Clinical Review Criteria

Diabetes Tests and Supplies

- Diabetes Sentry Monitor
- GlucoWatch Biographer™
- Home A1c Test
- iPort Injection TestPort

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Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Criteria</th>
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<tr>
<td>Diabetes Sentry Monitor</td>
<td>There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.</td>
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<tr>
<td>GlucoWatch Biographer™</td>
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<tr>
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The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Diabetes Sentry Monitor
GlucoWatch Biographer™
Home A1c Test
iPort Injection Test

Medical Technology Assessment Committee (MTAC)

Diabetes Sentry Monitor

BACKGROUND
There is evidence that tight glycemic control is associated with a lower incidence of diabetic complications including reduced rates of retinal, neurologic, and renal damage. Strict control of blood glucose, however, is associated with an increased risk of hypoglycemia (DCCT Research Group, 1993). Hypoglycemic episodes commonly occur at night. Mild episodes of nocturnal hypoglycemia are generally asymptomatic, but may affect mood and well-being the following day. Recurrent exposure to nocturnal hypoglycemia may impair cognitive function. Severe episodes can cause convulsions and coma and may lead to cardiac arrhythmias resulting in sudden death. Strategies to reduce nocturnal diabetes include regular blood glucose monitoring, eating appropriate bedtime snacks, and use of short- and long-acting insulin analogues (Allen & Frier, 2003).

The Diabetes Sentry monitor is designed to monitor hypoglycemia and alert patients when they are experiencing physiological symptoms. The device was originally developed as the Sleep Sentry monitor in approximately 1980s. The device was later taken off the market and a re-designed version received FDA approval in 2003. In 2005, the FDA approved the name change to Diabetes Sentry. The device is manufactured by Diabetes Sentry Products in Bellingham, WA.

According to manufacturer’s materials, the Diabetes Sentry monitors two symptoms of hypoglycemia: perspiration and drop in skin temperature (decrease of 2o F). Either of these symptoms will trigger an audible alarm loud enough to awaken most people. Patients are instructed that, when the alarm sounds, they need to verify whether they are in fact experiencing hypoglycemia with a blood glucose monitor. The company acknowledges that there are false-positive alarms since there are other reasons for nocturnal perspiration and temperature drop, for
example, change in room temperature or a shift in blankets. The manufacturer estimates that there will be an 
approximately one false alarm per night. The device is designed for people with insulin-dependent diabetes who 
have a severe enough problem with nocturnal hypoglycemia that they are willing to accept false-positives.

Other potential limitations of the Diabetes Sentry monitor are that patients may forget to turn on the device and 
some individuals may not awaken when the alarm sounds. In addition, the device is not useful for patients with 
hypoglycemia unawareness since they may not perspire or experience a drop in temperature during mild 
hypoglycemic episodes.

Unlike the Glucowatch, which is intended to measures blood glucose levels, the Diabetes Sentry measures 
symptoms of hypoglycemia (perspiration and temperature).

This is the first time that MTAC has reviewed the Diabetes Sentry.

Assessment objective: To evaluate the accuracy of the Diabetes Sentry for detecting hypoglycemic events. To 
evaluate the impact of device use on health outcomes (e.g. reduction in morbidity from hypoglycemia).

08/07/2006: MTAC REVIEW

Diabetes Sentry Monitor

Evidence Conclusion: There is no published evidence on the Diabetes Sentry approved by the FDA in 2003.

Articles: The search yielded 3 articles; all of these were small case series (n<25 each) and were published in the 
1980s on the original Sleep Sentry device. There were no published articles evaluating the re-designed Diabetes 
Sentry device approved by the FDA in 2003.

The use of Sleep Sentry Monitor in the treatment of Diabetes does not meet the Kaiser Permanente Medical 
Technology Assessment Criteria.

GlucoWatch

BACKGROUND

Intensive glucose control to maintain a lower level of blood glucose has been associated with fewer long-term 
complications of diabetes (e.g. UKPDS, 1998). Self-monitoring of blood glucose is an important part of a program 
to maintain tight glucose control. The standard procedure for self-monitoring of blood glucose involves frequent 
finger-stick measurements which can be painful and/or inconvenient for patients.

The GlucoWatch Biographer (Cygnus Inc., Redwood City, CA) is proposed as a non-invasive blood glucose self-
monitoring device. The GlucoWatch Biographer was approved by the FDA to supplement (not replace) the 
information provided by standard finger-stick, glucose monitoring devices. The theoretical advantages of the 
GlucoWatch over standard self-monitoring procedures are increased convenience and less pain since patients 
could take fewer finger-stick measurements, increased accuracy of blood glucose levels through continuous 
monitoring and increased safety since the GlucoWatch has the capacity to sound an alarm when blood glucose 
reaches a dangerous level.

The GlucoWatch is worn on the forearm and has the appearance of a wristwatch. It extracts extracellular fluid by 
applying a low level electrical current to the skin, a process known as reverse iontophoresis. The fluid is collected 
in gel discs on a single use component of the device, called the Autosensor. The fluid undergoes a chemical 
reaction after being catalyzed by glucose oxidate and. The GlucoWatch calculates a blood glucose level using the 
electrical signal produced by this chemical reaction, the strength of which is proportional to the glucose level.

After a 3-hour warm-up period and calibration with a blood glucose level, the Autosensor provides up to 12 hours 
of glucose readings produced every 20 minutes. The Glucowatch displays the most recent glucose level and 
stores the remaining readings. It can be set to produce an audible alarm if the glucose level is above or below pre-
specified limits. The alarm will also sound if the glucose level falls more than 35% compared to the last 
measurement, or if the device senses perspiration, which can interfere with functioning of the device and is also 
associated with hypoglycemia.

The FDA approved the GlucoWatch Biographer in March 2001 for individuals, age 18 and older. In August 2002, 
the GlucoWatch was approved for use by children between the ages of 7 and 17 years.

02/13/2003: MTAC REVIEW

GlucoWatch

Evidence Conclusion: Children: There is no published evidence on the efficacy of the GlucoWatch Biographer 
for monitoring blood glucose levels among children with diabetes.

Adults: There is no published evidence on whether use of the GlucoWatch Biographer improves health outcomes 
or glucose control among people with diabetes compared to standard self-monitoring techniques. The evidence on 
the accuracy of the GlucoWatch suggests that measurements are reasonably accurate compared to fingerstick
Home A1c Tests

BACKGROUND

A1c (also known as hemoglobin HbA1c or HbA1c) gives information about the average blood glucose level over the previous 2-3 months and is the best measure of overall blood glucose control for patients with diabetes (Kaiser Permanente diabetes guideline). The A1c test measures the concentration of glycosylated hemoglobin in the blood. A1c forms when some of the glucose circulating in the blood binds irreversibly to hemoglobin A, forming a stable glycohemoglobin complex. The A1c level is proportional to the amount of glucose in the blood over the life span of red blood cells. It does not fluctuate with daily blood glucose levels. An HbA1c target of <7% is recommended for most patients with type 1 or type 2 diabetes. Research has found that, if a patient's HbA1c level is higher than 8%, reducing it by one-tenth (e.g., from 10% to 9%) will slow down damage to their body by about 50% from the current rate (DCCT Research Group 1997). The Kaiser Permanente diabetes glycemic control guideline recommends that people with diabetes routinely monitor their HbA1c every 6 months. For patients who have elevated blood glucose and are attempting to reduce their blood glucose levels, Kaiser Permanente recommends checking HbA1c every 3 months until the target level is reached.

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months. For patients who have elevated blood glucose and are attempting to reduce their blood glucose levels,
Kaiser Permanente recommends checking HbA1c every 3 months until the target level is reached.

HbA1c tests have traditionally been conducted in a health-care setting. Several in-home HbA1c tests have been
cleared by the FDA. The FlexSite A1c At-Home test was FDA-approved in 1997 and is available over-the-counter.
It includes a blood sample collection kit that uses treated filter paper for spotting blood. The patient provides one
or two drops of blood to each of two target areas on the filter paper and lets the sample dry overnight. The dried
blood sample is then mailed to the FlexSite lab where it is evaluated. Results are available by phone or mail. The
manufacturer claims that its sample collection technique allows a dried blood sample to be transported for up to 12
days without significant artifactual in vitro glycation (manufacturer's website; Parkes et al., 1999).

Another home A1c test was approved by the FDA in 2002 under the name Metrica A1cNow. It was cleared both
for prescription and over-the-counter use. Beginning in 2004, the test has been distributed exclusively by Bristol-
Meyers Squibb and it is now called the ChoiceDM A1c Home test. Unlike the FlexSite test, the Metrika
A1cNow/Choice DM A1c Home test provides results at home. The test comes as a disposable, one-use device
about the size of a pager. It incorporates microelectronics, optics and dry-reagent chemistry strips. Individuals
collect a sample of whole blood via fingerstick or venipuncture, place the sample in a cartridge and mix it with the
dilution solution provided by the manufacturer. The diluted sample is added to the monitor which activates the
device (there are no buttons or switches, the device is self-activated). Activating the device causes blue
microparticles conjugated to an anti-HbA1c antibody to migrate along the reagent strips. The amount of blue
microparticles captured on the strips is proportionate to the amount of HbA1c in the sample. After about eight
minutes, the results are displayed in numeric form on the digital display. Total hemoglobin in the sample is also
measured (manufacturer's website; Kordella, 2002).

02/05/2007: MTAC REVIEW

Home A1c Test

Evidence Conclusion: No published evidence was identified on the Metrika A1cNow/Choice DM A1c Home test,
the test that provides results to patients within minutes at home. In addition, there was no published evidence the
ability of home A1c testing to improve clinical outcomes. One published study was identified on the FlexSite at-

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home A1c sampling kit, which requires mailing samples to a centralized laboratory. This study found that A1c levels using the usual method for analyzing in-home samples was highly correlated with two standard methods of establishing A1c levels. However, the accuracy e.g. sensitivity and specificity of any of the tests was not reported. In addition, the study involved having patients and staff collect blood samples, but the test results for the two types of samples were not reported in the analysis. The authors of the study had links to the test manufacturer which may have introduced bias.

**Articles:** No published studies were identified on the Metrika A1cNow/Choice DM A1c Home test. An FDA talk paper from 2002 states that the Metrica device was cleared for non-prescription use based on a study by the manufacturer comparing test results obtained by lay users to those obtained by medical professionals. The Medline search did not identify a published version of this study and the company did not respond to a request for the manuscript. One published study was identified on the Flexsite at-home test. This study was critically appraised: Parkes J, Ray R, Kerestan S et al. Prospective evaluation of accuracy, precision, and reproducibility of an at-home hemoglobin A1c sampling kit. Diab Tech Ther 1999; 1: 411-419. See [Evidence Table](#).

The use of Home A1c tests in the treatment of diabetes does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

**I-Port™ Injection Port**

**BACKGROUND**

The I-Port is a device that is placed on the skin, and through which patients can self-administer subcutaneous injections of prescription medications using a standard syringe and needle. A removable insertion needle allows placement of the body of the I-Port device on the skin. The device is held in place by an adhesive pad and a soft cannula. The I-Port body is 1.5” (38mm) in diameter and 1/3” (9mm) tall. The disposable I-Port can be worn for up to 72 hours and, during this time, up 75 needle sticks can be made through the soft cannula. During an injection of medication, the needle of the syringe remains above the surface of the skin. Medication is delivered through the cannula into the subcutaneous tissue. The I-Port is manufactured by Patton Medical Devices, a company founded by K.K. Patton, the inventor of the device. The I-Port was approved by the FDA in September 2005 as a class II device judged to be substantially equivalent to predicate devices. It is approved for marketing to adults and children who require multiple daily injections of prescription medication, including insulin.

The manufacturer materials warns consumers to use as specified by a health care provider and not to re-use the I-Port, not to use the same I-Port for longer than 72 hours and not to use a needle longer than 8mm or thicker than 28 gauge when injecting into the I-Port. In addition, the I-Port website Q&A section states that irritation, inflammation and infection are rare, but the potential for these exist, especially when the skin surface is not adequately cleaned before application or when the device is improperly applied to the body.

There was one adverse event report on the FDA Manufacturer and User Facility Device Experience Database (MAUDE) database. This was a device malfunction that occurred on July 24, 2007 with a life-threatening patient outcome. Details of the event were not included in the report.

**10/01/2007: MTAC REVIEW**

**I-Port™ Injection Port**

**Evidence Conclusion:** There is no published evidence to support the use of the I-Port and no published information on the safety of the device.

**Articles:** No published articles were identified.

The use of iPort in the delivering of prescription medications does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

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<td>02/13/2003MPC, 07/07/2015MPC, 05/03/2016MPC, 03/07/2017MPC</td>
<td>07/07/2015</td>
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MPC: Medical Policy Committee

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<tr>
<th>Revision History</th>
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**Codes**

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Home A1c: 83037
There are no specific codes for Sleep Sentry Monitor, GlucoWatch, iPort Injection Port