MEDICAL POLICY	Temporary Policy Emergency Provisions for: **Advanced Diabetes Management Technology** **(Medicare Only)**	
Effective Date: 1/1/2022  Medical Officer Date	Section: DME	Policy No: 392
	Medical Policy Committee Approved Date: 9/17, 12/17; 1/18; 6/18; 10/18; 10/19; 1/2021; 12/2021	

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

NEED AND DURATION OF EMERGENCY PROVISIONS

1. **Need for the temporary Provisions:** COVID-19 public health emergency
2. **Documents or source relied upon:**
   - Centers for Medicare & Medicaid Services (CMS) Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19
   - Centers for Medicare & Medicaid Services (CMS) final rules in response to the COVID-19 Public Health Emergency
   - CMS COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing
3. **Initial Effective Date: 3/1/2020**
4. **Re-review dates: 11/30/2020; 2/3/2021; 3/31/2021; 6/1/2021; 12/8/2021**
5. **Termination Date: 6/30/2022**
6. **Reassessment Date determined at Companies sole discretion: 6/29/2022, or sooner if regulations or clinical practice guidelines change.**

POLICY ADDENDUM

COVID-19 Public Health Emergency

On March 30th, 2020, the Centers for Medicare & Medicaid Services (CMS) released the final rules in response to the COVID-19 public health emergency, which states:

> *"National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) on Respiratory Related Devices, Oxygen and Oxygen Equipment, **Home Infusion Pumps** and Home Anticoagulation Therapy: Clinicians now have maximum flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at the home. The current NCDs and LCDs that restrict coverage of these devices and services to patients with certain clinical characteristics do not apply during the public health emergency. For example, Medicare will cover non-invasive ventilators, respiratory assist devices*

and continuous positive airway pressure devices based on the clinician's assessment of the patient."

"…we are finalizing on an interim basis that we will not enforce the clinical indications for therapeutic continuous glucose monitors in LCDs. For example, we will not enforce the current clinical indications restricting the type of diabetes that a beneficiary must have or relating to the demonstrated need for frequent blood glucose testing in order to permit COVID-19 infected patients with diabetes to receive a Medicare covered therapeutic continuous glucose monitor. This discretion is intended to permit COVID-19 patients to more closely monitor their glucose levels given that they are at risk for unpredictable impacts of the infection on their glucose levels and health. The use of therapeutic continuous glucose monitors may allow patients to proactively treat their diabetes and prevent the need for hospital-based diabetic care. Practitioners will also have greater flexibility to allow more of their diabetic patients to better monitor their glucose and adjust insulin doses from home by using a therapeutic continuous glucose monitor. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic."

Therefore, beginning 3/1/2020, the Medicare Guidelines below do not apply during this public health emergency. During this time, the DME addressed in this medical policy will be covered based solely on the clinician's assessment of the patient.

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

Notes:

- The following advanced diabetes management technologies are only available through retail Pharmacy, therefore requests for the following devices will be reviewed by Providence Health Plan's Pharmacy Department. If approved, these devices will be made available at the member's pharmacy at applicable durable medical equipment cost-share.

• Insulin Pump	• Continuous Glucose Monitors
• Omnipod Dash • V-Go Wearable Insulin Delivery	• Freestyle Libre • Dexcom G5/G6

- Centers for Medicare & Medicaid Services (CMS) does not specifically address integrated insulin infusion and continuous glucose monitor systems (CGMs), including sensor-augmented systems and artificial pancreas device systems. However, CMS does address the use of insulin pumps and CGMs, which may be applied to the use of integrated systems, for medical necessity determinations for Medicare members.

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
Continuous Glucose Monitor	• Local Coverage Determination (LCD): Glucose Monitors Devices (L33822)[1] • Local Coverage Article: Glucose Monitor – Policy Article (A52464)[2]
Implantable Continuous Glucose Monitors	• Local Coverage Determination (LCD): Implantable Continuous Glucose Monitors (I-CGM) (L38659)[3] • Local Coverage Article: Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM) (A58138)[4]
External Insulin Infusion Pump	• Local Coverage Determination (LCD): External Infusion Pumps (L33794)[5] (*Note: see criterion IV.*) • Local Coverage Article: External Infusion Pumps (A52507)[6]
Implantable Insulin Infusion Pump	National Coverage Determination (NCD) for Infusion Pumps (280.14) [7] *Note: see criterion C.2.*

BILLING GUIDELINES

- In accordance with the LCA for Glucose Monitors, a therapeutic CGM must be billed with codes K0554 and K0553 (for the supply allowance). If codes A9276, A9277, or A9278 are billed for a CGM they will deny to "rebill with correct code".
- Code A4224 will not be reimbursed more than 52 times per calendar year.
- Although insulin pumps alone do not require prior authorization when pumps are billed as part of an integrated system with a continuous glucose monitor, prior authorization is required.

- In accordance with the LCA for Glucose Monitors, a therapeutic CGM must be billed with codes K0554 and K0553 (for the supply allowance). If codes A9276, A9277, or A9278 are billed for a CGM they will deny to "rebill with correct code."
- Disposable insulin pumps (HCPCS code A9274) are part of the Part D Medicare benefit. Therefore, any requests for disposable insulin pumps in Medicare members must go through Pharmacy review.
- Implantation of an implantable continuous glucose monitor (I-CGM) that meets the appropriate criteria as mentioned in LCD L58138 Implantable Continuous Glucose Monitors (I-CGM) is reported with:
    - CPT® code 0446T - Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
- Removal of an I-CGM is reported with:
    - CPT® code 0447T - Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
- Removal with immediate subsequent replacement of an I-CGM is reported with:
    - CPT® code 0448T - Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
K0553	Supply allowance for therapeutic continuous glucose monitor (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
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via Incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation
No Prior Authorization Required	
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording

95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
A4230	Infusion set for external insulin pump, non needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
E0784	External ambulatory infusion pump, insulin
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each
K0602	Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each
K0603	Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each
Not Covered	
A9270	Non-covered item or service
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
A9999	Miscellaneous dme supply or accessory, not otherwise specified
E1399	Durable medical equipment, miscellaneous

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed

annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

- Diabetes: Blood Glucose Monitor and Supplies (All Lines of Business Except Medicare), DME206
- Diabetes: Blood Glucose Monitor and Supplies (Medicare Only), DME421
- Advanced Diabetes Management Technology (All Lines of Business Except Medicare), DME207
- Pharmacy Policy: Continuous Glucose Monitors for Personal Use (Non-professional): FreeStyle Libre

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Glucose Monitors (L33822). https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33822. Published 2019. Accessed 10/15/2020.
2. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A52464: Glucose Monitor. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52464. Published 2018. Accessed 10/15/2020.
3. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Implantable Continuous Glucose Monitors (I-CGM) (L38659). https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=38659. Published 2020. Accessed 2/4/2021.
4. Centers for Medicare & Medicaid Services. Local Coverage Article: Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM) (A58138). https://www.cms.gov/medicare-

coverage-database/details/article-details.aspx?articleId=58138. Published 2020. Accessed 2/4/2021.

5. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): External Infusion Pumps (L33794). https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33794. Published 2015. Accessed 7/19/2021.
6. Centers for Medicare & Medicaid Services. Local Coverage Article (LCA) A52507: External Infusion Pumps. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52507. Published 2018. Accessed 10/15/2020.
7. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Infusion Pumps (280.14). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=223. Published 2005. Accessed 10/15/2020.