ORIGINAL RESEARCH

Assessing Medicare Beneficiary Eligibility for Medication Therapy Management Programs Using PINNACLE, a National Cardiovascular Data Registry

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Background: Medication therapy management (MTM) is a mandated component of the 2003 Medicare Modernization Act for Part D prescription drug plans and Medicare Advantage plans, authorizing the pharmacist or other qualified provider to identify, resolve, and prevent medication-related problems for patients with chronic diseases. MTM programs have been shown to improve medication adherence and reduce medication errors while reducing overall costs in patients with cardiovascular (CV) disease; however, MTM has been greatly underutilized for patients with chronic diseases.

Objective: To identify the proportion of Medicare beneficiaries who are eligible for, and who could potentially benefit from, participating in MTM among patients enrolled in the National Cardiovascular Data Registry’s PINNACLE Registry.

Methods: Patient MTM eligibility is based on the presence of multiple chronic diseases and meeting a minimum annual insurance medication costs. We used patient data from 462 academic and private cardiology practices in the United States who participated in the PINNACLE Registry between May 1, 2008, and September 30, 2010, to determine Medicare beneficiaries’ eligibility to participate in an MTM program for patients meeting the MTM criteria of (1) a number of chronic diseases (in this case, the number of CV conditions) and (2) an estimated minimum annual medication expenses, using a weighted average cost calculated based on the average wholesale price of the most often prescribed medications, by class, as extracted from the HealthCore Integrated Research Database and weighted according to prescribing frequency within a class.

Results: Among the Medicare beneficiaries in the PINNACLE Registry, 93,089 (58%) had ≥3 chronic CV conditions, and the median annual estimated medication expenditure per patient enrolled in the PINNACLE Registry was $1329. Of the total of 93,089 Medicare beneficiaries, 21.4% were eligible for MTM, based on the 2010 minimum eligibility criterion of an annual insurer medication expenditure of $3000 or more. These costs ranged from $366 for low-cost generics to $3958 for the highest-cost drug in a class. In addition, based on the 2010 minimum eligibility rule, the proportion of patients eligible for MTM ranged from 7.9% for those eligible for MTM for low-cost generics to 64% of patients eligible for MTM for the highest-cost medication in a class.

Conclusions: These data serve to raise awareness regarding patients’ potential eligibility to receive the benefits of MTM programs. Providers caring for patients with multiple CV conditions, including specialists such as cardiologists, should explain to eligible patients about MTM programs and encourage these patients to take advantage of such programs.
Medication therapy management (MTM) is a mandated component of the 2003 Medicare Modernization Act for Part D prescription drug plans and Medicare Advantage plans, whereby the pharmacist or other qualified provider identifies, resolves, and prevents medication-related problems to optimize the therapeutic outcomes for individual patients. MTM programs typically involve a comprehensive review of all medications, both prescription and nonprescription (including natural and herbal products), that a patient is currently taking. In addition, an evaluation of the patient’s medication-taking behavior is conducted, as well as an assessment of the patient’s understanding, concerns, and expectations regarding his or her current medication regimen and health.

MTM differs greatly from traditional counseling offered by community pharmacists that occurs as part of the drug dispensing process. As part of non-MTM medication dispensing, pharmacists review the drug and identify its indications, directions for use, storage requirements, side effects, long-term toxicity, drug interactions, food interactions, and medication adherence factors. Depending on the number of medications, and whether the patient accepts or denies counseling by a pharmacist at the point of prescription pickup, this service may take approximately 5 to 10 minutes. By contrast, MTM may take 30 to 60 minutes and is a service that is independent of, but can occur in conjunction with, the provision of a medication product.

MTM promotes collaboration with other healthcare providers, which is especially important as patients undergo transitions in care environments. The pharmacist reviews the complete medication profile to explore ways to optimize the patient’s medication therapy. Strategies to optimize medication therapy may include interventions to resolve medication interactions, inappropriate dosing or formulation (eg, tablet vs patch), therapeutic duplication, and ways to improve adherence. These strategies are then discussed with the patient’s prescriber for his or her consideration. On prescriber approval, the pharmacist will inform the patient of any medication changes and will then educate the patient on the appropriate medication self-management.

MTM programs and services have been shown to improve drug therapy goal attainment and medication adherence, as well as to reduce medication errors while reducing overall costs in patients with cardiovascular (CV) disease; however, MTM has been greatly underutilized for chronic diseases, including CV conditions.

Beginning in 2010, Medicare Part D plans were required to implement covered MTM programs that target beneficiaries who have multiple chronic diseases, take multiple medications, and had an anticipated annual drug spending of $4000 in 2009 and $3000 beginning in 2010. Health insurance plans cannot require patients to have more than 3 chronic diseases to meet MTM eligibility, and the plans must target at least 4 of 7 core chronic diseases, including hypertension, heart failure, type 2 diabetes, dyslipidemia, respiratory disease, bone disease–arthritis, or mental health.

National surveys of payers offering MTM programs conducted by the American Pharmacists Association (AphA) indicate that payers believe that the most common challenge to implementing MTM programs is that patients are not interested in these programs or they decline to participate in them, as was indicated by 47% of respondents in a 2010 survey conducted by the AphA.

The purpose of this present study was to identify the proportion of patients who are eligible for, and who could potentially benefit from, participating in MTM, based on Medicare beneficiaries who were enrolled in a large nationally representative outpatient cardiac registry.

**KEY POINTS**
- Medication therapy management (MTM) for chronic diseases was mandated by the 2003 Medicare Modernization Act but is greatly underutilized.
- To participate in an MTM, patients must have ≥3 chronic diseases and meet a set amount of drug spending.
- MTM has been shown to improve drug medication adherence, reduce medication errors, and lower overall costs in patients with CV disease.
- This is the first non–claims data study to estimate patient MTM eligibility among Medicare beneficiaries with multiple cardiovascular (CV) conditions.
- Data used for this analysis came from the Medicare PINNACLE Registry, which collects information from outpatient cardiology practices in the United States to help improve care quality.
- Overall, 7.9% to 64% of patients with ≥3 chronic CV conditions are estimated to meet the $3000 minimum annual drug spending required for MTM program eligibility.
- Payers indicate that the most common barrier to implementing MTM programs is patient lack of willingness to participate in such programs.
- Providers should educate patients on the benefits of MTM programs and encourage their participation.
Methods

The PINNACLE Registry and Study Population

The PINNACLE Registry is a voluntary registry of the National Cardiovascular Data Registry (NCDR) that was initiated by the American College of Cardiology Foundation (ACCF) and that collects data from outpatient cardiology practices to enhance quality improvement. The registry has a standard data set with written definitions, uniform data entry and transmission requirements, and data quality checks. Details on the data collection process have previously been published.10,11

Within participating practices, a variety of patient data are collected at the point of care, including patients’ symptoms, vital signs, comorbidities, selected laboratory tests, medication classes, and health insurance. In addition, data for established performance measures for myocardial infarction, heart failure, dyslipidemia, and atrial fibrillation are collected.11

Data were collected through paper forms that were completed at the time of the clinic visits, or via modification of a practice’s electronic medical record data collection system to comprehensively capture the requisite PINNACLE Registry data elements. Data from practices are routinely submitted to the NCDR, and data quality checks and analyses for this study were performed at Saint Luke’s Mid America Heart Institute (Kansas City, MO), the primary analytical center for the PINNACLE program. The PINNACLE Registry has been reviewed and approved by the ACCF's contracted Institutional Review Board.

Identification of MTM-Eligible Patients

For the purpose of this study, we used patient data from 462 academic and private cardiology practices in the PINNACLE Registry between May 1, 2008, and September 30, 2010 (N = 315,973), consisting of 44 office practices representing all 5 regions of the United States. We further restricted the cohort to include only patients with Medicare insurance, which comprised 160,593 patients (Figure 1).

From the Medicare cohort of 160,593 patients, patients who were eligible for MTM were defined as (1) patients who met the criteria for the minimum number (ie, 3) of chronic diseases, and (2) patients who met the minimum drug spending requirements. Patients were included if they had ≥3 chronic diseases, including hypertension, heart failure, dyslipidemia, type 2 diabetes, or coronary artery disease. Of the total Medicare beneficiaries in the PINNACLE Registry, 93,089 (58%) had ≥3 chronic CV conditions, which constituted the final study sample.

Data extracted from the PINNACLE Registry included demographic information (ie, age, sex, race, and insurance type), CV medical history, and CV-related medications. Medication information collected in the PINNACLE Registry and used in this study included the current prescribing of beta-blockers, angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers, calcium channel blockers, diuretics, statins, nonstatin lipid-lowering medications, aspirin, aspirin plus dipyridamole, or thienopyridines.

Because the PINNACLE Registry collects data only on the medication classes that are prescribed and not at the individual medication level, and overall costs by medication class are not available, we used a weighted average cost calculation to assign costs to medication classes. The weighted average cost was calculated based on the market share data for individual medications from each medication class extracted from the HealthCore Integrated Research Database (HIRD), as well as the average wholesale price (AWP). HIRD data from 2010 were collected for 14 health plans, representing regions across the United States.

The market share for each individual medication in a class was calculated by summing all of the prescriptions for that medication and dividing by the total number of prescriptions for the medication class as a whole using the HIRD for 2010. Because the most common medications made up at least 91% of all drugs for a given medication category (range, 91%-100%), only these were used to determine the weighted average cost for each
medication class. The relative market share was then calculated based on the most common medications. This relative market share of the most common medications was multiplied by the AWP for the median dose of these medications and then added together to calculate the weighted average cost for each medication class.

Sensitivity analyses for determining eligibility were performed by varying drug costs using AWP for the highest cost and a 10-person multidisciplinary clinician panel–defined most frequently prescribed drug in each class. The drugs that were identified as the most frequently prescribed within each of the drug classes noted earlier were metoprolol tartrate, lisinopril, losartan, amiodipine, hydrochlorothiazide, simvastatin, fenofibrate, aspirin, aspirin plus dipyridamole, and clopidogrel. The descriptive statistics, means, medians, and frequency counts were utilized to report the results.

**Results**

Table 1 lists patient demographics, clinical characteristics, and medication use for the 93,089 (58%) Medicare beneficiaries enrolled in the PINNACLE Registry who had ≥ 3 CV conditions. The patients in the PINNACLE Registry are at high risk for CV events, as demonstrated by the high frequency of comorbid CV conditions in this patient population. More than 90% of the patients had hypertension and dyslipidemia, and more than 80% had coronary artery disease—the top 3 conditions in this population. Almost 50% of patients had heart failure, and more than 37% had type 2 diabetes.

As shown in Figure 2, the mean number of medications for CV disease prescribed per patient was 3.5 (± 1.5).

Using the weighted average cost calculation methodology, the median annual estimated medication insurer expenditure per patient was $1329 (Table 2). In the sensitivity analysis, these costs ranged from $366 (low-cost generics identified as frequently prescribed by the clinician panel) to $3958 (highest-cost medication in the class).

In addition, 21.4% of the Medicare patients enrolled in the PINNACLE Registry were eligible for MTM based on the 2010 minimum eligibility rule (ie, an annual insurer medication expenditure of ≥ $3000). The percentage of Medicare beneficiaries enrolled in the PINNACLE Registry who were eligible for MTM based on the 2010 minimum eligibility rule ranged from 7.9% (low-cost generics identified as frequently prescribed by the clinician panel) to 64% (highest-cost medication in the class).

Because of a lower annual expenditure requirement of $3000 for 2010 compared with $4000 for 2009, the percentage of patients eligible for MTM programs increased by more than 3-fold between 2009 and 2010 (from 6.7% to 21.4%).

### Table 1

<table>
<thead>
<tr>
<th>Patient Characteristics: Medicare Beneficiaries in the PINNACLE Registry with ≥3 Chronic CV Conditions</th>
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</thead>
<tbody>
<tr>
<td><strong>Patient characteristics</strong></td>
</tr>
<tr>
<td>Age, mean, yrs (± SD)</td>
</tr>
<tr>
<td>Male sex</td>
</tr>
<tr>
<td><strong>Race</strong></td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>Black</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td><strong>Health insurance type</strong></td>
</tr>
<tr>
<td>Medicare fee for service</td>
</tr>
<tr>
<td>Medicare managed care</td>
</tr>
<tr>
<td><strong>Chronic condition present</strong></td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Dyslipidemia</td>
</tr>
<tr>
<td>Coronary artery disease</td>
</tr>
<tr>
<td>Heart failure</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
</tr>
<tr>
<td>Myocardial infarction</td>
</tr>
<tr>
<td>Peripheral arterial disease</td>
</tr>
<tr>
<td>Previous stroke or transient ischemic attack</td>
</tr>
<tr>
<td><strong>Drug class used</strong></td>
</tr>
<tr>
<td>Statin</td>
</tr>
<tr>
<td>Aspirin</td>
</tr>
<tr>
<td>Beta-blocker</td>
</tr>
<tr>
<td>Diuretic</td>
</tr>
<tr>
<td>ACE inhibitor</td>
</tr>
<tr>
<td>Thienopyridine</td>
</tr>
<tr>
<td>Calcium channel blocker</td>
</tr>
<tr>
<td>Angiotensin receptor blocker</td>
</tr>
<tr>
<td>Nonstatin lipid-lowering drug</td>
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<tr>
<td>Warfarin</td>
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<tr>
<td>Aspirin plus dipyridamole</td>
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ACE indicates angiotensin-converting enzyme; CV, cardiovascular; SD, standard deviation.
in 2009 to 21.4% in 2010), based on the weighted average cost methodology.

Discussion

Based on the data from the PINNACLE Registry, we conservatively estimate that 1 in 5 patients in cardiology practices who have Medicare insurance are eligible for covered MTM programs, although variability exists based on the cost method used (ie, either low-cost generics or high-cost medication in class). We regard this as a conservative estimate, because information regarding other chronic core diseases (eg, respiratory disease, bone disease–arthritis, and mental health) targeted for MTM programs by Medicare plans, as well as medications (eg, insulin for diabetes, proton pump inhibitors, and selective serotonin reuptake inhibitors) were not collected in the PINNACLE Registry and therefore are not included in our analysis. Because MTM programs have been shown to improve medication adherence and therapy goal attainment,2-7 we believe that promoting the utilization of such programs to eligible patients should be the responsibility of all healthcare providers within the framework of care advocated by the American College of Cardiology within the framework of the patient-centered medical home for CV care. To our knowledge, this is the first article that estimates MTM eligibility using non-claims-based data.

Currently, physicians cannot make determinations about insurance eligibility for reimbursement of such insurer-sponsored programs. However, patients or their designees may call their health insurance plan and request information on eligibility for such programs, and healthcare providers can directly contact plans to inquire about existing programs that their patients may be eligible for.

Examples of such programs include (1) a medication review by pharmacists, such as eliminating duplication, such as a patient taking 2 ACE inhibitors, by communicating with prescribers; (2) monitoring by pharmacists of therapy goals, such as a pharmacist measuring a patient’s blood pressure (BP) at periodic pharmacy visits and notifying the cardiologist that his or her BP remains above goal; and (3) monitoring by pharmacists for medication adverse effects, such as a pharmacist reviewing medication adherence with a patient and notifying the prescriber that a statin secondary to myalgia has been discontinued and providing assistance with formulating a new plan for managing dyslipidemia. These programs all serve to enhance the quality of care and to assist patients with meeting their health goals.

Recently, the ACCF 2012 Health Policy Statement on Patient-Centered Care in Cardiovascular Medicine highlighted the need for a CV-focused patient-centered medical home (PCMH) that includes a recommendation

### Table 2  Eligibility for Medication Therapy Management

<table>
<thead>
<tr>
<th>Cost calculation methodology</th>
<th>Median annual medication cost, $a (interquartile range)</th>
<th>2009 MTM eligibility, N (%)</th>
<th>2010 MTM eligibility, N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weighted average cost</td>
<td>1329 (915-2609)</td>
<td>6202 (6.7)</td>
<td>19,903 (21.4)</td>
</tr>
<tr>
<td>Frequently prescribed low-cost drugs b</td>
<td>366 (193-1361)</td>
<td>1084 (1.2)</td>
<td>7326 (7.9)</td>
</tr>
<tr>
<td>Highest-cost drugs</td>
<td>3958 (2406-5358)</td>
<td>46,477 (49.9)</td>
<td>59,619 (64)</td>
</tr>
</tbody>
</table>

**NOTE:** MTM eligibility based on likelihood of exceeding drug cost thresholds of $4000 in 2009 and $3000 in 2010.

aCosts are in US dollars.

bMedications identified as most frequently prescribed by the multidisciplinary clinician panel were the low-cost generics metoprolol tartrate, lisinopril, losartan, amlodipine, hydrochlorothiazide, simvastatin, fenofibrate, aspirin, aspirin plus dipyridamole, and clopidogrel.

MTM indicates medication therapy management.
The potential for pharmacists to reduce hospital readmissions through provisions of MTM services during transitions in care has also been recently highlighted by the American College of Clinical Pharmacy and the American College of Cardiology.

Similar findings exist with respect to the management of dyslipidemia. In the SCRIP-plus study, community pharmacists in Canada assessed patient risk factors for CV disease through patient interviews, measured BP and finger-stick cholesterol levels, identified high-risk patients who were not at their goal low-density lipoprotein cholesterol (LDL-C) level, and worked with family physicians to help patients meet their goal. At 6 months, 31% of patients who were previously not at LDL-C goal achieved that goal. Improvement in LDL-C levels, as well as lower medication costs, were demonstrated in a study comparing pharmacist-based lipid clinic management to usual care.

Additional benefits of pharmacist MTM have been noted by physicians. McGrath and colleagues conducted focus group sessions to explore physicians’ perceptions of MTM programs led by pharmacists. Most physicians had not experienced pharmacist-provided MTM programs, and many physicians were not aware of pharmacist training, including a 6-year professional degree and residency, and preparation, including board certification in pharmacotherapy or ambulatory care, to provide this service. However, physicians believed that the greatest benefit of MTM was the receipt of an up-to-date complete medication list that is generated after a pharmacist completes an MTM encounter with a patient.

Another benefit that physicians found was that MTM programs would address common medication issues they identified in their practices, such as patient nonadherence, side effects, drug interactions, medication costs, and incomplete patient understanding of the medication regimen. The potential for pharmacists to reduce hospital readmissions through provisions of MTM services during transitions in care has also been recently highlighted by the American College of Clinical Pharmacy and the American College of Cardiology.

Pharmacists are also qualified to provide many services that are central to integrated care models, such as the PCMH and accountable care organizations. Expanding services, such as MTM, in these care delivery models presents the opportunity for improved clinical, economic, and humanistic outcomes, as well as increasing the pharmacists’ value to the evolving US healthcare system.

**Limitations**

Although this study involved a large sample size, the patients enrolled in the PINNACLE Registry at the time of the data collection represented 46 office practices and therefore may not necessarily be representative of the entire US cardiology patient population.

Furthermore, because drug class names (eg, ACE inhibitors) and not specific drug names (eg, enalapril, lisinopril) were provided in the registry for some medications, the exact drug costs could not be calculated. Therefore, drug costs were estimated by using a 10-person multidisciplinary clinician panel to identify the most frequently prescribed agents within each class.

Finally, because the PINNACLE Registry does not collect data on non-CV conditions and non-CV medications, the number of chronic diseases per patient and the medication costs were underestimated in this study.

**Conclusion**

This analysis serves to raise providers’ awareness of their patients’ potential eligibility to receive the benefits of MTM programs. Medicare Part D health plans often notify beneficiaries of potential eligibility for specific disease management programs, such as for hypertension, with subscriber mailings, but they do not inform cardiol-
ogists of their individual patient’s eligibility. Payers indicate that the most common barrier to implementing MTM programs is the lack of interest and willingness of patients to participate in such programs. By taking a few minutes to ask patients with multiple CV conditions who are seeing a cardiologist whether they have been contacted by their insurer to participate in an MTM program and by encouraging patients to participate, providers are in a position to explain and to encourage patients to take advantage of such programs.

Acknowledgments

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Author Disclosure Statement
Dr Spinler, Dr Cziraky, Dr Dueñas, Dr Thomas, Dr Reinhold, Dr Willey, and Ms Tang have reported no conflicts of interest.

References

Hanging Together for Patient-Centered Medical Care

By Albert Tzeel, MD, MHSA, FACPE
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The term “patient-centered care,” first espoused by the Institute of Medicine in its Crossing the Quality Chasm report,1 serves as 1 of the 6 key tenets of high-quality medical care. Patient-centered care implies just what it states: it is up to the patient to be an engaged and fully involved participant in his or her own health care. Successful treatment of a given condition lies, like beauty, in the eye of the beholder, and if the patient does not play an active role in improving or, at least, maintaining his or her own personal health, a good outcome is less likely to be achieved.

 providers/patients: A focus on “good outcomes” also dominates the current shift in accountabilities for a given patient’s care: such outcomes have served
as the impetus for various quality-based contracts between payers and providers. Although many of these contracts fall under the rubric of phrases such as “care coordination” or “shared risk,” others fall under the heading of “outcomes-based contracts” or “accountable care organizations” (ACOs). However, they all share the common trait that behavior change that results in aligned incentives between individual patients and their providers should promote “good outcomes.” To align the individual patient’s incentives for good health, a physician should, as Epstein and Street note, “invite the patient to participate” in his or her own care. But where should this “invitation” come from?

Most of the focus on providing patient-centered care has fallen on the primary care physician (PCP). Whether providing a patient-centered medical home for a panel of patients with chronic diseases or serving as the gatekeeper in various HMO-based products, the PCP has long been charged with the clinical and financial accountabilities for those under his or her care. Yet, in the new models of quality-based contracts noted above, such as the ACO, the PCP cannot be expected to manage the complete care of his or her patients alone. And that is where the article by Spinler and colleagues in this issue of *American Health & Drug Benefits* fits in.4

Spinler and colleagues’ study provides 3 key and exciting findings that enhance patient-centered care and accountability for care outcomes. First, their study shows that a non–claims-based system can be used to identify the appropriate members for outreach. It is when these members become engaged in their own healthcare that one can say that true patient-centered care is being provided and that better outcomes become possible. That a registry is being used rather than complete reliance on claims can also provide benefits in a time when the upcoming transition to the *International Classification of Diseases, Tenth Revision* could play havoc with multiple claims systems.

Second, their data show that we have significant room for improvement in addressing members who are eligible for medication therapy management (MTM); using a non–claims-based system could provide a complement to the routinely used claims-based systems and, hopefully, result in improved outreach and care.

Finally, and perhaps most important, Spinler and colleagues’ study shows that when it comes to improving the outcomes of care for members with cardiovascular (CV) disease, all providers have a responsibility to share in the accountability for improved outcomes through patient-centered care. As they so eloquently state, “we believe that promoting the utilization of such programs [ie, MTM] to eligible patients should be the responsibility of all healthcare providers within the framework of care advocated by the ACC within the framework of the patient-centered medical home for CV care.”

Although ACOs require the presence of PCPs, they can certainly include specialists, and many do. But, even if they do not, the PCPs who are accountable for the care of patients in their charge will need to make sure that the specialists they work with take an active role in making sure that their shared patients are “invited” to become engaged in their own healthcare, whether through MTM or some other entity; this is truly a shared responsibility and not one that merely falls on the PCPs. Why? Because for patient-centered care and accountable care to be successful, physicians will need to be accountable to each other, as well as to their patients: they will all need to hang together. Because, as Benjamin Franklin reminded his colleagues at the signing of the Declaration of Independence, “we must all hang together or, assuredly, we will all hang separately.”