Project 3.3 Target Population

* 3.3.1 - Adherence to Medications
* 3.3.3 - High-cost Pharmaceutical Ordering Protocols
* 3.3.4 - Documentation of Medication Reconciliation in the Medical Record for Patients Taking High Cost Pharmaceuticals

# Project 3.3 – Target Population

**Eligible Population**

**Encounter Codes**

 N/A

**PRIME Eligible Population for Designated Public Hospitals (DPHs) only:**

The **PRIME Eligible Population** includes the combination of both Population #1 and Population #2. An individual does not have to meet criteria of both Population #1 and Population #2. Any individual who meets either PRIME Eligible Population #1 criteria or PRIME Eligible Population #2 criteria must be included in the PRIME Eligible Population.

Population #1:

Individuals of all ages with at least 2 encounters with the PRIME Entity Primary Care team during the measurement period.

* + A Primary Care team encounter is counted if occurred with a member of the Primary Care Team from Family Medicine, Internal Medicine, or Pediatrics.  The PRIME Entity may choose to include populations who are seen for primary care in a specialty clinic (e.g. HIV)
	+ Encounters include either a face-to-face visit with a primary care provider OR any encounter included in the list of eligible non-traditional service types described in the Global Payment Program1 (for PRIME, encounters not limited to uninsured individuals.)
	+ Only encounters with the Primary Care team in the ambulatory setting will be counted toward the above 2 encounter requirement. Encounters with primary care team members in the inpatient setting do not count toward the two primary care encounter requirement. [This does not impact the expansion of the PRIME Eligible Population to include inpatient or acute care utilization as specified by the Project Target Population criteria e.g. in Domain 3]

OR

Population #2

Individuals of all ages who are in Medi-Cal Managed Care with 12 months of continuous assignment to the PRIME Entity during the Measurement Period.

* + No more than one gap in enrollment or assignment with the PRIME Entity of up to 45 days during the Measurement Period.
	+ Individual must be enrolled in the primary plan and assigned to the PRIME Entity on the final day of the Measurement Period.

**PRIME Eligible Population for District Municipal Hospitals (DMPHs) only:**

The **PRIME Eligible Population** is all individuals with at least two encounters during the measurement period with the participating PRIME entity among Medi-Cal Beneficiaries.

**Tenure Criteria for DPH PRIME Eligible Population Encountered Lives (DPH Population #1)**

* 1. The first of the two required primary care encounters (DPH) must occur during the first 6 months of the measurement period
	2. The second required (primary care) encounter may occur at any point during the measurement period.
	3. The two (primary care) encounters during the measurement period fulfilling the PRIME Eligible Population eligibility criteria cannot occur on the same day.

**Tenure Criteria for DMPH PRIME Eligible Population Encountered Lives**

* 1. The first of the two required Medi-Cal encounters (DMPH) must occur during the first 6 months of the measurement period.
	2. The second required Medi-Cal encounter may occur at any point during the measurement period.
	3. The two Medi-Cal encounters during the measurement period fulfilling the PRIME Eligible Population eligibility criteria cannot occur on the same day.

**Exclusion Criteria for DPH/DMPH PRIME Eligible Population**

Exclusion for patients no longer the responsibility of the PRIME Entity at the end of the measurement period:

* 1. Any patient meeting the PRIME Eligible Population Encountered Lives criteria in a given measurement period who then experiences any of the following scenarios, will be removed from the PRIME Eligible Population for that measurement period, to the extent that the PRIME entity has readily available documentation to demonstrate that before the end of the measurement period:
	2. The patient has died.
	3. The patient has changed their care to a PCP in a health system that is not the PRIME Entity.
	4. The patient has had a total time of incarceration during the measurement period that exceeded 45 days, regardless of the number of times the individual was incarcerated during the measurement period.

**Project 3.3 Target Population**

are those in the PRIME Eligible Population prescribed at least one of the high cost pharmaceuticals targeted for focus in the DY by the PRIME Entity.

***Project 3.3 Reporting of Cumulative Drugs and Dual Performance Rates***

As per Core Component #3 of Project 3.3 Project 3.3 Resource Stewardship: Therapies Involving High-Cost Pharmaceuticals on page 74 of the California 1115 Waiver – Medi-Cal 2020’s Standard Terms and Conditions, Attachment Q - PRIME Projects and Metrics Protocol, the PRIME entity will:

“3. Develop a data analytics process to identify the participating PRIME entity highest cost pharmaceuticals (high-cost medications or moderate-cost meds with high prescribing volume). Identify high-cost medications whose efficacy is significantly greater than available lower cost medications.

* 1. Using purchase price data, Identify the Top 20 medications and medication classes, focusing on the following: Analgesics, Anesthetics, Anticoagulants, Anti-Neoplastics, Diabetes, Hepatitis C, Immunoglobulins, Mental Health (Anti-Depressants/Sedatives/ Anti-Psychotics), Respiratory (COPD/Asthma), Rheumatoid Arthritis”

While not stated in Attachment Q, the PRIME Entity will be required to target, at minimum, 3 new medications each DY, so that by the end of DY 15, the PRIME Entity is monitoring adherence of 15 of the top 20 identified high cost pharmaceuticals referenced in Attachment Q. The same 3 drugs (at minimum) must be chosen across the board for each specification.

Number of high cost pharmaceuticals to be targeted for management under Project 3.3 by the PRIME Entity for each DY is as follows:

* 1. DY 11: 3 high cost pharmaceuticals
	2. DY 12: 6 high cost pharmaceuticals
	3. DY 13: 9 high cost pharmaceuticals
	4. DY 14: 12 high cost pharmaceuticals
	5. DY 15: 15 high cost pharmaceuticals

Entities should report the pharmaceuticals they are targeting in the PRIME reporting project narrative. Because of the difference in number of pharmaceuticals target each year, in order to create comparable numerators and denominators from one year to the next for the purposes of target setting and performance tracking, each PRIME entity will report two sets of performance data at the end of each reporting period as follows:

* 1. Rate #1: Metric performance based on the high cost pharmaceuticals targeted for management in the prior DY
	2. Pay for Performance with Achievement Value based on the metric performance rate meeting the metric target which is determined using standard PRIME P4P target setting methodology.
	3. Eligible Funding: 100% of the metric value
	4. Rate #2: Metric performance based on the high cost pharmaceuticals targeted for management in the current DY.
	5. Release of Funds for Reporting of each metric performance rate
	6. Release of funds for  Rate #1 Achievement Value will be contingent on reporting of Rate #2
	7. This rate establishes a baseline for the next DY. The rate is still required in DY15 because the expectation is each PRIME entity will continue measuring these rates after PRIME has concluded.

***Dual Reporting Rates: Reporting Business Logic***

The PRIME Entity will report two rates for each metric for each DY as follows:

* 1. DY 14:
	2. Rate #1 Initial Population =
	3. AND: PRIME Eligible Population
	4. AND: Occurrence of ≥2 two prescription drug claims for any of the 9 DY 13 specified high cost pharmaceutical medications during the measurement period
	5. Rate #2 Initial Population =
	6. AND: PRIME Eligible Population
	7. AND: Occurrence of ≥2 two prescription drug claims for any of the 12 DY 14 specified high cost pharmaceutical medications during the measurement period
	8. DY 15:
	9. Rate #1 Initial Population =
	10. AND: PRIME Eligible Population
	11. AND: Occurrence of ≥2 two prescription drug claims for any of the 12 DY 14 specified high cost pharmaceutical medications during the measurement period
	12. Rate #2 Initial Population =
	13. AND: PRIME Eligible Population
	14. AND: Occurrence of ≥2 two prescription drug claims for any of the 15 DY 15 specified high cost pharmaceutical medications during the measurement period

**Example:**

* 1. An entity selects the following high cost medications:
	2. DY13: 9 oncology medications
	3. DY14: 3 HIV medications
	4. Rates to report for DY12
	5. Rate #1: metric rates (adherence, medication reconciliation, and use of ordering protocols) of patients taking the 9 oncology medications
	6. Rate #2: metric rates of patients taking the 9 oncology medications and the 3 HIV medications
	7. The following year, the same entity selects the following high cost medications:
	8. DY15: 3 Hepatitis C medications
	9. Rates to report for DY15
	10. Rate #1: metric rates of patients taking the 9 oncology medications and the 3 HIV medications
	11. Rate #2: metric rates of patients taking the 9 oncology medications, the 3 HIV medications, and the 3 Hepatitis C medications

# 3.3.1 - Adherence to Medications

**Summary of Changes from DY14 Year End Reporting Manual**

* Metric Description
	+ Modified first sentence
		- From: “Percentage of high cost pharmaceuticals prescribed for individuals 18 years of age or older with that had a Proportion of Days Covered (PDC) of at least 0.8 during the treatment period.”
		- To: “Percentage of high cost pharmaceuticals prescribed for individuals 18 years of age or older with that had a Proportion of Days Covered (PDC) of at least 0.8 during the PDC period”
	+ Moved from Numerator Statement to Metric Description “If a patient is taking two or more specified high cost pharmaceuticals, a PDC is calculated separately for each high cost pharmaceutical they are taking.”
	+ Added “If selected medications are in the same drug class, the PDC is counted separately for each medication.”
* Numerator Statement
	+ Changed from “Individuals with high cost pharmaceuticals who had at least two drug claims or fills for the specified pharmaceuticals and had a PDC of at least 0.8 for the specified pharmaceuticals
	+ To “Denominator high cost pharmaceuticals that had a PDC of at least 0.8 during the PDC period.”
	+ Example
		- Added to end of first sentence: “…with 2+ fills for each medication.”
		- Denominator changed
			* From: “(patient is counted twice for taking two selected high cost medications)”
			* To: “(once for each of the selected high cost medications)”
* Numerator Details, removed first sentence as duplicative of Numerator Statement
* Denominator Statement, revised.
	+ From: “Individuals from the PRIME Eligible population at least 18 years of age as of the beginning of the measurement period with at least two prescription drug claims for any of the specified high cost pharmaceutical medications during the measurement period (12 consecutive months).”
	+ To: “High cost pharmaceuticals with at least two prescription drug claims during the PRIME measurement period by individuals from the PRIME Eligible population at least 18 years of age as of the beginning of the measurement period.”
	+ Last sentence removed as it refered to patients being counted, rather than medications.
	+ Language from Denominator Exclusion moved into a new Denominator Note “For infused medications, the high cost pharmaceutical should have a minimum duration of two doses. PRN or “as needed” medications are excluded.”
* Denominator Exclusions changed to “None”
	+ First statement removed as it only described a medication not meeting denominator criteria
	+ Second sentence moved to Denominator Statement, under Denominator Note.
* Definitions, rearranged to be in alphabetical order
* Definitions
	+ Treatment Period, added new second sentence “Starts on the first date of the drug claim or fill for a specific medicine and ends on the date of the end of the last supply date for that same specific medicine.”
	+ Proportion of Days Covered (PDC), changed “death” to “death of the patient prescribed the medication”
* Business Logic
	+ “Numerator” definition removed as duplicative of Numerator Statement.
	+ Throughout, changed language so that it is clear that the numerator is calculated based on medications not individuals.
	+ Step 3, added the word “drug”. First sentence now reads “Calculate the PDC for each individual drug.”
	+ Renumbered #6 as #5. Removed outline format from #5. Paragraph now follows after new step #5.
* Calculation Example
	+ Moved this section to follow the paragraph at the end the Business Logic, rather than precede former Step #6 of the Business Logic.
	+ Removed years from the example dates
	+ First bullet, Step c,i added:
		- “This calculation is for a once daily medication. For medications taken more than once daily, the days’ supply can be found by dividing the number of pills by the amount of pills taken per day.
			* Example: if a patient received a total of 30 pills and took the medication twice daily, then the number of days covered by the prescription fills is 15 days (30 pills/2 pills per day)”
	+ Both bullets, Step C, changed “Medication will last until…” to “Medication will last for 30 days until…”
* PDC Calculation from Patient Interview
	+ Changed Numerator “…60 tablets” to “…60 pills and takes one daily”
	+ Changed Denominator “pills” to “days supply”

**Summary of Changes from DY13 Year End Reporting Manual**

* Removed link:
	+ <http://www.pqaalliance.org/images/uploads/files/PQA%20PDC%20vs%20%20MPR.pdf>
* Added links to documents: “Shifting Days Supply PDC”, “PDC Shifting Example”, “PDC vs. MPR”
* Updated link to Proportion of Days Covered (PDC) Calculator

**Modification from Native Specification**

Specification Source: PRIME Innovative Measure Steward (Santa Clara Valley Health System), Variation on [NQF 2467](http://www.qualityforum.org/QPS/2467))

Measure Steward: Santa Clara Valley Health System

* N/A

**Value Sets for this metric:**

* N/A. No value sets or codes included in this metric.

CMS Special Innovation Project Maintenance and Development of Medication Measures

***Metric Description***

Percentage of high cost pharmaceuticals prescribed for individuals 18 years of age or older that had a Proportion of Days Covered (PDC) of at least 0.8 during the PDC period. The intent of the metric is to improve patients’ level of adherence to taking high cost pharmaceuticals.

a PDC is calculated high cost pharmaceutical If selected medications are in the same drug class, the PDC is counted separately for each medication.

***Subject/Topic Areas***

Cross-Cutting Areas: Disparities, Safety: Medication Safety

***Numerator Statement***

High cost pharmaceuticals from the denominator that had a PDC of at least 0.8 during the PDC Period.

Example: a patient is taking one selected HIV medication and one selected Hepatitis C medication with 2+ fills for each medication. The PDC was found to be: Hepatitis C medication = 0.9 and HIV medication = 0.7

* Numerator = 1 (only Hepatitis C medication had a PDC of at least 0.8)
* Denominator = 2 (once for each of the selected high cost medications)

***Time Period for Data***

The measurement period.

***Numerator Details***

The PDC is calculated as follows:

***PDC NUMERATOR***

The PDC numerator is the sum of the days covered by the days’ supply of all prescription drug claims for all the high cost pharmaceutical medications targeted by the PRIME entity for PRIME Project 3.3. The period covered by the PDC (“PDC Period”) starts on the day the first prescription is filled (index date) and lasts through the end of one of the following (whichever comes first):

* the treatment period
* the measurement period, if treatment period spans multiple demonstration years
* death

For prescription drug claims with a days’ supply that extends beyond the end of the measurement period, count only the days for which the drug was available to the individual during the measurement period. If claims for the same drug (generic name) overlap, then adjust the prescription start date to be the day after the previous fill has ended.

For medications infused by a healthcare professional, the numerator may be calculated using the number of medication doses given as documented in the Medication Administration Record (MAR).

*\* If any of the Project 3.3 targeted high cost pharmaceutical medications are for Hepatitis C treatment with an anticipated duration of 24 weeks or fewer, the PRIME Entity should exclude the first fill of the Hepatitis C medication from the PDC calculation. Thus the PDC Period for Hepatitis C medications starts on the day the second prescription is filled.*

***PDC DENOMINATOR***

The PDC denominator is the number of days in the PDC Period.

For medications infused by a healthcare professional, the denominator may be calculated using the number of medication doses scheduled as specified in the physician order.

***Denominator Statement***

High cost pharmaceuticals with at least two prescription drug claims during the PRIME measurement period by individuals from the PRIME Eligible population at least 18 years of age as of the beginning of the measurement period.

While not stated in Attachment Q, the PRIME Entity will be required to target, at minimum, 3 new medications each DY, so that by the end of DY 15, the PRIME Entity is monitoring adherence of 15 of the top 20 identified high cost pharmaceuticals referenced in Attachment Q.

*Denominator Note:*

***Denominator Exclusions***

None.

***Denominator Codes***

Each PRIME entity will be responsible for identifying the targeted high cost pharmaceuticals, the corresponding tracking codes (e.g., NDC, or local codes) and the mechanisms with which to obtain the prescription claims data, from within their own institutions and/or from partner dispensing pharmacies or agencies.

Each PRIME entity will be required to include their own PRIME entity uninsured pharmacy claims data and work with a minimum of one Medi-Cal Managed Care plan for the plan pharmacy claims data. PRIME Entities will be encouraged to work with more than one plan over the 5 year duration of PRIME, although this is not a requirement. In addition to insurance data, other sources of claims data (e.g. audit results, pharmacy data, or patient interviews) may be used. For infused medications, the MAR will serve as the source of data for the adherence calculation.

***Definitions***

**High Cost Pharmaceuticals**

As per Core Component #3 of Project 3.3 Project 3.3 Resource Stewardship: Therapies Involving High-Cost Pharmaceuticals on page 74 of the California 1115 Waiver – Medi-Cal 2020’s Standard Terms and Conditions, Attachment Q - PRIME Projects and Metrics Protocol, the PRIME entity will:

“3. Develop a data analytics process to identify the participating PRIME entity highest cost pharmaceuticals (high-cost medications or moderate-cost meds with high prescribing volume). Identify high-cost medications whose efficacy is significantly greater than available lower cost medications.

* 1. Using purchase price data, Identify the Top 20 medications and medication classes, focusing on the following: Analgesics, Anesthetics, Anticoagulants, Anti-Neoplastics, Diabetes, Hepatitis C, Immunoglobulins, Mental Health (Anti-Depressants/Sedatives/ Anti-Psychotics), Respiratory (COPD/Asthma), Rheumatoid Arthritis ”

**Index Prescription Date**

The day the first prescription is filled.

**Proportion of Days Covered (PDC) Period**

The number of days from the date of the first prescription drug claim (index date) through the end of one of the following (whichever comes first):

* the treatment period
* the measurement period if treatment period spans multiple demonstration years
* death of the patient prescribed the medication

**Treatment Period**

The indicated duration of treatment. Starts on the first date of the drug claim or fill for a specific medicine and ends on the date of the end of the last supply date for that same specific medicine. The treatment period will always be equal to or less than the full measurement period.

***Business Logic***

Report two performance rates for this metric at each reporting period as per [Dual Reporting Rates: Reporting Business Logic](#_Dual_Reporting_Rates:).

Create Numerator:

For each high cost pharmaceutical in the denominator, calculate the PDC according to the following methods:

1. Determine the medication’s PDC Period.
	1. For medications infused by a healthcare professional, if the order is held, this should be interpreted as the end of therapy for the patient. If the patient restarts the medication, the date of the restart can be considered the index prescription date.
2. Within the PDC Period, count the days the individual was covered by that high cost pharmaceutical based on the prescription drug claim service date and days of supply.
	1. Calculate the number of days covered by the specified high cost pharmaceutical.
		1. Assume patients start taking the medication the day after they received the medication. At the latest, high cost medications should be filled on the day when patients are taking the last pill in order to assure compliance.
		2. For prescription drug claims with a days’ supply that extends beyond the end of the measurement period, count only the days for which the drug was available to the individual during the measurement period.
		3. If claims for the same drug (generic name) overlap, then adjust the prescription start date to be the day after the previous fill has ended.
3. Calculate the PDC for each individual medication. Divide the number of covered days found in Step 2 by the number of days for each medication’s PDC Period found in Step 1.

An example of SAS code for Steps 1-3 was adapted from Pharmacy Quality Alliance (PQA) and is also available at the URL: <http://www2.sas.com/proceedings/forum2007/043-2007.pdf>.

1. Of the medications identified in Step 3, count the number of medications with a calculated PDC of at least 0.8. This is the numerator.

Calculating the PDC is only possible if claims or fill data for the high cost pharmaceutical is available. As stated previously, each PRIME entity is required to work with a minimum of one MediCal Managed Care plan for the plan pharmacy claims data. Using claims data is the most accurate method of calculating PDC and should be the primary method. However, if the plan provides claims data for fewer than the minimum number of PRIME patients allowed (30) or if claims data is otherwise unavailable, a secondary method of calculating PDC may be accomplished via phone calls or in-person interviews:

* 1. There must be patient contact on at least a monthly basis either by phone or in-person consultation.
	2. **Questions to ask patient**:
		1. Regarding your last bottle of medication, on the label of the bottle:
		2. What is the date written on the label?
		3. How many pills does it say were in the bottle?
	3. Using the patient responses, you will be able to calculate the PDC (see calculation example below) after obtaining information from at least two fills.
	4. **Exclusion criteria:** patients who do not have their original bottle of medication for at least two consecutive fills or who have filled their medication only once.

**Calculation example**

Drug: Harvoni (ledipasvir/sofosbuvir) 90mg/400mg one tablet PO daily

* Regarding your last bottle of medication, on the label of the bottle:
	1. What is the date written on the label? **August 22**
	2. How many pills does it say were in the bottle? **30**
	3. Medication will last for 30 days until September 21
		1. Assume patients start taking the medication the day after they received the medication. At the latest, high cost medications should be filled on the day when patients are taking the last pill in order to assure compliance. This calculation is for a once daily medication. For medications taken more than once daily, the days’ supply can be found by dividing the number of pills by the amount of pills taken per day.
			1. Example: if a patient received a total of 30 pills and took the medication twice daily, then the number of days covered by the prescription fills is 15 days (30 pills/2 pills per day)
* Regarding your last bottle of medication, on the label of the bottle:
	1. What is the date written on the label? **September 22**
	2. How many pills does it say were in the bottle? **30**
	3. Medication will last for 30 days until October 22

**PDC Calculation from Patient Interview**

* Numerator: Number of days covered by prescription fills = **60** days
	+ Patient received a total of 60 pills and takes one daily
* Denominator: Treatment duration = (# of days’ supply + coverage gap) = 60 + 1 = **61** days
	+ The first medication fill lasted until 9/21, but was not filled again until 9/22, which led to a coverage gap of 1 day

**PDC: 60/61= 98.4%**

See links for more information on calculating adherence:

* Shifting Days Supply PDC:
	+ <https://safetynetinstitute.org/wp-content/uploads/2019/01/shifting-days-supply-pdc.docx>
* PDC Shifting Example:
	+ <https://safetynetinstitute.org/wp-content/uploads/2019/01/pdc-shifting-example.xlsx>
* PDC vs MPR:
	+ <https://safetynetinstitute.org/wp-content/uploads/2019/01/pdcvsmprfinal.pdf>
* Link to Proportion of Days Covered (PDC) Calculator - PRIME 3.3.1:
	+ [https://www.scvmc.org/health-care-services/Pharmacy/Specialty-Pharmacy/Documents/PDC-calculator-PRIME-3-3.xlsx](https://na01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.scvmc.org%2Fhealth-care-services%2FPharmacy%2FSpecialty-Pharmacy%2FDocuments%2FPDC-calculator-PRIME-3-3.xlsx&data=02%7C01%7C%7Cd23fe28cc23241eab47e08d671c244d6%7C9fbc74aee1b649bb859660f4976881c1%7C0%7C0%7C636821476515145973&sdata=hKtLc%2FIh3S7EK0jA3uLFBVyrinzEWZmwTvliDF%2BXuyQ%3D&reserved=0)

***Sampling***

Not applicable; this metric does not use a sample or survey.

***Survey/Patient-Reported Data***

Not applicable; this metric does not use a sample or survey.

***Missing Data***

To reduce the potential for metric result bias, patients who have prescription drug claims with missing days’ supply are excluded from the analysis.

***Data Source***

* Administrative Claims
* Electronic Clinical Data: Pharmacy

**Measure Steward of** [NQF 2467](http://www.qualityforum.org/QPS/2467)

Centers for Medicare & Medicaid Services (CMS)

Point of Contact: CMS Measures Management System, CMS.Measures.Inventory@hsag.com

Measure Developer: FMQAI, 5201 W. Kennedy Blvd., Suite 900, Tampa, Florida, 33609

***Other Notes as applicable***

A higher rate indicates better quality.

# 3.3.3 - High-cost Pharmaceutical Ordering Protocols

**Summary of Changes from DY14 Year End Reporting Manual**

* Metric Numerator, changed from “…protocol was employed” to “…protocol was used”
* Denominator: added “For PRIME reporting, each entity must list the pharmaceuticals they are monitoring in the project narrative.”
* Exclusions
	+ Renamed to “Denominator Exclusions”
	+ All language modified to exclude the medication rather than the patient.
* Percentage of prescriptions ordered using the protocol
	+ Last sentence, changed “abiding by” to “that utilized”

**Modification from Native Specification**

Specification Source: PRIME Innovative Measure Steward (Santa Clara Valley Health System)

Measure Steward: Santa Clara Valley Health System

* N/A

**Value Sets for this metric:**

* N/A. No value sets or codes included in this metric.

***Metric Description***

Percentage of newly\* prescribed high cost pharmaceutical orders placed abiding by a protocol that was developed and approved by a PHS PRIME entity multidisciplinary team. Only count orders for high cost medications that are newly prescribed to the patient (do not count refills). The protocol must list lower cost alternative and appropriateness of therapy.

\*It is up to each institution to define what a “new” prescription is, but the definition must be independently auditable.

***Metric Numerator***

Number of newly prescribed prescriptions from the denominator in which an ordering protocol was used.

***Numerator Code/s (CPT, ICD10, other)***

* Patient ID
* Date of Ordering Protocol
* Name and date of last revision of Ordering Protocol (reference to the original protocol - need some way of determining that the protocol exists and is up to date)"

***Metric Denominator***

Number of newly prescribed prescription orders for (the identified) high cost pharmaceutical.

While not stated in Attachment Q, the PRIME Entity will be required to target, at minimum, 3 new medications each DY, so that by the end of DY 15, the PRIME Entity is monitoring adherence of 15 of the top 20 identified high cost pharmaceuticals referenced in Attachment Q. See [Project 3.3 Target Population](#_Project_3.3_Target) for number of high cost pharmaceuticals to be targeted in each DY. For PRIME reporting, each entity must list the pharmaceuticals they are monitoring in the project narrative.

***Denominator Code/s (CPT, ICD10, other)***

* Patient ID
* Order date of prescription for Index Medication
* High-Cost Pharmaceuticals as defined in the Core Components of PRIME Project 3.3

***Denominator Exclusions***

* High cost pharmaceutical ordered for inpatient administration during a time when the patient’s status is inpatient or observation
* High cost pharmaceutical received by a patient via home health
* High cost pharmaceutical received by a patient from non-owned and non-contracted clinics

***Reporting Business Logic***

Report two performance rates for this metric at each reporting period as per [Dual Reporting Rates: Reporting Business Logic](#_Dual_Reporting_Rates:).

At the beginning of the demonstration year, the PRIME entity should analyze high cost pharmaceutical purchase price data from the previous 12 months to determine a minimum of three ordering protocols to create during the next demonstration year.

***Definitions as applicable***

**High cost pharmaceuticals**

As per Core Component #3 of Project 3.3 Project 3.3 Resource Stewardship: Therapies Involving High-Cost Pharmaceuticals on page 74 of the California 1115 Waiver - MediCal 2020’s Standard Terms and Conditions, Attachment Q - PRIME Projects and Metrics Protocol, the PRIME entity will:

“3. Develop a data analytics process to identify the participating PRIME entity highest cost pharmaceuticals (high-cost medications or moderate-cost meds with high prescribing volume). Identify high-cost medications whose efficacy is significantly greater than available lower cost medications.

* 1. Using purchase price data, Identify the Top 20 medications and medication classes, focusing on the following: Analgesics, Anesthetics, Anticoagulants, Anti-Neoplastics, Diabetes, Hepatitis C, Immunoglobulins, Mental Health (Anti-Depressants/Sedatives/ Anti-Psychotics), Respiratory (COPD/Asthma), Rheumatoid Arthritis”

Protocols must be based upon current evidence-based literature and developed by a multidisciplinary team. Protocols must include entity-determined inclusion and exclusion criteria, dosing guidelines, laboratory testing requirements, patient monitoring parameter, algorithm for drug selection, and an alternate lower cost therapy option (if available). Note that protocols can be disease state-specific (i.e., multiple drugs in the protocol) or drug-specific (i.e., single drug in the protocol).

**Ordering Protocol**

There are 3 categories of protocols related to medications. All the elements of both #1: Ordering Protocols and #3: SMART Monitoring Protocol, must be included in the “High Cost Pharmaceuticals Ordering Protocols” tracked by this metric:

1. Ordering Protocol:
	1. Disease
	2. Disease state
	3. Algorithm for drug selection
	4. Alternate low-cost therapy option (if available)
	5. Pre-order check list
		1. Pre-Labs (ex: TB)
		2. Interactions (drug-drug, drug-disease)
	6. Medication Order
		1. Drug
		2. Dose
		3. Route
		4. Frequency
		5. Duration/Refills
	7. Monitoring (labs, imaging)
	8. Follow-up clinic visit
	9. Side effect management
		1. Nonpharmacologic
		2. Pharmacologic
			1. OTC
			2. Prescription
2. Health Plan Criteria (not required for PRIME):
	1. Specific to, and the responsibility of, the payer of the ordered medication
	2. PRIME Entities may consider embedding the Health Plan Criteria into the Ordering Protocol, but an entity may interact with multiple plans each with their own Criteria for a specific medication, such integration is not required for the purposes of PRIME
3. SMART Monitoring Protocol
	1. Side Effect Monitoring and management (ordering protocol is surrogate measure)
	2. Medication Reconciliation (including OTCs) (measured by 3.3.2)
	3. Adherence Monitoring (measured by 3.3.1)
	4. Refill (proactive) coordination (3.3.1 is a surrogate measure)
	5. Therapeutic Validation (Appropriateness of Therapy) (ordering protocol is surrogate measure)

The SMART Monitoring Protocol (#3) is connected to the Ordering Protocol (#1) and other PRIME metrics in 3.3. The SMART Protocol on the back end ensures all needed monitoring structures are in place as shown in the following document.

Link to 3.3 graphic <https://safetynetinstitute.org/wp-content/uploads/2016/10/3-3-graphic.docx>

**Percentage of prescriptions ordered using the protocol**

PRIME entity should retrospectively determine all prescription orders for identified high cost pharmaceuticals on a monthly basis. This count will be the denominator for the metric. The numerator will be the number of prescription orders placed per month that utilized the protocol with supporting documentation.

***Other Notes as applicable***

A higher rate indicates better quality.

The PRIME Entity is required to establish a minimum of three new High Cost Pharmaceutical Ordering Protocols each DY, so that by the end of DY 15, the PRIME Entity is monitoring the use of these protocols for 15 of the top 20 identified high cost pharmaceuticals referenced in Attachment Q.

Supporting documentation may include order set activation, a pre-printed protocol checklist, or prescriber documentation that the protocol was followed.

Metric 3.3.3 has no requirements nor restrictions on the proportion of medications selected that are prescribed from inpatient versus outpatient settings.

# 3.3.4- Documentation of Medication Reconciliation in the Medical Record for Patients Taking High Cost Pharmaceuticals

**Summary of Changes from DY14 Year End Reporting Manual**

* None.

**Summary of Changes from DY13 Year End Reporting Manual**

* None.

**Modification from Native Specification**

Specification Source: PRIME Innovative Measure Steward (Santa Clara Valley Health System)

* Concept drawn from [NQF 0419: Documentation of Medications](http://www.qualityforum.org/QPS/0419)

Measure Steward: Santa Clara Valley Health System

**Value Sets for this metric:**

* N/A. No value sets or codes included in this metric.

***Metric Type***

Process

***Metric Description***

Percentage of primary care and relevant specialty care visits that have an associated medication reconciliation documented in the medical record for individuals at least 18 years of age as of the beginning of the measurement period who were prescribed high cost pharmaceuticals and had at least two prescription drug claims or fills for specified high cost pharmaceuticals.

***Numerator Statement***

Primary care and relevant specialty care visits where an associated medication reconciliation is documented in the medical record for patients taking selected high cost pharmaceuticals.

***Numerator Details***

Primary care and relevant specialty care visits from the denominator that had documentation of medication reconciliation in the medical record occur at most within 15 days of each visit.

Examples of documentation of medication reconciliation include: a medication reconciliation note or a check box in the EHR that says the clinician has “reviewed” medications.

***Numerator Codes***

* None

***Denominator Statement***

All primary care and relevant specialty care visits for individuals from the Project 3.3 Target population at least 18 years of age as of the beginning of the measurement period with at least two prescription drug claims or fills for the specified high cost pharmaceutical during the measurement period.

The definition of a visit will be left to each entity’s discretion, but must be independently auditable. The data for a visit should be reproducible and defendable to an external auditor.

While not stated in Attachment Q, the PRIME Entity will be required to target, at minimum, 3 new medications each DY, so that by the end of DY 15, the PRIME Entity is monitoring adherence of 15 of the top 20 identified high cost pharmaceuticals referenced in Attachment Q.

***Denominator Codes***

* None

***Denominator Exclusions***

* None

***Definitions***

**High Cost Pharmaceuticals**

As per Core Component #3 of Project 3.3 Project 3.3 Resource Stewardship: Therapies Involving High-Cost Pharmaceuticals on page 74 of the California 1115 Waiver - MediCal 2020’s Standard Terms and Conditions, Attachment Q - PRIME Projects and Metrics Protocol, the PRIME entity will:

“3. Develop a data analytics process to identify the participating PRIME entity highest cost pharmaceuticals (high-cost medications or moderate-cost meds with high prescribing volume). Identify high-cost medications whose efficacy is significantly greater than available lower cost medications.

* 1. Using purchase price data, Identify the Top 20 medications and medication classes, focusing on the following: Analgesics, Anesthetics, Anticoagulants, Anti-Neoplastics, Diabetes, Hepatitis C, Immunoglobulins, Mental Health (Anti-Depressants/Sedatives/ Anti-Psychotics), Respiratory (COPD/Asthma), Rheumatoid Arthritis”

**Medication Reconciliation (adapted from PRIME Project 2.2)**

Medication Reconciliation – A type of review in which patient-stated current medications are reconciled with the most recent medication list in the medical record. Documentation in the medical record must include evidence of medication reconciliation and the date on which it was performed. Any of the following evidence meets criteria: (1) Documentation of the current medications with a check box in the EHR that attests to a clinician reviewing medications or (2) Documentation of the patient’s current medications with a medication reconciliation note in the EHR

**Treatment Period**

The indicated duration of treatment for medications. Starts on the first date of drug claim or fill and ends on the date of the end of the last supply date. The treatment period will always be less than or equal to the full measurement period.

***Reporting Business Logic***

Report two performance rates for this metric at each reporting period as per [Dual Reporting Rates: Reporting Business Logic](#_Dual_Reporting_Rates:).

$TargetEncounter = Union of:

"Encounter, Performed: Primary Care Outpatient encounter" during "Measurement Period"

"Encounter, Performed: Relevant Specialty Care Outpatient encounter" during "Measurement Period"

* Initial Population = Project 3.3 Target Population
	+ AND: Age ≥18 years at start of measurement period
	+ AND: ≥2 prescriptions drug claims or dispense for each of the targeted high cost pharmaceuticals during: “Measurement Period”
* Denominator =
	+ AND: “Initial Patient Population
	+ AND: Occurrence of $TargetEncounters during “Measurement Period”
* Numerator =
	+ AND: Procedure Performed: Medication Reconciliation occurrence starts during “Measurement Period”
	+ AND: Fulfills one of the following:
		- OR: Procedure Performed: Medication Reconciliation starts = ≤15 days before $TargetEncounters
		- OR: Procedure Performed: Medication Reconciliation ends = ≤15 days after $TargetEncounters

***Additional Note as applicable***

All primary care visits are to be associated with medication reconciliation.

“Relevant Specialty Care Outpatient encounters” are to be determined by the specialty department of the ordering provider of the high cost pharmaceutical.

* Example #1: If a high cost pharmaceutical is ordered by a provider in rheumatology, subsequent rheumatology visits must be associated with a medication reconciliation
* Example #2: If one high cost pharmaceutical is ordered by rheumatology and one is ordered by gastroenterology, subsequent rheumatology and gastroenterology visits must be associated with medication reconciliation
* Example #3: If high cost pharmaceuticals are ordered by a primary care provider and not by any specialty provider, then there are no relevant specialty care clinics to include in the denominator for measurement of medication reconciliation

***Sampling***

Not applicable; this metric does not use a sample or survey. All patients in the Project 3.3 Target Population must be measured for this metric.

***Data Source***

* Patient medical records
* Pharmacy dispense records
* Health plan claims records

***Other Notes as applicable***

A higher rate indicates better quality.