Evaluation of a Program to Improve Diabetes Care Through Intensified Care Management Activities and Diabetes Medication Copayment Reduction

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ABSTRACT

BACKGROUND: Medication copayment reduction can be integrated with disease management programs to incentivize patient engagement in chronic care management. While disease management programs in diabetes have been evaluated across a range of settings and designs, less is known regarding the effectiveness of copayment reduction as a component of disease management.

OBJECTIVE: To evaluate the short-term results of a diabetes-focused disease management program that included copayment reduction, care coordination, and patient goal setting, focusing on rates of evidence-based care processes and all-cause pharmacy and health care costs.

METHODS: Blue Cross & Blue Shield of Rhode Island offered large employer groups the opportunity to participate in a diabetes disease management initiative that featured reduced copayments (from $7/$25/$40 for generic, tier 2, and tier 3 drugs, respectively, to $0 for generic and $0-$2 for brand drugs) for diabetes-related medications. In return for the copayment reduction, participants agreed to the following: (a) participate in care coordination with a case manager, (b) have an annual physical examination, (c) have a hemoglobin A1c blood test at least twice annually, and (d) have a low-density lipoprotein cholesterol (LDL-C) test at least once annually. Patients received personalized support provided by a registered nurse and dietitian, disease-related education provided by nurses, and intensified case management services, including working with a health coach to establish healthy behavioral change goals. All study subjects were aged 18 years or older and had at least 1 ICD-9-CM code for diabetes and at least 1 claim for an antidiabetic drug during a 12-month measurement period, which was each subject's most recent 12-month period of continuous enrollment from January 1, 2008, through May 31, 2010. Administrative claims data were used to determine the percentage of intervention (participating) and nonintervention (nonparticipating) subjects from among all of the plan's employer groups who received at least once-yearly monitoring of A1c, high-density lipoprotein cholesterol (HDL-C), and LDL-C; medical attention (or drug therapy) for nephropathy; and an eye examination. We conducted multivariate logistic regression analyses to assess the effect of the intervention and other patient characteristics and comorbidities on rates of performance of these care processes, aggregating the 5 processes of care into an “all or none” single composite outcome. We also developed a propensity score-weighted model to attempt to adjust for differences between the intervention and nonintervention groups resulting from the nonrandomized study design. Additionally, we quantified average plan payments to providers less than other enrolled members with diabetes. Younger patients and those utilizing oral antidiabetic monotherapy as their drug regimens were less likely to have these processes of care performed compared with users of multiple oral therapies (OR=1.23, 95% CI=1.11-1.36) and insulin (OR=1.59, 95% CI=1.41-1.78). PPPY prescription drug costs incurred by the plan were greater for intervention than comparison patients (means [SDs] of $3,139 [$3,426] vs. $2,854 [$3,938], respectively, P<0.001); and the generic-dispensing ratio was slightly lower (means [SDs] of 62.1% [22.4%] and 65.4% [23.0%], respectively, P<0.001). There were no significant differences between the intervention and comparison groups in mean [SD] PPPY all-cause medical care costs ($7,475 [$17,601] vs. $8,577 [$22,972], respectively, P=0.213) or total all-cause costs ($10,613 [$18,590] vs. $11,431 [$24,060], P=0.666).

CONCLUSIONS: Patients participating in this incentive program featuring diabetes medication copayment reduction and disease management components did not receive recommended care any more or less frequently than other enrolled members with diabetes. Younger patients and those utilizing oral antidiabetic monotherapy as their drug regimens were less likely to have the recommended processes of care performed. While prescription drug expenditures incurred by the plan were greater for intervention patients, between-group differences in total costs for medications and all-cause medical care were not statistically significant. Further follow-up is required to determine the success of this program over the longer term in promoting quality of care and achieving cost reductions and improved health outcomes.

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Diabetes mellitus is a major burden on the U.S. health care system. Estimates from the U.S. Centers for Disease Control indicate that approximately 26 million people in the United States are living with diabetes, including 7 million Americans who are undiagnosed, while nearly 2 million adults were newly diagnosed with diabetes during 2010.1 It is estimated that 1 in 3 people in the United States will develop diabetes during their lifetime.2 Diabetes is the sixth leading cause of death in the United States, contributing to approximately 225,000 deaths yearly.3 In 2002, diabetes contributed to 16.9 million days of hospitalization and 62.6 million physician office visits, and total average health care expenditures were $13,243 for every person with diabetes compared with $5,642 for every person without diabetes, controlling for age and other demographic characteristics.4 These figures underscore why the health care system continues to devise and implement interventions to manage the disease and reduce diabetes-related complications and associated costs.

As a result of the high prevalence5 and cost burden6 associated with diabetes and its complications, managed care organizations are redirecting significant resources towards ensuring that evidence-based care is routinely delivered to promote risk reduction and averting untoward health outcomes. Quality of care recommendations for diabetes supported by the American Diabetes Association include the routine measurement of glycated hemoglobin (A1c), blood lipids and renal function, and routine diabetic retinal examinations for preventing disease complications.7 Poor glycemic control and dyslipidemia are significant risk factors for coronary artery disease (CAD)
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in patients with diabetes. For example, using data from the United Kingdom Prospective Diabetes Study to assess risk factors for CAD, Turner et al. (1998) reported a hazard ratio (HR) of 2.26 for low-density lipoprotein cholesterol (LDL-C; 95% confidence interval [CI] = 1.70-3.00); HR = 1.52 for A1c (95% CI = 1.15-2.01); and HR = 0.55 for high-density lipoprotein cholesterol (HDL-C; 95% CI = 0.41-0.73), comparing patients categorized within the upper-third versus lowest-third levels. Zhang et al. (2010) determined the prevalence of retinopathy among NHANES IV participants with diabetes receiving a medical examination, finding that 4.4% had retinopathy classified as being a threat to vision.

Results from the 2009 National Committee on Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) reveal a generally high level of performance of diabetes-related quality of care processes among patients enrolled in commercial plans: approximately 40% of patients with type 2 diabetes have some degree of chronic kidney disease, findings that underscore the importance of early detection and intervention. According to data from the National Health and Nutrition Examination Survey (NHANES IV), approximately 40% of patients with type 2 diabetes have some degree of chronic kidney disease, findings that underscore the importance of early detection and intervention. Moreover, A1c and lipid measurements performed were considered lost to follow-up. Participants in the Asheville Project reported that the medication copayment waiver was a highly important factor in agreeing to participate in the program. Results of the Diabetes Ten City Challenge included increases in rates of performance of several diabetes-related processes of care, including eye examinations (from 57% at baseline to 81%), while eye examinations were received by 61% of patients. These results also indicate opportunity for improving these core measures of routine diabetes care.

Disease management approaches in diabetes have included components such as enhanced patient education, improved care coordination, increased involvement of pharmacists, and the use of remote call centers for patient support. The Medicare Health Support (MHS) Pilot Program, which is the largest evaluation of disease management delivered to older patients with diabetes published to date, found that disease management programs employing remote call centers staffed by nurses were ineffective in decreasing hospital admissions or reducing overall costs of care. In the MHS, more than 240,000 patients with diabetes or heart failure were randomized to either the disease management intervention or standard care. Improvements were noted for only 14 of 40 of the processes of care measured, with only small percentage point changes observed.

A cluster-randomized trial conducted by Sonnichsen et al. (2010) evaluated a disease management intervention comprising interdisciplinary care, face-to-face physician and patient education, standardized medication documentation, and shared physician-patient goal setting delivered to 649 Austrian patients with diabetes. Compared with the 840 study patients receiving usual care, intervention patients more frequently had recommended care performed (e.g., eye and foot examinations and A1c measurement) and experienced reductions in body mass index and blood cholesterol. A small improvement (0.13 percentage point) was observed in reduction of A1c among intervention patients, yet the difference in A1c reduction between intervention and control patients was not sustained after statistical adjustment for cluster effects and status at baseline.

A randomized trial by Hogg et al. (2009) found that Anticipatory and Preventive Team Care (APTCare) involving nurse practitioners and pharmacists delivered to 120 patients yielded improvements in guideline-based processes of care across several conditions including diabetes. However, the improvements in the diabetes-specific measures were not statistically significant nor were significant differences observed in rates of hospitalization or patient quality of life between the intervention and usual care groups.

Disease management programs including diabetes medication copayment reduction or waiver have been evaluated as a means of improving diabetes care and reducing cost. Noteworthy models include the Asheville Diabetes Care Project (Asheville Project) and the subsequent Diabetes Ten City Challenge. While the primary focus of the Asheville Project was to apply pharmaceutical care services specific to diabetes management, the initiative also offered participants copayment waivers for diabetes medications and supplies. The evaluation measures used in the Asheville Project focused upon the achievement of therapeutic goals; patients who did not have A1c and lipid measurements performed were considered lost to follow-up. Participants in the Asheville Project reported that the medication copayment waiver was a highly important factor in agreeing to participate in the program. Results of the Diabetes Ten City Challenge included increases in rates of performance of several diabetes-related processes of care, including eye examinations (from 57% at baseline to 81%), yearly A1c testing (54% to 97%), and yearly lipid profile tests (51% to 92%), while average total health care costs per person were reduced by $1,080 for the 1-year study period.

However, the improvements in diabetes care and outcomes reported in these 2 studies should be interpreted cautiously in consideration of the nonexperimental designs employed and the health status of study participants at baseline. Patients participating in the Asheville Project were not randomized to the intervention, and a majority (more than 61%) of patients entered the study with poorly controlled diabetes (A1c level exceeding 7%). In the Diabetes Ten City Challenge, patient enrollment was voluntary, and the study employed a pre-post design without a control group comparison. While improvements in rates of performance of diabetes-related care processes were substantial, it is uncertain if these improvements differed from usual care patterns among the employers’ non-participating employees with diabetes.
In the years following these 2 important studies, the value of medication therapies has been a growing consideration in formulary designs, and the results of comparative effectiveness research may yet support copayment variation based on expected value for a particular patient's clinical circumstance. Yet, there has been a paucity of research examining the effect of copayment waiver or reduction on patient health outcomes, quality of care, and cost.

Gibson et al. (2011) described the outcomes of a value-based insurance design including copayment reduction for diabetes medications, as evaluated separately and when coupled with a disease management program. This was a voluntary program offered by one large employer to all of its employees with diabetes. These researchers found that the intervention including both the pharmacy copayment reduction and disease management components yielded higher rates of completion of A1c, lipid testing, and urinalysis, compared with disease management alone. The results were sustained over a 3-year follow-up period. Chernew et al. (2008) and Chang et al. (2010) also reported improvements in diabetes medication adherence associated with copayment reduction or waiver, although neither of these studies employed a randomized design, and in the study by Chang et al., copayment reduction was not incorporated within a defined disease management program.

In 2008, Blue Cross & Blue Shield of Rhode Island (RI) initiated an employer-based voluntary pilot program to improve diabetes-related care. Our aim was to describe the association of the program with the quality of care received, focusing upon the performance of 5 diabetes-related processes of care: annual LDL-C, HDL-C, and A1c testing; medical attention for nephropathy; and eye examinations. We sought to determine if patients participating in the program more frequently received these processes of care during a 12-month period compared with other Blue Cross & Blue Shield of RI members with diabetes who were not enrolled in the program. Between these groups, we also compared the average per-member costs associated with the utilization of prescription drugs and medical services.

**Methods**

**Design and Intervention**

We employed a retrospective, cross-sectional design, using electronic claims data to describe patients’ health service utilization and associated cost during a 12-month time frame between January 1, 2008, and May 31, 2010. All patients had at least 12 continuous months of enrollment and were at least 18 years of age. The data sources used in this analysis included medical, pharmacy, and enrollment data files, providing demographic information, medical diagnoses, health care procedures, medication dispensings, and hospital discharge records. These data included associated costs where applicable.

The main elements of the program included disease education, counseling, and close oversight provided by assigned nurse case managers and copayment reductions for diabetes-related medications. Specifically, medication copayments for intervention members were reduced to either $2.00 for brand name medications and $0 (zero) for generic medications, or to a $0 copayment for both brand and generic anti-diabetic medications, depending upon the account. The 3-tier pharmacy benefit design for members not participating in the program remained as $7/$25/$40 for generic, tier 2, and tier 3 medications, respectively. The program required that participants agree to the following: (a) participate in care coordination with their case managers, (b) have an annual physical exam, (c) have an A1c blood test at least twice a year, and (d) have an LDL-C test performed at least once per year. Additionally, patients received personalized support provided by a registered nurse and dietician, which included working to achieve health-related goals. Patients also received disease-related education provided by nurses and intensified case management services, including working with a health coach to establish healthy behavioral change goals. Members also completed a contract that pledged their agreement to remain engaged in care and to receive recommended tests and health exams. Participants were informed that the copayment reduction would be rescinded if they did not receive recommended tests and participate in care coordination. Patients not participating in the program received usual care, which included the plan's usual disease management components such as the provision of educational materials and case management following a hospital visit, but without personalized goal setting or copayment reductions.

The diabetes care management activities and diabetes medication copayment reduction program (i.e., the “intervention”) was offered to the plan's larger employer groups with 1,000 or more employees. Five of these groups agreed to participate. Patient recruitment was performed by Blue Cross & Blue Shield of RI, which had sole responsibility for identifying members with diabetes in the participating employer groups; invitations to participate in the program were mailed by the health plan to these patients' homes. The mailings were followed by a telephone voice reminder message sent 2 weeks later.

The intervention group for the study comprised those members who were offered the program and agreed to participate through May 31, 2010. For these patients, the study time frame consisted of the most recent 12 months of participation in the program. The comparison group comprised all other members identified by the plan as having diabetes during the time frame, including those members from both the large employer groups from which the intervention patients were recruited and from among all of the plan's other groups. For the comparison cohort, the most recent 12 months of continuous enrollment comprised the study time frame. All patients in both groups received a dispensing for either an oral or injectable medication for diabetes during the 12-month study time
frame and had a diagnosis of diabetes documented during this 12-month period. We excluded patients who had a primary or secondary diagnosis of polycystic ovary syndrome, for which metformin may be prescribed. The flowchart in Figure 1 presents an overview of the study inclusion criteria and sequence.

Study Outcomes and Statistical Analyses

Our main objectives were to compare (a) rates of performance of recommended diabetes-related care processes between the intervention and nonintervention groups and (b) all-cause pharmacy and medical care costs between groups. We determined the percentages of patients who received at least once-yearly monitoring of A1c, HDL-C, LDL-C, and medical attention for nephropathy, which included evidence of renal function monitoring, a diagnosis of nephropathy, or use of an angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker (at least 1 pharmacy claim during the measurement period). We also determined if patients received a dilated eye exam during this time span.

We created an “all or none” single composite outcome comprising all these aspects of recommended care. Our measurement specifications were based on the 2009 HEDIS diagnosis and procedure code listings, with the exception of eye examinations; due to our 12-month measurement time frame we were unable give credit for negative retinal exam results obtained in the prior year, as the HEDIS methodology allows. Annual HDL-C monitoring is not included in the HEDIS comprehensive diabetes care measure set. Our measure was

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*Nonintervention patients include those who were offered the intervention program through their employers and patients identified as having diabetes by other employer groups that did not offer the intervention.*

*Diabetes diagnosis verified by presence of at least 1 defining ICD-9-CM code and at least 1 medication for diabetes dispensed during the 12-month measurement period (Appendix).*

ICD-9-CM = International Classification of Diseases, Ninth Revision, Clinical Modification; Rx = prescription drug.

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TABLE 1

<table>
<thead>
<tr>
<th>Variable</th>
<th>Intervention (n = 649)</th>
<th>Nonintervention (n = 9,049)</th>
<th>P Valuea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years [SD]</td>
<td>53.4 [10.72]</td>
<td>54.2 [9.68]</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>61.3 (398)</td>
<td>60.7 (5,496)</td>
<td>0.798</td>
</tr>
<tr>
<td>Female</td>
<td>38.7 (251)</td>
<td>39.3 (3,553)</td>
<td>0.798</td>
</tr>
<tr>
<td>Diabetes medication useb</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral monotherapy (no insulin)</td>
<td>25.4 (165)</td>
<td>30.0 (2,713)</td>
<td>0.016</td>
</tr>
<tr>
<td>Multiple oral therapy (no insulin)</td>
<td>43.6 (283)</td>
<td>44.3 (4,005)</td>
<td>0.770</td>
</tr>
<tr>
<td>Any insulin</td>
<td>31.0 (201)</td>
<td>25.8 (2,331)</td>
<td>0.004</td>
</tr>
<tr>
<td>Comorbidityc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>5.5 (36)</td>
<td>7.5 (681)</td>
<td>0.074</td>
</tr>
<tr>
<td>COPD</td>
<td>1.1 (7)</td>
<td>2.7 (244)</td>
<td>0.017</td>
</tr>
<tr>
<td>CAD</td>
<td>11.9 (77)</td>
<td>16.5 (1,491)</td>
<td>0.002</td>
</tr>
<tr>
<td>CHF</td>
<td>4.0 (26)</td>
<td>4.3 (392)</td>
<td>0.774</td>
</tr>
<tr>
<td>Mental health diagnosis</td>
<td>8.9 (58)</td>
<td>10.0 (908)</td>
<td>0.408</td>
</tr>
</tbody>
</table>

Number of unique medications utilized during the 12-month follow-up measurement periodd:

<table>
<thead>
<tr>
<th>Mean [SD] number</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12.2 [7.5]</td>
<td>12.9 [7.6]</td>
<td>0.032</td>
</tr>
<tr>
<td></td>
<td>% (n)</td>
<td>% (n)</td>
<td></td>
</tr>
<tr>
<td>0-5</td>
<td>13.7 (89)</td>
<td>12.9 (1,165)</td>
<td>0.579</td>
</tr>
<tr>
<td>6-10</td>
<td>35.7 (232)</td>
<td>31.3 (2,833)</td>
<td>0.021</td>
</tr>
<tr>
<td>11-20</td>
<td>37.6 (244)</td>
<td>42.1 (3,812)</td>
<td>0.027</td>
</tr>
<tr>
<td>21 or more</td>
<td>12.9 (84)</td>
<td>13.7 (1,239)</td>
<td>0.632</td>
</tr>
</tbody>
</table>

*Values determined from Pearson chi-square tests for all categorical comparisons and t-tests for independent samples for number of unique medications used and age.

*Measured during the 12-month follow-up period.

*Defined as at least 1 relevant confirming diagnosis or procedure code (Appendix) during the 12-month follow-up measurement period.

*Unique chemical entity regardless of dosage form or strength.

*CAD = coronary artery disease; CHF = congestive heart failure; COPD = chronic obstructive pulmonary disease; SD = standard deviation.

In addition to comparing rates of these processes of care between groups, the intervention and nonintervention groups were compared according to age, gender, type of diabetes medication used, and comorbidities. Most of the patients enrolled by this commercial insurer were middle-aged, non-elderly working adults and their family members. We created age categories that roughly approximated tertiles of the distribution, while also maintaining at least a 10-year range for the middle strata. Medication burden was determined according to the number of unique medications utilized during the 12-month study time period, identified via National Drug Code (NDC) numbers. This variable represented the sum of unique medications utilized during the 12-month study period, counting each chemical entity only once, regardless of the number of dispensings or the dosage form or strength. The type of diabetes medication regimen used during the 12-month period was classified as follows: (a) oral monotherapy without insulin use; (b) multiple oral therapy without insulin use; or (c) any insulin use, with or without concomitant oral medication use, also identified using product NDC numbers. We also identified the following comorbidities via relevant ICD-9-CM codes (appearing at least once during the 12-month time frame): asthma, chronic obstructive pulmonary disease (COPD), CAD, heart failure, and a mental health condition, which included the diagnoses of depression, bipolar disorder, and schizophrenia.

Rates of performance were determined for each of the diabetes-related processes of care and for the aggregated composite measure, and these rates were stratified by group status and according to the covariates identified above. Pearson chi-square tests were applied to determine the statistical significance of differences in these rates and also to assess differences in patient characteristics and the presence of comorbidities between the intervention and nonintervention groups.

A multivariate logistic model was developed to determine the effect of the intervention on the outcome of the “all or none” measure, defined as having all of the measured processes of care performed during the 12-month period. The model was created using a manual backward stepwise process. The log-likelihood test was used to assess the multivariate model at each step, removing least statistically significant covariates with each iteration and evaluating differences between full and reduced models for statistical significance (P<0.05). Gender and age remained in the model throughout. The Hosmer-Lemeshow goodness-of-fit test was used to assess the calibration of the final model. The measure of effect was presented as an odds ratio (OR) with corresponding 95% CIs.

To mitigate bias resulting from the nonrandomized design, an inverse propensity score-weighted model was also utilized to adjust for the likelihood of intervention group inclusion. A 2-stage propensity score approach was applied as described by D’Agostino (1998), which attempted to account for differences in diabetes severity and comorbidities between groups, recognizing that volunteers for the diabetes management program may have differed in health status from the plan members with diabetes who did not participate in the intervention. The first
Diabetes medication use

- Medical attention for nephropathy includes use of an angiotensin-converting enzyme inhibitor or angiotensin II receptor blocker drug or documentation of a range of procedures that indicate provider attention to renal function.

Results

The insurer identified 21,153 patients with diabetes, 843 of whom agreed to participate in the diabetes incentive program; 20,310 were members identified as having diabetes using algorithms employed by the plan but did not participate in the program. Approximately 5.5% of intervention patients and 9.0% of nonintervention patients were excluded after application of the continuous enrollment criterion. Among those enrolled for at least 12 months, 12 intervention patients and 172 nonintervention patients were less than 18 years of age and were excluded. We required that patients had at least 1 diagnosis of diabetes and at least 1 dispensing of an antidiabetic medication during the 12-month period. This criterion resulted in the additional exclusion of 136 intervention and 9,245 nonintervention patients. After excluding 26 patients from the nonintervention group with a diagnosis of polycystic ovary disease, the final study sample consisted of 9,698 patients with diabetes, 649 of (6.7%) of whom were participants in the intervention. No intervention patients withdrew from the program during the study time frame.

The mean (standard deviation [SD]) ages of patients in the intervention and nonintervention groups were similar (53 [10.7] vs. 54 [9.7] years, respectively), as were the percentages

### TABLE 2

<table>
<thead>
<tr>
<th>Group</th>
<th>HDL-C Test % (n)</th>
<th>LDL-C Test % (n)</th>
<th>A1c Test % (n)</th>
<th>Medical Attention for Nephropathyb % (n)</th>
<th>Eye Exam (n)</th>
<th>All Performed % (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention (n = 6,449)</td>
<td>85.7 (556)</td>
<td>86.7 (563)</td>
<td>92.3 (599)</td>
<td>83.8 (544)</td>
<td>51.2 (332)</td>
<td>40.1 (260)</td>
</tr>
<tr>
<td>Usual care (n = 9,049)</td>
<td>89.7 (8,120)</td>
<td>89.8 (8,125)</td>
<td>94.1 (8,514)</td>
<td>83.3 (7,537)</td>
<td>48.0 (4,339)</td>
<td>38.9 (3,516)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>18-48 (n = 2,418)</td>
<td>85.2 (2,061)</td>
<td>85.2 (2,060)</td>
<td>91.9 (2,223)</td>
<td>77.3 (1,868)</td>
<td>41.1 (995)</td>
<td>30.5 (738)</td>
</tr>
<tr>
<td>49-59 (n = 4,239)</td>
<td>90.8 (3,849)</td>
<td>91.1 (3,860)</td>
<td>94.6 (4,010)</td>
<td>83.7 (3,549)</td>
<td>46.8 (1,982)</td>
<td>38.0 (1,609)</td>
</tr>
<tr>
<td>60 and older (n = 3,041)</td>
<td>91.0 (2,766)</td>
<td>91.0 (2,768)</td>
<td>94.7 (2,880)</td>
<td>87.6 (2,664)</td>
<td>55.7 (1,694)</td>
<td>47.0 (1,429)</td>
</tr>
<tr>
<td>Gender</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Male (n = 5,894)</td>
<td>89.9 (3,301)</td>
<td>90.1 (3,310)</td>
<td>94.0 (3,541)</td>
<td>83.6 (4,929)</td>
<td>46.7 (2,751)</td>
<td>38.0 (2,240)</td>
</tr>
<tr>
<td>Female (n = 3,804)</td>
<td>88.7 (3,375)</td>
<td>88.8 (3,378)</td>
<td>93.9 (3,572)</td>
<td>82.9 (3,152)</td>
<td>50.5 (1,920)</td>
<td>40.4 (1,536)</td>
</tr>
<tr>
<td>Diabetes medication use</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Oral monotherapy (n = 2,878)</td>
<td>88.4 (2,543)</td>
<td>88.3 (2,541)</td>
<td>91.9 (2,644)</td>
<td>76.3 (2,195)</td>
<td>44.3 (1,274)</td>
<td>32.5 (936)</td>
</tr>
<tr>
<td>Multiple oral therapy (n = 4,288)</td>
<td>91.4 (3,920)</td>
<td>91.6 (3,927)</td>
<td>95.2 (4,081)</td>
<td>85.3 (3,657)</td>
<td>48.1 (2,063)</td>
<td>39.7 (1,703)</td>
</tr>
<tr>
<td>Any insulin (n = 2,532)</td>
<td>87.8 (2,222)</td>
<td>87.7 (2,220)</td>
<td>94.3 (2,388)</td>
<td>88.0 (2,229)</td>
<td>52.7 (1,334)</td>
<td>44.9 (1,137)</td>
</tr>
</tbody>
</table>

*Between-group differences comparing intervention versus comparison group patients were assessed using Pearson chi-square tests.

A1c = hemoglobin A1c; HDL-C = high-density lipoprotein cholesterol; LDL-C = low-density lipoprotein cholesterol.
of patients within each age stratum among these groups (Table 1). Males represented 61% of both the intervention and nonintervention groups. A higher percentage of patients in the intervention group were insulin users (31.0% vs. 25.8%, P = 0.004), while in the nonintervention group a higher percentage of patients were users of oral antidiabetic monotherapy (30.0% vs. 25.4%, P = 0.016). Comorbidities, identified by relevant diagnosis codes documented during the 12-month period, were more frequent among nonintervention patients than intervention patients, with statistically significant differences observed for the prevalence of COPD (2.7% vs. 1.1%, respectively, P = 0.017) and CAD (16.5% vs. 11.9%, P = 0.002). The mean number of unique medications utilized per patient during the 12-month period was 12.2 for the intervention group compared with 12.9 for the nonintervention group (P = 0.032).

Patients in the intervention group were as likely as nonintervention patients to have all of the recommended processes of care performed (40.1% vs. 38.9%, respectively, P = 0.543; Table 2). Among all processes of care, annual A1c testing was performed with the greatest frequency (92.3% of patients in the intervention group; 94.1% of nonparticipating patients, P = 0.064). Patients in the intervention group had lipid monitoring tests performed slightly less frequently than nonintervention patients (HDL-C testing: intervention group 85.7% vs. nonintervention group 89.7%, P = 0.001; LDL-C testing: intervention group 86.7% vs. nonintervention group 89.8%, P = 0.014). Rates of renal function testing (or use of a renoprotective medication) were approximately the same between groups (intervention group 83.8% vs. nonintervention group 83.3%, P = 0.726). The percentage of patients who received an eye examination during the 12-month period was the lowest of all measures, with 51.2% of intervention patients having documentation of an eye exam during the period, compared with 48.0% of nonintervention patients (P = 0.114 between groups).

Younger patients received all 5 of the recommended care processes less frequently than older patients (30.5%, 38.0%, and 47.0% for patients aged 18-48 years, 49-59 years, and 60 years or older, respectively, P < 0.001). Females had all recommended processes of care performed more frequently than males (40.4% vs. 38.0%, P = 0.019), as did patients who were utilizing insulin (rate among patients with insulin use: 44.9% compared with 39.7% and 32.5% for patients using multiple oral therapy and 47.0% for patients aged 18-48 years, 49-59 years, and 60 years or older, respectively, P < 0.001). The likelihood of having the processes of care performed increased with age, as patients aged 49-59 years were 38% more likely to receive recommended care compared with patients aged 18-48 years (OR = 1.38, 95% CI = 1.23-1.53), while patients aged 60 years or older were approximately twice as likely to receive recommended care compared with the youngest age group (OR = 1.97, 95% CI = 1.75-2.21). Patients in the intervention group were as likely as nonintervention patients to have all of the recommended processes of care performed compared with users of oral antidiabetic monotherapy (OR = 1.23, 95% CI = 1.11-1.36), and patients who utilized insulin at any time during the measurement period were 59% more likely than users of oral monotherapy to receive these processes of care.

### TABLE 3

<table>
<thead>
<tr>
<th>Characteristic (n)</th>
<th>Beta Coefficient</th>
<th>Standard Error</th>
<th>Odds Ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Usual care (9,049)</td>
<td>-</td>
<td>-</td>
<td>Reference</td>
</tr>
<tr>
<td>Intervention (649)</td>
<td>0.0588</td>
<td>0.0847</td>
<td>1.061 (0.898-1.252)</td>
</tr>
<tr>
<td><strong>Age, years</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-48 (2,418)</td>
<td>-</td>
<td>-</td>
<td>Reference</td>
</tr>
<tr>
<td>49-59 (4,239)</td>
<td>0.3181</td>
<td>0.0557</td>
<td>1.375 (1.233-1.533)</td>
</tr>
<tr>
<td>60 and older (3,041)</td>
<td>0.6759</td>
<td>0.0602</td>
<td>1.966 (1.747-2.212)</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (3,804)</td>
<td>-0.0678</td>
<td>0.0446</td>
<td>0.934 (0.856-1.020)</td>
</tr>
<tr>
<td>Male (5,894)</td>
<td>-</td>
<td>-</td>
<td>Reference</td>
</tr>
<tr>
<td><strong>Diabetes medication use</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral monotherapy</td>
<td>-</td>
<td>-</td>
<td>Reference</td>
</tr>
<tr>
<td>Multiple oral therapy (4,288)</td>
<td>0.2064</td>
<td>0.0525</td>
<td>1.229 (1.109-1.363)</td>
</tr>
<tr>
<td>Any insulin (2,532)</td>
<td>0.4621</td>
<td>0.0592</td>
<td>1.587 (1.414-1.783)</td>
</tr>
<tr>
<td><strong>Comorbidity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reference</td>
<td>-</td>
<td>-</td>
<td>Reference</td>
</tr>
<tr>
<td>Asthma (717)</td>
<td>-0.1176</td>
<td>0.0836</td>
<td>0.889 (0.755-1.047)</td>
</tr>
<tr>
<td>CAD (1,568)</td>
<td>0.0393</td>
<td>0.0620</td>
<td>1.040 (0.921-1.174)</td>
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<tr>
<td>CHF (418)</td>
<td>0.0178</td>
<td>0.0108</td>
<td>1.082 (0.794-1.426)</td>
</tr>
<tr>
<td>COPD (251)</td>
<td>-0.2410</td>
<td>0.1366</td>
<td>0.786 (0.601-1.027)</td>
</tr>
<tr>
<td>Mental health diagnosis (966)</td>
<td>-0.0818</td>
<td>0.0730</td>
<td>0.921 (0.799-1.063)</td>
</tr>
<tr>
<td><strong>Number of unique medications utilized during the 12-month follow-up period</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0-5 (1,254)</td>
<td>-</td>
<td>-</td>
<td>Reference</td>
</tr>
<tr>
<td>6-10 (3,065)</td>
<td>0.3229</td>
<td>0.0759</td>
<td>1.381 (1.190-1.603)</td>
</tr>
<tr>
<td>11-20 (4,056)</td>
<td>0.6217</td>
<td>0.0750</td>
<td>1.862 (1.607-2.167)</td>
</tr>
<tr>
<td>21 or more (1,323)</td>
<td>0.7000</td>
<td>0.0930</td>
<td>2.014 (1.678-2.417)</td>
</tr>
</tbody>
</table>

*a* = *c-statistic* = 0.60.

*b* Reference group is the absence of the particular comorbidity.

CAD = coronary artery disease; CHF = congestive heart failure; CI = confidence interval; COPD = chronic obstructive pulmonary disease.
(OR = 1.59, 95% CI = 1.41-1.78). The likelihood of having the processes of care performed increased with each category of the number of unique medications used during the period, with patients utilizing 21 or more unique medications being most likely to receive the processes of care compared with patients utilizing 5 or fewer medications during the period (OR = 2.01, 95% CI = 1.68-2.42). Neither gender nor comorbidity status was associated with differences in the likelihood of receiving the processes of care.

The multivariate model incorporating the propensity-score weights included the intervention status variable and the predictors determined to be statistically significant in constructing the propensity-score weighted model. These included age category, gender, the type of diabetes medication utilized, the comorbidities of asthma and COPD, and the number of unique medications used during the period. The propensity-score adjusted model (Table 4) indicated that intervention group status was associated with a small yet statistically significant increase in the likelihood of receiving all of the recommended care processes during the 12-month time frame (adjusted OR = 1.09, 95% CI = 1.03-1.16).

We calculated mean per-patient all-cause health care costs accrued during the 12-month study period, categorized as medical care cost; prescription drug cost (for all drugs, not just diabetes drugs); and total costs, which represented the sum of medical and prescription drug costs (Figure 2). Prescription drug costs incurred by the payer over the 12-month period were greater for the intervention group than for nonparticipating patients ($3,139 vs. $2,854, respectively, P = 0.001). The average per-patient pharmacy copayment amounts for all drugs during the measurement period were $542 for intervention patients and $545 for nonintervention patients (P = 0.341). The average per-patient 12-month all-cause medical care costs were lower for intervention patients; however, this difference in cost was not statistically significant ($7,475 vs. $8,577, respectively, P = 0.213). Differences in mean per-patient total costs incurred between the intervention and nonintervention groups were also not statistically significant ($10,614 vs. $11,431, respectively, P = 0.666).

### Discussion

This study evaluated the results of a multifaceted approach implemented by a commercial health insurer designed to enhance diabetes management by providing patients with intensified oversight and counseling as provided by nurse case managers, coupled with reduced copayments for diabetes-related medications as an incentive for participating in the intervention including care coordination and agreeing to receive recommended tests. The evaluation of this program focused upon determining rates of performance of 5 recommended care processes and calculating costs of medical care and prescription drugs used during a 12-month period. As we were interested in evaluating the program during its initial phase, our approach was to compare results among
intervention patients with usual care, by forming a comparison group comprising plan members with diabetes who did not participate in the intervention. This approach introduced the possibility of selection bias, as those agreeing to participate in the program may have differed in important ways from nonparticipating members. For example, patients volunteering to participate in the program may have been more inclined than nonvolunteering patients to comply with blood testing for cholesterol monitoring and instructions for glycemic control. While the intervention patients were similar to patients in the comparison group with respect to age distribution and gender, they also utilized insulin more frequently and had a lesser prevalence of COPD (1.1% vs. 2.7%, respectively, \( P = 0.017 \)) and CAD (11.9% vs. 16.5%, \( P = 0.002 \)). These differences suggest that the intervention group in general had a lesser comorbidity burden; yet, they may have had greater diabetes severity, as indicated by the larger percentage of patients with insulin dependence among intervention patients compared with nonintervention patients (31.0% vs. 25.8%, respectively, \( P = 0.004 \)).

We attempted to control for the possibility of selection bias through the use of a propensity score-weighted model, as derived from a separate multivariate model that determined significant predictors of intervention group status. The results of this model were consistent with the findings of the bivariate analyses, which found that intervention group members received these processes of care at a rate similar to that of patients who did not participate in the intervention (40.1% vs. 38.9%, respectively). In the multivariate logistic regression model including all covariates, intervention group status was not predictive of higher rates of performance of the recommended care processes. When assessed using a multivariate model adjusted by propensity score, we found that members enrolled in the program were slightly more likely to have all of the recommended processes of care performed during the measurement period compared with members not enrolled in the program (OR = 1.09, 95% CI = 1.03-1.16).

While this model indicated a small increase in the likelihood of receiving all tests among intervention members, this finding was likely driven by the between-group difference in the rate of one particular test—eye examination rates (51.2% intervention vs. 48.0% nonintervention, \( P = 0.114 \))—as rates of LDL-C and HDL-C testing were slightly lower among intervention patients. In sum, our results indicate that no meaningful difference existed between the intervention and nonintervention groups with regard to performance of the processes of care measured.

Our methodological approach did not permit randomization of patients to the intervention; thus, our findings may have been influenced by between-group differences in the burden of disease and associated intensity of clinical management. Our analyses revealed that the intervention group patients were healthier than nonintervention patients during the study period, as measured by the prevalence of comorbidities and the number of medications utilized. This difference may have yielded closer oversight, more frequent provider contact, and perhaps more aggressive monitoring for nonintervention patients than for the relatively healthier patients in the intervention group. Another proxy for disease burden is the number of unique medications utilized during the study timeframe. The patients in the intervention group were less frequently categorized as using more than 10 medications, a finding that further suggests that intervention members were healthier and perhaps less intensely followed by care providers.

Our analyses identified several factors that were associated with increased rates of performance of recommended care. Age was a most significant predictor, as patients aged 60 years or older were nearly twice as likely as patients aged 18 to 48 years to receive these processes of care. Users of antidiabetic monotherapy and patients utilizing 5 or fewer different medications during the period were also less likely to have all of the processes of care performed. While the margin of improvement for the rates of performance of these processes care was greatest among younger patients and patients utilizing antidiabetic monotherapy (compared with users of combination therapies or insulin), further research is necessary to determine how these subgroups specifically may respond to diabetes disease management programs.

For comparison, we contrasted the rates observed in the present study with the NCQA HEDIS benchmarks described earlier. While we also included HDL-C monitoring in our evaluation, this measure is not included within HEDIS, yet is recommended by the American Diabetes Association. We assumed that HEDIS rates for HDL-C screening would be similar to HEDIS rates for LDL-C screening because both procedures are usually obtained with the same test. In contrasting our intervention sample’s rates with those published by the NCQA representing commercial insurers overall, we found intervention patients to have slightly higher rates for yearly A1c testing (92.3% vs. 89% for HEDIS), LDL-C testing (86.7% vs. 84.8% for HEDIS), and medical attention for nephropathy (83.8% vs. 82.4% for HEDIS). The percentage of members having a yearly eye examination was slightly lower in our intervention sample, with a rate of 51.2% versus 56.5% for HEDIS. Among nonintervention patients in our sample, rates were similar to those of intervention patients and, in fact, higher for lipid measurements. Thus, performance rates for these diabetes-related processes of care among both intervention and nonintervention patients were high, reflecting previous and/or existing standard disease management programs provided to all members having diabetes. As such, the opportunity for improvement resulting from this diabetes incentive program may have been limited given the high baseline rates for most of these measures.

An additional aim of this study was to determine whether
Evaluation of a Program to Improve Diabetes Care Through Intensified Care Management Activities and Diabetes Medication Copayment Reduction

the diabetes incentive program was associated with differences in the costs of medical care and prescription drug utilization. While pharmacy costs were greater among the intervention group members, neither annual per-member medical costs nor total costs differed in statistical significance. The difference in average per-patient overall medical care cost during the period was $1,102, with the intervention patients incurring less spending. This finding may reflect the difference in comorbidity prevalence between the intervention and nonintervention groups yet also was influenced by outlier patients having extremely higher costs, as indicated by the difference in the range of costs between groups (intervention patients $43.9 to $199,694, SD = $17,601; nonintervention patients $0 to $514,394, SD = $22,972). The outlier values would not dramatically influence the nonparametric statistical test applied, which explains the lack of statistical significance for the difference in medical care cost experienced between the groups. Further evaluation of this program over time will be informative in determining if cost reduction among intervention participants is achieved over the longer term.

Intervention participants incurred higher expenditures for prescription drug utilization compared with nonintervention patients. This finding aligned with program expectations, given the expected increased cost borne by the plan for the reduced copayments for antidiabetic medications among intervention members. Yet further analyses revealed that dispensings for lower-cost generic medications were more frequent among nonintervention members. The mean (SD) generic dispensing ratio for all drugs (not just diabetes drugs) was 62.1% (22.4%) among intervention patients compared with 65.4% (23.0%) among nonintervention patients (P < 0.001, t-test, 2 sided). Due to the limitations of our observational study design, we were unable to determine the frequency of dispensing of generic medications among those patients who were offered the program but declined to participate, which would enable a better understanding of the relative value of copayment reduction as perceived by patients using brand-name medication. Further research examining the effects of copayment reduction as a component of disease management in diabetes is warranted, particularly considering that the value of medication therapies is likely to be an increasingly important aspect of formulary designs.

Limitations
Several limitations of this study should be recognized. First and most importantly, we were unable to make comparisons with prior periods to enable a pre-intervention versus postintervention analysis. The intervention may have provided greater gains in performance rates or greater reductions in cost from the previous year for those participating in the program, yet we were unable to measure this possible effect. Also, given the brief 12-month measurement time frame, we were unable to determine the temporal relationships between variables. For example, a member could have been diagnosed with asthma on the last day of the 12-month period and would have been classified as having asthma for the entire study period.

Second, we evaluated all-cause costs but did not examine diabetes-related costs specifically. We sought to determine the overall cost impact associated with this disease management program, which included components potentially affecting expenditures for both diabetes and other health conditions, such as cardiovascular and renal disease. Additionally, we believed that reductions in diabetes-related costs would be more likely than reductions in all-cause costs to occur after the end of the 12-month measurement period. Nevertheless, there may have been a significant impact of this disease management program on diabetes-related costs in particular that was not identified.

Third, we did not evaluate patient adherence to antidiabetic medications. While it was envisioned that copayment reduction might promote medication adherence, the copayment incentive was primarily designed to encourage patient interest and involvement in the disease management program to enhance the quality of care overall, as assessed according to the diabetes-related care processes evaluated in this study. To participate in the program and qualify for the copayment reduction, patients agreed to have an annual physical examination, have A1c and cholesterol testing performed at recommended intervals, and work with a care coordinator. Patients were not required to achieve a particular level of medication adherence. Thus, we focused our evaluation on the program components described in the patient pledge.

Fourth, the all-or-none approach to the composite measure, which represented whether all of the processes of care were performed, could have missed overall better care. For example, receipt of 4 of 5 measures and receipt of 0 of 5 measures were both classified as failing to receive all recommended care. However, it was evident from the rates observed for each specific measure that the processes of care were performed with similar frequency for both the intervention and nonintervention members. Another important limitation pertains to the lack of data available to identify the achievement of therapeutic goals. We determined only whether a test was performed; we were unable to determine the percentage of members who had their blood glucose and lipid levels reduced to recommended goals. Patients could have had all tests performed but still have values representing high risk of diabetic complications.

A fifth limitation of this study is the nature of the administrative data source, which contained information about paid claims only. Any diagnosis, procedure, or medication dispensing that occurred and was not recorded or that was paid out-of-pocket was not included in this study. Additionally, we assumed that dispensed medications were actually taken as prescribed by members, and in this analysis we did not assess adherence to dispensed medications.
Sixth, members choosing to participate in this diabetes incentive program could have been more motivated in managing their health and thus utilized more health care resources. As with any observational study, the lack of randomization allows for the presence, and influence, of biases that we have not identified. Seventh, we chose to include only patients who were utilizing antidiabetic medications. Our results may have differed if we also included patients who were identified as having diabetes but not yet utilizing pharmacotherapy for the condition.

Conclusions
As measured by a composite indicator comprising 5 diabetes-related processes of care, receipt of recommended care was not significantly different for patients participating in a disease management program that included copayment reduction for antidiabetic medications and intensive health coaching, compared with nonparticipating patients with diabetes. Younger patients and those utilizing oral antidiabetic monotherapy were less likely to have these recommended processes of care performed. While prescription drug expenditures incurred by the plan were greater for intervention patients, between-group differences in total costs for medications and medical care were not statistically significant. Further follow-up is required to determine the success of this program over the longer term in promoting quality of care and achieving cost reductions and improved health outcomes.

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DISCLOSURES
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Concept and design were performed by Higgins, Johnson, and Kogut. Data were collected primarily by Higgins and were interpreted primarily by Johnson, Quilliam, and Kogut. The manuscript was written primarily by Johnson and Kogut and was revised primarily by Kogut with Johnson's assistance.

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REFERENCES


### APPENDIX

**ICD-9-CM and CPT Codes Applied in Determining Process-of-Care Rates and Comorbidities**

<table>
<thead>
<tr>
<th>CODE</th>
<th>DESCRIPTION</th>
</tr>
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<tr>
<td>A1c (CPT)</td>
<td>83036, 83037</td>
</tr>
<tr>
<td>Asthma (ICD-9-CM)</td>
<td>493.XX</td>
</tr>
<tr>
<td>COPD (ICD-9-CM)</td>
<td>491.XX, 492.XX, 496</td>
</tr>
<tr>
<td>Coronary artery disease (ICD-9-CM)</td>
<td>410.XX - 414.XX</td>
</tr>
<tr>
<td>Diabetes mellitus (ICD-9-CM)</td>
<td>250.XX, 357.2, 366.41, 648.0X</td>
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<td>Eye examination (CPT/ICD-9-CM)</td>
<td>CPT: 67028, 67030, 67036, 67038-67043, 67101, 67105, 67107, 67108, 67110, 67112, 67114, 67141, 67145, 67208, 67210, 67218, 67220, 67221, 67227, 67228, 92002, 92004, 92012, 92014, 92018, 92019, 92225, 92226, 92230, 92235, 92240, 92250, 92260</td>
</tr>
<tr>
<td>HDL-C (CPT)</td>
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</tr>
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<td>Heart failure (ICD-9-CM)</td>
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</tr>
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<td>LDL-C (CPT)</td>
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</tr>
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<td>Medical attention for nephropathy (CPT/ICD-9-CM)</td>
<td>81000-81003, 81005, 82042, 82043, 82044, 84156, 36145, 36800, 36810, 36815, 36818, 36819-36821, 36831-36833, 50300, 50320, 50340, 50360, 50365, 50370, 50380, 90920, 90921, 90924, 90925, 90935, 90937, 90939, 90940, 90945, 90947, 90989, 90993, 90997, 90999, 99512</td>
</tr>
<tr>
<td>Mental health diagnoses (ICD-9-CM)</td>
<td>293.XX, 294.XX, 295.XX, 296.XX, 297.XX, 298.XX, 299.XX</td>
</tr>
<tr>
<td>Polycystic ovary syndrome (ICD-9-CM)</td>
<td>256.4</td>
</tr>
</tbody>
</table>

*Code sets based upon HEDIS specifications except where noted.20*

*CPT code list also includes codes for eye procedures as a proxy for dilated eye exam.

*HDL-C testing is not a HEDIS measure.

*Codes include a range of procedures that indicate provider attention to renal function per HEDIS specifications.

*Includes code sets for psychosis, schizophrenia, depression, and paranoia.