

Measure Specifications

1. Concurrent Use of Opioids and Benzodiazepines

Description

This measure examines the percentage of individuals 18 years and older with concurrent use of prescription opioids and benzodiazepines.

The denominator includes individuals 18 years and older by the first day of the measurement year with 2 or more prescription claims for opioids filled on 2 or more separate days, for which the sum of the days supply is 15 or more days during the measurement period. Patients in hospice care and those with a cancer diagnosis are excluded.

The numerator includes individuals from the denominator with 2 or more prescription claims for benzodiazepines filled on 2 or more separate days, and concurrent use of opioids and benzodiazepines for 30 or more cumulative days.

Definitions

Opioids	See Table COB-A: Opioids
Benzodiazepines	See Table COB-B: Benzodiazepines
Concurrent Use	Overlapping supply for an opioid and a benzodiazepine for 30 or more cumulative days.
Measurement Year	The time period when the measure is assessed, generally the calendar year.

Rationale

The purpose of quality measurement is to improve quality of care, inform consumers and influence payment. At this time, the goal is to develop measure concepts that are indicative of potential improvements in or to our healthcare system so that evidence-based patient care can be provided and positive patient outcomes can be achieved, while considering costs, and ultimately, patient safety.

Since 1999, the amount of prescription opioids sold in the U.S. nearly quadrupled, as did deaths from prescription opioids.¹ Prescription opioid-related deaths are now considered to be one of the leading preventable public health problems.² In 2010, the US government released its first National Drug Control Strategy, stating that overdoses from opioids is a “growing national crisis”.³ In 2010, opioids were associated with the most pharmaceutical-related overdose deaths (75.2%), followed by benzodiazepines (29.4%).⁴ In addition, benzodiazepines use was associated with 30.1% of opioid overdose deaths and opioid use was associated with 77.2% of benzodiazepine overdose deaths. Concurrent use of opioids and benzodiazepines, both central nervous system (CNS) depressants, increases the risk for severe respiratory depression, which can be fatal. These adverse events can occur in patients that do not exhibit signs of drug abuse.

Several studies suggest that concurrent use of opioids and benzodiazepines might put patients at greater risk for potentially fatal overdose. Three studies of fatal opioid overdose deaths found evidence of concurrent benzodiazepine use in 31%–61% of decedents.^{5–7} In one study, the rates of nonmedical use-related emergency department visits and overdose deaths involving both opioid analgesics and benzodiazepines approximately tripled from 2004 to 2011, and benzodiazepines were involved in 31% of opioid overdose deaths in 2011.⁷ Benzodiazepines were determined to be involved in 61% of opioid-related deaths in 2010 among North Carolina residents receiving prescription opioids.⁶ Furthermore, benzodiazepines are increasingly involved in opioid overdose deaths. The number of opioid overdose deaths involving benzodiazepines increased 14% on average each year from 2006 through 2011, while the number of opioid analgesic overdose deaths not involving benzodiazepines did not change significantly.⁸ Lastly, a case-cohort study found that concurrent use of benzodiazepines among US veterans using opioids raised the risk of drug overdose deaths four-fold (hazard ratio = 3.86, 95% confidence interval = 3.49-4.26) compared with patients not using benzodiazepines.⁹ See Appendix A for an evidence table of evaluated studies.

Despite the risks described above, concurrent prescriptions for opioids and benzodiazepines is common and increasing.^{10,11} In one study, approximately half of the patients received both the opioid and benzodiazepine prescriptions from the same prescriber on the same day.¹⁰ In an analysis from 2015 in the non-cancer or non-hospice enrolled Medicare Part D opioid user population, the prevalence of opioid and benzodiazepine concurrent use (any day with overlapping supply) was 24%.¹¹

According to the *Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain – United States, 2016*, clinicians should avoid prescribing opioid pain medications and benzodiazepines whenever possible.¹² This is a Category A recommendation (applies to all persons; most patients should receive the recommended course of action) and is based on Type 3 evidence (observational studies or randomized clinical trials with notable limitations). In August 2016, the US Food and Drug Administration added concurrent use of opioids and benzodiazepines as a boxed warning to the labeling of prescription opioid pain and cough and benzodiazepines products.¹³ The Centers for Medicare and Medicaid Services (CMS) is also concerned with both the high prevalence of concurrent opioids and benzodiazepines therapy, as well as instances of very long durations of use. In the 2017 Final Call Letter,¹⁴ CMS discussed these concerns and encouraged Part D sponsors to evaluate their claims data and use available drug utilization management tools to help address the concurrent use of these drug classes. Starting in October 2016, CMS added a concurrent opioid-benzodiazepine use flag to the OMS reports in an effort to assist Part D sponsors in addressing this issue.¹⁵

This measure was designed for monitoring and improving quality of care across populations of patients. Patients with cancers diagnoses and those receiving hospice care are excluded from the measure because of the unique therapeutic goals, ethical considerations, opportunities for medical supervision, and balance of risks and benefits with opioid therapy in such care.¹² Concurrent use of opioids and benzodiazepines has an unfavorable balance of benefit and harm for most individuals.

Although there are circumstances when it might be appropriate to prescribe opioids to a patient receiving benzodiazepines (e.g., severe acute pain in a patient taking long-term, stable low-dose benzodiazepine therapy), clinicians should avoid prescribing opioids and benzodiazepines concurrently whenever possible. The CDC guideline cautions against abrupt withdrawal from benzodiazepines, which can be associated with hallucinations, seizures, and in rare cases, death; the guideline also provides specific strategies to improve safety while tapering opioids or benzodiazepines.¹²

Intended Use	Performance measurement for health plans.
Related Measures	PQA Performance Measures: <ul style="list-style-type: none">• <i>Use of Opioids from Multiple Providers or at High Dosage in Persons Without Cancer</i>

Eligible Population

Ages	18 years and older by the first day of the measurement year.
Benefit	Pharmacy.
Treatment Period	The individual's treatment period begins on the date of the first prescription claim of any target medication (Tables COB-A: Opioids and COB-B: Benzodiazepines) and extends through whichever occurs first: the last day of the measurement year, death, or disenrollment.
Continuous Enrollment ...using enrollment data	Individuals should be continuously enrolled during the treatment period.
Allowable Gap for Medicaid	No more than one gap in continuous enrollment of up to 45 days during the treatment period. To determine continuous enrollment for a Medicaid beneficiary for whom enrollment is verified monthly, the enrollee may not have more than a 1-month gap in coverage (i.e., an enrollee whose coverage lapses for 2 months [60 consecutive days] is not considered continuously enrolled).

Administrative Specification

Data Sources	Medical claims, Pharmacy claims, Prescription Drug Hierarchical Condition Categories (RxHCCs)
Denominator	The number of individuals from the eligible population with 2 or more prescription claims for any opioid (see Table COB-A: Opioids) filled on 2 or more separate days, for which the sum of the days supply is 15 or more days during the measurement period.

Numerator	<p>The number of individuals from the denominator with:</p> <ul style="list-style-type: none"> • 2 or more prescription claims for any benzodiazepine (Table COB-B: Benzodiazepines) filled on 2 or more separate days, AND • Concurrent use of opioids and benzodiazepines for 30 or more cumulative days. <p>Concurrent use is identified using the dates of service and days supply of an individual's opioid and benzodiazepine prescription drug claims. The days of concurrent use is the sum of the number of days during the treatment period with overlapping days supply for an opioid and a benzodiazepine.</p>
Exclusion	<p>Hospice: Any patient with a hospice indicator from the enrollment database during the measurement year is excluded from the denominator.</p> <p>Cancer diagnosis: Any patient with a cancer diagnosis during the measurement year is excluded from the denominator.</p> <p>Commercial, Medicaid, or Medicare data (if available):</p> <ul style="list-style-type: none"> • ICD-9 or ICD-10 codes, based on the American Medical Association-convened Physician Consortium for Performance Improvement Cancer value set (OID: 2.16.840.1.113883.3.526.3.1010). Available at: https://vsac.nlm.nih.gov/ (See Appendix B: Cancer Diagnosis Codes) • A cancer diagnosis is defined as having a by having at least one claim with any of the listed cancer diagnoses, including primary diagnosis or any other diagnosis fields during the measurement year. <p>Medicare Data (if ICD codes not available)</p> <ul style="list-style-type: none"> • RxHCCs 8, 9, 10, 11 for Payment Year 2015; or RxHCCs 15, 16, 17, 18, 19 for Payment Year 2016 Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvRateStats/Risk-Adjustors.html
Stratification	<p>Commercial, Medicaid, Medicare (report each product line separately).</p> <p>Low-income subsidy (LIS) population (report rates for LIS population and non-LIS population separately).</p>

Medication Tables

Table COB-A: Opioids^a

Opioid Medications		
buprenorphine ^b	hydromorphone	oxycodone
butorphanol	levorphanol	oxymorphone
codeine	meperidine	pentazocine
dihydrocodeine	methadone	tapentadol
fentanyl ^c	morphine	tramadol
hydrocodone	opium	

^a Excludes injectable formulations.

^b Excludes single-agent and combination buprenorphine products used to treat opioid use disorder (i.e., buprenorphine sublingual tablets, Probuphine® Implant kit subcutaneous implant, and all buprenorphine/naloxone combination products).

^c Excludes Ionsys® (fentanyl transdermal patch), as it is only for inpatient use and is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS).

Table COB-B: Benzodiazepines^a

Benzodiazepines		
alprazolam	diazepam	oxazepam
chlordiazepoxide	estazolam	quazepam
clobazam	flurazepam	temazepam
clonazepam	lorazepam	triazolam
clorazepate	midazolam	

^a Excludes injectable formulations

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2. Adherence to Non-Infused Disease Modifying Agents Used to Treat Multiple Sclerosis

Description

The percentage of patients 18 years and older who met the Proportion of Days Covered (PDC) threshold of 80% during the measurement period for medications treating multiple sclerosis (MS).

Definitions

Proportion of Days Covered (PDC)	The proportion of days in the measurement period “covered” by prescription claims for the same medication or another in its therapeutic category.
PDC Threshold	The level of PDC above which the medication has a reasonable likelihood of achieving most of the potential clinical benefit.
Index Date	The date of the first fill of the target medication.
Medications Use to Treat Multiple Sclerosis	<p>Oral or self-administered (included in the measure):</p> <ul style="list-style-type: none">• beta interferons (Avonex, Betaseron, Extavia, Rebif)• glatiramer (Copaxone)• fingolimod (Gilenya)• teriflunomide (Aubagio)• dimethyl fumarate (Tecfidera)• peginterferon beta-1a (Plegridy) <p>Infused (excluded from the measure):</p> <ul style="list-style-type: none">• alemtuzumab (Lemtrada)• mitoxantrone (Novantrone)• natalizumab (Tysabri)

Rationale

Multiple sclerosis (MS) is an inflammatory demyelinating disease most commonly occurring in females with a typical onset between the ages of 30 and 45. In approximately 85% of cases, it is characterized by an early relapsing-remitting inflammatory phase (called relapsing-remitting multiple sclerosis or RRMS), followed by a secondary progressive course in which the patient’s disability progresses. During RRMS, the patient will experience relapses that tend to increase in number, duration and severity. As the

disease progresses, patient disability and the burden on society also increase.

While there is no cure for MS, there are disease modifying agents that may limit the number of relapses a patient experiences, and thus slow disease progression. While these therapies have been shown to be effective in reducing the severity and frequencies of relapses in RRMS patients, there are potential barriers that patients face when taking these medications, which can lower adherence. If the patient is non-adherent to the medications, the clinical effectiveness may be compromised leading to disease progression and an increase in relapse severity, frequency, and duration. Additionally, as the disease progresses, a patient's quality of life decreases and their ability to work is compromised.

Eligible Population

Age	19 years and older as of the last day of the measurement period.
Continuous enrollment ...using enrollment data	<ul style="list-style-type: none">Subjects should be continuously enrolled during the measurement period, with no lapse in coverage.To determine continuous enrollment for a Medicaid beneficiary for whom enrollment is verified monthly, the member may not have more than a 1-month gap in coverage (i.e., a member whose coverage lapses for 2 months [60 consecutive days] is not considered continuously enrolled).
Measurement Period	The patient's measurement period begins on the date of the first fill of the target medication (i.e., index date) and extends through the last day of the enrollment period or until death or disenrollment. The index date should occur at least 91 days before the end of the measurement period.
Benefit	Pharmacy
Stratification	Commercial, Medicaid, Medicare (report each product line separately)

Administrative Specification

Data Source: Prescription claims data

Denominator: Patients who filled at least two prescriptions for non-infused disease modifying agents treating multiple sclerosis on two unique dates during the measurement period and who received at least 56 days supply of the medication during the measurement period.

Exclusions: Patients who received one or more prescriptions for a medication in Table

MS PDC-B: Infused Medications Treating MS in the measurement period.

Numerator: The calculation for this adherence measure will be the same as other PQA adherence measures using the steps below.

Numerator The number of patients in the denominator that met the PDC threshold during the measurement year. Follow the steps below for each patient to determine whether the patient meets the PDC threshold.

Step 1 Determine the patient's measurement period, defined as the index prescription date to the end of the enrollment year, disenrollment, or death.

Step 2 Within the measurement period, count the days the patient was covered by at least one drug in the class based on the prescription fill date and days of supply. If prescriptions for the same drug (generic ingredient) overlap, then adjust the prescription start date to be the day after the previous fill has ended.*

Step 3 Divide the number of covered days found in Step 2 by the number of days found in Step 1. Multiply this number by 100 to obtain the PDC (as a percentage) for each patient.

Step 4 Count the number of patients who had a PDC of 80% or greater and then divide by the total number of eligible patients.

*Adjustment of overlap should also occur when there is overlap of a single drug product to a combination product containing the single target drug or when there is an overlap of a combination product to another combination product where at least the target drug is common.

An example of SAS code for steps 1-3 is available from PQA upon request, and is also available at the URL: <http://www2.sas.com/proceedings/forum2007/043-2007.pdf>

Table MS PDC-A: Non-Infused Disease Modifying Agents Treating MS

Beta Interferons		
• interferon beta 1a	• interferon beta 1b	• peginterferon beta-1a
Immunomodulators		
• glatiramer	• fingolimod	
Pyrimidine Synthesis Inhibitors		
• teriflunomide		
Nrf2 Activators		
• dimethyl fumarate		

Table MS PDC-B: Infused Disease Modifying Agents Treating MS (Exclusions)

Infused Disease Modifying Agents Treating MS		
alemtuzumab	mitoxantrone	• natalizumab

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