

## Measure Overview and Rationale:

### Proportion of Days Covered Composite (Pharmacy) (PDC-CMP-PH)

#### Description

The composite percentage of individuals attributed to the pharmacy  $\geq 18$  years of age who met the Proportion of Days Covered (PDC) threshold of 80% for diabetes medications, RAS antagonists, and statins.

This is a composite pharmacy performance measure that combines rates from the following component measures:

- Component 1: Proportion of Days Covered: Diabetes All-Class (PDC-DR-CMP-PH)
- Component 2: Proportion of Days Covered: Renin Angiotensin System Antagonist (PDC-RASA-CMP-PH)
- Component 3: Proportion of Days Covered: Statins (PDC-STA-CMP-PH)

A higher rate indicates better performance.

#### Additional Information

##### Intended Use

Performance measurement for pharmacies.

This measure requires a minimum denominator of 30 for reliability. This minimum denominator requirement is assessed at the composite measure level, not at the component measure level. If the minimum denominator size is not met, the measure should not be used in accountability programs.

#### Composite Calculation

- Step 1** Calculate each component rate separately for PDC-DR-CMP-PH, PDC-RASA-CMP-PH, and PDC-STA-CMP-PH. Please see the measure specifications for additional detail.
- Note: Individuals are counted separately in the denominator and numerator of each component measure, even if they are included in the denominator and numerator of multiple component measures.
- Step 2** Aggregate measure rates from each component measure by summing the denominators and numerators of each component measure. This is the composite denominator and numerator.
- Step 3** Apply the minimum denominator requirement of 30 to the composite denominator. Do not report measure rates for pharmacies that do not meet the minimum denominator requirement of 30.
- Step 4** Calculate the composite measure rate as the composite numerator divided by the composite denominator.

#### Rationale

The PDC Composite (Pharmacy) measure was developed to address stakeholder interests and needs for a reliable measure to assess pharmacy quality at the pharmacy-payer level and aligned with Medicare Part D measurement. Because pharmacies are a smaller unit of analysis (vs. health plans, for example), denominators for individual PDC measures can be small, often below the standard threshold of 30 commonly used for reliability estimates. Compositing individual component measures is an approach that can be used to address challenges with small denominators. Previous PQA-endorsed individual pharmacy PDC measures required calculation at the aggregate Medicare line of business (i.e., not payer specific) which limited their usability. As a result, the PDC Composite was developed with the intention of being reliable at the pharmacy-payer level.

## Proportion of Days Covered: Diabetes All Class (PDC-DR-CMP-PH)

### Description

The percentage of individuals attributed to the pharmacy  $\geq 18$  years of age who met the Proportion of Days Covered (PDC) threshold of 80% for diabetes medications during the measurement year.

A higher rate indicates better performance.

### Additional Information

<b>Intended Use</b>	Performance measurement for pharmacies.
<b>Data Sources</b>	Prescription claims, medical claims.
<b>Denominator</b>	Individuals attributed to the pharmacy $\geq 18$ years of age who filled $\geq 2$ prescriptions for diabetes medications on different dates of service in the treatment period.
<b>Exclusions</b>	Hospice, end-stage renal disease (ESRD), $\geq 1$ prescription claims for insulin during the treatment period.
<b>Numerator</b>	Individuals who met the PDC threshold of 80% during the measurement year.

### Rationale

Diabetes mellitus is a chronic disease that has reached epidemic proportions in the U.S. and can lead to increased rates of heart disease, stroke and death. The UKPDS trial is the seminal research to link lowered A1c with health outcomes.<sup>1</sup> For those patients who require chronic medication therapy, adherence to hypoglycemic agents can lower blood sugar and decrease complications such as visual loss and renal failure.<sup>2,3</sup> The 2018 American Diabetes Association Standards of Medical Care in Diabetes support strategies to improve medication adherence, and the guidelines state: "In general barriers to medication adherence (such as cost and side effects) should be identified and addressed."<sup>4</sup> The updated 2021 American Diabetes Association standards continue to support medication adherence.<sup>5</sup> Moreover, there are several studies showing improved clinical outcomes for patients who are adherent to their medications.

Roebuck and colleagues in 2011 showed that an increase in medication adherence (defined as the 80% threshold) reduced total annual health care spending, primarily through decreased inpatient hospital days and emergency department visits. Regarding patients with diabetes, adherence decreased annual medical spending by \$4,413, providing a benefit-cost ratio of 6.7:1.<sup>6</sup> Another article by Roebuck and colleagues in 2018 assessed medication adherence on health service utilization in a Medicaid population. In this research, adherence was measured at a PDC level of 80% as defined by the Pharmacy Quality Alliance.<sup>7</sup>

Finally, a 2016 article by Boye and colleagues examined the association between adherence and outcomes. The results showed at higher adherence levels, all-cause acute care and outpatient costs declined. The mean outpatient and acute-care costs were \$17,298 and \$13,373 with a PDC  $\geq 80\%$  compared to \$28,086 and \$32,340 with a PDC  $< 20\%$  ( $P < 0.005$ ). The results were progressive based on each PDC interval ( $< 20\%$ ;  $\geq 20\%$ - $40\%$ ;  $\geq 40\%$ - $60\%$ ;  $\geq 60\%$ - $80\%$ ;  $\geq 80\%$ ). Additionally, diabetes-related costs showed the same general trend.<sup>8</sup>

Patient impact analyses and cost estimates were conducted for the PDC-DR measure for PDPs and MA-PDs (2011–2015) as part of the 2018 National Impact Assessment of CMS Quality Measures.<sup>9</sup> Approximately 520,000 million additional diabetes patients were adherence versus baseline, with associated savings of \$659.5 million–\$3.8 billion. These patient impact analyses and cost estimates were updated in the 2021 National Impact Assessment.<sup>10</sup> Updated estimates were 893,811 more beneficiaries than expected and costs avoided of \$3.4 billion–\$7.2 billion.

## Proportion of Days Covered: Renin Angiotensin System Antagonists (PDC-RASA-CMP-PH)

### Description

The percentage of individuals attributed to the pharmacy  $\geq 18$  years of age who met the Proportion of Days Covered (PDC) threshold of 80% for RAS Antagonists during the measurement year.

A higher rate indicates better performance.

### Additional Information

<b>Intended Use</b>	Performance measurement for pharmacies.
<b>Data Sources</b>	Prescription claims, medical claims.
<b>Denominator</b>	Individuals attributed to the pharmacy $\geq 18$ years of age who filled $\geq 2$ prescriptions for RAS antagonists on different dates of service in the treatment period.
<b>Exclusions</b>	Hospice, end-stage renal disease (ESRD), $\geq 1$ prescription claims for sacubitril/valsartan during the treatment period.
<b>Numerator</b>	Individuals who met the PDC threshold of 80% during the measurement year.

### Rationale

Renin-angiotensin system antagonists (RASAs), including angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), and direct renin inhibitors are commonly used in the treatment of hypertension. RASAs are also important for the chronic treatment of hypertension and proteinuria in patients with diabetes, in which these drugs have been shown to delay renal failure and heart disease.<sup>2</sup> The 2017 American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines recommend ACE inhibitors and ARBs as first-line monotherapy for the treatment of hypertension along with thiazide diuretics and dihydropyridine calcium channel blockers (CCBs).<sup>11</sup> These recommendations are consistent with the 2018 and 2021 American Diabetes Association guidelines.<sup>4, 5</sup> According to these guidelines, medication nonadherence is a major contributor to poor control of hypertension and a key barrier to reducing mortality. Moreover, there are several studies showing improved clinical outcomes for patients who are adherent to their medications.<sup>3</sup>

One study examined patients who previously had a myocardial infarction. Those who achieved adherence to statins, beta-blockers, and ACE inhibitors/ARBs—measured by proportion of days covered (PDC) greater than 80%—had significantly better disease-free survival.<sup>12</sup> Another study showed that poor adherence to ACE inhibitors/ARBs was associated with a 20% increased risk of recurrent AMI.<sup>13</sup> A study by Roebuck and colleagues in 2018 assessed medication adherence on health service utilization in a Medicaid population.<sup>7</sup> This study found that the impact of adherence (PDC  $\geq 80\%$ ) among Medicaid enrollees with hypertension was associated with a 15% reduction in inpatient hospitalizations, a 9% reduction in emergency department visits, and a 5% reduction in outpatient physician or clinic visits. In 2019 Axon et al.<sup>14</sup> analyzed the association of RASA adherence (PDC  $\geq 80\%$ ) with healthcare utilization and expenditures among commercially-insured adults (N= 4,842,058). Adherence was associated with fewer inpatient (RR=0.612, 95% CI=0.607-0.617) and outpatient visits (RR=0.995, 95% CI=0.994, 0.997); and lower inpatient (CR=0.614, 95% CI=0.613-0.615) and total (CR=0.876, 95% CI=0.874-0.878) healthcare costs.

In 2019, Lloyd et al.<sup>15</sup> estimated the cost of medication nonadherence (PDC <80%) among Medicare fee-for-service beneficiaries with hypertension among other chronic diseases (N=14,657,735). Medication nonadherence was calculated to be 25% for hypertension. The authors estimated the avoidable health care costs that could be saved if nonadherent beneficiaries with hypertension became adherent was \$13.7 billion annually. Patient impact analyses and cost estimates were conducted for the PDC-RASA measure for PDPs and MA-PDs (2011–2015) as part of the 2018 National Impact Assessment of CMS Quality Measures.<sup>9</sup> Approximately 2.5 million additional RASA patients were adherence versus baseline, with associated savings of \$2.1 billion–\$19.8 billion. These patient impact analyses and cost estimates were updated in the 2021 National Impact Assessment.<sup>10</sup> Updated estimates were 3.0 million more beneficiaries than expected and costs avoided of \$18.2 billion–\$25.7 billion.

## Proportion of Days Covered: Statins (PDC-STA-CMP-PH)

### Description

The percentage of individuals attributed to the pharmacy  $\geq 18$  years of age who met the Proportion of Days Covered (PDC) threshold of 80% for statins during the measurement year.

A higher rate indicates better performance.

### Additional Information

<b>Intended Use</b>	Performance measurement for pharmacies.
<b>Denominator</b>	Individuals attributed to the pharmacy $\geq 18$ years of age who filled $\geq 2$ prescriptions for statins on different dates of service in the treatment period.
<b>Exclusions</b>	Hospice and end-stage renal disease (ESRD).
<b>Numerator</b>	Individuals who met the PDC threshold of 80% during the measurement year.

### Rationale

HMG-CoA reductase inhibitors, also known as statins, are recommended for the management of dyslipidemia and primary prevention of cardiovascular disease (CVD) in several treatment guidelines.<sup>16-20</sup> By lowering LDL cholesterol, statins decrease the risk of CVD morbidity and mortality.<sup>21</sup> Although long-term treatment with statins is effective in preventing CVD, patients often do not take their medications as prescribed. Numerous studies have shown improved clinical outcomes for patients who are adherent to their medications.<sup>3</sup> Specifically, in patients with dyslipidemia, adherence studies have shown a strong relationship between adherence to statins and reduced risk of CVD events, and lower overall health services utilization and costs.

One study evaluated the association between medication adherence levels and major adverse cardiovascular events (MACE) or atherosclerotic disease (ATH) over two years. Claims data with 4,015 post-MI patients and 12,976 patients with ATH from a large US health insurance company was analyzed. In the post-MI cohort, fully adherent (PDC $\geq 80\%$ ) patients had a significantly lower rate of MACE than non-adherent patients (18.9% vs. 26.3%; hazard ratio [HR]: 0.73;  $p=0.0004$ ). In the ATH cohort, fully adherent patients (PDC $\geq 80\%$ ) had a significantly lower rate of MACE than non-adherent patients (8.42% vs. 17.17%; HR: 0.56;  $p<0.0001$ ). This study showed PDC $\geq 80\%$  adherence in the post-MI population was associated with a lower rate of MACE and ATH.<sup>22</sup> Another study aimed to evaluate the relationship between statin adherence and ischemic stroke (IS) in patients with diabetes. A cohort of 52,868 statin initiators with diabetes (1995–2006) using Finnish health registers was evaluated. Adherence to statins (PDC  $\geq 80\%$ ) was associated with a 23% decreased incidence of IS (95% CI 14–32%) compared with non-adherence (PDC $<80\%$ ). This association remained broadly unchanged when stratified by sex, age, history of atherosclerotic cardiovascular disease or IS. There was a dose–response relationship between adherence level and the risk of IS (RR 0.63 [0.53–0.75] for PDC  $\geq 80\%$  versus PDC $<20\%$ ,  $p$  for trend  $<0.0001$ ). Sensitivity analyses supported the robustness of the analysis.<sup>23</sup>

Roebuck and colleagues in 2011 showed an increase in medication adherence (defined as the 80% threshold) reduced total annual health care spending primarily through decreased inpatient hospital days and emergency department visits. Regarding dyslipidemia, adherence decreased annual medical spending by \$1,860 for a benefit-cost ratio of 3.1.<sup>6</sup> Another article by Roebuck and colleagues in 2018 assessed medication adherence on health service utilization in a Medicaid population. In this research, adherence was measured at a PDC level of 80% as defined by the Pharmacy Quality Alliance. Medication adherence was significantly and negatively associated with outpatient physician and clinic visits for dyslipidemia.<sup>7</sup>

In 2014, Choudhry et al.<sup>12</sup> conducted a retrospective analysis to evaluate the relationship between medication adherence (PDC  $\geq 80\%$ ) and post-myocardial infarction adverse coronary events (N=4,117). Compared with patients randomized to usual care, patients who were adherent to statins, beta-blockers, and ACE/ARBs were significantly less likely to experience first major vascular event or revascularization (hazard

ratio [HR] range, 0.64-0.81). In contrast, non-adherent patients showed no benefit (HR range, 0.98-1.04;  $P \leq 0.01$  for the difference in HRs between adherent and non-adherent patients). Similar findings were observed with statin adherence. In 2019 Chinthammit et al.<sup>24</sup> evaluated the association of statin adherence (PDC  $\geq 80\%$ ) with healthcare utilization and expenditures among commercially insured adults (N= 4,450,308). Adherence was associated with fewer inpatient visits (RR=0.746, 95% CI=0.739-0.753) and lower inpatient (CR=0.780, 95% CI=0.779-0.782) and total (CR=0.975, 95% CI=0.973-0.977) healthcare costs.

Patient impact analyses and cost estimates were conducted for the PDC-STA measure for PDPs and MA-PDs (2011–2015) as part of the 2018 National Impact Assessment of CMS Quality Measures.<sup>9</sup> Approximately 2.8 million additional statin patients were adherence versus baseline, with associated savings of \$1.5 billion–\$3.3 billion. These patient impact analyses and cost estimates were updated in the 2021 National Impact Assessment. Updates estimates were 4.0 million more beneficiaries than expected and costs avoided of \$5.4 billion–\$13.7 billion.<sup>10</sup>

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