BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

INSULIN PUMPS:
Insulet: Omnipod, Omnipod Dash, Omnipod 5 G6
Medtronic MiniMed: 530G, 630G, 670G, 770G
Tandem: T:Slim, T:Slim X2

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

Section A. Type 1 Diabetes Mellitus:

- **Criteria for Initial therapy:** Insulin Pump for type 1 diabetes mellitus is considered ***medically necessary*** and will be approved with medical record documentation of **ALL** of the following criteria:

  1. Prescriber is a physician or other prescriber specializing in diabetes or is in consultation with an Endocrinologist

  2. Individual has a confirmed diagnosis of **Type 1** diabetes mellitus

3. Individual age is **ONE** of the following:
    a. **For Omnipod Dash**: 2 years of age or older
    b. **For Omnipod**: Adults and children
    c. **For Omnipod 5 G6:** 6 years of age or older
    d. **For MiniMed 530G System**: 16 years of age or older
    e. **For MiniMed 630G System**: 14 years of age or older
    f. **For MiniMed 670G System**: 7 years of age or older
    g. **For MiniMed 770G System:** 2 years of age or older
    h. **For T:Slim**: 12 years of age or older
    i. **For T:Slim X2**: 6 years of age or older

4. Insulin Pump is considered ***medically necessary*** and will be approved with medical record documentation of **ALL** of the following criteria:
    a. Completion of a diabetes self-management education program
    b. Treatment program including at least three insulin injections per day with frequent self-adjustments of insulin dose for at least three months
    c. Documented blood glucose self-testing an average of at least four times per day or documented use of a therapeutic factory calibrated CGM during the two months prior to initiation of an insulin pump

Approval duration: 12 months

Section B. Type 2 Diabetes Mellitus:

- **Criteria for initial therapy:** Insulin Pump for type 2 diabetes mellitus is considered ***medically necessary*** and will be approved with medical record documentation of **ALL** of the following criteria:

1. Prescriber is a physician or other prescriber specializing in diabetes or is in consultation with an Endocrinologist
2. Individual has a confirmed diagnosis of **Type 2** diabetes mellitus
3. Individual has HgA1c of greater than 7% with 2 consecutive HbA1c
4. Individual is currently on multi-regimen diabetes treatment including GLP-1 and SGLT-2
5. Individual is using greater than 220 units of insulin per day
6. Completion of a diabetes self-management education program
7. Treatment program including at least three insulin injections per day with frequent self-adjustments of insulin dose for at least three months
8. Documented blood glucose self-testing an average of at least four times per day or documented use of a therapeutic factory calibrated CGM during the two months prior to initiation of an insulin pump

Initial approval duration: 12 months

Section C. Criteria for Replacement of External Insulin Pump or System Component:

- **Criteria for replacement:** The replacement of an existing external insulin pump or an insulin pump system component required for the delivery of insulin is considered ***medically necessary*** for an individual with successfully managed type 1 or type 2 diabetes mellitus when **BOTH** of the following criteria are met:

  1. Documentation that the pump/component is malfunctioning, cannot be repaired, and no longer under warranty

  2. Evidence of an evaluation by an endocrinologist managing the diabetes within the last six months that includes a recommendation supporting continued use of a replacement device

- **Additional requirements for Type 2 diabetes**:
  1. Individual's condition responded while on therapy with response defined as **THREE** of the following:
     a. Achieved and maintains HgA1C of 7% or 8% for elderly (65 years or older)
     b. 50% reduction in daily insulin dose required
     c. There has been a reduction in recurrent, unexplained, unexpected hypoglycemic episodes
     d. There is no hypoglycemia unawareness
     e. There is no post-prandial hyperglycemia
     f. There has been a reduction in diabetic ketoacidosis

- **Not Covered:**
  EACH of the following is considered a convenience item and ***not medically necessary***:
  1. Replacement of a currently functioning insulin pump for the sole purpose of receiving the most recent insulin pump technology (i.e., "upgrading" for improved technology)

  2. Additional software or hardware required for downloading data to a device such as personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus

- Arizona statutory coverage mandates do not require coverage of continuous glucose monitoring devices unless ***medically necessary***.

- Although rental of the device is ***not eligible for coverage***, the professional services for consultation and review of data are ***eligible for coverage*** as evaluation and management (E/M) services with appropriate documentation.

- Insulin Pump for the treatment of diabetes mellitus is considered ***experimental or investigational*** when any one or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or

  3. Insufficient evidence to support improvement outside the investigational setting

  These indications include, but are not limited to:
  - Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, when appropriate.

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PHARMACY COVERAGE GUIDELINE

INSULIN PUMPS

Description:

Benefit Type:

Pharmacy Benefit:

Insulet: Omnipod
Insulet: Omnipod 5 G6
Insulet: Omnipod Dash (Omnipod Dash Kit Intro can be obtained via Insulet at 1(800)591-3455. Pods do require prior authorization.)

Medical Benefit:

Medtronic: 530G, 630G, 670G, 770G
Tandem: T:Slim, T:Slim X2

Coding:

HCPCS: A9274 (Omnipod); **E0784, E0787** (Medtronic 530G, 630G, 670G, 770G and Tandem T:Slim, T:Slim X2)

Insulin delivery with a pump uses a short- or rapid-acting insulin to minimize variability of administration and reduce the chances of glucose fluctuations. Pump technology has progressed to the level of precisely mimicking physiological demands. The pump delivers a programmable basal amount of insulin that is personalized to the patient's glucose profile over a 24-hour period. Pumps have the capability of programming the basal rate and can deliver bolus insulin to cover meals and correct for high glucose readings. There are a number of different types of insulin pumps on the market.

Resources:

1.01.20 BCBS Association Medical Policy Reference Manual. Continuous Glucose Monitoring. Review date January 2022. Accessed January 24, 2022.

1.01.32 BCBS Association Medical Policy Reference Manual. Artificial Pancreas Device Systems. Review date May 2021. Accessed January 24, 2022.

Arizona Revised Statutes. Annotated sections 20-828, 20-1057, and 20-2325.

Weinstock RS. Continuous subcutaneous insulin infusion (insulin pump). In: UpToDate, Hirsch RS, Mulder JE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated November 11, 2020. Accessed January 25, 2022.

Weinstock RS. Glucose monitoring in the management of nonpregnant adults with diabetes mellitus. In: UpToDate, Hirsch RS, Mulder JE (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Topic last updated June 29, 2021. Accessed January 25, 2022.

Grunberger G, Abelseth JM, Bailey TS, et al. Consensus statement by the American Association of Clinical Endocrinologists/American College of Endocrinology Insulin Pump Management Task Force. Endocrine Practice 2014;20(5):463-489. DOI: 10.4158/EP14145.PS. Accessed January 26, 2022.