Guidelines for Medical Necessity Determination for Diabetes Management Devices: Continuous Glucose Monitoring Systems and Insulin Pumps

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for continuous glucose monitoring (CGM) systems and insulin pumps. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at 130 CMR 409.000 (Durable Medical Equipment Services), 130 CMR 450.000 (Administrative and Billing Regulations), Subchapter 6 of the Durable Medical Equipment (DME) Manual, the online MassHealth DME and Oxygen Payment and Coverage Guidelines Tool, and Therapeutic Class Table 78 of the MassHealth Drug List (Diabetes Medical Supplies and Emergency Treatments) for information about coverage, limitations, service conditions, and other prior-authorization (PA) requirements.

Providers serving members enrolled in a MassHealth-contracted Accountable Care Partnership Plan (ACPP), Managed Care Organization (MCO), One Care Organization, Senior Care Options (SCO), or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, One Care Organization's, SCO's, or PACE's medical policies for covered services.

MassHealth requires PA for CGM systems and insulin pump devices. MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

MassHealth considers approval for coverage of the CGM systems and insulin pump devices on an individual, case-by-case basis, in accordance with 130 CMR 450.204: *Medical Necessity*. MassHealth covers both insulin pumps and CGM systems under DME services. Note that members may obtain insulin pumps only from DME providers under MassHealth's Medicaid Management Information System (MMIS). However, the CGM system and parts may be obtained from DME pharmacy providers who bill through MMIS, or pharmacy providers who bill through the Pharmacy Online Processing System (POPS).

These Guidelines address the MMIS-based PA process administered through the Long Term Services and Supports Management System (LTMS) or Provider Online Service Center (POSC) for insulin pumps or CGM systems supplied by either a MassHealth-enrolled DME provider or a pharmacy that uses MMIS. For pharmacies that are only using POPS, submission criteria can be found in the MassHealth Drug List, Therapeutic Class Table 78: Diabetes Medical Supplies and Emergency Treatments (non-drug formulary).

SECTION I. GENERAL INFORMATION

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I. CONTINUOUS GLUCOSE MONITOR

A CGM system is a small wearable glucose monitoring device that continuously measures and tracks a person´s glucose levels for the management of diabetes.

Glycemic control is fundamental to the medical management of diabetes mellitus. Tools that assist with glucose monitoring and trending play an important role in managing diabetes and avoiding or limiting diabetic complications attributed to blood sugar levels that are too high or too low. Traditional finger stick blood glucose monitoring provides individuals with diabetes an immediate blood glucose level reading and is used to regulate insulin dosing (Americans With Disabilities Act [ADA], 2013). For many, it is necessary to perform six to eight (or more) finger sticks a day. Glycated hemoglobin (A1C) tests, performed in a provider's office, measure the attachment of glucose to hemoglobin, which reflects the average of a person's blood glucose levels over the previous three months, thereby estimating overall glucose trends. CGM introduces the ability to measure interstitial glucose levels on a more continuous basis and reveal glucose level trends that might be important for management. CGM systems measure blood glucose either in a minimally invasive manner through continuous measurement of interstitial fluid or noninvasively by applying electromagnetic radiation through the skin to blood vessels in the body. Results are available to the member in real time or retrospectively.

CGM systems have three main components: an external receiver (monitor), an external transmitter, and a disposable subcutaneous sensor (National Institute of Diabetes and Digestive and Kidney Diseases, 2017). Usually, the sensors are implanted on the abdomen or on the lower back for three to seven days. Interstitial glucose levels are sent from the sensor to the receiver in one- to five-minute intervals. The glucose values are read on the receiver (monitor). Data from the CGM system may be stored in the device and can alert the individual that they may be experiencing a potentially harmful, sudden fluctuation in blood sugar level. A CGM system can be customized; each individual user may customize the threshold settings to detect high and low glucose levels that trigger the alarm; and the alarm is shareable, for example, to alert a parent of their child's blood sugar. The US Food and Drug Administration (FDA) labeling for CGM systems notes they are not to be used as a replacement for standard blood glucose monitors (ADA, 2013; FDA, 2017). Their intent is to supplement standard glucose monitors and assist in future diabetes management. Data from CGM systems include glycemic trends and the appropriate timing and frequency of finger stick blood glucose samples. Any changes in an individual's insulin therapy should be confirmed by a finger stick blood glucose sampling and not a CGM system.

The individual using CGM should use the information provided to take an active, collaborative role with their professional health care provider to develop a diabetes care plan. The treatment plan should include updates on the use of CGM and contain targeted, personalized goals and outcomes. It should also reflect the individual's active role in their current diabetes management status. CGM systems may be used to monitor unexplained glycemic excursions and episodes of hypoglycemic unawareness. If not addressed, hypoglycemia may cause complications such as seizures, diabetic coma, or brain damage (Wolpert, 2007).

Members with diabetes need to be closely monitored. When blood glucose levels are poorly controlled, members are at risk of complications, including heart disease, peripheral vascular disease, stroke, retinal damage, kidney disease, impotence, and nerve damage. Members should also be monitored for

comorbidities that may not be present during the early stages of the disease, but develop as the disease progresses; these include hearing impairment, fatty liver disease, sleep apnea, periodontal disease, depression, anxiety, cognitive impairment, and fractures.

Reasonable A1C goals for diabetic members should be customized for the individual member, balancing established benefits with prevention of complications and risk of hypoglycemia. Goals vary depending on age, members with comorbidities, limited lifetime expectancy, and benefits of intensive therapy. Members with type 1 diabetes and pregnancy may require stricter control.

For members with type 1x diabetes mellitus (T1DM), tight glucose control is critical because they require ongoing treatment with exogenous insulin. Self-monitoring of blood glucose (SMBG) is normally accomplished by measuring blood glucose concentration through intermittent capillary blood sampling with a reagent strip, cartridge, or cuvette and a drop of capillary blood from a finger puncture. Different testing frequency may be indicated for type 1 and type 2 diabetes as well as for gestational diabetes or cystic-fibrosis-related diabetes. Devices are available for continuous glucose monitoring from interstitial fluid, but SMBG testing must still be used in conjunction with CGM systems to confirm high and low continuous glucose monitoring values.

CGM offers the most benefit in members or members' parents who are willing to use them consistently and in members with hypoglycemic unawareness who are at risk or have a history of severe recurrent hypoglycemia. Recent studies show that continuous glucose monitoring is associated with improved glycemic control in adult members with type 1 diabetes. Studies for the role of CGM in Type 2 diabetes mellitus (T2DM) are less clear, and studies in pregnancy show only minimal benefit (HgA1C reduction of only 0.2) with some forms of CGM systems (CONCEPTT Trial, 2017). The decision to use CGM systems for T2DM, pregnancy, or other conditions thus must be the result of careful decision-making between member and provider, with guidance regarding the pros, cons, risks, and benefits clearly delineated.

II. INSULIN PUMP

An ambulatory infusion pump (insulin pump) is an externally worn device for the continuous or pulsed subcutaneous administration of insulin to diabetics who require insulin but who either are unable to self-administer medication or require meticulous medication to minimize effects or complications of diabetes. It consists of an external battery-operated pump that carries the insulin beneath the skin.

Insulin pumps should be used in diabetic members who are demonstrated to have T1DM or are insulinopenic. With T1DM, most or all insulin-producing capacity is lost within 12 months of presentation. In T2DM, insulin capacity may not be impaired initially. Members typically have insulin resistance and can produce high levels of endogenous insulin, but the insulin is less effective. Thus, for T2DM, oral agents are used first-line to either cause more insulin to be released or improve the effectiveness of available insulin. Over time, however, the pancreatic beta cells become exhausted, and oral agents become less effective. Other rare conditions may also cause insulinopenia.

III. DEFINITIONS

For the purposes of these Guidelines, "poorly controlled blood sugar level" is defined as unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, or recurrent diabetic ketoacidosis.

SECTION II. CLINICAL GUIDELINES

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I. CLINICAL COVERAGE

A. CGM SYSTEMS

MassHealth considers CGM systems medically necessary for insulin-dependent individuals with poorly controlled blood sugar level. MassHealth bases its determination of medical necessity for CGM systems on clinical information including, but not limited to, indicators that would affect the relative risks and benefits of using the device. These criteria include the following:

1. INITIAL—MassHealth considers initial use of CGM systems medically necessary in members who experience problems controlling blood glucose levels and meet ALL of the following criteria:

   a) The member has a diagnosis of diabetes mellitus; AND

   b) The member's treatment regimen includes insulin administration, or an insulin pump is being used (claims in MassHealth's systems or previous documented history showing need of a short acting insulin or concurrent claims for multiple types of insulin are sufficient). Exceptions: Providers may request an exception from the insulin use requirement for members not receiving insulin due to physical disability, visual impairment, documented needle phobia, cognitive impairment, or age <18; such instances may bypass this requirement. Other comorbidities should be reviewed on a case-by-case basis; AND

   c) The member meets at least one of the following:

      i. glycosylated hemoglobin (HbA1c) ≥7% or at a value that does not meet documented target treatment; OR

      ii. frequent hypoglycemia or nocturnal hypoglycemia; OR

      iii. history of hypoglycemic unawareness; OR

      iv. dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL; OR

      v. history of emergency room visit or hospitalization related to ketoacidosis or hypoglycemia; OR

      vi. use of a compatible insulin pump to achieve glycemic control; OR

      vii. pregnancy.

   OR

   d) The member has another non-diabetes-based condition causing disorder of glucose metabolism or improper endogenous insulin secretion resulting in frequent hypoglycemia or nocturnal hypoglycemia or hypoglycemic unawareness. Such disorders may include, but are not limited to, seizure disorder, insulinoma, genetic conditions causing hyperinsulinemia, effects from post-surgical conditions including post esophagectomy, post fundoplication, post gastrectomy, post gastric bypass, and post sleeve gastrectomy. Such cases should speak to hypoglycemic risk and events and will be reviewed on a case-by-case basis.

2. CONTINUED USE—Continuation of CGM use is considered medically necessary in each of the following circumstances:

   a) There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual members); OR

   b) There is documented evidence of compliance with a current CGM treatment plan based on log data of the device; OR

   c) A member is new to MassHealth from another insurer and is stable on CGM.

B. **INSULIN PUMPS**

MassHealth bases its determination of medical necessity for insulin pumps on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of using the device. There are criteria for initial use and for continued use of an insulin pump. The criteria are as follows:

1. INITIAL—Initial use criteria include, but are not limited to, the following, as documented in the clinical record:

   a) The member has:

      i. a primary diagnosis of diabetes mellitus;

      OR

      ii. another non-diabetes-based condition causing insulinopenia. Such disorders may include post pancreatectomy and others. Such cases should speak to insulinopenic risk, and events will be reviewed on a case-by-case basis.

   AND

   b) The member has been performing multiple daily injections (MDIs) consisting of at least three injections per day. Exceptions: Providers may request an exception to the compliance requirement for individuals with comorbidities that inhibit the ability to self-administer. Such requests will be reviewed on a case-by-case basis; AND

   c) The member's current treatment plan involves testing blood glucose at least four times per day; AND

   d) Indications of **at least one** of the following factors (i–v) are present.

      i. The member has a history of recurring hypoglycemia; OR

      ii. The member has experienced fluctuations of more than 100 mg/dL in blood glucose before mealtime; OR

      iii. The member has experienced dawn phenomenon with fasting blood sugars exceeding 200 mg/dL; OR

      iv. The most recent lab values indicate an HbA1clevel > 7.0 percent; OR

      v. The member has a history of severe glycemic excursions; AND

   e) Prior treatments with MDIs were tried and were not effective in managing blood sugars and/or medical symptoms.

2. CONTINUED USE—At the time of the PA request for continued use of the insulin pump:

a) The HbA1c level has stabilized or improved (compared to baseline); AND

b) There is clinical evidence demonstrating stabilization or improvement of the initial indication for the device, including, but not limited to, the following:

i. The member's recent history of recurring hypoglycemia has stabilized or improved; OR

ii. The member's fluctuations of more than 100 mg/dL in blood glucose before mealtime have stabilized or improved; OR

iii. The member's experience(s) of dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL has stabilized or improved; OR

iv. The member's history of severe glycemic excursions has stabilized or improved; AND

c) Continued coverage of an insulin pump requires that the member be seen and evaluated by the prescribing provider at least every three months, or as determined by clinical need, and that the prescribing provider work closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy; AND

d) Any other pertinent clinical information requested by MassHealth about the member's clinical presentation. OR

3. The member is new to MassHealth from another insurer and the provider provides clinical evidence that the member is stable on the insulin pump as described in subsections B.2.a and B.2.b.

4. The member has diabetes in pregnancy endangering fetal health.

C. **REPLACEMENT**

MassHealth considers the replacement of a CGM system, insulin pump, or combined system as reasonable and medically necessary when ALL of the following indications are met:

1. Supporting documentation is in the form of clinical notes or letters generated by a clinician overseeing the member's diabetic condition; AND

2. The present monitor has been rendered ineffective or inoperable due to EITHER:

a) a change in member condition that the current monitor is unable to accommodate, OR

b) damage by events outside the control of the user; AND

3. The device has been used according to a current treatment plan; AND

4. Continued use of the device is clinically supported; AND

5. Device replacement cannot be obtained from the manufacturer or supplier for reasons including the expiration of device warranty; AND

6. Loss/damage is not attributable to abuse, damage, or neglect on the part of the user; AND

7. The cost of replacement rather than repair is justified by the nature of the damage and the useful lifetime of the device; AND

8. In the case of CGM systems, replacement is not an additional/backup monitor; AND

9. In the case of CGM systems, replacement monitor is synonymous to the monitor being replaced unless replacement has been necessitated by a change in member condition that the old device is unable to accommodate.

Note: In cases where neither the make and model of the device being replaced nor directly competitive devices from other brands are available, approval of a new device will be based on meeting the requirements set forth in Sections 2.I.A or 2.I.B

D. NON-COVERAGE

MassHealth does not consider CGM systems or other products to be medically necessary under certain circumstances where effectiveness has not been established or when there is noncompliance or an inability to comply with a current treatment plan. Examples of such circumstances include, but are not limited to, the following:

1. Non-FDA-approved devices.
2. Remote continuous glucose monitoring devices, accessories, and additional hardware or software that are ancillary to CGM systems and are not considered medically necessary (e.g., complementary watches).
3. Replacement of an existing CGM system with another CGM system for additional features that are not medically necessary.
4. CGM systems are contraindicated for individuals who are unable or unwilling to perform required necessary calibration of a CGM system, which may include, but not be limited to, self-monitored blood glucose checks at least twice per day; or a member's symptoms and clinical presentation do not match/align with device readings; or a member does not maintain contact with their health care professionals.
5. The member enrolled in an initial three-month insulin pump trial and either failed or is not motivated or is otherwise noncompliant with a current treatment plan and is not likely to benefit from another three-month trial.
6. The member is unable to perform frequent blood glucose monitoring or is unable to technically operate an insulin pump because of behavioral, psychological, or other reasons.

SECTION III: SUBMITTING CLINICAL DOCUMENTATION

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Requests for PA for CGM systems or insulin pumps must be accompanied by clinical documentation that supports the medical necessity of the requested device.

Clinical documentation by the provider (endocrinologist) of the supporting rationale for the requested device (insulin pump or CGM system) must show that the member's blood sugar remains poorly controlled despite appropriate adjustments to a physician-ordered and physician-monitored treatment plan based on previous self-monitoring. Specifically, documentation of medical necessity **must include all of the following**:

1. Documentation that indicates that the member remains compliant with the insulin therapy recommended by an endocrinologist for at least three months. **Exceptions**: Providers may request an exception to the compliance requirement due to comorbidities that inhibit the ability to self-monitor blood sugar or self-administer insulin. Requests for exceptions will be considered on a case-by-case basis.

2. Documentation that indicates the member's HbA1C level(s) (at least two readings representing at least six months).

3. Documentation demonstrating that criteria for Sections 2.I.A, B, or C are met as appropriate to the clinical situation as outlined above.

DME providers must submit all information related to the PA request through the LTMS or by mail, completing a MassHealth Prior Authorization Request (PA-1) form and attaching supporting documentation. If submitting a nonelectronic request, a DME provider should mail the PA-1 form, and any supporting documentation, to the address on the back of the PA-1 form. DME providers with any questions about LTMS access may direct them to the MassHealth Long Term Services and Supports Provider Service Center at (844) 368-5184.

When submitting PA requests for Community Case Management Program members, DME providers must submit all information related to the PA request through the POSC or by completing a PA-1 form and attaching the supporting documentation. If submitting a nonelectronic request, the provider should mail the PA-1 form, and any supporting documentation, to the address on the back of the PA-1 form. Providers with any questions about POSC access may direct them to the MassHealth Customer Service Center at (800) 841-2900, TDD/TTY: 711.

For pharmacy providers that are only using POPS, submission criteria may be found on the MassHealth Drug List in Therapeutic Class Table 78: Diabetes Medical Supplies and Emergency Treatments.

APPENDIX:

MASSHEALTH COVERED DIABETES MANAGEMENT DEVICES

CODE	DESCRIPTION
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4255	Platforms for home blood glucose monitor, 50 per box
A4256	Normal, low and high calibrator solution/chips
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor, invasive (e.g., subcutaneous), disposable, for use with interstitial CGM system
A9277	Transmitter, external for use with interstitial CGM system
A9278	Receiver (monitor), external for use with interstitial CGM system
E0784	External ambulatory infusion pump, insulin
K0553	Supply allowance for therapeutic CGM, includes all supplies and accessories, 1 unit of service = 1 month's supply
K0554	Receiver (monitor), dedicated, for use with therapeutic continuous glucose monitor system

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These Guidelines are based on review of the medical literature and current use of continuous glucose monitoring systems. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products or services. Some language used in this communication may be unfamiliar to other readers; in this case, contact your health-care provider for guidance or explanation.

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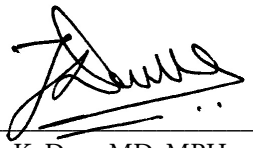
Approved by: 

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