

Evolving Strategies for Optimal Care Management and Plan Benefit Designs

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Abstract

As a prevalent, complex disease, diabetes presents a challenge to managed care. Strategies to optimize type 2 diabetes care management and treatment outcomes have been evolving over the past several years. Novel economic incentive programs (eg, those outlined in the Patient Protection and Affordable Care Act of 2010 that tie revenue from Medicare Advantage plans to the quality of healthcare delivered) are being implemented, as are evidence-based interventions designed to optimize treatment, reduce clinical complications, and lower the total financial burden of the disease. Another step that can improve outcomes is to align managed care diabetes treatment algorithms with national treatment guidelines. In addition, designing the pharmacy benefit to emphasize the overall value of treatment and minimize out-of-pocket expenses for patients can be an effective approach to reducing prescription abandonment. The implementation of emerging models of care that encourage collaboration between providers, support lifestyle changes, and engage patients to become partners in their own treatment also appears to be effective.

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For author information and disclosures, see end of text.

Why Managed Care Is Concerned About Diabetes

Diabetes is a striking example of how slowly population health improvements such as strengthened primary care, new models of care coordination, efforts to prompt consumers to change behavior, and payment incentives to stimulate quality improvement and appropriateness of care are implemented.¹ As benefit designs evolve, many employer groups will shift to an intensive focus on diabetes management by investing in efforts that will help their employees achieve significant reductions in their out-of-pocket expenses for diabetes care. Diabetes can also serve as a model for other long-term care situations, such as hypertension and weight loss. Payment incentives can ultimately stimulate quality care improvement. Economic incentives are also necessary to motivate implementation of the patient-centered medical home and accountable care models of care delivery.

Diabetes currently affects 25.8 million adults in the United States, or 8.3% of the population.² By 2050, the adult prevalence is projected to be as high as 1 in 3.³ Diabetes is the leading cause of adult blindness and end-stage kidney disease, and also increases the risk of cardiovascular disease by 2- to 4-fold.² Prediabetes, an intermediate state between normal glucose homeostasis and diabetes, is projected to affect more than one-third of the American population by 2021.¹

Total costs for plan members with diabetes are 2.7 times higher than those for patients without diabetes.¹ If, as predicted, 15% of American adults have diabetes by 2021, the estimated total costs of the disease will exceed \$3.5 trillion.¹ The total cost of medical care in individuals with diabetes increases as the glycated hemoglobin (A1C) levels increase,⁴ most likely because elevated A1C level is associated with a greater number of complications.⁵ For example, every 1% increase in A1C level increases the risk of microvascular complications by 37%, any diabetes-related complication by 21%, fatal and nonfatal myocardial infarction by 14%, and diabetes-related death by 21%.⁵

In addition to its value as an indicator of diabetic complications, A1C level is used to examine the relationship between glycemic control and healthcare utilization and cost. Successful glycemic control was shown to have positively affected healthcare utilization and cost when examining (1) baseline A1C levels and costs over a 3-year follow-up; (2) mean A1C level over a 3-year period and adjusted

■ **Table.** Aggressive Antidiabetic Treatment Is Necessary to Favorably Impact Healthcare Costs Attributable to T2DM⁶

	Cost per Member per Year		
	<7.0	>7.0 to ≤9.0	>9.0
A1C level, %	<7.0	>7.0 to ≤9.0	>9.0
Level of glycemic control	Good	Fair	Poor
Diabetes prescription drug costs, \$	377	465 ^a	423 ^a
Total annual costs attributable to diabetes, \$	1505	1801	1871

A1C indicates glycated hemoglobin; T2DM, type 2 diabetes mellitus.
^aP < .05 vs patients with A1C level <7.0 mg/dL.
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rates for hospital admissions; and (3) the effect of change in A1C level on total healthcare expenditures.⁶

Guidelines published by the American Diabetes Association⁷ (ADA) and the American Association of Clinical Endocrinology/American College of Endocrinology⁸ (AACE/ACE) emphasize the importance of lowering A1C level to less than 7.0%, a level that minimizes the risk of microvascular and macrovascular complications and is associated with lower overall costs (Table).⁶ However, nearly half of patients diagnosed with type 2 diabetes mellitus (T2DM) have suboptimal glycemic levels.⁶ Oglesby et al reported that compared with patients with “good” glycemic control (A1C level ≤7%), patients with “poor” control (A1C level >7.01%) account for the greatest proportion of the cost burden associated with diabetes.⁶ Thus, an investment in intensive glycemic control can provide a substantial cost benefit.⁶

Diabetes Treatment Guidelines

Guidelines developed by 2 of the most prominent professional organizations involved in the care of patients with diabetes, the ADA and AACE/ACE, provide evidence-based recommendations for the diagnosis and treatment of patients with diabetes.^{7,8} Although it is critical that guidelines reflect the most recent advances in medical therapy to be relevant, keeping the guidelines up-to-date can be difficult in a disease state with rapidly evolving treatment options.

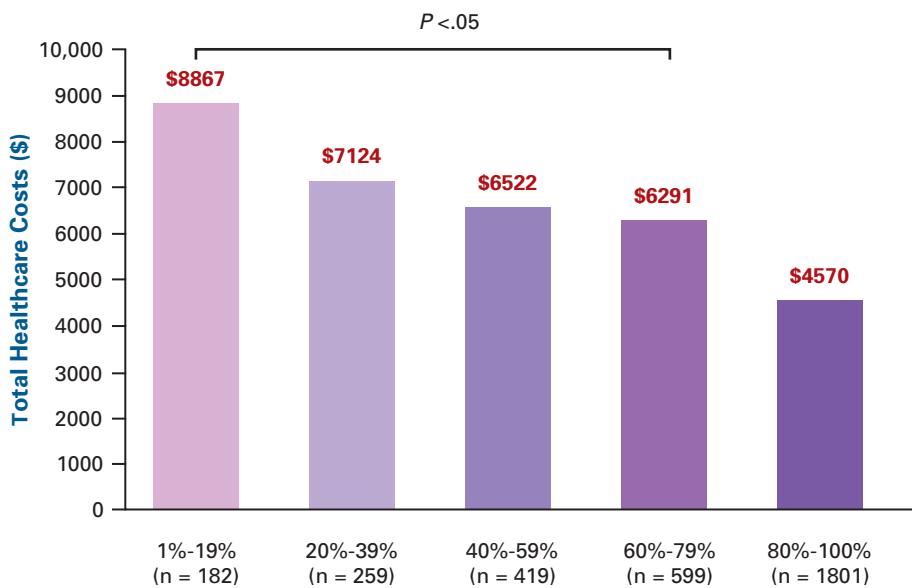
Although there are minor differences in the glucose targets recommended by the ADA and AACE/ACE (<7.0% and ≤6.5% for the ADA and AACE/ACE, respectively), both sets of guidelines emphasize early diagnosis and intensification of therapy to achieve and maintain control of A1C level.^{7,8} Treatment goals should be aligned with patient characteristics: more stringent A1C targets (eg, 6.0%-6.5%) might be considered in patients with long life expectancy, no significant risk of cardiovascular disease, and short-duration disease if an A1C target of less than 6.5% can be achieved without significant hypoglycemia or other adverse treatment

effects.^{7,8} Conversely, less-stringent A1C goals (eg, 7.5%-8.0%) are appropriate for patients with a history of severe hypoglycemia, short life expectancy, or extensive comorbid conditions, and those in whom the A1C target is difficult to attain.⁹ Progress toward the goal should be monitored every 2 to 3 months and therapeutic adjustments made to ensure achievement and/or maintenance of the desired glycemic response.^{7,8}

Both sets of guidelines recommend intervention at the time of diagnosis with metformin in combination with lifestyle changes (eg, weight loss, exercise, diabetes self-management education, and healthy dietary changes) and ongoing timely augmentation of therapy with additional agents as a means of achieving and maintaining target levels of glycemic control.^{7,8,10} If A1C targets are not achieved, treatment should be intensified by the addition of another agent from a different class.¹⁰ For example, if lifestyle changes and metformin monotherapy do not achieve/maintain glycemic control after approximately 3 months of treatment, the next step would be to add a second oral agent, a GLP-1 receptor agonist, or basal insulin. If no clinically meaningful glycemic reduction is demonstrated with the addition of the second drug, that agent should be discontinued and another with a different mechanism of action substituted.⁹ If hypoglycemia or weight gain are of concern, an incretin-related drug is recommended.^{10,11} Because there are insufficient data from long-term comparative effectiveness trials, uniform recommendations on the best agent to be combined with metformin cannot be made. Thus, advantages and disadvantages of specific drugs for each patient should be considered.⁹

The AACE/ACE and ADA algorithms are similar with the major exception that the AACE/ACE treatment recommendations are stratified by A1C levels.⁸ When A1C level is between 6.5% and 7.5%, the AACE/ACE generally recommends metformin monotherapy as first-line therapy, although therapies such as incretins and thiazolidinediones (TZDs) are recommended when necessary.⁸ For patients

■ **Figure 1. Medication Adherence Rates Compared With Total Healthcare Costs¹⁶**



Adherence to therapy (defined as the percentage of days a patient had a supply of medication for the diagnosed condition) decreased as the copayment amount increased. Total healthcare costs were significantly ($P < .05$) higher when adherence was less than 80%. Reprinted with permission from Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. *Med Care*. 2005;43(6):521-530.

with A1C levels between 7.6% and 9.0%, dual therapy is the initial recommendation, with earlier addition of a GLP-1 receptor agonist and a TZD.⁸ For these patients, the sulfonylureas are introduced earlier because of concerns about hypoglycemia and/or weight gain.⁸ When A1C level exceeds 9.0%, or for symptomatic patients, immediate insulin therapy is recommended along with other agents.⁸

Managed Care Treatment Algorithms

To successfully impact treatment outcomes, treatment algorithms must be easy to use, serve as a quick reference, act as a shared voice within the health plan and its affiliated practice groups, and advocate classes of agents rather than specific products. Treatment recommendations contained within the algorithm must also be consistent with the pharmacology of the available agents, offer several therapeutic options, and provide follow-up guidelines. Most importantly, the algorithm must be successful in getting patients to goal.

Step therapy and treatment algorithms are used in many managed care settings to encourage use of preferred therapies to control cost while also ensuring the delivery of high-quality care. Step therapy utilizes an algorithm that requires first-line use of a medication(s) within the drug class (usually a generic) before receiving coverage for a second-line agent (usually a branded agent).¹² Step therapy is promoted

through the use of online claim edits, prior authorization, or implementation of approved guidelines.¹² At the current time, most managed care algorithms position metformin as the primary first-line agent. In many cases, it is the only real step edit in place. Beyond first line, barriers to the other classes of drugs have mostly been removed.¹³

The development of many managed care diabetes treatment algorithms is driven not by the health plan, but by the medical group practices affiliated with the plan. The role of the health plan is to review patient outcomes resulting from use of the algorithm. Rather than looking at whether a patient

is on or off a protocol, the focus of the plan administrators is on the clinical data. For example, plan administrators review data on adverse events, achievement of A1C targets, titration of the current therapy, timing of the implementation of a new therapy, introduction of multidrug therapy, and clinical laboratory data.¹³ Predictive modeling is used to analyze outcomes, with the results used to make adjustments in the clinical pathways and treatment plans. This process is relatively straightforward when the health plan and affiliated medical groups share an integrated electronic medical record system.

Benefit Design, Adherence, and Healthcare Costs

In an effort to manage prescription drug expenditures, many health plans have implemented a pharmacy benefit that shifts a greater proportion of drug costs to the patient through the use of higher copayments. However, high out-of-pocket expenses can negatively affect patient adherence and increase treatment abandonment.^{14,15} For example, Taira et al demonstrated that patient adherence to prescribed therapy decreased as copayment amounts increased,¹⁴ an observation that strengthens the argument that reducing copayments may be a successful strategy to increase adherence.¹⁵ Adherence to treatment is not only important for improving clinical outcomes, but also for controlling overall healthcare costs.

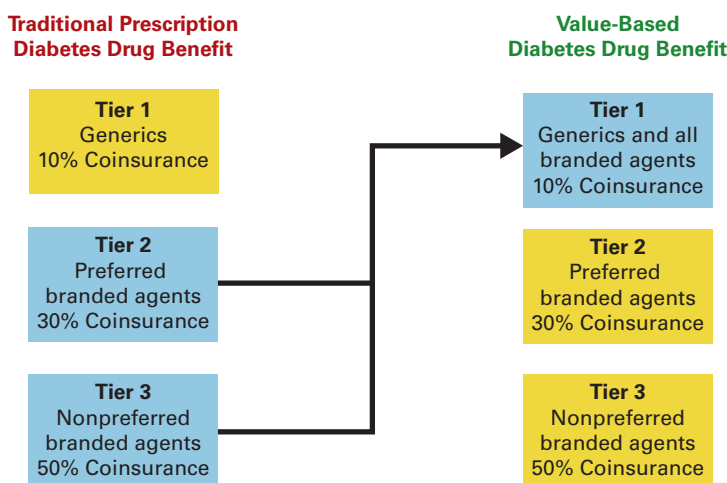
Sokol et al reported that total healthcare costs for patients with at least 80% adherence to a diabetes treatment regimen were significantly lower than those for patients with adherence rates less than 80% (Figure 1).¹⁶

In an effort to minimize the patient's share of the cost of care while maintaining high-quality treatment outcomes, several payers have implemented a value-based pharmacy benefit. Value-based benefits adjust patients' out-of-pocket costs for specific services based on an assessment of the clinical benefit achieved: the greater the clinical benefit, the lower the patient's cost share.¹⁵ In a value-based benefit, copayments are reduced for asthma, diabetes, hypertension, and lipid-lowering therapy, but not eliminated for patients who are likely to migrate to the high-resource utilization demographic.

The earliest users of the value-based benefit design were forward-thinking employer groups who hoped to motivate patients to make healthy lifestyle choices through the use of positive incentives. For example, patients were reimbursed for the cost of a gym membership or for the cost of weight loss and nutritional counseling. More recently, the use of disincentives has become the norm as payers have begun to penalize patients for poor health choices. Now, it is more common for out-of-pocket expenses to increase if patients fail to achieve certain weight loss, blood pressure reduction, or glycemic control goals. With substantial savings possible for some individuals, it is an innovative way to motivate patients to achieve their goals.

Value-based benefit design has helped improve compliance and quality. Employers such as Pitney Bowes and Marriott have seen improved achievement of treatment targets as well as a 10% to 15% improvement in medication adherence when copayments were reduced.¹⁵ At Pitney Bowes, all antidiabetic drugs and devices were shifted from tiers 2 and 3 to tier 1 to reduce out-of-pocket costs (Figure 2).¹⁵ Follow-up data collected 3 years after revising the pharmacy benefit indicated that medication possession rates increased significantly and the use of fixed-combination drugs increased.¹⁷ Additionally, average total pharmacy cost decreased by 7% and emergency department visits were reduced by 22%, suggesting a significant reduction in overall direct healthcare costs.¹⁷ Participants with diabetes had a 6% lower cost using a strategy that encouraged the use of

■ **Figure 2.** Comparison of a Traditional Versus Value-Based Pharmacy Benefit Design for Diabetes¹⁵



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combination therapy and disease management for improving adherence.¹⁷

Emerging Model of Healthcare Delivery

Political and economic pressures are driving the development of new payment models and creating incentives for more coordinated and higher-quality healthcare. The Patient Protection and Affordable Care Act (PPACA) of 2010 included the ability for the Centers for Medicare & Medicaid Services (CMS) to tie the revenue from Medicare Advantage plans to their performance in a quality assessment program called the CMS Star Rating System.¹⁸ This system provides Medicare with a tool to assess 50 performance measures associated with clinical quality, the effectiveness of clinical processes, clinical outcomes, member satisfaction, and administrative performance of the plan. Each plan is rated between 1 and 5 stars, with 1 star representing poor performance, 3 stars representing average performance, and 5 stars representing excellent performance. The performance measures used to derive a plan's 2012 star rating are derived from the Healthcare Effectiveness Data and Information Set, Consumer Assessment of Healthcare Providers and Systems, Medicare Health Outcomes Survey, Part D medication metrics, and plan administrative data.¹⁸

In 2012, Medicare Advantage plans will begin to receive bonus payments based on quality ratings. These payments were initially established in the PPACA, which provides for bonus payments to plans that receive at least

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4 stars and to unrated plans beginning in 2012. In addition to the bonus payments established by the healthcare reform law, CMS launched a 3-year demonstration in 2012 that increases the size of bonuses for these plans and also provides bonuses to plans receiving 3 or 3.5 stars. According to CMS, the purpose of the demonstration is to encourage plans to improve performance at various star rating levels and to test whether providing scaled bonuses will lead to more rapid and larger year-to-year quality improvements in Medicare Advantage program quality scores compared with the bonus structure under the healthcare reform law. Ultimately, the performance of the health plan will be used to determine plan revenue, and beginning with the 2014 star rating (which is based on 2012 calendar year data), plans without at least 4 stars will lose approximately 5% of revenue annually.¹⁸

Other emerging models designed to improve the quality of healthcare include the creation of accountable care organizations, patient-centered medical homes, home-based chronic care management, community health teams, and healthcare innovation zones. Many of these efforts are intended to increase the participation of patients in their own healthcare, and include outreach strategies that effectively extend the patient-provider relationship beyond the clinic and into patients' homes. For example, using inexpensive chip technology and wireless devices, home glucometers regularly update the patient record every time a blood glucose level is measured outside the clinic. In addition, body weight, blood pressure measurements, and other variables can be transferred to the electronic medical record via a smartphone. Technology, specifically text and e-mail, is also changing the way patients communicate with their physician and other providers.

Conclusion

The prevalence of T2DM and its associated costs continue to rise. Effective treatment guidelines and algorithms have been established, but they must be implemented in routine practice to create a change in outcomes. Guidelines must also be up-to-date and reflect the most recent therapeutic advances. New care delivery models and payment strategies and incentives for coordinating care and increasing quality are necessary. Leveraging opportunities with novel care delivery models such as accountable care organizations and medical homes can favorably impact treatment outcomes. Economic incentive strategies similar to the CMS 5-Star Rating System can motivate plans to improve coordination of care. A value-based benefit design is a proven strategy to increase T2DM treatment adherence and it emphasizes high-

value medical services by lowering out-of-pocket expenses for patients. Implementing these changes could help managed care organizations enhance the quality of healthcare delivery, provide incentives for patients to take more responsibility for their health, and effectively improve treatment outcomes while managing costs.

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REFERENCES

1. Vojta D, De Sa J, Prospect T, Stevens S. Effective interventions for stemming the growing crisis of diabetes and prediabetes: a national payer's perspective. *Health Aff (Millwood)*. 2012;31(1):20-26.
2. Centers for Disease Control and Prevention. National diabetes fact sheet: national estimates and general information on diabetes and prediabetes in the United States, 2011. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2011.
3. Number of Americans with diabetes projected to double or triple by 2050 [press release]. Center for Disease Control and Prevention; October 22, 2010. <http://www.cdc.gov/media/press-rel/2010/r101022.html>. Accessed June 28, 2012.
4. Gilmer TP, O'Connor PJ, Manning WG, Rush WA. The cost to health plans of poor glycemic control. *Diabetes Care*. 1997;20(12):1847-1853.
5. Stratton IM, Adler AI, Neil HA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ*. 2000;321(7258):405-412.
6. Oglesby AK, Secnik K, Barron J, Al-Zakwani I, Lage MJ. The association between diabetes related medical costs and glycemic control: a retrospective analysis. *Cost Eff Resour Alloc*. 2006;4:1.
7. Nathan DM, Buse JB, Davidson MB, et al; American Diabetes Association; European Association for Study of Diabetes. Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. 2009;32(1):193-203.
8. Rodbard HW, Jellinger PS, Davidson JA, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology consensus panel on type 2 diabetes mellitus: an algorithm for glycemic control. *Endocr Pract*. 2009;15(6):540-559.
9. Inzucchi SE, Bergenstal RM, Buse JB, et al; American Diabetes Association; European Association for the Study of Diabetes. Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care*. 2012;35(6):1364-1379.
10. American Diabetes Association. Standards of medical care in diabetes-2011. *Diabetes Care*. 2011;34(suppl 1):S11-S61.
11. Handelsman Y, Mechanick JI, Blonde L, et al; AACE Task Force for Developing Diabetes Comprehensive Care Plan.

- American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for developing a diabetes mellitus comprehensive care plan. *Endocr Pract*. 2011;17(suppl 2):1-53.
12. Gleason PP, Tran T, Tiberg K, West B, Walters C, Lassen D. Angiotensin receptor blocker (ARB) and brand angiotensin-converting enzyme inhibitor (ACEI) step-therapy program outcomes [abstract]. *J Manag Care Pharm*. 2007;13(2):164-165.
13. Scan Health Plan, Inc. Guidelines for diabetes. <http://www.scanhealthplan.com/documents/cme/clinical-guidelines/diabetes.pdf>. Published November 2011. Accessed June 28, 2012.
14. Taira DA, Wong KS, Frech-Tamas F, et al. Copayment level and compliance with antihypertensive medication: analysis and policy implications for managed care. *Am J Manag Care*. 2006;12(11):678-683.
15. Mahoney JJ. Value-based benefit design: using a predictive modeling approach to improve compliance. *J Manag Care Pharm*. 2008;14(6 suppl B):3-8.
16. Sokol MC, McGuigan KA, Verbrugge RR, Epstein RS. Impact of medication adherence on hospitalization risk and healthcare cost. *Med Care*. 2005;43(6):521-530.
17. Chernew ME, Shah MR, Wegh A, et al. Impact of decreasing copayments on medication adherence within a disease management environment. *Health Aff (Millwood)*. 2008;27(1):103-112.
18. Congressional Research Service. Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA): Summary and Timeline. <http://www.ncsl.org/documents/health/ACAMCProv.pdf>. Published January 24, 2011. Accessed July 26, 2012.