KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Diabetes Tests and Supplies

- Home A1c Test
- iPort Injection Port

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article (LCA)	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, ***"Diabetes Tests and Supplies"*** for medical necessity determinations. Refer to the Non-Medicare criteria below.

Service	Criteria
• Home A1c Test • i-Port/i-Port Advance Injection Port	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.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information 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 (no longer available)
GlucoWatch Biographer™ (no longer available)
Home A1c Test
iPort Injection Port

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).

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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 measure 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.

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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 measurements (approximately 70% of measurements would lead to clinically correct decisions and about 95% would lead to clinically acceptable decisions). However, the data may be biased because all studies were conducted by investigators affiliated with the device manufacturer, and most data were collected in a controlled clinical environment and accuracy may differ in a “real-life” setting.
Articles: The search yielded nine articles. One was an article reviewing several glucose monitoring devices, one was a report announcing the new technology, and the remaining seven were authored by the Cygnus Research Team. There were no studies reporting on the effect of glucose self-monitoring with the GlucoWatch on health outcomes e.g. macrovascular or microvascular complications of diabetes. There were also no studies reporting on the effect of glucose self-monitoring with the GlucoWatch on the ability to maintain tight glucose control. The empirical data all addressed the accuracy of the GlucoWatch to detect current blood glucose levels. All of the studies were conducted among adults. The two studies on accuracy with the strongest methodology were critically appraised. Features examined for study selection were sample size, thoroughness of methods description, setting (controlled environment vs. home setting) and comparison with finger-stick measurements. The following articles were reviewed: Tierney MJ, Tamada JA, Potts et al. Clinical evaluation of the GlucoWatch biographer: a continual, non-invasive glucose monitor for patients with diabetes. *Biosensors & Bioelectronics* 2001; 16: 621-629. See Evidence Table

The use of GlucoWatch in the evaluation of diabetic control does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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 glycated hemoglobin 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.
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-

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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-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.

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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.*

Applicable Codes

Home A1c- Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use

iPort- Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
A4211	Supplies for self-administered injections

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/13/2003	02/13/2003[MPC], 07/07/2015[MPC], 05/03/2016[MPC], 03/07/2017[MPC], 01/09/2018[MPC], 11/06/2018[MPC], 11/05/2019[MPC], 11/03/2020[MPC], 11/02/2021[MPC], 11/01/2022[MPC], 11/07/2023[MPC]	11/03/2020

[MPC] Medical Policy Committee

Revision History	Description
11/03/2020	Removed Diabetes Sentry Monitor and GlucoWatch Biographer from list of services as the specific products are no longer available.

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