PARTNERSHIP HEALTHPLAN OF CALIFORNIA GUIDELINE / PROCEDURE

Guideline/Procedure Number: MPUG3025 (previously UG100325)				Lead Department: Health Services Business Unit: Utilization Management			
Guideline/Procedure Title: Insulin Infusion Pump and Continuous				External Policy			
Glucose Monitor Gu	udelines			Internal Policy			
Original Date: 04/19/1996		Next Review Date: Last Review Date:	06/11/2026 06/11/2025				
Applies to:	Employees		🛛 Medi-Cal	\boxtimes	🛛 Partnership Advantage		
Reviewing Entities:	IQI		🗌 P & T	\boxtimes	QUAC		
	OPERATIONS				COMPLIANCE DEPARTMEN		
Approving Entities:	BOARD		COMPLIANCE		FINANCE	PAC	
	CEO		CREDENTIALING DEPT. DIREC		CTOR/OFFICER		
Approval Signature: Robert Moore, MD, MPH, MBA			Approval Date: 06/11/2025				

I. RELATED POLICIES:

- A. MCUP3041 Treatment Authorization Request (TAR) Review Process
- B. MCUG3007 Authorization of Ambulatory Procedures and Services
- C. MCUP3042 Technology Assessment
- D. MCUP3013 Durable Medical Equipment (DME) Authorization
- E. MPUP3139 Criteria and Guidelines for Utilization Management

II. IMPACTED DEPTS:

- A. Health Services
- B. Claims
- C. Member Services

III. DEFINITIONS:

- A. <u>California Children's Services (CCS)</u>: A state program for children up to 21 years of age, who have been determined eligible for the CCS program due to the presence of certain diseases or health problems.
- B. <u>Continuous glucose monitor</u>: A device to measures glucose levels in the interstitial fluid through the use of a sensor placed under the skin. A transmitter sends information about glucose levels to a wireless monitor attached externally. These devices display glucose levels at either 1 or 5 minute intervals with the option to set alarms alerting the individual to abnormal glucose levels. Greater amounts of data collection may provide more insight regarding glucose patterns.
- C. <u>Diabetologist</u>: A physician who is Board Certified in Advanced Diabetes Management (BC-ADM). [*Note that this is not an American Board of Medical Specialties (ABMS) board certification.*]
- D. <u>Direct Member</u>: Direct Members are those whose service needs are such that Primary Care Provider (PCP) assignment would be inappropriate. Assignment to Direct Member status may be based on the member's aid code, prime insurance, demographics or administrative approval based on qualified circumstances. A Referral Authorization Form (RAF) is not required for Direct Members to see Partnership network providers and/or certified Medi-Cal providers willing to bill Partnership for covered services. However, many specialists will still request a RAF from the PCP to communicate background patient information to the specialist and to maintain good communication with the PCP.
- E. <u>Insulin pump</u>: Also known as subcutaneous insulin infusion (CSII), an insulin pump is an external ambulatory infusion device used for managing insulin-requiring Diabetes Mellitus (DM). By continuous administration of short acting insulin at preselected rate, the insulin pump can improve the patient glycemic control and delay, prevent, or reduce their risk of complications (e.g. neuropathy, nephropathy, retinopathy.)

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- F. <u>Partnership Advantage</u>: Effective January 1, 2027, Partnership HealthPlan of California will operate a Centers for Medicare & Medicaid Services (CMS)-approved Dual-Eligible Special Needs Plan (D-SNP) in specific counties as described in the Department of Health Care Services (DHCS) CalAIM Dual Eligible Special Needs Plan Policy Guide. This line of business will be known as Partnership Advantage and will be a Medicare Advantage plan offered to all full-benefit, dual-eligible beneficiaries 21 years of age or older who reside in the applicable counties. Partnership Advantage Members will be qualified to receive both Medi-Cal and Medicare services as described in the Partnership Advantage Member Handbook.
- G. <u>Whole Child Model (WCM</u>): This program provides comprehensive treatment for the whole child and care coordination in the areas of primary, specialty, and behavioral health for Partnership HealthPlan of California (Partnership) pediatric members with a CCS-eligible condition(s).

IV. ATTACHMENTS:

- A. CCS NL 06-1120 Authorization of Insulin Infusion Pumps Revised 11/17/2020
- B. <u>CCS NL 15-1222 Continuous Glucose Monitoring Systems as a CCS/GHPP Program Benefit</u> <u>12/23/2022</u>

V. PURPOSE:

To describe the guidelines used by Partnership HealthPlan of California's Utilization Management (UM) staff when reviewing a Treatment Authorization Request (TAR) for an external insulin infusion pump and/or a continuous glucose monitor.

VI. GUIDELINE / PROCEDURE:

- A. Partnership reviews Treatment Authorization Requests (TARs) for external insulin infusion pumps and/or a continuous glucose monitors according to appropriate regulatory guidance as described in policy MPUP3139 Criteria and Guidelines for Utilization Management.
 - 1. F<u>or Partnership Medi-Cal Members:</u> TARs are reviewed according to required standards set forth by the State of California Department of Health Care Services (DHCS) and criteria provided in the DHCS Medi-Cal Provider Manual Guidelines.
 - a. InterQual[®] and other industry accepted guidelines will also be used, along with other policies developed by Partnership, as described in MPUP3139 Criteria and Guidelines for Utilization Management.
 - b. For Members under the age of 21 who are eligible for California Children's Services (CCS), please also refer to CCS guidelines for Insulin Infusion Pumps in Attachment A and CCS guidelines for Continuous Glucose Monitoring (CGM) in Attachment B.
 - 2. <u>For Partnership Advantage Members</u>: TARs are reviewed according to <u>Section 40 of the CMS</u> <u>Medicare guidance for Part C & D Organization/ Coverage Determinations</u> and other CMS guidelines and criteria sets that may include, but are not limited, to the following:
 - a. Medicare National Coverage Determination (NCD) Manual
 1) For insulin infusion pumps see NCD 280.14
 - b. Medicare Local Coverage Determination (LCD) policy
 - 1) For external insulin infusion pumps see L33794
 - 2) For glucose monitors see L33822
 - c. In the event that national and/or local coverage determination is silent on the matter, Partnership uses InterQual[®] and other industry accepted guidelines, along with other policies developed by Partnership, as described in MPUP3139 Criteria and Guidelines for Utilization Management.
- B. An insulin infusion pump must be ordered by the Primary Care Provider (PCP) or endocrinologist or diabetologist treating the member through a referral from the PCP. For Direct Members, the insulin infusion pump must be ordered by the physician who is currently managing the medical care for the

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Applies to:	□ Employees	🛛 Medi-Cal	🛛 Partnership Advantage	

member.

- 1. Partnership utilizes $InterQual^{(R)}$ criteria to determine the necessity of a pump.
 - a. For Partnership Advantage Members, Medicare guidelines will also be considered.
- 2. The TAR for an insulin infusion pump must include documentation of the medical necessity for home use of the insulin infusion pump that includes the following information related to the condition:
 - a. A valid order/prescription
 - b. The most recent Hgb A1c results
 - c. Chart notes from the PCP or specialist managing the diabetes care of the member which include the following:
 - 1) Length of time the member has had diabetes
 - 2) Documentation the insulin pump is needed as part of the plan of care in managing the diabetes
 - 3) Evaluation of the member's compliance with the diabetes treatment plan
 - 4) 30 consecutive day self-tested blood glucose log
- 3. Partnership authorizes the least costly medically necessary insulin pump.
 - a. Omnipod pumps may be considered for CCS members on a case by case basis according to criteria specified in CCS Numbered Letter <u>06-1120</u> (Attachment A).
 - Omnipod pumps may be considered for Partnership Advantage Members on a case by case basis according to Section 40 of the CMS Medicare guidance for Part C Organization Determinations and criteria stated in <u>NCD 280.14</u> and LCD <u>L33794</u>.
- 4. Insulin infusion pumps should only be prescribed and managed by practitioners familiar with this operation.
- C. Continuous glucose monitoring (CGM) requests will be reviewed on a case by case basis for medical necessity according to <u>Medi-Cal</u> or <u>Medicare</u> guidelines (including Medicare LCD <u>L33822</u>) as applicable for Partnership Medi-Cal or Partnership Advantage Members. CGMs can be authorized through Partnership if ordered through a contracted Durable Medical equipment (DME) provider, or they can be dispensed through a pharmacy provider as described below.
 - 1. To Authorize through Partnership if ordered through a Contracted DME Provider:
 - a. The TAR for a CGM should include documentation of the medical necessity for home use of CGM therapy that includes the following information related to the condition:
 - 1) A valid order/prescription
 - 2) The most recent Hgb A1c results
 - 3) Chart notes from the PCP or specialist managing the diabetes care of the member with the following information:
 - a) Length of time the member has had diabetes
 - b) Documentation that CGM is needed as part of the plan of care in managing the diabetes
 - c) Evaluation of the member's compliance with the diabetes treatment plan
 - d) Documentation by provider that member checks blood glucose readings 3- 4 times daily.
 - 2. CGMs Dispensed through a Pharmacy Provider:
 - a. <u>Partnership Medi-Cal Members:</u> The pharmacy (prescription) benefit was carved-out to State Medi-Cal as of January 1, 2022. For State Medi-Cal authorization requirements, please refer to the State Medi-Cal Rx Education & Outreach page at this website <u>https://medi-calrx.dhcs.ca.gov/home/education/</u>
 - b. <u>Partnership Advantage Members</u>: Effective January 1, 2027, the pharmacy benefit for Partnership Advantage Members is delegated to a pharmacy benefit manager.
 - Note that Medicare prohibits Part D (pharmacy) coverage when Part B (DME) is available.
 Continuous Glucose Monitoring is proven and considered medically necessary in the following

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clinical scenarios:

- Short-term (3 7 days) of continuous glucose monitoring by a healthcare provider for diagnostic purposes is proven and medically necessary for patients with diabetes. Current Procedural Terminology (CPT) codes used for this service are 95250 and 95251. Limit one of each code per dates of service in a single calendar month. No TAR is required.
- b. Long-term continuous glucose monitoring for personal use at home is proven and medically necessary as a supplement to self-monitoring of blood glucose (SMBG) for patients with type 1 diabetes, cystic fibrosis related diabetes, or sequelae of a CCS eligible condition that requires chronic insulin therapy, who have demonstrated adherence to a physician ordered diabetic treatment plan.
 - 1) InterQual® criteria will apply for coverage determination for adults and children with type 1 diabetes mellitus.
 - 2) CGMs are a covered benefit for children 20 years of age or younger with type 1 diabetes mellitus.
- c. Long-term continuous glucose monitoring for patients with type 2 or gestational diabetes are reviewed on a case-by-case basis for medical necessity. CGM for patients with type 2 diabetes may be indicated for patients with:
 - Recurrent severe hypoglycemic {two of more episodes in a 30-day period of ADA Level 2 hypoglycemia [blood glucose less than 3.0 mmol/L (54 mg/dl) with unawareness in a patient taking insulin]} or despite appropriate modifications in insulin regimen and compliance with frequent self-monitoring (at least 4 finger sticks/day), OR
 - Frequent nocturnal hypoglycemia {ADA Level 1 hypoglycemia [blood glucose of 3.9 mmol/L (70 mg/dl) or less despite modifications to insulin treatment]} and compliance with frequent glucose self-monitoring (at least four times a day), OR
 - 3) Poor diabetes control when ordered by a diabetologist as defined in III.C., a board certified endocrinologist, or an internal medicine or family physician.
 - a) InterQual[®] criteria will apply for coverage determination.
- 3. Long term CGM is considered experimental and investigational for nesidioblastosis (primary islet cell hypertrophy) and for monitoring blood glucose in non-diabetic persons following gastric bypass surgery.
- 4. CGM using an implantable glucose sensor is considered investigational and unproven and therefore not covered for non-U.S. Food and Drug Administration (FDA) approved devices.

VII. REFERENCES:

- A. InterQual[®] 2025 DME criteria Continuous Glucose Monitoring, Insulin Pumps, and Automated Insulin Delivery Technology.
- B. Medicare National Coverage Determinations (NCD) <u>Manual 100-03</u>: <u>Chapter 1, Part 4, Section 280.14</u> Infusion Pumps. Implementation date 02/18/2005 or any subsequent updates published by CMS.
- C. Medicare Local Coverage Determination (LCD) <u>L33794 External Infusion Pumps</u> Revision Effective Date 10/01/2024 or any subsequent updates published by CMS.
- D. Medicare Local Coverage Determination (LCD) <u>L33822 Continuous Glucose Monitors</u>, Revision Effective Date 10/01/2024 or any subsequent updates published by CMS.
- E. McCulloch DK. Blood glucose self-monitoring in management of adults with diabetes mellitus. UpToDate Inc., Waltham, MA.
- F. International Hypoglycemia Study Group. Diabetes Care. November 21, 2016 http://care.diabetesjournals.org/content/early/2016/11/09/dc16-2215
- E. *Diabetes Care* 2019;42(8):1593-1603. International Consensus Report: <u>Clinical Targets for Continuous</u> <u>Glucose Monitoring Data Interpretation: Recommendations from the International Consensus on Time in</u>

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Range.

- F. Diabetes Therapy 2019;10:853-863. A View Beyond HbA1c: Role of Continuous Glucose Monitoring.
- G. <u>CCS Numbered Letter (NL) 06-1120</u> Authorization of Insulin Infusion Pumps Revised 11/17/2020
- H. <u>CCS Numbered Letter (NL) 15-1222</u> Continuous Glucose Monitoring Systems as a CCS/GHPP Program Benefit 12/23/2022
- I. Department of Health Care Services (DHCS) All Plan Letter (APL) 22-012 Governor's Executive Order N-01-19, Regarding Transitioning Medi-Cal Pharmacy Benefits from Managed Care to Medi-Cal RX (*Revised* 12/30/2022)

VIII. DISTRIBUTION:

- A. Partnership Department Directors
- B. Partnership Provider Manual

IX. POSITION RESPONSIBLE FOR IMPLEMENTING PROCEDURE: Chief Health Services Officer

X. **REVISION DATES:**

Partnership Advantage (Effective 01/01/2027) 06/11/25

Medi-Cal

04/28/00; 06/20/01; 09/18/02; 09/15/04; 11/16/05; 08/20/08; 10/01/10; 05/16/12; 04/15/15; 03/16/16; 04/19/17; 10/18/17; *11/14/18; 11/13/19; 10/14/20; 02/10/21; 04/14/21; 03/09/22; 03/08/23; 03/13/24; 06/11/25

*Through 2017, Approval Date reflective of the Quality/Utilization Advisory Committee meeting date. Effective January 2018, Approval Date reflects that of the Physician Advisory Committee's meeting date.

PREVIOUSLY APPLIED TO:

Healthy Kids MPUG3025 (Healthy Kids program ended 12/01/2016) 08/20/08; 10/01/10; 05/16/12; 04/15/15; 03/16/16 to 12/01/2016

<u>Healthy Families</u> MPUG3025 - 10/01/10 to 03/01/2014

In accordance with the California Health and Safety Code, Section 1363.5, this policy was developed with involvement from actively practicing health care providers and meets these provisions:

- Consistent with sound clinical principles and processes
- Evaluated and updated at least annually
- If used as the basis of a decision to modify, delay or deny services in a specific case, the criteria will be disclosed to the provider and/or enrollee upon request

The materials provided are guidelines used by Partnership to authorize, modify or deny services for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under Partnership.

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Partnership's authorization requirements comply with the requirements for parity in mental health and substance use disorder benefits in 42 CFR 438.910.