

**VETERANS HEALTH ADMINISTRATION
OFFICE OF PATIENT CARE SERVICES
TECHNOLOGY ASSESSMENT PROGRAM**

Brief Overview:

**Appropriate Use of
Insulin Pump—Real-Time Continuous Glucose Monitoring Systems
in the Veteran Population**

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July 2006

TECHNOLOGY ASSESSMENT PROGRAM

An Effective Resource for Evidence-based Managers

VA's Technology Assessment Program (VATAP) is a national program within the Office of Patient Care Services dedicated to advancing evidence-based decision making in VA. VATAP responds to the information needs of senior VA policy makers by carrying out systematic reviews of the medical literature on health care technologies to determine "what works" in health care. "Technologies" may be devices, drugs, procedures, and organizational and supportive systems used in health care. VATAP reports can be used to support better resource management.

VATAP has two categories of products directed toward filling urgent information needs of its VA clients. VATAP assigns a category to each new request based largely on the availability of studies from results of initial searches of peer-reviewed literature databases:

- The **Short report** is a self-contained, rapidly-produced qualitative systematic review of between 5 and 20 pages. It provides sufficient background information and clinical context to its subject technology to be accessible to a wide audience, including non-clinician managers.
- The **Brief overview** originated as an internal memo to VA clients with both well-defined and urgent information needs. It usually comprises 2 to 10 pages and assumes sufficient existing knowledge regarding clinical context and technology issues by its readers to omit these components of other VATAP products. It often requires some additional reading of documents (provided with the overview for the client) to obtain a full and comprehensive picture of the state of knowledge on the topic.

All VATAP products are reviewed internally by VATAP's physician advisor and key experts in VA. Additional comments and information on this report can be sent to:

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A SUMMARY FOR HTA REPORTS
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VATAP is a member of the International Network of Agencies for Health Technology Assessment (INAHTA) [www.inahta.org]. INAHTA developed this checklist[®] as a quality assurance guide to foster consistency and transparency in the health technology assessment (HTA) process. VATAP has added this checklist[®] to its reports produced since 2002.

This summary form is intended as an aid for those who want to record the extent to which a HTA report meets the 17 questions presented in the checklist. It is NOT intended as a scorecard to rate the standard of HTA reports – reports may be valid and useful without meeting all of the criteria that have been listed.

Brief Overview:			
Appropriate Use of Insulin Pump—Real-Time Continuous Glucose Monitoring Systems in the Veteran Population			
July 2006			
Item	Yes	Partly	No
Preliminary			
1. Appropriate contact details for further information?	√		
2. Authors identified?	√		
3. Statement regarding conflict of interest?			√
4. Statement on whether report externally reviewed?			√
5. Short summary in non-technical language?			√
Why?			
6. Reference to the question that is addressed and context of the assessment?	√		
7. Scope of the assessment specified?	√		
8. Description of the health technology?	√		
How?			
9. Details on sources of information?	√		
10. Information on selection of material for assessment?	√		
11. Information on basis for interpretation of selected data?	√		
What?			
12. Results of assessment clearly presented?	√		
13. Interpretation of the assessment results included?	√		
What Then?			
14. Findings of the assessment discussed?	√		
15. Medico-legal implications considered?		√	
16. Conclusions from assessment clearly stated?	√		
17. Suggestions for further actions?		√	

Brief Overview:

Appropriate Use Of Insulin Pump—Real-Time Continuous Glucose Monitoring Systems In The Veteran Population

POLICY ISSUE

A representative from the Vietnam Veterans of America approached the VA Under Secretary for Health (USH) to consider making available to veterans a new device from Medtronic Minimed (Northridge, CA), which allows continuous automated subcutaneous interstitial insulin delivery (insulin pump) combined with real-time continuous glucose monitoring.

The USH requested that the Office of Patient Care Services (OPCS) review the available evidence and advise on the appropriate use of the technology and other similar systems in the veteran population. OPCS then requested that the Diabetes Field Advisory Committee (FAC) recommend guidance for use within a six week delivery schedule and that the VA Technology Assessment Program (VATAP) conduct a systematic literature review to inform the group.

BACKGROUND

In 2006, Medtronic Minimed received FDA premarket approval for modifications made to their Paradigm® insulin pump and to their Guardian RT® sensor to enable the pump and sensor components to communicate directly with one another and to improve ease of use and viewing of real-time data (FDA 2006). The device will be marketed under the trade name Guardian Real-time® Continuous Glucose Monitoring System (CGMS). It is the first system to modulate insulin delivery with real-time data monitoring of interstitial glucose values and feature programmable alarms.

The Guardian Real-time® CGMS is indicated for continuous or periodic monitoring of interstitial glucose levels in adults (ages 18 and older) with diabetes mellitus, for the purpose of improving diabetes management.¹ As with all CGMS, this system augments, but does not replace, self-monitoring of blood glucose. All therapy adjustments should be based on measurements obtained using a home glucose meter. However, values obtained with this system can provide an indication of when a finger stick is required. This system can also allow users to track patterns in glucose concentrations and to possibly identify episodes of low and high blood glucose levels. To ensure successful patient outcomes, significant professional training and clinical support are required, along with a motivated patient. This new innovation is advancing the field toward an eventual closed-loop delivery system based on subcutaneous glucose sensing with subcutaneous insulin delivery.

The Diabetes FAC convened in June 2006 to outline the objectives of the project. Due to the fact that the continuous sensing methodology had only recently been approved and cannot be evaluated from the perspective of efficacy, the FAC agreed that evidence-based guidance on

¹ Following completion of this report, in March 2007 FDA approved Guardian Real-time® CGMS for use in pediatric populations [<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/PMA.cfm?ID=9204>], accessed November 28, 2007.

the appropriate use of insulin pumps in the veteran population was needed before use of any CGMS could be determined.

The FAC agreed on the following questions to address:

1. *For whom are insulin pumps indicated? Specifically, what are the efficacy and cost-effectiveness of subcutaneous infusion insulin pumps compared with multiple daily injections for managing patients with diabetes?*
2. *What are the safety, efficacy and cost-effectiveness of real-time CGMS versus conventional CGMS versus self-monitoring of blood glucose for managing patients with diabetes? What constitutes long-term use of these monitors and their discontinuance?*
3. *What current reimbursement policies/guidance are in place for the use of insulin pumps, CGMS devices, and the newly approved combined real-time CGMS-insulin pump system in managing patients with diabetes?*

METHODS

To comply with the information needs and time requirements of the FAC, VATAP conducted a two-tiered approach, relying heavily on existing health technology assessments (HTA) and updating them with recent clinical trial data.

Search strategy

In June 2006 preliminary searches of the Cochrane Collaboration© database and the HTA database (www.inahta.org) uncovered several recent reports from the international HTA community published in English that were relevant to the project, and VATAP forwarded them immediately to the FAC:

Insulin pumps

- Colquitt JL, Green C, Sidhu MK, Hartwell D, Waugh N. Clinical and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes. *Health Technology Assessment*, 2004:1-186. [National Coordinating Centre for HTA, United Kingdom]
- AETMIS. Comparison of the insulin pump and multiple daily insulin injections in intensive therapy for type 1 diabetes. Report prepared by Brigitte Cote and Carole St.-Hilaire, 2005, xv-83p. [Agence d'évaluation des technologies et des modes d'intervention en santé, Quebec, Canada]

Continuous Glucose Monitoring Systems (not real-time)

- BCBS TEC. Use of Intermittent or Continuous Interstitial Fluid Glucose Monitoring in Patients with Diabetes Mellitus. Volume 18, No. 16, December 2003. [Blue Cross Blue Shield Technology Evaluation Center, United States]
- NHSQIS. Continuous glucose monitors in diabetes mellitus—the Continuous Glucose Monitoring System (CGMS). Evidence Note 8, January 2005. [NHS Quality Improvement Scotland, Scotland]

VATAP then conducted comprehensive searches of the peer-reviewed published literature to update the HTAs on the clinical and cost-effectiveness of insulin pumps and to identify new information about the combined real-time product. VATAP searched the Cochrane

Collaboration© database, MEDLINE, EMBASE, and Current Contents databases to retrieve citations addressing both CGMS and insulin infusion pumps concepts. Search strategies utilized evidence filters as well as the word phrases and thesaurus terms describing continuous glucose monitoring and insulin infusion pumps. Hand searching of the American Diabetes Association annual meeting abstracts for 2006 and end references of all retrieved citations was also carried out.

Inclusion criteria and critical appraisal

Studies on the clinical or cost-effectiveness of insulin pumps compared with multiple daily injections (MDI) or of CBGM were included if they enrolled adults or adolescents with diabetes and were published in English. Key outcomes of interest identified by the FAC were: changes in glycemic hemoglobin A_{1c} (HbA_{1c}) but not glucose variability; incidences of hypoglycemia or ketosis; and changes in Quality of Life.

Additional inclusion criteria for updating existing HTAs or systematic reviews were:

- Use of Insulin pumps in patients with Type 1 Diabetes: Results of studies comparing insulin pumps with MDI in patients with insulin dependent diabetes published since July 2004 (to update AETMIS 2005)
- Use of Insulin pumps in adults with Type 2 Diabetes: Results of studies comparing insulin pumps with MDI in adults with insulin dependent Type 2 diabetes published since June 2002 (to update Colquitt 2004)

VATAP augmented the general search by consulting Medtronic Minimed, FDA, and patent applications for data supporting the recent FDA approval decision and any new information supporting the clinical use of the real-time CGMS product. VATAP solicited evidence-based guidance on the use of insulin pumps and CGMS from US government sources and selected large US insurers and other national governments, restricting its inquiries to publicly available on-line sources to comply with the time constraints of the project.

A modified version of the Consolidated Statement of Reporting Trials (Altman 2001; Moher 2001) statement was used to critically appraise the quality of reporting of the included studies.

RESULTS

The searches uncovered 183 citations. Upon review of title and abstract information, 34 were retrieved as potentially relevant to the project, including the assessments mentioned above. Eight citations met criteria for inclusion in the report.

1. For whom are insulin pumps indicated? Specifically, what are the efficacy and cost-effectiveness of subcutaneous infusion insulin pumps compared with multiple daily injections for managing patients with diabetes?

Two comprehensive HTAs (Colquitt 2004;AETMIS 2005) systematically evaluated the evidence of the clinical and cost-effectiveness of the insulin pump versus multiple daily injections (MDI) primarily in patients with Type 1 diabetes; evidence of their use in Type 2 diabetics was scant. To summarize, the insulin pump has existed for many years as an alternative to MDI in Type 1 diabetics who require intensive therapy as a means of maintaining glycemic control, thereby reducing the risk of short- and long-term diabetic complications.

The HTAs concluded that insulin pumps are safe for patients: 1) who are motivated; 2) who have experienced difficulty in controlling their diabetes, and; 3) who are adequately trained and supported by a specialized team. The insulin pump offers modest improvement in glycemic control for the general population of diabetics, but may provide significant improvement, and hence be most cost-effective for the selected subgroup of patients mentioned above who suffer from severe hypoglycemic episodes or early morning hyperglycemia (the “dawn phenomenon”). Limited evidence suggests that the main benefit of insulin pumps may be in offering greater flexibility in lifestyle and, hence, quality of life. Future research on the use of insulin pumps should consider quality of life factors, including psychological impact, which may assist in developing more robust estimates of cost-effectiveness.

Four citations met the criteria for inclusion as updates to the above assessments on the effectiveness of insulin pumps in diabetic patients (see annotated end references). One study of Type 1 patients (Hirsch, 2005) provided full text details of an abstract published by the same study group on the same study (Bode 2003). Bode (2003) was reviewed by AETMIS (2005). The additional information provided by Hirsch (2005) did not expand the study base nor did it alter the conclusions of the above assessments.

The other three studies (Herman 2005; Raskin 2003; Wainstein 2005) provide new information on the relative effectiveness of insulin pumps versus MDI using various insulin analogues in Type 2 diabetics (see Table 1). Study designs were randomized, cross over or parallel studies of duration equal to or less than one year and considered a range of primarily obese insulin users whose duration of disease was at least six months and who were also managed with oral anti-diabetes medications and diet. Methods for recruitment into the screening phase of each study were not clearly specified (eg. time period covered, consecutive enrollment), so selection bias could be significant in these populations.

Results from these studies suggest comparable safety and efficacy of the insulin pump versus MDI in selected adults with insulin-treated, uncontrolled, Type 2 diabetes. Results also suggest preferences for the insulin pump based on quality of life factors such as convenience, flexibility, and ease of use. However, these results are preliminary and should be confirmed in larger studies of sufficient power and more clearly defined populations that incorporate cost data and quality of life indicators from which reliable estimates of cost-effectiveness of the available treatment options can be derived. Such information could better inform health systems such as VA that serve large numbers of patients with Type 2 diabetes. Ultimately, these preliminary results do not alter the conclusions of earlier assessments.

2. What are the safety, efficacy and cost-effectiveness of real-time CGMS versus conventional CGMS versus self-monitoring of blood glucose for managing patients with diabetes? What constitutes long-term use of these monitors and their discontinuance?

VATAP identified two evidence reports evaluating the use of conventional (not real-time) CGMS in patients with diabetes (BCBS TEC 2003; NHSQIS 2005). The BCBS TEC report considered systems that provide intermittent near real-time readout of interstitial glucose levels and systems that require retrospective analysis of nearly continuous glucose level data, while NHSQIS focused on the latter and incorporated data from the BCBS TEC report in its review. Both reports outlined similar diabetic populations for whom continuous interstitial glucose monitoring may most likely benefit, i.e. patients:

- With poor glycemic control regardless of therapeutic adjustment;
- With asymptomatic or nocturnal hypoglycemia;

- Who are starting or changing insulin regimens;
- Who require monitoring of insulin pump use.

The Medtronic Minimed Continuous Glucose Monitoring System® (CGMS) is the conventional continuous glucose monitoring system for which there was the most evidence available. It continuously records interstitial fluid glucose levels up to 72 hours, which may be downloaded and displayed on a computer and reviewed by health professionals.

These reports found that the best available evidence on the effects of using conventional CGMS on diabetes-related morbidity consists of several randomized controlled trials that use HbA1c as a predictor of diabetes complications primarily in patients with Type 1 diabetes. However, the quality and consistency of the evidence from these trials are variable and preclude drawing firm conclusions. The evidence suggests that while the use of CGMS increases identification of hypo- and hyper-glycemic episodes that would otherwise have remained undetected by intermittent finger stick testing, no studies conclusively demonstrated a significant improvement in either quality of life or in the frequency or severity of clinically significant, symptomatic glycemic events with the use of CGMS. The impact on the cost effectiveness of incorporating CGMS into the management of patients with diabetes is presently unknown.

In light of the recent FDA approval of the Medtronic Minimed Guardian Real-time® CGMS, the FAC asked VATAP to focus on obtaining available evidence on the performance of real-time CGMS. VATAP uncovered one meeting abstract (Danne 2006) that presented the results of institutional experiences with the Medtronic Minimed Integrated Insulin Pump and Real-Time CGMS in 38 pediatric and adult patients in a multi-center study in Germany. While most patients rated the education, support and experience with the new system favorably, few therapeutic changes based on the system information were made during the study.

Medtronic Minimed confirmed that there were no unpublished or published studies on the combined product, but that one small private twelve month randomized controlled trial (RCT) was in progress and had just finished enrolling patients. Medtronic expects results at six and twelve month intervals. Thus, no firm conclusions on the impact of real-time CGMS on managing patients with diabetes can be made at this time.

3. What current reimbursement policies/guidance are in place for the use of insulin pumps, conventional CGMS devices, and the newly approved combined real-time CGMS-insulin pump system in managing patients with diabetes?

A limited selection of evidence-based guidance on the use of insulin pumps was identified (see Table 2). Generally, insulin pump therapy is recommended as an option for patients with Type 1 diabetes in whom multiple-dose insulin therapy has failed to maintain glycemic control without the occurrence of disabling hypoglycemia despite a high level of self-care and in whom commitment and competence to use the therapy effectively has been demonstrated.

VATAP found selected evidence-based guidance on the use of conventional CGMS devices produced by the National Institutes for Clinical Excellence (NICE) in the United Kingdom, AETNA, and Blue Cross Blue Shield of Massachusetts. No specific guidance on the use of real-time CGMS was identified.

- NICE Guidance Type I Diabetes webpage:
<http://www.nice.org.uk/page.aspx?o=CG015&c=endocrine>. Diagnosis and management of type 1 diabetes adults. CG015. July 2004. Section 7.1 Recommendation R43.

- AETNA Clinical Policy Bulletin. Number 0070. Diabetes Programs and Supplies. Reviewed April 21, 2006. <http://www.aetna.com/cpb/data/CPBA0070.html>
- Blue Cross Blue Shield Massachusetts. Diabetic Supplies. Document 202. Posted 3/28/06. http://www.bluecrossma.com/common/en_US/medical_policies/202%20Diabetic%20Supplies%20prn.pdf

The NICE guidance states: “Continuous glucose monitoring systems have a role in the assessment of glucose profiles in adults with consistent glucose control problems on insulin therapy, notably: 1) repeated hyper- or hypoglycemia at the same time of day, and; 2) hypoglycemia unawareness, unresponsive to conventional insulin dose adjustment.” This guidance was based on available preliminary, albeit inconclusive, evidence from observational studies and one quasi-experimental study, taking into account the potential for this technology to improve overall management of patients.

On the other hand, AETNA and Blue Cross Blue Shield of Massachusetts consider the Medtronic MiniMed CGMS experimental and investigational based on the failure of the available evidence to demonstrate improvement in final health outcome, such as improved diabetic control, improved HbA1c values, or decreased incidence of hypoglycemia.

Table 1. Studies Comparing the Clinical Utility of Insulin Pump versus Multiple Dose Injection in Selected Insulin-Treated Type 2 Diabetics

Study	Raskin 2003	Herman 2005	Wainstein 2005
Objective	<ul style="list-style-type: none"> To compare the efficacy and safety of CSII v. MDI in insulin-treated type 2 older adults To test the feasibility of training pump-naïve type 2 diabetics as outpatients to use the pump 	<ul style="list-style-type: none"> To compare the efficacy and safety of CSII v. MDI in insulin-treated type 2 older adults To assess treatment satisfaction and QOL 	<ul style="list-style-type: none"> To compare the efficacy and safety of CSII v. MDI in insulin-treated obese type 2 older adults
Population (eligibility criteria, settings, locations)	<ul style="list-style-type: none"> ≥ 35 years of age Type 2 diabetes of ≥ 2 yrs duration Treated for ≥ 6 months with at least one insulin dose/day w/ or w/o oral anti-diabetic meds Fasting C-peptide level > 0.2 nmol/l, BMI ≤ 43 kg/m², HbA1C ≥ 6% and ≤12% Exclusions: impaired renal, hepatic, cardiac function, recurrent major hypoglycemia, women who were pregnant, breast-feeding or not practicing contraception 	<ul style="list-style-type: none"> ≥ 60 years of age Type 2 diagnosis for ≥ 1 year ≥ one injection per day for the past month, with or w/o oral anti-diabetes medications A1C ≥ 7.0% Exclusions: BMI > 45 kg/m²; impaired renal, hepatic, cardiac function; physical, psychological or cognitive impairments in conflict with therapy program; > 2 episodes of severe hypoglycemia in past year; history of hypoglycemia unawareness 	<ul style="list-style-type: none"> 30-70 years of age Treated ≥ 3 months with diet, metformin and 2-3 insulin injections per day HbA1c > 8.5% BMI 30-45 kg/m² Exclusions: new onset < 6 months, Type 1, diabetes secondary to pancreatitis or other disease, history of active IHD or CVA within last 12 months, pre-proliferative or proliferative diabetic retinopathy, advanced nephropathy, elevated liver enzymes twice upper limit of normal range, HbA1c > 15% at screening
Study design	14 center, 24 week, open-label, randomized parallel-group trial	Two center, 12 month, prospective, randomized, controlled clinical trial	Single center, 36 week, randomized cross over study
Intervention	MDI w/ NPH/aspart vs CSII w/ aspart	MDI with lispro/glargine vs CSII with lispro	MDI w/ regular insulin, Humulin R, or Humulin N vs. CSII w/ lispro
Outcome measures	<ul style="list-style-type: none"> Mean A1C at 8, 20, 24 weeks 8-point BG profiles at weeks 8, 16,20, 24 Hypoglycemic events Patient-reported pump malfunctions, interruptions in pump use Patient satisfaction, quality of life (QOL) and preferences using PHASE V questionnaire 	<ul style="list-style-type: none"> Mean A1C measured at multiple visits Frequency of hypoglycemia Weight Infusion site and injection site problems Changes in treatment satisfaction and QOL using DQOLCTQ, physical and mental health in SF-36 v2 	<ul style="list-style-type: none"> HbA1c Weight Daily insulin dose Hypoglycemic episodes
Statistical methods	<ul style="list-style-type: none"> ANCOVA model with treatment and center as fixed effects, corresponding baseline measurement as covariate, using last observation carried forward approach to account for missing data Results = mean ± SD 	<ul style="list-style-type: none"> ITT analysis with repeated-measures ANOVA adjusted for sex and baseline A1C Results = mean ± SD 	<ul style="list-style-type: none"> Carry over effects, period effects, and direct treatment effects for ITT cohort and completer's cohort Last observation carried forward approach used in ITT to account for missing data Results = mean ± SD
Numbers analyzed	<ul style="list-style-type: none"> 205 patients screened, 132 randomized 5 withdrew (3 from CSII, 2 from MDI) MDI group=61; CSII group=66 90% completion rate in both arms Similar baseline values of age, A1C, BMI, insulin requirements and diabetes complications 	<ul style="list-style-type: none"> 144 subjects screened, 107 randomized MDI group=54; CSII group=53 8 withdrew (4 each arm), one death due to cancer 98% completion rate (MDI=50; CSII=48) 	<ul style="list-style-type: none"> 58 patients screened, 40 randomized, 29 completed MDI group=20; CSII group=20 Drop outs: MDI=6; CSII=5 75% completion rate Similar baseline values
Results	<ul style="list-style-type: none"> Mean A1c improved significantly from baseline to end of study in both groups (CSII: -0.62 ± 1.11%; MDI: -0.46 ± 0.89% (P<0.05) but no significant differences between groups The CSII group showed a trend toward lower eight-point BG values at most time points (only significant 	<ul style="list-style-type: none"> Mean A1C: CSII = 6.6% (1.7 ± 1.0%) vs. MDI = 6.4% (1.6 ± 1.2%) (P = 0.02) No statistically sig differences in frequency of minor (P = 0.17) or severe episodes (P = 0.49) of hypoglycemia, rates of severe hypoglycemia (P = 0.61) , or weight gain (P = 0.70) between groups 	<ul style="list-style-type: none"> Treatment with CSII significantly reduced HbA1c compared with treatment with MDI(P=0.007) Reduced meal-test glucose AUC was significantly lower in the CSII group than in MDI group (P=0.02) Initial reduction of daily insulin requirement observed in CSII-treated subjects during the first treatment period

Study	Raskin 2003	Herman 2005	Wainstein 2005
	<p>90 min after breakfast; 167 ± 48 vs. 192 ± 65 mg/dl for CSII and MDI, respectively; $P = 0.019$)</p> <ul style="list-style-type: none"> • No significant difference in increase in mean weight of subjects in each arm or hypoglycemic episodes • 11 MDI patients reported 26 hyperglycemic episodes vs. 3 CSII subjects reported six; No significant differences in hypoglycemic episodes between groups reported • CSII had greater improvement in treatment satisfaction than MDI group ($P < 0.001$) • 93% of CSII-treated subjects preferred the pump to their previous injectable insulin regimen for reasons of convenience, flexibility, ease of use, and overall preference; 89% response rate. • Safety assessments were comparable for both treatment groups 	<ul style="list-style-type: none"> • Treatment satisfaction: improved within both groups ($P < 0.0001$) but no significant difference between groups ($P = 0.58$) 	<p>was attributable to a period effect and did not persist over time.</p>

Table 2. Selected Guidance on the Use of Continuous Subcutaneous Insulin Infusion (CSII) for Patients with Diabetes Issued by Government and Private Payers

Organization/source	Guidance
<p>National Institute for Clinical Excellence (United Kingdom)</p> <p>Source: Technology Appraisal No. 57 February 2003 www.nice.org.uk</p>	<p>CSII is one option for people with type 1 diabetes in whom multiple-dose insulin therapy (including using insulin glargine when appropriate) has failed, and they are willing and able to use CSII effectively.</p> <p>Failure is defined as unable to maintain HbA1c levels no greater than 7.5%, or 6.5% in the presence of microalbuminemia or adverse features of the metabolic syndrome) without “disabling hypoglycemia”, defined as repeated and unpredictable hypoglycemic episodes for which they need help from other people, and which make them anxious about the episodes occurring again and significantly spoil their way of life.</p> <p>These recommendations about insulin pump therapy for type 1 diabetes are also valid for children, adolescents, pregnant women and women who are intending to become pregnant. However, pregnant women and women who are intending to become pregnant should only change to insulin pump therapy when under the care of the specialist team (see below).</p> <p>NICE does not recommend insulin pump therapy for people who have type 2 diabetes and need to take insulin.</p> <p>Insulin pump therapy should only be started by a trained specialist team. This team should include a doctor who specializes in insulin pump therapy, a diabetes nurse and a dietitian.</p> <p>Individuals beginning CSII therapy should be provided with specific training in its use, along with ongoing support from a specialist team, especially when first initiating treatment.</p> <p>Established users of CSII therapy should have their insulin management reviewed by a specialist team, so that a decision can be made about whether a trial switch to MDI incorporating insulin glargine would be appropriate.</p>
<p>CMS (USA)</p> <p>Source: Medicare NCD Manual. Ch 1. Part 4, Section 280.14. B.e. CSII (Effective for Services Performed On or after Dec. 17, 2004)</p>	<p>CSII and related drugs/supplies are covered as medically reasonable and necessary in the home setting for the treatment of diabetic patients who:</p> <ol style="list-style-type: none"> (1) either meet the updated fasting C-Peptide testing requirement, or, are beta cell autoantibody positive; and, (2) satisfy the remaining criteria for insulin pump therapy as described below. <p>Patients must meet either Criterion A or B as follows: Criterion A: The patient has completed a comprehensive diabetes education program, and has been on a program of MDI of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin doses for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria while on the MDI regimen:</p> <ul style="list-style-type: none"> • Glycosylated hemoglobin level (HbA1c) > 7.0 percent; • History of recurring hypoglycemia; • Wide fluctuations in blood glucose before mealtime; • Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dl; or, • History of severe glycemic excursions. <p>Criterion B: The patient with diabetes has been on a pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.</p> <p>General CSII Criteria In addition to meeting Criterion A or B above, the following general requirements must be met: The patient with diabetes must be insulinopenic per the updated fasting C-peptide testing requirement, or, as an alternative, must be beta cell autoantibody positive.</p> <p>Updated fasting C-peptide testing requirement:</p> <ul style="list-style-type: none"> • Insulinopenia is defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory’s measurement method.

Organization/source	Guidance
	<p>• For patients with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) ≤ 50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method.</p> <p>Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose ≤ 225 mg/dL. Levels only need to be documented once in the medical records. Continued coverage of the insulin pump would require that the patient be seen and evaluated by the treating physician at least every 3 months. The pump must be ordered by and follow-up care of the patient must be managed by a physician who manages multiple patients with CSII and who works closely with a team including nurses, diabetes educators, and dietitians who are knowledgeable in the use of CSII.</p>
<p>AETNA</p> <p>Source: Clinical Policy Bulletin No. 0161. Insulin pumps. March 31, 2006. www.aetna.com/cpb/data/CPBA0161.html</p> <p>Note: Aetna's medical necessity criteria for external infusion pumps for diabetes were adapted from Medicare national policy on external insulin infusion pumps, as outlined in CMS's Coverage Issues Manual Section 60-14.</p>	<p>Aetna considers external insulin infusion pumps medically necessary DME for persons with diabetes: 1) who are beta cell autoantibody positive or have a documented fasting serum C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method*, and 2) who meet all of the following criteria:</p> <ol style="list-style-type: none"> a. The member has completed a comprehensive diabetes education program; and b. The member has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day), with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump**; and c. The member has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump**; and d. The member meets at least one of the following criteria while on multiple daily injections (more than 3 injections per day) of insulin: <ul style="list-style-type: none"> • Elevated glycosylated hemoglobin level (HbA1c greater than 7.0%, where upper range of normal is less than 6.0%; for other HbA1c assays, 1% over upper range of normal); or • History of recurring hypoglycemia (less than 60 mg/dL); or • Wide fluctuations in blood glucose before mealtime (e.g., pre-prandial blood glucose levels commonly exceed 140 mg/dL); or • Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or • History of severe glycemc excursions; <p><i>or</i></p> <p>The member has been on a pump prior to enrollment in Aetna, and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Aetna enrollment.</p> <p>Footnotes:</p> <p>* Fasting C-peptide levels will be considered valid only with a concurrently obtained fasting glucose less than 225 mg/dL. For persons with renal insufficiency and creatinine clearance (actual or calculated from age, gender, weight, and serum creatinine) less than 50 ml/minute, insulinopenia is defined as a fasting C-peptide level that is less than or equal to 200% of the lower limit of normal of the laboratory's measurement method.</p> <p>** It may be considered medically necessary to initiate the use of insulin infusion pumps during pregnancy earlier than the criteria stated above to avoid fetal and maternal complications of diabetes and pregnancy. It may be considered medically necessary for poorly controlled women with diabetes to sometimes get started on the pump pre-pregnancy or in the first trimester.</p> <p>Notes on external insulin infusion pumps:</p> <ul style="list-style-type: none"> • External subcutaneous insulin infusion pumps are only considered medically necessary for persons who have demonstrated ability and commitment to comply with a regimen of pump care, frequent self-monitoring of blood glucose, and careful attention to diet and exercise. • The pump must be ordered by and follow-up care of the member must be managed by a physician with experience managing persons with insulin infusion pumps and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of insulin infusion pumps. • Documentation of continued medical necessity of the external insulin infusion pump requires that the member be seen and evaluated by the treating physician at least once every 6 months.

Organization/source	Guidance
<p>Blue Cross Blue Shield Massachusetts Pumps, Pens, and Jet Injectors for Blood Glucose Monitors</p> <p>Posted: 6/22/06</p> <p>http://www.bluecrossma.com/common/en_US/medical_policies/332%20Insulin%20Delivery%20Devices%20prn.pdf</p>	<p>Some external insulin infusion pumps are able to take results of the blood glucose reading, wirelessly transmit the results from the blood glucose monitor to the pump, and automatically adjust the insulin infusion rate, saving the member some extra steps. Wireless transmission from the blood glucose monitor to the pump and automated insulin infusion rate adjustment are considered integral features of the external insulin infusion pump and blood glucose monitor.</p> <p>Inclusion</p> <ul style="list-style-type: none"> • Patient has insulin dependent diabetes (IDDM, Type 1). • The pump is prescribed by a diabetologist familiar with insulin pump management. • Patient is capable of and committed to intensive insulin therapy, and has demonstrated substantial improvement in diabetic control while on multiple daily insulin injections. Patients must be willing to monitor blood sugar at least four times a day, and follow prescribed eating and activity patterns. • Patient has undergone a successful trial period with a loaned pump of at least three months, demonstrating that the patient is capable of managing the pump and that the desired improvement in metabolic control can be achieved. • The patient is at high risk for preventable complications of diabetes, early signs of diabetic complications including micro albuminuria or is found to have persistent difficulty in achieving optimal control despite good compliance with an intensive multiple injection regimen. <p>Exclusion</p> <ul style="list-style-type: none"> • Patients with non-insulin-dependent diabetes (NIDDM or IR-NIDDM, Type 2), even if they take insulin. • Patients with end-stage complications (such as renal failure). • Patients who are pregnant. If a woman is attempting to conceive, this may not be the best time to begin pump therapy. If a patient is already on the pump and doing well, pumps may be continued during pregnancy. However, because of the small risk for increased diabetic ketoacidosis episodes with pump therapy, starting the pump at these times results in possible increased risk for miscarriage. • Patients who are unable, because of, behavioral, psychological problems, or functional ability, to technically operate the pump and perform frequent blood glucose monitoring. • Our subscriber contracts do not permit coverage of items used for convenience purposes. Insulin pumps are covered for patients who are committed to achieving possibly tighter blood sugar control, to improve health outcomes. When excellent control is achieved with multiple daily injections, pump therapy is not covered merely because some may find it more convenient.

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TECHNOLOGY ASSESSMENT PROGRAM

Mission Statement

To enhance the health of veterans and the nation by providing and fostering technology assessment for evidence-based health care

Values

Integrity and pride in the work that we do

Quality products that are clinically valid and methodologically transparent

Objectivity in evaluating and presenting research evidence

Commitment to continuous quality improvement and to the guiding principles of evidence based practices

Flexibility in responding to changes in VA and the larger healthcare environment

Innovation in designing products and their dissemination to best meet VA's needs

Accessibility of products and services