

Meeting Report

The Center for Insulin-Dependent Diabetes Access Reimbursement Advisory Panel Meeting Summary, December 12, 2003

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BACKGROUND

THE CENTER FOR INSULIN-DEPENDENT DIABETES ACCESS (the Center) was created to ensure that those with insulin-dependent (Type I) diabetes have full access to new technologies as determined by their physician. During its first year of operation, the Center focused on identifying and understanding coverage and payment barriers to intensive diabetes management technologies, including insulin pumps, minimally and noninvasive blood glucose monitoring devices, and other available technologies, as well as helping to ensure patient access to new innovations such as islet cell transplantation. The Center was created by the Juvenile Diabetes Research Foundation International (JDRF) and is funded by an unrestricted educational grant from the Medtronic Foundation. Reimbursement and policy experts at The Health Strategies Consultancy, LLC (Health Strategies) staff the Center.

On December 12, 2003, the Center convened the first meeting of its Reimbursement Advisory Panel (the Panel) in Washington, DC to bring together key stakeholders to discuss the relationship between reimbursement (coverage, coding, and payment) and patient access to existing and new evolutions in care for Type I diabetes. The overall goal of the Panel was to assess the clinical, economic, and other data needs required from various reimbursement

stakeholders in order to expand access to Type I diabetes treatments associated with intensive insulin management. The Panel's first meeting also was designed to educate key decision-makers about new technologies for the treatment of Type I diabetes, including islet cell transplantation, and to develop a network of thought-leaders with a vested interest in improving access to and reimbursement for these technologies.

Participants on the Panel represent perspectives from the research, clinical, payer (public and private), and patient communities. Specifically, the Panel was composed of the following individuals (see Appendix for a complete list of panel participants):

1. Public payers: former and current Medicare carrier medical directors;
2. Private payers: medical directors from private health insurance plans;
3. Patients: a certified diabetes educator and a JDRF government relations committee volunteer (and parent of a child with Type I diabetes);
4. Physicians: clinicians and researchers involved with diabetes treatments and technologies, including those with experience in reimbursement issues; and
5. Technology researchers and evaluators: individuals with experience evaluating new technologies for coverage and payment.

In order to address the Panel's objectives, the meeting was divided into two sessions. The first session focused on reimbursement for currently available diabetes technologies used in intensive insulin management, with a focus on noninvasive/minimally invasive blood glucose monitoring systems. The second session addressed curative treatments in development for Type I diabetes with a focus on islet cell transplantation. The following presentations were given to the Panel:

- Jenifer Levinson from Health Strategies provided an overview of the evolution in treatments for Type I diabetes, including public and private payer reimbursement limitations. Specifically, Ms. Levinson provided background on the reimbursement environment for existing diabetes treatments and technologies, as well as those in development.
- John Mastrototaro, Ph.D., from Medtronic MiniMed presented on noninvasive/minimally invasive blood glucose monitoring systems, including those for consumers. His presentation outlined existing technologies along with technologies in development. He also presented some of the clinical and economic challenges that developers of new technologies for Type I diabetes face.
- Bernhard Hering, M.D., from the University of Minnesota provided an overview of islet cell transplantation, including details of the procedure and information on ongoing clinical trials, recent successes, and future research plans. His presentation addressed study limitations—largely those related to funding and strict inclusion criteria—that have restricted the number of study patients to date.

After each presentation, the Panelists engaged in a facilitated discussion to identify obstacles and ways to overcome such obstacles in order to improve reimbursement and patient access to Type I diabetes treatments and technologies. It is important to note that the Panel was not designed to obtain consensus opinions. Rather, the Panel focused on obtaining a variety of perspectives on reimbursement issues related to Type I diabetes care.

The following document summarizes the major points discussed at the meeting and, based on the Panel discussion, identifies possible next steps to obtain widespread coverage and payment for existing and new diabetes-related technologies.

INTENSIVE INSULIN MANAGEMENT

The first session of the Panel was devoted to reimbursement barriers for intensive insulin management. The Panel noted the Diabetes Control and Complications Trial (DCCT)¹ conclusively established hemoglobin A1c (HbA1c) as an appropriate proxy for measuring outcomes in individuals with Type I diabetes and that DCCT also demonstrated intensive insulin management was successful in reducing HbA1c levels. The Panel members agreed that: (1) intensive insulin management should be the standard of care, and (2) acceptance of intensive insulin management is not as widespread as it should be. Panel members, particularly the providers, thought that reimbursement is an important barrier to widespread adoption of intensive insulin management. Reimbursement and other barriers to intensive insulin management discussed by the Panel are outlined below.

Discussion among Panel members indicated that intensive insulin management is an effective method to control diabetes; however, perverse payment incentives discourage providers from prescribing it. Impediments to more widespread use of intensive insulin management include differences between how providers and payers view the added value of such services, lack of expertise among certain provider groups [particularly primary care physicians (PCPs)], patient compliance issues, and lack of financial incentives to provide quality care, among others. Each of the major Panel perspectives is outlined below.

The provider perspective

Physicians and diabetes educators agreed that the current episodic nature of payment for provider services is unsuitable for the chronic care paradigm associated with Type I diabetes treatment. As a result, many services related to

effective patient management such as telephone and e-mail communication, data interpretation, and ongoing patient education often are not reimbursed or are under-reimbursed by most payers, discouraging providers from committing resources to these services.

The practicing physicians on the Panel—all of whom practice at leading institutions—were confident that intensive insulin management is currently the best manner with which to monitor and treat Type I diabetes. However, the Panel acknowledged the importance of intensive insulin management is not well understood by *all* physicians, particularly PCPs and community endocrinologists; nor is the importance of intensive insulin management well understood by all third-party payers.

Providers expressed frustration regarding the inability of the provider community to communicate the importance of intensive insulin management to other stakeholders. Panelists felt efforts to educate community physicians, PCPs, and endocrinologists as well as payers should be intensified with possible financial incentives related to improved patient outcomes.

In some areas of the country, steps have been taken to improve outcomes for individuals with Type I diabetes through financial incentives. For example, several large employers and health plans have collaborated to operate a program called “Bridges to Excellence” that financially awards physicians for using technologies that improve outcomes for plan members with Type I diabetes. To further align incentives, Bridges to Excellence offers financial awards to patients for managing their diabetes effectively. Despite some moderate successes in designing quality- and technology-motivated incentive programs, most current programs are not far enough along to make conclusive results available on program effectiveness. Moreover, it is generally agreed that these programs are extremely difficult to design and implement. Nonetheless, there may still be opportunities for pursuing financial incentive programs to improve diabetes outcomes and encourage uptake of new technologies.

The payer perspective

Similar to providers, there appears to be a general understanding among payers that

HbA1c levels are an accurate determinant of diabetes patient outcomes. (It is important to note that payers are a diverse group, and the Panel including a range of payers, including both public and private. Where relevant, we have noted where different payers on the Panel expressed differing opinions.) However, payers claim the effectiveness of technologies used to manage diabetes and HbA1c levels must be more explicitly demonstrated through clinical studies. This is particularly challenging for the less tangible services associated with intensive insulin management, such as education programs. Payers also noted that certain services associated with intensive insulin management, including insulin pump initiation and operation, have historically been provided by product manufacturers. Thus, payers are unlikely to reimburse for these services.

A key issue identified by payers is that the components of intensive insulin management are not clearly defined, and thus it is difficult for payers to assign value to them. In other words, there is no “standard” for intensive insulin management. While payers can identify specific data needs for certain technologies that may be a component of intensive insulin management, such as insulin pumps or blood glucose monitoring technologies, intensive insulin management is not clearly understood as a service. This further complicates payers’ ability to evaluate the clinical benefits of these services and to assign appropriate payment levels to them.

Panel members acknowledge the difficulty in determining exactly what services are included in intensive insulin management because such services vary by patient, provider, facility, and geography. Furthermore, it is difficult to determine which subgroup of patients is most likely to benefit from technologies, like insulin pumps, designed to help achieve normal HbA1c levels. The lack of standardization is perhaps the biggest impediment to obtaining increased reimbursement for services related to intensive insulin management and may be at least partly responsible for past Current Procedural Terminology (CPT) code denials. Absence of a CPT code specific to intensive insulin management may delay adoption and use of a relevant new technology.

Convincing private insurers to pay for intensive insulin management is complicated by the fact that they must sell these services to their customers—in most cases, large employers or employer groups. Payers must convince their customers of the value of paying for intensive insulin management through outcomes measures relevant to their customers, for example, a decrease in lost workdays and increased productivity. Employers may be skeptical of such claims in the absence of clinical data. Moreover, because the number of patients with Type I diabetes is relatively small (overall, and compared with Type II diabetes), employers may be less willing to pay more for technologies that focus on improving outcomes for Type I diabetes.

Both the public and private payers on the Panel were able to identify a number of areas where coordination is needed among providers, particularly specialty societies, to develop standards or industry-wide guidelines for intensive insulin management:

- The definition of services involved, including the amount of time and resources typically associated with intensive insulin management;
- Identification of the qualifications providers should have to be eligible to receive payment for providing intensive insulin management services, possibly through accreditation or certification programs; and
- Consensus on the type(s) of patients eligible to receive the standardized set of intensive insulin management services.

ADOPTION OF NEW PRODUCTS AND TECHNOLOGIES

Increased reimbursement for new diabetes products and technologies is dependent on data illustrating that the products improve patient outcomes. Convincing payers of the clinical and economic benefits of new technologies is complicated by a number of issues. First, from the private insurers' perspective, employers who purchase health plans want new technologies to improve employee productivity in order to justify their additional cost. Second, both public

and private payers will not pay more for a technology if it is viewed as merely a "convenience" for patients without proof that it actually improves patient compliance and patient-oriented outcomes. Payers will require substantial data supporting claims of improved outcomes with use of the new technology before they cover and pay more for it.

In the remainder of this section, we discuss several key aspects of how payers evaluate new diabetes technologies for coverage and payment, including outcomes measures, evaluating incremental technology improvements, and data needs and modeling.

Outcomes measures

Quality. Employers and health plans often have different incentives in terms of the quality measures used to evaluate treatments for chronic illnesses such as diabetes. Employers tend to focus on measures that reduce the number of days missed from work and expedite the time it takes employees to return to work after illness. Health plans are focused on measures that help them maintain or improve their scores according to The Health Plan Employer Data and Information Set [HEDIS[®], National Committee for Quality Assurance (NCQA), Washington, DC], which is used by health plan customers (including employers) to evaluate health plan performance. (HEDIS is a set of standardized performance measures designed to ensure that purchasers and consumers have the information they need to reliably compare the performance of managed health care plans. The performance measures in HEDIS are related to many significant public health issues such as cancer, heart disease, smoking, asthma, and diabetes. HEDIS also includes a standardized survey of consumers' experiences that evaluates plan performance in areas such as customer service, access to care, and claims processing. HEDIS is sponsored, supported, and maintained by the NCQA.) Thus, in the case of diabetes technology, health plans may have a particular interest in diabetes-related HEDIS measures. According to the private payer representatives on the Panel, employers also are interested in health plan performance relative to HEDIS measures, but when evalu-

ating whether to spend additional resources on specific technologies, employers tend to focus on measures that improve the productivity of employees (see the payer perspective discussion regarding intensive insulin management, above).

Quality of life/compliance/convenience. There is a discrepancy among providers, patients, and payers regarding the value of quality-of-life improvements and their effect on patient compliance and long-term outcomes. (During the discussion, there appeared to be a conflict over the term “convenience.” This term received a negative reaction from payers and technology assessment experts, whereas providers and patient representatives were more comfortable with the term. Upon discussion, it became clear that what Type I diabetes providers and patient representatives call “convenience” may relate to what payers would call “compliance” or “quality of life.” The conversation demonstrated that use of the terms compliance and quality of life will be better understood by the payer community than the term convenience.) For example, physicians and payers often disagree over whether an individual with Type I diabetes who can control his or her HbA1c levels with five or six (or more) daily insulin injections should be eligible for an insulin pump. Often, new technologies for treating Type I diabetes are reserved for patients who have failed to achieve normal HbA1c levels using “conventional” insulin management alone. However, this criterion cannot always distinguish between patients who have “failed” because of factors beyond his or her control or factors such as lifestyle choices. Moreover, failure on conventional treatments as a criterion for receiving more intensive therapy can penalize compliant patients—the very patients who are most likely to benefit from intensive insulin management.

While all stakeholders on the Panel (providers, payers, technology researchers/evaluators) agreed that quality of life is an important outcome for Type I diabetes treatments, providers and patient representatives seemed to assign a higher value to these outcomes than did the payer representatives. The providers and patient representatives noted that, with

Type I diabetes, patient compliance is absolutely crucial to clinical outcomes; therefore, technologies that improve patient compliance have great clinical value. Moreover, they seemed willing to accept the notion that increased convenience leads to increased compliance. Although payers acknowledged the potential link between patient compliance and clinical outcomes, they suggested that data must prove the link exists for a particular service or technology. In other words, payers *will not assume* that technologies that are more convenient will (a) improve compliance and (b) improve outcomes; data demonstrating these links are required.

Clinical outcomes: beyond HbA1c. As discussed above, Panel members seemed to agree that HbA1c is an appropriate proxy for Type I diabetes outcomes; however, payers are aware that the majority of patients have not achieved desired HbA1c levels. Payers and technology assessment experts on the Panel thought that, because HbA1c is an acceptable proxy, long-term data are not necessarily needed to demonstrate the clinical value of most new Type I diabetes technologies. In general, 6–12 months of data were believed to be sufficient in terms of demonstrating the clinical benefits of Type I diabetes technologies, at least in most cases. However, longer-term data demonstrating durability of the benefit also may be necessary.

The Panel engaged in a discussion regarding other clinical outcomes that might be appropriate in terms of measuring the benefit of Type I diabetes technologies. One area of interest was hypoglycemia. Providers, payers, and patient representatives believe that reducing the incidence of severe hypoglycemia is a valuable clinical benefit; however, a better definition of asymptomatic, moderate, and severe hypoglycemia is needed to allow stakeholders to make more informed treatment and payment decisions. Payers recognized the value of avoiding emergency room (ER) visits (hypoglycemia is a common cause of ER visits among individuals with Type I diabetes), but did not assume that fewer or less severe hypoglycemic events would lead to reduced ER visits or other clinical benefits. A similar discussion occurred related to hypoglycemia unawareness. There

seems to be even more need to better define and understand hypoglycemia unawareness as an outcome measure. This discussion was particularly relevant to islet cell transplantation, as hypoglycemia unawareness is a major outcome measure being tested (see section entitled “Reimbursement for Potential Cures” below).

The Panel members, including third-party payer representatives and technology assessment experts, agreed that additional studies of hypoglycemia (including hypoglycemia unawareness) and its clinical importance in Type I diabetes would be highly valuable. In particular, hypoglycemia unawareness and asymptomatic hypoglycemia, i.e., biochemically defined hypoglycemia, likely will require more data to illustrate their correlation to patient outcomes before payers accept these measures as appropriate for evaluating Type I diabetes technologies. The Panel identified hypoglycemia and hypoglycemia unawareness as areas in need of additional patient, provider, and payer research and education.

Incremental improvements in technology

As with many medical technology developments, diabetes technology tends to evolve as a series of incremental improvements, rather than a single, “break-through” development. Many of the new diabetes technologies, including continuous blood glucose monitoring, offer an “add-on” or additional benefit to existing technologies. For instance, new continuous blood glucose monitoring systems may provide a more comprehensive way to monitor and address hypoglycemic unawareness and its associated complications than currently available monitors. Although a technology may offer valuable additional data, but may require frequent monitoring to ensure accuracy, the cost for these new monitors is often additive to that of traditional monitoring products.

There is no clear consensus on what level of added benefit is necessary to justify increased reimbursement. However, third-party payers were adamant that they would not pay more for any new technology—incremental improvement or otherwise—without data that illustrate the clinical benefit. In order to obtain additional payment for more expensive up-

grades or new versions of technologies such as insulin pumps or blood glucose monitors, there must be data to show the upgrades or improvements offer a clear benefit. Data also should illustrate which patients are likely to see the most benefit from these improvements. There may be cases where an incremental improvement offers a true benefit to one subgroup of patients with Type I diabetes and not to another. An example is blood glucose monitors with audio read-outs—a valuable option for sight-impaired patients, but of minimal benefit for others.

Finally, Panel members noted that a technology will almost always be viewed more favorably once it can be demonstrated as a complete replacement of an existing technology (for example, an artificial pancreas) rather than an add-on to current services.

Data needs and modeling

Robust data are crucial to the adoption of new technologies. Both clinical and economic data are necessary to convince payers that additional reimbursement is justified for new products. As previously noted, the payers on the Panel indicated for Type I diabetes treatments, because HbA1c is a good proxy for longer-term outcomes, 1 year of data is adequate to illustrate improved patient outcomes as long as a direct link is established between positive outcomes and use of the technology being evaluated.

In the past, the use of models as a tool for developing reimbursement strategies for new technologies has not been widely adopted for Type I diabetes. However, payers, including the Centers for Medicare and Medicaid Services (CMS), the federal government agency that manages the Medicare program, have given increased credence to data modeling when evaluating technologies in other disease areas for coverage. From an industry perspective, modeling is particularly attractive in the diabetes arena, because technologies are continually improved and updated after they are approved by the U.S. Food and Drug Administration (FDA) and introduced in the market.

Payers and technology assessment experts on the Panel agreed that models are only as

useful as the data that go into them; the responsibility rests on manufacturers and researchers to populate them with appropriate inputs in order to produce valuable outputs. For example, in order to influence payers' decisions, a model must make a credible link between technology and HbA1c levels, or it must illustrate an improvement in meaningful shorter-term outcomes (avoided ER visits and decreased episodes of hypoglycemia). Panel members generally agreed that well-designed models based on valid clinical data can be a valuable means to demonstrate the use of technology in controlling HbA1c levels and improving patient outcomes—necessary factors to convince payers to pay more for such technologies.

REIMBURSEMENT FOR POTENTIAL CURES: ISLET CELL TRANSPLANTATION AND ARTIFICIAL PANCREAS

Islet cell transplantation is considered an experimental procedure by most payers and is not covered by Medicare; only a few private payers currently reimburse for the procedure and only in limited cases. Data collection for the procedure is still in the early stages; 2–3 years of post-transplant data are now available for some trials. The Panel's discussion on islet cell transplantation encompassed many of the themes previously addressed for other new technologies, including the need for clinical standards and sufficient and appropriate data to positively influence coverage and payment decisions.

A major discussion topic concerned inclusion criteria for patients in islet cell transplantation clinical studies. From a reimbursement perspective, payers, including CMS, are likely to limit coverage for islet cell transplants to the eligibility requirements currently used in clinical trials. Unfortunately, funding restrictions, combined with a limited source of available islet cells and a challenging immunosuppressive regimen, have resulted in most studies being conducted with a small, homogeneous patient population. Since islet cell transplants are expensive (according to 2003 figures provided

by JDRF, the average 1-year cost of an islet cell transplant including the cost for the islets is approximately \$157,000, while the annual cost of immunosuppressive therapy post-transplant is about \$26,000), payers likely will want to restrict the number of patients eligible and will look to the patient subgroups identified in the clinical trials for guidance. Such restrictions may limit the number and type of patients for which the procedure will be covered in the future.

Additional concerns were raised that certain trial end points, such as hypoglycemia unawareness, may be too subjective and therefore may not be relevant to payers and other reimbursement stakeholders. In other words, demonstrating that islet cell transplantation improves hypoglycemia unawareness may not be sufficient for payers to cover the costly service. The Panelists suggested developing a "gold standard" for patients enrolled in islet cell transplant studies to eliminate subjectivity in terms of a future enrollment criterion. Panel members also encouraged researchers to expand the potential patient population included in the study and to evaluate other possible outcomes measures to be included in future studies. In particular, payers and technology assessment experts recommended that improvements in HbA1c levels or restoration of euglycemia be included as an end point in future studies.

Panelists were anxious to see improvements in the rigor and volume of available data on islet cell transplants. Generally, payers agreed that approximately 3–5 years of post-procedure data will be necessary before islet cell transplants would be widely approved for coverage. It was noted that currently 3–5 years of data documenting insulin independence for whole-pancreas transplants were required before payers began covering the procedure. Further, survival data should be comparable to those for pancreas and kidney transplants to justify the cost—1-year post-transplant outcomes for islet cell transplantation match those for pancreas transplantation in the United States. Studies also should attempt to demonstrate decreased costs associated with the islet cell transplantation procedure (via reduced ER visits, fewer complications, improved HbA1c levels, and the

replacement of other chronic treatments, including insulin). To this end, the Panelists suggested exploring alternatives to insulin independence as the ultimate end point of islet cell transplants, i.e., a functional end point. Payers also suggested that a prospective randomized clinical trial of intensive pump therapy versus islet transplantation would be helpful.

Researchers should focus on how to leverage additional funding from the National Institutes of Health and other sources to improve scientific understanding of the procedure, and to expand the clinical trials to include more patients. In addition, Panel members strongly recommended engaging CMS early in order to help increase the chances for Medicare coverage following FDA approval. This includes meeting with CMS to discuss the design of future clinical studies and providing CMS with routine updates as studies progress. In addition, minimizing the cost and health risks of the immunosuppressive regimen will be important to widespread adoption. As such, researchers should continue to identify possible alternatives to the current immunosuppressive therapy.

The Panel also discussed adoption and reimbursement issues related to glucose sensing technologies and the artificial pancreas. Next-generation continuous glucose sensing technologies are being developed to provide glucose information to patients in “real-time.” Specifically, the future of insulin pump therapy involves integration with glucose monitoring technologies and various levels of ongoing insulin dosing adjustments. Ultimately, the combination of continuous insulin infusion with continuous sensing for closed-loop glycemic control in an artificial pancreas will revolutionize care of individuals with diabetes.

The Panel acknowledged clinical limitations of these new technologies—such as the inability for an artificial pancreas to “predict” mealtimes and adjust insulin levels accordingly—but agreed that overall the development of an artificial pancreas may be a “cure,” particularly if it eliminates long-term care and high costs associated with treating Type I diabetes. The Panel also agreed that many of the reimbursement issues currently affecting insulin pumps also may affect coverage and payment for the

artificial pancreas and should be addressed in unison with providers and payers.

RECOMMENDATIONS AND NEXT STEPS

Advances in medical technology for the treatment of Type I diabetes continue to evolve more quickly than the reimbursement structure designed to pay for them. The episodic model of provider reimbursement, among other factors, has led to the creation of a payment system that is becoming increasingly inadequate in light of the diversity and sophistication of new medical technologies. These payment systems are particularly lacking when it comes to care for chronic illnesses, which are, by definition, not episodic in nature. Specifically, individuals with conditions like Type I diabetes who require ongoing and intensive management, continue to be denied access to the most effective technologies and therapies largely because these technologies are not reimbursed adequately.

Fundamentally changing the reimbursement environment in the United States is beyond the scope of the Panel’s objectives. Instead, based on the Panel’s input, we have identified key areas in which effective strategies can be developed and implemented within the current system. Below, we list a range of options that may be pursued by providers, patient groups/diabetes educators, payers, and employers to improve reimbursement and patient access to technologies for the treatment of Type I diabetes:

- *Develop and disseminate more specific clinical standards defining intensive insulin management.* To enable widespread use by all physicians who treat patients with Type I diabetes (including community endocrinologists and PCPs), and to create services that payers can effectively evaluate and value, intensive insulin management must be more clearly defined. Diabetes thought-leaders and associated professional organizations such as the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, and the American Diabetes Association should work with payers to de-

velop a set of guidelines or standards that more clearly define intensive insulin management and its importance in the treatment of individuals with Type I diabetes. Included in such guidelines should be the standard services offered as part of intensive insulin management, the specific skills required of providers of intensive insulin management (both physicians and non-physicians), the typical number of patient visits, and the types of technology used. Providers also should work with payers to align incentives in a concerted effort to obtain new CPT codes to bill for services related to intensive insulin management.

- *Increase education efforts surrounding hypoglycemia/hypoglycemia unawareness.* Many of the Type I diabetes technologies in development can improve Type I diabetes outcomes by decreasing episodes of hypoglycemia unawareness and decreasing severe hypoglycemic events. Diabetes thought-leaders should work to educate patients, providers, and payers about the costs of hypoglycemia unawareness and the benefits of improving hypoglycemia awareness in individuals with Type I diabetes. Future research studies could include end points such as clinically relevant patient-oriented outcome measures such as symptomatic or severe hypoglycemia events and those that demonstrate the link between changes in asymptomatic hypoglycemia and clinical events resulting from hypoglycemia. Venues for education efforts could include specific scientific conferences on the topic, publications in the peer-reviewed literature, and scientific presentations at key diabetes meetings. Diabetes stakeholders also may work with the FDA to use clinically significant hypoglycemia events as an additional outcomes measure when evaluating new technologies.
- *Explore appropriateness of creating diabetes "centers of excellence."* Diabetes providers can work together with payers to better understand the potential for the creation of formal diabetes centers of excellence, at which intensive insulin management services would be adequately reimbursed in exchange for quality assurance. Specific certification or accreditation programs may need to be developed to justify increased reimbursement at these centers. Certification programs also could be made available for individual diabetes programs or individual providers. Such programs would need to ensure third-party payers that a standardized set of services that have been demonstrated to improve outcomes are being provided by qualified personnel. In exchange, payers would make additional reimbursement available. Financial incentives for quality outcomes also could be incorporated into these programs. The advantages and disadvantages of creating such centers should be discussed further with providers, payers, and patient representatives.
- *Work with employer groups to develop financial incentive programs for high-quality care.* Where possible, stakeholders should work with large employer groups and payers to develop quality- or technology-based financial incentive programs to improve Type I diabetes patient outcomes and encourage technology uptake. Patient groups and industry could leverage their existing experience to join or endorse current efforts to implement these types of programs. Opportunities exist within existing quality measurement frameworks such as HEDIS and the NCQA. There may also be opportunities to create new quality measures that incorporate key Type I diabetes measures.
- *Gather data illustrating improved patient outcomes through the use of specific technologies.* Industry and groups that fund diabetes research should work with providers and diabetes-related specialty societies (for example, the American Association of Clinical Endocrinologists and the American Association of Diabetes Educators) to create studies that directly link the use of new technologies to improved patient outcomes, including reductions in HbA1c and employer-focused outcomes, such as employee absenteeism and increased productivity. This will help justify the value of new technologies to third-party payers whose primary customers are employers. Researchers should ensure that their study protocols in-

clude appropriate strategies for communicating results to key stakeholders, including third-party payers.

- *Communicate with payers, particularly CMS, about future break-throughs in Type I diabetes care, including islet cell transplantation and the artificial pancreas.* In addition to increased funding for research for treatments/cures for Type I diabetes, a strategy should be developed to approach major payers about the research and value of new procedures and technologies like islet cell transplantation and the artificial pancreas. One possibility is to create a reimbursement sub-Panel with key stakeholders to develop a strategy for approaching CMS and key private payers about coverage and payment for new procedures and technologies. Open and frequent communication with payers will create an environment where data can be shared and concerns about new technologies and therapies can be discussed and addressed appropriately.

APPENDIX: CENTER FOR INSULIN-DEPENDENT DIABETES ACCESS REIMBURSEMENT ADVISORY PANEL

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