

**PARTNERSHIP HEALTHPLAN OF CALIFORNIA
GUIDELINE / PROCEDURE**

Guideline/Procedure Number: MPUG3025 (previously UG100325)		Lead Department: Health Services		
Guideline/Procedure Title: Insulin Infusion Pump and Continuous Glucose Monitor Guidelines		<input checked="" type="checkbox"/> External Policy <input type="checkbox"/> Internal Policy		
Original Date: 04/19/1996		Next Review Date: 03/13/2025 Last Review Date: 03/13/2024		
Applies to:	<input checked="" type="checkbox"/> Medi-Cal		<input type="checkbox"/> Employees	
Reviewing Entities:	<input checked="" type="checkbox"/> IQI	<input type="checkbox"/> P & T	<input checked="" type="checkbox"/> QUAC	
	<input type="checkbox"/> OPERATIONS	<input type="checkbox"/> EXECUTIVE	<input type="checkbox"/> COMPLIANCE	<input type="checkbox"/> DEPARTMENT
Approving Entities:	<input type="checkbox"/> BOARD	<input type="checkbox"/> COMPLIANCE	<input type="checkbox"/> FINANCE	<input checked="" type="checkbox"/> PAC
	<input type="checkbox"/> CEO	<input type="checkbox"/> COO	<input type="checkbox"/> CREDENTIALING	<input type="checkbox"/> DEPT. DIRECTOR/OFFICER
Approval Signature: Robert Moore, MD, MPH, MBA			Approval Date: 03/13/2024	

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

II. IMPACTED DEPTS:

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

III. DEFINITIONS:

- A. **California Children's Services (CCS):** 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. **Continuous glucose monitor:** A device to measure 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. **Diabetologist:** 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. **Insulin pump:** 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.)
- E. **Whole Child Model (WCM):** In participating counties, 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 (PHC) 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. [CCS NL 15-1222 Continuous Glucose Monitoring Systems as a CCS/GHPP Program Benefit - 12/23/2022](#)

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V. PURPOSE:

For members age 21 years or over, the following guidelines are used by the Utilization Management (UM) staff when reviewing a Treatment Authorization Request (TAR) for an external insulin infusion pump and/or a continuous glucose monitor. For members under the age of 21 who are eligible for California Children’s Services (CCS), please refer to CCS guidelines for Insulin Infusion Pumps in Attachment A and CCS guidelines for Continuous Glucose Monitoring (CGM) in Attachment B.

VI. GUIDELINE / PROCEDURE:

- A. The 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 member.
1. Partnership HealthPlan of California (PHC) utilizes InterQual® criteria to determine the necessity of a pump.
 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. PHC authorizes the least costly medically necessary insulin pump. Omnipod pumps may be considered for CCS members on a case by case basis according to criteria specified in CCS Numbered Letter 06-1120 (Attachment A).¹
 4. Insulin infusion pumps should only be prescribed and managed by practitioners familiar with this operation.
- B. Continuous glucose monitoring (CGM) requests will be reviewed on a case by case basis for medical necessity. CGM’s are a covered Medi-Cal benefit and can either be dispensed to the member by a Medi-Cal Rx pharmacy provider (when approved through the State Medi-Cal Pharmacy TAR process) or they can be authorized through PHC if ordered through a contracted Durable Medical Equipment (DME) provider:
1. To Dispense through a Medi-Cal Rx Pharmacy Provider:
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 website <https://medi-calrx.dhcs.ca.gov/home/>

¹ For Members under age 21 with a CCS-eligible condition, services and supplies for the CCS-eligible condition will either be authorized by PHC under the Whole Child Model program, or by the State CCS program (*see policy MPCP2002 California Children’s Services*). In PHC’s service area, 14 counties participate in the Whole Child Model program (Del Norte, Humboldt, Lake, Lassen, Marin, Modoc, Mendocino, Napa, Shasta, Siskiyou, Solano, Sonoma, Trinity, Yolo). As of January 1, 2024, the following 10 counties in PHC’s service area are participants in the State’s CCS program and are not participants in PHC’s Whole Child Model program: Butte, Colusa, Glenn, Nevada, Placer, Plumas, Sierra, Sutter, Tehama, and Yuba.

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2. To Authorize through PHC if ordered through a contracted DME Provider:
 - a. The TAR for 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.
 - b. Continuous Glucose Monitoring is proven and considered medically necessary in the following clinical scenarios:
 - 1) 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.
 - 2) 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.
 - a) InterQual® criteria will apply for coverage determination for adults and children with type 1 diabetes mellitus.
 - b) CGMs are a covered benefit for children 20 years of age or younger with type 1 diabetes mellitus.
 - 3) 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:
 - a) 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
 - b) 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
 - c) Poor diabetes control when ordered by a diabetologist as defined in III.C., a board certified endocrinologist, or an internal medicine or family physician.
 - i. 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 investigational, unproven and not medically necessary due to lack of U.S. Food and Drug Administration (FDA) approval.

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VII. REFERENCES:

- A. InterQual® 2023 DME criteria – Insulin Pump, Ambulatory
- B. InterQual® 2023 DME criteria – Continuous Glucose Monitoring (CGM)
- C. McCulloch DK. Blood glucose self-monitoring in management of adults with diabetes mellitus. UpToDate Inc., Waltham, MA.
- D. 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: [Clinical Targets for Continuous Glucose Monitoring Data Interpretation: Recommendations from the International Consensus on Time in Range.](#)
- F. *Diabetes Therapy* 2019;10:853-863. [A View Beyond HbA1c: Role of Continuous Glucose Monitoring.](#)
- G. [CCS Numbered Letter \(NL\) 06-1120](#) Authorization of Insulin Infusion Pumps - Revised 11/17/2020
- H. [CCS Numbered Letter \(NL\) 15-1222](#) 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. PHC Department Directors
- B. PHC Provider Manual

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

X. REVISION DATES:

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

*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

Healthy Families

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

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- 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 PHC 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 PHC.

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