequately managed pain, authors suggest that their findings show that for most cases, a 7 days' supply of opioid analgesics is sufficient (if not more than necessary). However, the authors note that refills are an imperfect marker and may reflect physical dependence, withdrawal, or the need for additional pain control that could possibly be managed by nonopioid alternatives.

In a 2020 study, Riva et al. performed a systematic review and meta-analysis of observational studies from inception to 2020 to explore factors associated with persistent opioid use following initial prescriptions for acute musculoskeletal injury. Initial prescriptions for greater than 7 days' supply (5 cohorts; n= 2,087,624 patients) demonstrated a consistent association with increased risk for prolonged opioid use (median absolute risk increase 4.5%).(12)

In a 2020 retrospective cohort study, Weiner et al. evaluated the characteristics of initial opioid prescriptions among opioid-naïve patients and their associations with chronic opioid use using Ohio prescription drug monitoring program data from 2010-2017 (n=4,252,809 patients).(13) Chronic use was defined as at least six opioid prescriptions in one year and either one or more years between the first and last prescription or an average of less than or equal to 30 days not covered by an opioid during that year. Days' supply, as well as quantity, were found to be significantly associated with chronic use; the average days' supply among patients with no chronic use was 6.8 days while the average days' supply among patients with chronic use was 12.3 days (p<0.001).

In a 2022 retrospective cohort study by Weiner et al., authors assessed the patient and prescription-related factors associated with opioid-related fatal or nonfatal overdose among opioid-naïve adult patients.(14) Analyses were conducted by combining claims data from 2013-2018 with several public health data sets to create the Oregon Comprehensive Opioid Risk Registry. To be considered opioid naive, individuals must not have had more than 1 index prescription; an opioid use disorder-related buprenorphine formulation as the index prescription

or in the index period; or any opioid prescriptions, opioid-related hospitalizations, or emergency department visits in the 12 months before the index prescription dispense date. Index opioid prescriptions were found to be associated with a significantly higher overdose rate per 100,000 person-years when the days' supply was greater than 7 days (191.3, 95% CI 163.1-224.4) compared to less than or equal to 7 days (108.9, 95% CI 99.9-118.7).

In a 2022 retrospective cohort study, Young et al. evaluated potential impacts of prescribing limits by examining the relationship between length of initial opioid prescriptions and risk of prolonged opioid use.⁽¹⁵⁾ This study identified opioid naïve adults undergoing surgery (n=1,060,596) using Medicare claims from 2007-2017. Among the 70.0% of these patients who received a postoperative opioid, increased days' supply of the initial prescription was associated with increasing risk of prolonged opioid use, ranging from 0.7% (1 day supply) to 4.4% (15 or more days' supply). In evaluating prescribing limits, a limit of 4 days was associated with the largest reduction in absolute risk from 24.4 to 19.6 per thousand patients, suggesting the 7-day threshold used in the IOP-LD measure may be relatively less restrictive.

In a 2024 study, Nguyen et al. found the likelihood of an opioid refill within 90 days increased with greater initial prescription duration based on a retrospective cohort study focused on outpatient pain visits from 2013-2018 (n=220,797).⁽¹⁶⁾ Within the cohort, 22.4% of patients received greater than 7 days' supply, and 23.5% of patients had a refill during the follow-up window; longer initial prescription length was associated with greater adjusted likelihood of a refill for all conditions although magnitudes of effect varied. Per the authors' analyses, about 1-3 fewer patients would receive a refill within 3 months for every 100 patients initially prescribed 3 vs. 7 days' supply of opioids for most pain diagnoses.

References:

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2.4 Performance Gap

The Pharmacy Quality Alliance (PQA) reviewed IOP-LD measure scores using data from the measure's implementation by CMS in Medicare Part D. Specifically, PQA calculated the distribution of rates using data from the Part D Patient Safety Reports from calendar years 2020-2022. These datasets, provided by CMS directly and confidentially to PQA, include contract-level data from both MAPDs and PDPs participating in the Part D program. The number of included contracts and patients are as follows:

- 2020 - MAPD: 680 contracts, 2,825,411 patients; PDP: 60 contracts, 3,206,213 patients
- 2021 - MAPD: 736 contracts, 3,171,556 patients; PDP: 60 contracts, 3,106,406 patients
- 2022 - MAPD: 785 contracts, 3,418,304 patients; PDP: 55 contracts, 2,968,052 patients

The numerator and denominator in the Part D Patient Safety Reports are measured using beneficiary member-years, which represent the number of beneficiaries covered by a contract adjusted for the portion of the year during which they were enrolled (e.g., six months of enrollment equals 0.5 member-years). Where whole numbers are required for various analyses in subsequent sections (e.g., signal-to-noise reliability), rounding to the next highest integer was applied.

2.4a Attach Performance Gap Results

[IOP-LD_PerformanceGap_CBE.pdf](#)

2.6 Meaningfulness to Target Population

Patient involvement is a critical component of PQA's systematic, transparent, and consensus-based measure development and maintenance process. PQA gathered patient input prior to and during the development of the IOP-LD measure through the convening of a Patient and Caregiver Advisory Panel (PCAP). The PCAP was a group of 12 individuals, selected by PQA staff through a nomination process, to provide patient and caregiver input into the measure development process and thereby reflect patients' perspectives in PQA measures. Selected individuals self-identified as patients, caregivers, patient advocates, or more than one of these roles. Three participants also worked as healthcare professionals.

In a survey following the introduction of three measure concepts focused on initial opioid prescribing, including IOP-LD, all PCAP members were asked, "Is the evaluation of initial opioid prescriptions important to patients and caregivers?" All respondents indicated "Yes."

Further, the CDC curates patients' frequently asked questions about prescription opioids.⁽¹⁾ These questions, listed below, illustrate patients' concerns about risks of opioid use, misuse, and overdose. This underscores the value and meaningfulness of the IOP-LD measure to patients.

- Will I develop an opioid use disorder?
- How do I take and store opioids properly?
- Can I avoid side effects and risks of opioids?
- What increases my risk of overdose from opioids and other drugs?

Finally, PQA's transparent, systematic, consensus-based measure maintenance process includes two patient representatives on the Measure Update Panel, which reviews and evaluates potential changes to measures, including updates made to the IOP-LD measure since its original development. Substantive changes to measures are further reviewed by PQA's Quality Metrics Expert Panel, which also includes two patient representatives. These individuals help ensure the ongoing importance and meaningfulness of PQA measures to patients.

References:

1. Centers for Disease Control and Prevention. Patients' Frequently Asked Questions About Prescription Opioids. U.S. Department of Health & Human Services. Updated November 1, 2024. Accessed April 18, 2025. <https://www.cdc.gov/overdose-prevention/manage-treat-pain/patients-faqs...>

3.1 Contributions Towards Closing Care Gaps

Evidence of Known Disparities:

We note that literature provides evidence of a variety of disparities related to opioids and initial opioid prescribing, many of which were recently addressed in the CMS Proposed Rule CMS-4208-P, excerpted below.⁽¹⁾

"According to the CDC, there are widening disparities among various population groups for overdose death rates, which have recently been driven by illicitly manufactured fentanyl use.³⁰¹ In 2020, the overdose death rates per 100,000 people increased by 44% for the Black population and 39% for American Indian and Alaska Native (AI/AN) population compared to 2019. Additionally,

among Black males 65 years and older, the overdose death rate was nearly seven times more than their White male counterparts of the same age group.

Additionally, officials from the Substance Abuse and Mental Health Services Administration (SAMHSA), CDC, and the National Institute on Drug Abuse published a study that followed a cohort of 136,762 Medicare beneficiaries who experienced an index nonfatal drug overdose in 2020.³⁰² This population consisted primarily of Hispanic (5.8%), non-Hispanic Black (10.9%), and non-Hispanic White (78.8%) beneficiaries. The researchers followed the beneficiaries 12 months after the initial index nonfatal drug overdose and found that 23,815 beneficiaries (17.4%) had at least one more nonfatal drug overdose and 1,323 beneficiaries (1.0%) died of a fatal overdose. The study found that opioids were involved in 72.2% of these fatal drug overdoses.

Differences are seen in the Medicare Part D population based on internal analysis of PDE [prescription drug event] and administrative claims data by CMS. In 2023, the percentages of non-MOUD opioid Part D users were 24% for Black beneficiaries, 24% for AI/AN beneficiaries, and 22% for White beneficiaries. We found that overall, the number of Part D beneficiaries with a primary opioid overdose claim decreased from 32,120 in 2018 to 28,365 in 2023 (0.83 per 1,000 to 0.62 per 1,000 Part D beneficiaries). The opioid overdose rates varied among the Part D population in 2023 (January 1, 2023 to December 31, 2023): 1.52 per 1,000 AI/AN Part D beneficiaries, 1.35 per 1,000 Black Part D beneficiaries, and 0.57 per 1,000 White Part D beneficiaries.

The disparities in opioid overdose rates existing among different population groups, as highlighted by CMS's internal data analysis, underscore the urgency to address the widening gap in health outcomes. As discussed previously, there is room for improvement and variations in IOP-LD rates among Part D sponsors. The IOP-LD measure is a preventative-focused quality measure that addresses initial prescription opioid exposure to reduce the likelihood of long-term opioid use and reduce the risk of opioid overdose.

301. CDC Newsroom Release. Overdose death rates increased significantly for Black, American Indian/Alaska Native people in 2020: <https://www.cdc.gov/media/releases/2022/s0719-overdose-rates-vs.html>.

302. JAMA Internal Medicine: Overdose, Behavioral Health Services, and Medications for Opioid Use Disorder After a Nonfatal Overdose: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/28201...>."

Methodology:

The measure has been used in Medicare Part D quality programs since 2020, where measure rates are reported at the contract level. Measure performance data made available by CMS do not include beneficiary-level demographic information; therefore, empirical assessment of differences in IOP-LD performance scores among socio-contextual variables is not feasible using data from implementation.

During the original development of IOP-LD, the measure concept was tested in Medicare, Medicaid, and commercial data samples from 2014, 2016, and 2017. Four testing organizations calculated measure rates and provided results to PQA. To better understand how the measure affects different subpopulations, these results were stratified by sex (male, female), age group (18-50, 51-64, 65-84, greater than or equal to 85 years), and Low-Income Subsidy (LIS) status (LIS, non-LIS), based on standard data elements that were available to all tester organizations at the time

PQA explored options to perform analyses on more recent data but were unable to provide results for this optional element of the submission.

Results/Interpretation

Across four testing organizations, overall IOP-LD measure rates ranged from 43.0%-50.9% in Medicare, 25.9%-26.3% in commercial, and 15.1%-28.3% in Medicaid, revealing differences in performance across lines of business. Stratified measure rates also highlighted differences among several subpopulations.

Across all Medicare samples, female patients had consistently higher (worse) measure rates, with scores approximately 8% higher than males. These results stood in contrast to sex-stratified rates reported in commercial and Medicaid data, where female patients, on average, had rates between 0.8% and 5.3% *lower* than males.

Age-stratified results showed higher rates in Medicare patients aged 51-64 and 85 and older compared to those aged 65-84. In commercial and Medicaid samples, measure rates increased with each subsequent age stratum, with patients aged 18-50 having the lowest scores and those aged 85 and older having the highest scores.

A focused evaluation of 183,545 Medicare beneficiaries enrolled in PDPs showed that LIS recipients had a higher measure rate than non-LIS individuals by approximately 2%, indicating that those with greater financial need have worse performance on the measure on average.

These results draw attention to differences in performance among various subpopulations. They notably demonstrated the increased prevalence of initial long-term opioid prescribing in older adults. Such prescribing was especially prominent in the Medicare population, more than three-quarters of whom are aged 65 or older, in 2016 and 2017. These findings raise concern given the noted risk of opioid overdose in older adults.

However, average IOP-LD measure rates in Medicare have since decreased by more than half following the implementation of enhanced opioid safety edits by CMS in 2019 as well as the uptake and use of IOP-LD in quality programs. This suggests that health plans have been able to successfully implement strategies to improve performance on the measure and can continue to identify and address disparities in performance.

Anticipated Impact

Differences in performance across subpopulations described above can provide valuable information for health plans seeking to understand vulnerable subgroups amongst their covered populations and close gaps in care. As a claims-based measure, calculation of IOP-LD is relatively straightforward and can be stratified by sociodemographic beneficiary information when available to support identification of disparities and efforts to improve health equity.

Also of note, the PQA Health Equity Technical Expert Panel (TEP) recently provided several recommendations for stratification of PQA measures on a program-by-program basis, including for the IOP-LD measure. The Health Equity TEP's top priorities for stratification in Medicare Part D included age, sex, geography, and race/ethnicity. PQA has shared these recommendations with program administrators, who are ultimately responsible for decisions about stratified reporting.

Beyond a programmatic approach, individual health plans can also use their data internally to stratify by recommended variables and identify interventions that seek to reduce disparities. To support this broad approach, PQA published the PQA Health Equity Technical Expert Panel's recommendations and has disseminated them to promote broad adoption.

References

1. Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, 89 Fed. Reg. 99,340 (Dec. 10, 2024). <https://www.govinfo.gov/content/pkg/FR-2024-12-10/pdf/2024-27939.pdf&nb...>;

4.1a Data Structure and Availability

The IOP-LD measure has been implemented in the Medicare Part D Patient Safety Reports since 2020 and Part D Display page since program year 2023 (2021 data). During this time, no feasibility challenges were reported with the use of the measure. All required data elements are routinely generated and readily available in structured fields. No concerns with missing data have been identified.

Although the measure has not yet been implemented in the Medicaid Adult Core Set, no issues with feasibility were identified by the workgroup during their evaluation of the measure and resulting recommendation to add the measure to the Medicaid Adult Core Set.

No changes to the measure since initial endorsement have impacted feasibility.

4.1b Implementation Costs and Burden

Measured entities (health plans) are not anticipated to face significant costs or burden due to implementation of the IOP-LD measure. Prescription and medical claims data, which are needed for measure calculation, are routinely generated by plans. However, costs may arise due to acquisition of other relevant data or analytic tools.

Standalone Part D prescription drug plans (PDPs) may not have timely access to medical claims data and could experience related delays, though such data are only needed to apply the measure's exclusions. Of note, AB2D—an Application Programming Interface (API) recently developed by CMS—helps to provide PDPs with Medicare Parts A and B (medical) data in an efficient and secure manner. More information is available at <https://ab2d.cms.gov/>.

4.1c Confidentiality

IOP-LD is a population-level measure that does not require the collection or reporting of any patient-identifying information. Further, the measure's specifications indicate that an organization should not report a measure rate in instances where the denominator includes fewer than 30 individuals, which reduces concerns about small sample sizes that may compromise

confidentiality.

4.3 Feasibility Informed Final Measure

No adjustments have been made to the measure's specifications in response to feasibility concerns.

4.4 Proprietary Information

Proprietary measure or components with fees

4.4a Fees, Licensing, or Other Requirements

All uses of PQA measures are subject to such conditions as PQA specifies, and certain uses of the measures may be subject to a licensing agreement specifying the terms of use and the licensing fee. Government agencies do not pay a license royalty.

5.1.1 Data Used for Testing

PQA conducted reliability testing using the Medicare Part D Patient Safety Report data from calendar years 2020, 2021, and 2022. We conducted validity testing using the Medicare Part D Display data from calendar years 2021 and 2022. Both datasets include contract-level data from both MAPD and PDP contracts.

5.1.1a Dates of Testing Data

Field not required Spring 2025

5.1.2 Differences in Data

Empirical validity testing was conducted using data from the Medicare Part D Display for calendar years 2021 and 2022. The Medicare Part D Display data provides contract-level scores for the IOP-LD measure and other measures on which PQA performed convergent validity testing. However, these data only include measure rates and do not provide denominator size by contract. As a result, they cannot be used for reliability testing.

Reliability testing was conducted using data from the Medicare Part D Patient Safety Report program from calendar years 2020, 2021, and 2022. Medicare Part D Patient Safety Reports include rate, denominator, and numerator data by contract, which are required to calculate signal-to-noise reliability using the Adams approach.

5.1.3 Characteristics of Measured Entities

For reliability and validity testing, PQA utilized data sources that are reflective of the real-world implementation of this measure in the Medicare Part D Patient Safety Report and Medicare Part D Display programs.

Reliability testing was conducted across three years of Medicare Part D Patient Safety Report data (2020-2022) and represented a total of 2,376 Part D contracts and 18,695,942 beneficiaries in the IOP-LD eligible population across the three years.

Validity testing was conducted across two years of Medicare Part D Display data (2021-2022) and represented a total of 699 contracts in 2021 and 725 contracts in 2022. The number of beneficiaries per contract is not reported within Part D Display data; however, it is expected that the vast majority of Medicare Part D beneficiaries are represented within the data reported.

5.1.4 Characteristics of Units of the Eligible Population

The Medicare Part D Patient Safety Reports and Medicare Part D Display data provide contract-level information, but do not contain beneficiary-level demographic information such as age, sex, or race. The demographics of Medicare beneficiaries receiving opioid prescriptions has been the subject of previous studies, with evidence suggesting that older beneficiaries and white beneficiaries are more likely to receive opioids.^(1,2) As a result, older and white beneficiaries may constitute a relatively larger portion of the eligible population of the IOP-LD measure.

The distribution of eligible population size by contract for the Medicare Part D Patient Safety Reports is provided below by year and contract type (MAPD or PDP), after limiting contracts to only those with 30 or more individuals in the denominator.

In 2020, the average number of beneficiaries was 4,155 (SD: 12,768) in MAPD contracts and 53,436 (SD: 128,505) for PDPs. In 2021, the average number of beneficiaries was 4,309 (SD: 13,846) in MAPD contracts and 51,773 (SD: 124,648) for PDPs. In 2022, the average number of beneficiaries was 4,354 (SD: 14,417) in MAPD contracts and 53,964 (SD: 138,923) for PDPs.

References:

1. Raman SR, Bush C, Karmali RN, Greenblatt LH, Roberts AW, Skinner AC. Characteristics of New Opioid Use Among Medicare Beneficiaries: Identifying High-Risk Patterns. *J Manag Care Spec Pharm*. Sep 2019;25(9):966-972. doi:10.18553/jmcp.2019.25.9.966

2. Chronic Conditions Warehouse. All CCW Medicare Enrollment Charts Data 2022. U.S. Department of Health & Human Services. Accessed April 18, 2025. <https://www2.ccwdata.org/documents/10280/19099067/medicare-charts-enrol...>;

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

Using the data described in section 5.1.1 and 5.1.2, the reliability of the computed measure scores was measured as the ratio of signal-to-noise. This analysis was conducted to evaluate the differences between contract-level measure scores by comparing the proportion of variance that is attributable to consistent measurement (signal) compared to non-systematic or random error (noise); this is represented in the data as the variation in measure scores between contracts (signal) and variation within a single contract (noise).

The beta-binomial method published by Adams in 2009⁽¹⁾ was used to calculate reliability for individual contracts grouped by measure year (2020-2022) and health plan type (MAPD, PDP). Reliability scores range from 0-1, with a score of 0 signifying that all variation is due to measurement error. A value of 1 signifies that the variation represents true differences in performance scores between contracts. In accordance with PQA guidance, contracts with less than 30 individuals in the denominator were not included for analysis.

References:

1. Adams JL. *The reliability of provider profiling: a tutorial*. 2009. Accessed September 20, 2024. https://www.rand.org/pubs/technical_reports/TR653.html;

5.2.3 Reliability Testing Results

The statistical results of signal-to-noise reliability testing are presented in Tables 2a-2f by contract type and calendar year. The results suggest a high level of reliability across all contracts with all 2020, 2021, and 2022 MAPD contracts meeting the minimum required reliability value of 0.6 and more than 90% of 2020, 2021, and 2022 PDP contracts meeting the minimum required reliability value of 0.6.

5.2.3a Attach Additional Reliability Testing Results

[IOP-LD_Reliability_CBE.pdf](#)

5.2.4 Interpretation of Reliability Results

The results of the signal-to-noise reliability testing demonstrate that IOP-LD is a highly reliable measure for each contract type and calendar year. This demonstrates that the differences in performance scores seen between contracts are due to actual differences in performance rather than measurement error.

5.3.1 Level(s) of Validity Testing Conducted

Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.2 Type of Accountable Entity Level Validity Testing Conducted

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis), Systematic assessment of face validity of the measure's performance score as an indicator of quality or resource use

5.3.3 Method(s) of Validity Testing

Systematic Assessment of Face Validity

PQA uses a systematic, transparent, evidence- and consensus-based measure development process. This process, used in 2018-2019 to develop the IOP-LD measure, is outlined below:

- Step 1: Measure concepts for development are prioritized by PQA staff based on input from PQA's Measure Advisement Group, Implementation Advisory Panel, and Patient and Caregiver Advisory Panel. Environmental scans are conducted to identify whether similar measures exist, ensuring harmonization and avoiding duplication. Selected concept ideas are considered to represent areas in which there are measurement and performance gaps to have the greatest chance of implementation in existing measure sets and performance systems, and to align with the National Quality Strategy.
- Step 2: PQA Measure Development Teams (MDTs) and Task Forces (TFs), composed of experts in all phases of drug use and management, discuss and draft specifications for measure concepts that may be appropriate for development into fully specified performance measures. The MDTs/TFs focus on specific aspects of the medication-use system and/or specific therapeutic areas and benefit by having their development work reviewed by larger groups, Stakeholder Advisory Panels. They may also receive input from the Patient & Caregiver Advisory Panel, Implementation Advisory Panel, and Risk Adjustment Advisory Panel.
- Step 3: PQA MDTs/TFs recommend measure concepts to the PQA Quality Metrics Expert Panel (QMEP) for evaluation and refinement. The QMEP reviews and provides an initial assessment of the measure concept focusing on the criterion of importance (i.e., evidence supports that measurement can have a positive impact on healthcare quality). The QMEP votes to approve the

measure concept to move forward for testing.

- Step 4: PQA staff prepare technical specifications (including National Drug Code [NDC] lists) for pilot testing and use MDT/TF and QMEP recommendations to formulate a testing plan for each draft measure.
- Step 5: PQA selects partners to test the draft measures. These partners are often PQA member health plans or academic institutions with expertise in quality and performance measure testing that also have access to the data sources needed to calculate the measure rates. The testing partner implements the draft technical specifications within their existing datasets and provides a report to PQA that details testing results and recommendations for modifications of the technical specifications.
- Step 6: The QMEP reviews the testing results and recommendations and determines final criteria for the measure based on the findings. The QMEP provides a final assessment of the draft measures' feasibility and reliability and recommends whether measures should move forward for PQA endorsement consideration. 90% (18/20) QMEP members recommended that the measure move forward for PQA endorsement consideration.
- Step 7: The Measure Validity Panel (MVP), an independent group of individuals not involved in the development or review of the measure concept or draft measure, determines through discussion and vote whether the performance measure score is an accurate reflection of quality and can distinguish good from poor performance (i.e., face validity). Through discussion and vote, the MVP determines whether the performance measure scores have face validity.
- Step 8: Performance measures that are recommended by the QMEP for endorsement consideration by the PQA membership are posted on the PQA web site for member review, written comments are requested, and a webinar for member organizations is held to gather feedback and address any questions. This process allows members to discuss their views on the measures in advance of the voting period.
- Step 9: PQA member organizations vote on endorsement of the performance measure.

Empirical Validity Testing

Empirical validity testing of the IOP-LD measure used a convergent validity approach to assess the association between performance on the IOP-LD measure and other conceptually-related measures. Correlations in expected directions between measures that capture similar aspects of quality and/or benefit from overlapping or similar interventions provide evidence of validity.

The PQA team began by reviewing measures included on the Part D Display page, where the IOP-LD scores are publicly reported and can be compared to other publicly reported measures. PQA initially limited the list of measures to those that assess medication use quality, then further refined the list to only those that evaluate medication safety. The resulting four measures include Concurrent Use of Opioids and Benzodiazepines (COB), Use of Opioids at High Dosage in Persons Without Cancer (OHD), Polypharmacy: Use of Multiple Anticholinergic Medications in Older Adults (POLY-ACH), and Polypharmacy: Use of Multiple CNS-Active Medications in Older Adults (POLY-CNS). Much like IOP-LD, these are health plan level measures intended to reduce potentially inappropriate medication use, in turn leading to reduced health care resource utilization and improved patient safety. A lower rate indicates better performance for all measures included in this assessment.

An analysis of rates indicated non-normal distributions, so the Spearman correlation coefficient was used to assess the association between performance on the IOP-LD measure and the four related measures. It was hypothesized that measure scores for IOP-LD would be weakly-to-moderately correlated with measure scores for COB, POLY-ACH, and POLY-CNS included in the analysis in the positive direction. It is expected that health plans perform similarly on several quality measures that aim to reduce potentially inappropriate medication use, likely through an organizational approach to implementation of medication management programs, safety edits, physician outreach and education, and other services. However, strong associations between these measures were not expected as differences in performance across related but different metrics can still be caused by various factors (e.g., measure or population-specific nuances, health plan priorities).

Measure scores for IOP-LD and OHD were not hypothesized to be correlated due to significant differences in the characteristics of the measures' eligible populations: the IOP-LD measure primarily captures acute opioid use while OHD primarily captures chronic opioid use. As a result, clinical considerations and intervention types may be significantly different between these two measures, and regulatory requirements also differ between initial opioid prescribing versus high-dose, longer-term opioid prescribing.

5.3.4 Validity Testing Results

Face Validity

Through discussion and vote, the Measure Validity Panel (MVP), described in section 5.3.3, determined that the IOP-LD measure had face validity. Of the 7 MVP members who voted on the face validity of IOP-LD, 100% agreed or strongly agreed that the scores obtained from the measure as specified will provide an accurate reflection of quality and can be used to distinguish good and poor quality between contracts.

Empirical Validity

The results of the criterion validity testing are presented in the attachment by calendar year. The results are consistently statistically significant (where expected), in the expected directions, and at expected strengths.

Strengths of association are interpreted using the following scale: Very Weak (0-0.19) / Weak (0.20-0.39) / Moderate (0.40-0.59) / Strong (0.60-0.79) / Very Strong (0.80-1).⁽¹⁾ We note that given the typical strengths of associations seen in quality measure convergent validity testing, these interpretations may be conservative.

References:

1. T D V Swinscow. *Statistics at Square One, Ninth Edition*. 1997. BMJ Publishing Group. Accessed September 20, 2024. <https://www.bmj.com/about-bmj/resources-readers/publications/statistics...>;

5.3.4a Attach Additional Validity Testing Results

[IOP-LD_VValidity_CBE.pdf](#)

5.3.5 Interpretation of Validity Results

Based upon the PQA Measure Validity Panel's and Quality Metrics Expert Panel's assessments, described in section 5.3.3, the IOP-LD measure has been determined to have face validity.

The correlations produced in our empirical validity analyses showed statistically significant, weak-to-moderate positive correlations of IOP-LD measure rates with rates for COB, POLY-CNS, and POLY-ACH. These correlations were in the expected (positive) direction, suggesting that health plans perform similarly on several quality measures that aim to reduce potentially inappropriate medication use, likely through the implementation of consistent medication management programs and services. Effect sizes were also consistent with our hypotheses.

Additionally, as expected, analyses revealed negligible correlations between IOP-LD and OHD, with the relationship only statistically significant in one year at a very weak effect size. While the IOP-LD measure assesses *initial* opioid prescribing—that is, opioid prescriptions for individuals who have not received an opioid prescription in the previous 90 days—the OHD measure includes opioid users with two or more opioid prescriptions totaling 15 or greater total days’ supply and therefore captures a high number of chronic opioid users versus opioid naïve individuals.

Furthermore, OHD assesses the proportion of such opioid users receiving an average daily dosage greater than or equal to 90 MME over a period of 90 or more days. As such, the types of interventions that may be deployed by a plan to improve performance on these measures may differ vastly, especially considering that individuals receiving opioids at high dosage are clinically dissimilar to those receiving initial opioid prescriptions and have unique risk/benefit considerations. This is also reflected in differing CMS regulatory requirements for drug utilization reviews for initial opioid prescribing for long duration versus the dispensing of high dose opioids greater than 90 MME.⁽¹⁾ General sensitivities around opioid tapering, along with the relative lack of available guidance on opioid tapering protocols in chronic pain, further differentiate how health plans may approach improving performance on OHD compared to IOP-LD.

As with all convergent validity testing, these analyses are subject to limitations. In particular, the options for measures to assess IOP-LD against are limited by available data; only certain measures are publicly reported for comparison to IOP-LD, and these measures are not perfect comparators. However, these findings provide reasonable empirical evidence that IOP-LD is a valid measure of health plan quality, and a valuable tool that health plans can use to improve the quality of care for their members.

References:

1. Centers for Medicare & Medicaid Services. *A Prescriber’s Guide to Medicare Prescription Drug (Part D) Opioid Policies*. 2024. Accessed April 18, 2025. <https://www.cms.gov/files/document/mln2886155-prescribers-guide-medicar...>;

5.4.1 Methods Used to Address Risk Factors

No risk adjustment or stratification

6.1.1 Current Status

In use

6.1.3 Current Use(s)

Public Reporting

6.1.3 Program Details

Name of the program and sponsor

CMS Medicare Part D Display Page

URL of the program

<https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data>

Purpose of the program

The Part D Display Page publicly reports measure rates and can be used to facilitate quality improvement by Medicare Part D plan sponsors. Performance on Display measures does not contribute to Medicare plans' Star Ratings and is not tied to payment.

Geographic area and percentage of accountable entities and patients included

National quality program that includes all Medicare Part D plan sponsors in all 50 states and the District of Columbia. As of 2024, 53 million patients were enrolled in Medicare Part D plans.

Applicable level of analysis and care setting

Health Plan

6.2.1 Actions of Measured Entities to Improve Performance

This measure is intended for retrospective, population-level analysis and is not intended to serve as a guide for individual patient care decisions. However, measured entities can use the measure to identify opportunities to decrease initial opioid prescriptions for long duration that may place patients at increased risk for long-term opioid use, misuse, overdose, and other negative outcomes.

Health plans can utilize various strategies to identify such opportunities. This may include implementing safety edits for days' supply limits for initial opioid fills that prompt an additional safety and appropriateness review to be conducted prior to dispensing an initial opioid prescription for long duration. Federal regulations (42 CFR § 423.153(c)(2)) require that Medicare Part D plan sponsors must have "Concurrent drug utilization review systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor's Part D plan, typically at the point-of-sale or point of distribution.(1) The review must include, but not be limited to,

- (i) Screening for potential drug therapy problems due to therapeutic duplication.
- (ii) Age/gender-related contraindications.
- (iii) Over-utilization and under-utilization.
- (iv) Drug-drug interactions.
- (v) Incorrect drug dosage or duration of drug therapy.
- (vi) Drug-allergy contraindications.

(vii) Clinical abuse/misuse.”

Per published guidance from CMS,(2,3) “to help prevent and combat prescription opioid overuse through improved concurrent DUR [drug utilization review], sponsors are expected to implement real-time opioid safety edits at the POS [point-of-sale], including an edit to limit initial opioid prescription fills for opioid naïve beneficiaries to no more than a 7 days’ supply.”

An internal analysis conducted by CMS of Part D prescription drug event (PDE) data from 2018 to 2023 showed that the percentage of Part D claims for opioids (excluding medications used for opioid use disorder) with 7 days’ supply or less positively increased from 18.4% in 2018 to 27.7% in 2023 after the implementation of enhanced opioid safety edits at POS in 2019.(2) For the IOP-LD measure specifically, measure rates have decreased by roughly 1-2% per year in both MAPD and PDP lines of business, as shown in Section 2.4 Performance Gap.

Additionally, Medicare plan sponsors are required to establish a drug management program (DMP) for beneficiaries at risk for misuse or abuse of frequently abused drugs, and beneficiaries with potential patterns of opioid misuse or with a history of opioid-related overdose are to be included in DMPs per the established retrospective criteria codified at § 423.153(f).

Given these regulatory requirements and observed reductions in initial opioid-prescribing of long duration, there is ample evidence that health plans can implement effective strategies to improve performance on this measure.

References:

1. Centers for Medicare & Medicaid Services. *42 CFR § 423.153 Drug utilization management, quality assurance, medication therapy management (MTM) programs, drug management programs, and access to Medicare Parts A and B claims data extracts*. 2025. Accessed April 18, 2025. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-423/...>
2. Centers for Medicare & Medicaid Services. *Contract Year (CY) 2025 Medicare Part D Opioid Safety Edits – Submission Instructions, Recommendations, and Reminders*. 2024. Accessed April 18, 2025. <https://www.cms.gov/files/document/cy-2025-opioid-safety-edit-submissio...>
3. Centers for Medicare & Medicaid Services. *Medicare Part D Opioid Safety Edit Reminders and Recommendations and Frequently Asked Questions (FAQs)*. 2022. Accessed April 18, 2025. <https://www.cms.gov/files/document/cy-2023-opioid-safety-edit-reminders...>
4. Centers for Medicare & Medicaid Services. *Medicare and Medicaid Programs; Contract Year*

2026 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly. 2024. p. 427.

6.2.2 Feedback on Measure Performance

PQA surveys measure licensees to understand the use of PQA measures and related needs. Across 300 responses received since 2021, none have included comments specifically related to performance, implementation concerns, or unintended consequences associated with the IOP-LD measure.

PQA also provides no-cost technical assistance to measure users and the public. Since 2022, PQA has received a total of seven technical assistance requests regarding the IOP-LD measure. Six of those requests sought clarification of the measure's specifications; one request was related to the measure's value sets. Each question received is reviewed for potential specification updates.

PQA is in regular contact with the program administrator for the Medicare Part D quality program (i.e., CMS), where the IOP-LD measure is in use. The CMS Part C&D team has not raised specific questions or concerns with the implementation of the IOP-LD measure within the program.

6.2.3 Consideration of Measure Feedback

In response to feedback received through PQA technical assistance channels, PQA has made minor modifications to the measure's specifications to improve clarity, outlined below:

--Added language to improve clarity for the Negative Medication History definition to note that for an individual to have a negative medication history, there should be no prescription claims for opioids "with a date of service" in the lookback period.

--Removed language from the Eligible Population note section, related to calculating days' supply, that was not applicable to the denominator. The removed language was applicable only to the numerator and therefore was not removed from the numerator note.

PQA maintains measures using a transparent, systematic, consensus-based process that involves several multistakeholder panels, including the Measure Update Panel (MUP) and Quality Metrics Expert Panel (QMEP). Potential changes to measures are considered by the PQA team and discussed and voted on by the aforementioned panels. Additional refinements to the IOP-LD

measure specifications were made through this process in response to updated evidence. These included adding new exclusions for individuals receiving palliative care or with cancer-related pain.

6.2.4 Progress on Improvement

Across MAPDs and PDPs, average measure scores improved (i.e., decreased, as a lower score indicates better performance) each year from 2020 to 2022. Overall rates across MAPDs decreased from 21.0% in 2020, to 18.9% in 2021 and 18.2% in 2022. Rates among PDPs decreased from 15.7% in 2020, to 14.0% in 2021 and 12.9% in 2022.

These trends are promising and evidence that the measure is an effective tool to reduce high-risk initial opioid prescriptions. However, there is still room for improvement. Among MAPD contracts in 2022, contracts in the tenth decile had an average rate of 54.5% with a maximum of 89.6%.

6.2.5 Unexpected Findings

There were no unexpected findings during the implementation of this measure.

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The measure developer is different from the measure steward

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