Introduction

The following document is the first step in the Center for Insulin-Dependent Diabetes Access’ (the Center’s) Medicaid monitoring efforts. The memorandum provides the current status of diabetes services in five state Medicaid programs of interest: California (CA), Colorado (CO), New Jersey (NJ), Texas (TX) and Washington (WA).

Currently, most state Medicaid programs offer fairly broad coverage for diabetes (Type I, Type II, and gestational) treatments, including standard supplies such as insulin and blood glucose monitoring supplies, as well as more sophisticated treatments such as insulin pumps. However, as state governments struggle to balance their budgets, Medicaid has become a frequent target of cost-cutting efforts. Specifically, diabetes treatments may become the subject of budget cuts, thereby limiting access to care for the most needy diabetes patients. Such coverage limitations are of particular concern for the more intensive insulin management services, which are more expensive and are typically targeted toward Type I diabetes.

For this reason, the Center is monitoring policies that define the accessibility to and reimbursement for Type I diabetes management treatments and supplies in select Medicaid programs. The five states that were targeted for research were picked in light of their diversity in terms of size, geographic location, as well as an anticipated range of policies. These states provide a snapshot of Medicaid policies so that the Center can better understand the obstacles to obtaining diabetes management supplies and services for low-income populations. This knowledge can better equip the Center to work towards changing policies for the benefit of individuals with Type I diabetes. The specific services to which we focused our research include the following:

- Insulin and insulin syringes,
- Blood glucose monitors,
- Testing strips,
- Lancets,
- Insulin pumps (with corresponding infusion sets), and
- Diabetes education and/or case management programs.
We have conducted additional focused research regarding the coverage of insulin pumps in two of the five states, CA and TX. Both of these states have implemented policies that limit coverage for insulin pumps, an important Type I diabetes service of particular interest to the Center.

In the remainder of this memo, we provide background on each state’s program and summarize each state’s policies with respect to the diabetes services listed above. Finally, we provide recommendations for additional work to address the diabetes policy issues identified in our baseline research.

**Background**

Of the five target states, only CO has a percentage of patients with diabetes that is below the national average of eight percent as illustrated in Table 1.

**Table 1: Percent age of Population with Diabetes within Target State, 2001**

<table>
<thead>
<tr>
<th>Target State</th>
<th>Percent Diabetic Population in State**</th>
<th>Total Medicaid Population (thousands), by Category*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>TANF/SSI recipients*</td>
</tr>
<tr>
<td>CA</td>
<td>9 to 10%</td>
<td>3,973</td>
</tr>
<tr>
<td>CO</td>
<td>4 to 6%</td>
<td>211</td>
</tr>
<tr>
<td>NJ</td>
<td>9 to 10%</td>
<td>419</td>
</tr>
<tr>
<td>TX</td>
<td>7 to 8%</td>
<td>910</td>
</tr>
<tr>
<td>WA</td>
<td>7 to 8%</td>
<td>Information unavailable***</td>
</tr>
</tbody>
</table>

Since state data regarding the number of Medicaid beneficiaries with diabetes are limited, it is unclear exactly how many patients with diabetes are eligible for Medicaid benefits. However, because Medicaid provides health benefits to the neediest patients, Medicaid policy plays an important role in terms of patient access for all chronic conditions, including diabetes care.

Medicaid is a state-federal partnership program; therefore, states have a great deal of latitude in formulating their own list of covered services. This flexibility allows states to try new programs to both improve beneficiary care and keep costs down. Given the difficult budget environment...
in many states, the most innovative state programs to date focus on chronic diseases such as diabetes and have been directed towards cost containment rather than quality improvement.

Medicaid cost containment strategies have been implemented and/or are being considered in every state, raising questions about possible changes to coverage for diabetes care supplies and services. However, it is conceivable that denying supplies and services to diabetics in the short-term may lead to long-term conditions requiring expensive treatment and management.\(^1\)\(^2\)\(^3\) Therefore, ensuring access to diabetes services is critical to the successful management of the condition, and could even save state Medicaid funds in the long-term.

By identifying both positive and negative Medicaid policies and programs in terms of beneficiary access to Type I diabetes services, the Center can create strategies to encourage states to adopt “best practices” in terms of diabetes programs and policies. We also can identify harmful policies that stakeholders should attempt to overturn.

**Research Methods**

Initially, the Center conducted secondary research via publicly available state Medicaid websites to obtain information about coverage and payment for diabetes products and services in each of the target states. The degree of information publicly available varied greatly among states. While some states posted provider handbooks and other materials online, other states had little information publicly available.

Therefore, in order to obtain more detailed information about states’ specific coverage and payment policies, the Center conducted follow-up primary research to supplement our secondary research. Specifically, we corresponded with senior Medicaid officials, staff in a variety of divisions within a Medicaid program, patient advocates, and state-based consultants with expertise in a specific state or regarding a specific area of benefits. The results of our research are provided below.

**Findings**

The target states have specific coverage policies for all the diabetes products and supplies researched, but these policies have not changed significantly over the past few years. Moreover, in accord with federal law that governs Medicaid, access to diabetes products generally is unrestricted, and physicians largely control beneficiary access. Physicians can override quantity and frequency limits when necessary for the patient’s benefit. However, there are examples of new diabetes programs in several of the states that are designed to control costs, including disease management and education programs.


Another important factor in terms of patient access to diabetes treatment and supplies is how much state Medicaid programs pay for such services. Reimbursement for diabetic supplies through Medicaid generally is adequate for the purchase of generic products. However, payment rates are often inadequate to support the purchase of brand name supplies or high-cost devices with added features. Because balance billing\(^4\) is not allowed in Medicaid programs, beneficiaries only can procure higher-cost items if the providers or suppliers are willing to accept the relatively low Medicaid payment rates. There is some evidence that Medicaid beneficiaries have reduced access to care, at least partly caused by lower reimbursement as compared to private insurance\(^5,6,7\), but the impact in terms of access to diabetes equipment and supplies is less clear.

Coverage criteria and payment rates in the five target states for the diabetes products, supplies, and services included in our research are outlined in the remainder of this section.

**Insulin and Insulin Syringes (Table 2):** As shown in Table 2, insulin and insulin syringes are covered in all target states. Neither of these products requires prior authorization and restrictions on the frequency and size of insulin refills are left to the prescribing physician’s discretion. The number of prescriptions allowed for insulin syringes in a specific time period is not restricted; however, the number of syringes available per prescription is often limited. Insulin is one of the few non-prescription drugs covered under the pharmacy benefits of these Medicaid programs.

Of the five states studied, only CA and WA have operating preferred drug lists (PDL), and access to insulin is not restricted by prior authorization in either state. TX has plans to implement a PDL in February 2004; currently, there is no indication that access to insulin will be restricted. Plans for a PDL in NJ have been stifled.

**Table 2: Insulin and Insulin Syringe Coverage and Payment Policies for Five Target States**

<table>
<thead>
<tr>
<th>State</th>
<th>Insulin</th>
<th>Insulin Syringes</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Covered (Y/N)</td>
<td>Covered (Y/N)</td>
</tr>
<tr>
<td>CA</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>CO</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>NJ</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>TX</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>WA</td>
<td>Y</td>
<td>Y</td>
</tr>
</tbody>
</table>

\(^4\)Balance billing is the illegal practice in Medicare and Medicaid of charging beneficiaries the remainder of the cost of a service after Medicare or Medicaid has reimbursed for a pre-determined amount.


Blood Glucose Monitors (Table 3): Blood glucose monitors are covered in all target states. While some states require beneficiaries to receive prior authorization before obtaining a monitor, no states have brand restrictions. In addition, monitors with voice simulation are covered in some states; information regarding coverage for these specialized monitors in other states was unavailable. The reimbursement amount for blood glucose monitors varies by state, but for the states researched, reimbursement generally is high enough to cover standard monitors, but inadequate to cover the market price of monitors with additional features (for example, automatic recording and monitoring features, computer connectivity, etc.). Moreover, there is variability in the frequency to which beneficiaries can obtain a new monitor. Some states like CA allow beneficiaries to obtain a new monitor once a year, while other states like TX only allow a new monitor once every five years.

Table 3: Blood Glucose Monitor Coverage and Payment Policies for Five Target States

<table>
<thead>
<tr>
<th>State</th>
<th>Covered (Y/N)</th>
<th>Prior authorization required (Y/N)</th>
<th>Frequency Limitations</th>
<th>2003 Allowable Payment</th>
<th>Additional Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Y</td>
<td>Data unavailable</td>
<td>Once per year</td>
<td>Data unavailable</td>
<td></td>
</tr>
<tr>
<td>CO</td>
<td>Y</td>
<td>N</td>
<td>Information not publicly available</td>
<td>$47.50</td>
<td>Batteries and platforms also covered</td>
</tr>
<tr>
<td>NJ</td>
<td>Y</td>
<td>Y</td>
<td>Information not publicly available</td>
<td>$90</td>
<td></td>
</tr>
<tr>
<td>TX</td>
<td>Y</td>
<td>N</td>
<td>Once per five years</td>
<td>$50</td>
<td>Monitor with voice simulator reimbursed at $340. Battery and calibration strips also covered.</td>
</tr>
<tr>
<td>WA</td>
<td>Y</td>
<td>Y</td>
<td>Once per three years</td>
<td>$66.49</td>
<td>Monitor with voice synthesizer reimbursed at $578.72</td>
</tr>
</tbody>
</table>
Testing Strips (Table 4): All states researched cover testing strips without prior authorization. In some states, the amount dispensed per script is restricted by a quantity limit (for example, four boxes per month in TX), while in other states, beneficiaries receive a certain quantity per script with no limitation on the number of scripts per period of time (NJ). Our state sources explained that the prescribing physician usually can override quantity limitations by submitting a short explanation as to the reason for the exception.

In NJ, testing strips can be billed as durable medical equipment (DME) or as a pharmacy product; this technicality impacts the quantity of strips that a beneficiary can receive in a given time period. Classification as DME or a pharmacy product depends entirely on who files the claim—a provider that is certified under a state DME license versus a provider certified under a state pharmacy license. For providers that have a DME license, the DME program reimburses for the claim, but if the claim-submitting provider has a pharmacy license, the claim is reimbursed through the pharmacy program.

In Washington, a claims modifier is required to indicate whether the beneficiary is insulin dependent. This modifier does not affect reimbursement, though, and the data only is used internally for monitoring.

Table 4: Testing Strip Coverage and Payment Policies for Five Target States

<table>
<thead>
<tr>
<th>State</th>
<th>Covered (Y/N)</th>
<th>Frequency Limitations</th>
<th>2003 Allowable Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Y</td>
<td>None</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>CO</td>
<td>Y</td>
<td>None</td>
<td>50 strips reimbursed at $31.50</td>
</tr>
<tr>
<td>NJ</td>
<td>Y</td>
<td>DME Program: 200 strips per prescription Pharmacy Program: greater of 34-day supply or 100 dosage units</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>TX</td>
<td>Y</td>
<td>Limit four boxes per month</td>
<td>50 strips reimbursed at $30.74</td>
</tr>
<tr>
<td>WA</td>
<td>Y</td>
<td>None</td>
<td>50 strips reimbursed at $34.80</td>
</tr>
</tbody>
</table>
**Lancets (Table 5):** All states cover lancets without prior authorization. In each state, the amount per script is limited. In WA, a modifier is required to indicate whether the beneficiary is insulin dependent or not insulin dependent. As with blood glucose monitoring supplies, the state Medicaid agency uses this information for monitoring; it has no bearing on whether the claim is reimbursed.

**Table 5: Lancets Coverage and Payment Policies for Five Target States**

<table>
<thead>
<tr>
<th>State</th>
<th>Covered (Y/N)</th>
<th>Frequency Limitations</th>
<th>2003 Allowable Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA</td>
<td>Y</td>
<td>None</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>CO</td>
<td>Y</td>
<td>None</td>
<td>$.10 per lancet</td>
</tr>
<tr>
<td>NJ</td>
<td>Y</td>
<td>DME Program: 200 per prescription Pharmacy Program: greater of 34-day supply or 100 dosage units</td>
<td>Data unavailable</td>
</tr>
<tr>
<td>TX</td>
<td>Y</td>
<td>Limit 2 boxes of 100 per month, 2 spring powered devices for lancets reimbursed per year</td>
<td>100 lancets reimbursed at $12.68</td>
</tr>
<tr>
<td>WA</td>
<td>Y</td>
<td>None</td>
<td>100 lancets reimbursed at $12.74. Spring-powered lancet devices reimbursed 1 per 6 months at $18.05</td>
</tr>
</tbody>
</table>

**Insulin Pumps and Infusion Sets:** For those states with information publicly available, prior authorization is required for reimbursement of insulin pumps; the criteria for approval vary as outlined below. As mentioned previously, in TX and CA, Medicaid beneficiaries are required to complete a trial period before permission is granted for permanent purchase of an insulin pump. For all states, Healthcare Common Procedure Coding System (HCPCS) code E0784, external ambulatory infusion pump, insulin, is used to code for the insulin pump on Medicaid claims.
In CA, prior approval for an insulin pump is granted when there is documented frequent and severe glycemic excursions requiring visits to a physician, emergency room, or hospital; demonstrated ability to self-monitor blood glucose levels four or more times per day; and motivation to achieve and maintain glycemic control. The trial period lasts for four months. Anecdotally, most of these trial periods lead to subsequent approval. The only hurdle to coverage, then, is completing the necessary and somewhat burdensome paperwork required to begin the initial trial period for the Medicaid beneficiary. Other difficulties with this trial period system are related to the changing personnel in CA's government and program inconsistencies.

**CA requires the following HCPCS codes to bill for insulin pumps for Medicaid beneficiaries:**

- E0784, external ambulatory infusion pump, insulin
- A4230, infusion set for external insulin pump, nonneedle cannula type
- A4231, infusion set for external insulin pump, needle type
- A4232, syringe with needle for external insulin pump, sterile, 3cc

Allowable reimbursement amount and frequency of reimbursement information was unavailable.

Prior authorization is required for pumps and infusion sets. Reimbursement for insulin pumps and infusion sets is based on a manufacturer's invoice maintained in the provider's files. The 2003 allowable amount for reimbursement of an external ambulatory infusion pump is $5,103.14.

**CO uses the following HCPCS codes for insulin pumps:**

- E0784, External ambulatory infusion pump, insulin
- A4230, infusion set for external insulin pump, nonneedle cannula type
- A4231, infusion set for external insulin pump, needle type
- A4232, syringe with needle for external insulin pump, sterile, 3cc
New Jersey

Currently, there are no criteria for providing insulin pumps in NJ, but prior authorization is required. NJ is considering criteria for insulin pump coverage based on Medicare criteria including: mandatory education for patients with documentation from an educator, documentation of need for multiple injections per day, and frequency and results of self-testing documented at an average of four times per day. Additional Medicare criteria require that the device must be ordered and managed by a physician who has many diabetic patients and a staff trained in diabetes care. The physician must submit a letter of medical necessity with documentation of failure in other treatment methods, and must have documentation of at least one of the following clinical criteria: Dawn phenomenon, recurrent hypoglycemia, fluctuations before meals, and/or severe excursions.

Reimbursement for insulin pumps is cost plus 30 percent. Currently, there are no limitations on the frequency of reimbursement.

Texas

In TX, to obtain prior authorization for an insulin pump, the following minimum documentation of medical necessity is required for consideration:

- Any wide fluctuations in blood glucose before mealtimes.
- Any Dawn phenomenon where fasting blood glucose level often exceeds 20 mg/dL.
- Day-to-day variations in work schedule, mealtimes, and/or activity level, which require multiple insulin injections.
- Completed and signed Home Health (Title XIX) DME/Medical Supplies Physician Order Form.

This documentation is submitted to the Medicaid Home Health Unit for prior authorization. Currently, approvals for insulin pumps take approximately four to six months. This process has become more complex in light of the change of the program administrators; National Heritage Insurance Company was the administrator for over 25 years, but the new administrator is Affiliated Computer Services.

Initially, an insulin pump is granted for a trial period of three months. After three months, if the physician believes that the pump has been an effective method for the patient to manage his or her diabetes, and the patient has effectively complied with pump indications, the patient will obtain permanent ownership of a pump. Physicians are not reimbursed for the insulin pump initiation or instruction.

The 2003 allowable amount of reimbursement of an external ambulatory infusion pump for insulin is $4,387.82, and beneficiaries are limited to one pump per five years.
TX uses the following HCPCS codes for insulin pumps and infusion sets:

- E0784, external ambulatory infusion pump, insulin
- A4230, infusion set for external insulin pump, nonneedle cannula type
- A4231, infusion set for external insulin pump, needle type
- A4232, syringe with needle for external insulin pump, sterile, 3cc

WA reimburses for external ambulatory infusion pumps. More information on the details of WA’s coverage and reimbursement policies for insulin pumps was not available through secondary means. Subsequently, several attempts were made to contact the state Medicaid program to better understand these policies, but we were unable to contact the appropriate staff person. The Center will continue to pursue more information in this area and disseminate it when available.

**Diabetes Education and Disease Management Programs:** Four of the five target states have or recently had a disease management program for diabetes. NJ is the only state without either a diabetes education or disease management program. These disease management programs are designed to help patients with diabetes learn how to manage their own care, increase compliance, and establish direct lines of communications between patients and knowledgeable providers like case managers.

None of the five states examined have disease management programs specifically for Type I diabetes. CA’s pilot program was specifically for Type II diabetes; CO’s, TX’s, and WA’s programs encompass all types of diabetes. CA and WA have moved beyond the pilot stage and have included diabetes disease management in their range of provided services. These services are directed towards high-cost cases.

Disease management field staff and telephonic nurses assist Medicaid fee-for-service (FFS) beneficiaries with managing their diabetes. Some states offer group clinical visits, in which clients diagnosed with diabetes meet in discussion groups of two or more led by a physician or an advanced registered nurse practitioner. Participants discuss ongoing issues with diabetes including medications, lifestyle, and emotional complications of the disease. They also can obtain basic personalized attention and advice from the medical staff.

Additional state-specific details of the various programs are outlined below.
CA had a disease management pilot program that ran from July 1, 1995 through June 30, 1999. The program enlisted 362 Medicaid recipients over the age of 18 with Type II diabetes to participate for more than one year. Patients with HbA1C levels less than 7.5 percent or with serious complications were excluded. Participants were randomly assigned to either an intervention group or a control group. The former received ongoing case management and disease management services while the control group received traditional diabetes treatment. Monitoring glycemic control by serial HbA1C measurements over several years assessed the effect of the intervention. Clinical sites in three southern CA counties serving low income, ethnic minority populations participated in the study. The treatment group experienced statistically significant reductions in HbA1C levels as compared to the control group.

In light of the positive findings from this pilot program, CA now provides diabetes disease management to Medicaid beneficiaries.

The diabetes disease management pilot in CO was approved in legislation passed in 2002. Since then, the state’s Medicaid program has used funding from Eli Lilly and Company to finance the pilot for 250 enrollees. However, this money is used to pay the vendor (McKesson Health Care Solutions) with the state accepting all risk for the project. Enrollees are high-risk, high-cost clients with any type of diabetes. They are provided with education to increase and improve self-management of their disease including diet and exercise; adherence to physician and pharmaceutical advice are key components of this program. Analysis of the enrolled clients’ annual pre-intervention claims will be compared to their intervention claims data over 12 months; this data will be analyzed quarterly to determine if any trends are statistically significant. This project is ongoing.

The pilot program in TX is no longer operating. Previously, however, it enrolled Medicaid beneficiaries with any type of diabetes. Communities were chosen for participation based on a high incidence of diabetes and high death rate from diabetes, but enrollment was voluntary. Participating providers were asked to attend six hours of Continuing Medical Education on diabetes care, and beneficiaries were asked to attend extensive education training. Through this program, DME and other diabetes supplies for blood glucose level testing were made available to the 234 enrollees. Providers were asked to keep track of clinical outcomes data as well as educational session attendance for participating beneficiaries on specifically designed software, but this part of the program was abandoned.
The pilot program was evaluated by TX Medicaid and it was perceived as unsuccessful for a variety of reasons including: (1) voluntary enrollment led to too few enrollees for rigorous clinical/statistical analysis; (2) gestational diabetics became eligible for this pilot halfway through the program, but this form of diabetes presents late in pregnancy so these enrollees attended approximately one educational session prior to giving birth and then discontinued participation; (3) participants had to re-enroll in Medicaid during the pilot making continuous data difficult to collect; (4) program lacked incentives for enrollees especially since testing equipment and DME promised to pilot participants became available to all Medicaid beneficiaries mid-way through the program, which lowered incentives to take part in the pilot; (5) tracking of pilot participants was supposed to occur through specialized physician software, but the excessive burden on physicians caused the provision to be stricken halfway through the program; and (6) there were substantial barriers to communicating with physicians from the initial enrollment until termination of the pilot program.

McKesson conducted WA’s pilot program for 7,000 to 8,000 participants with Type I or Type II diabetes. Through mailed communications, face-to-face interactions, and nurse telephonic interventions, McKesson is expected to reduce avoidable hospitalizations and unnecessary use of the emergency department to produce an overall cost savings of five percent and quality of life improvements through health status surveys. More specifically, improvements are expected in HbA1C values, flu shot utilization, and lipid profile. The University of Washington will evaluate this program using per member/per month costs to determine program savings due for completion at the end of 2003. Measures include: health processes and outcome indicators, utilization and medical costs, client satisfaction with the program and staff, access to and satisfaction with provided care, and health status at baseline and quarterly.
Summary and Recommendations

All of the major diabetes supplies and services included in our research are covered by the five states of interest. While there is variation in the level of reimbursement for different supplies and the limits on prescription frequency and quantity, states have, for the most part, created policies that allow physicians to override these for patient benefit. As with many Medicaid benefits, the payment rates for diabetes supplies and services are not generous and generally cover only the most basic equipment available, without additional features that may improve patient convenience and compliance. However, the relative (un)generosity of payment rates for diabetes supplies and services is consistent with other Medicaid services, and does not represent a deliberate effort to limit beneficiary access to these services.

Most of the states have implemented education and disease management programs for diabetes in the last few years. Unfortunately, despite clinical success, several states have terminated their diabetes programs due to financial concerns. The program in WA is among the most rigorous in terms of evaluating both cost and quality outcomes of diabetes disease management programs, and the results of the WA program evaluation will be important in terms of other states’ willingness to adopt similar programs.

We identified restrictive policies in TX and CA for coverage of insulin pumps that merit additional focus by the Center. Specifically, a trial period is required before beneficiaries are granted permanent access to an insulin pump, which can create a barrier to physicians prescribing pumps for Medicaid beneficiaries. These policies represent an opportunity for the Center to effect change by eliminating these waiting periods. Addressing these policies for insulin pumps in the key states of TX and CA also will help prevent such policies from spreading to other states, including NJ where a similar policy is being developed.