BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

INSULIN PUMPS:
Beta Bionics: iLet
Insulet: Omnipod, Omnipod Dash, Omnipod 5 G6, G7
Medtronic MiniMed: 630G, 670G, 770G, 780G
Tandem: 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 prior authorization 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 iLet**: 6 years of age or older
    b. **For Omnipod Dash**: 2 years of age or older
    c. **For Omnipod**: Adults and children
    d. **For Omnipod 5 G6 and G7:** 2 years of age or older
    e. **For MiniMed 630G System**: 14 years of age or older
    f. **For MiniMed 670G and 780G System**: 7 years of age or older
    g. **For MiniMed 770G System:** 2 years of age or older
    h. **For T:Slim X2**: 6 years of age or older

4. There is evidence individual has completed or is enrolled in a diabetes self-management education program

5. Treatment program includes at least three insulin injections per day with frequent self-adjustments of insulin dose.

6. There is documentation of blood glucose self-testing on an average of at least four times per day or documented use of a therapeutic factory calibrated CGM during the one month prior to initiation of an insulin pump

Omnipod approval duration: 12 months
iLet, MiniMed, and T:Slim approval: 1 time

- **Criteria for continuation of coverage (renewal request): ALL Omnipod pumps** for ***type 1 diabetes mellitus*** is considered ***medically necessary*** and will be approved with medical record documentation of **ALL** of the following criteria:

1. Individual continues to be seen by a physician or other prescribers specializing in diabetes or is in consultation with an Endocrinologist

2. Individual's condition has responded while on therapy with response defined as **THREE** of the following:
    a. Achieved and maintains HgA1C of 7% or less **OR** 8% or less for 65 years and older
    b. There has been a reduction in recurrent, unexplained, unexpected hypoglycemic episodes
    c. There is no hypoglycemia unawareness
    d. There is no post-prandial hyperglycemia
    e. There has been a reduction in diabetic ketoacidosis

Renewal 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 age is **ONE** of the following:
    a. **For MiniMed 630G System**: 14 years of age or older
    b. **For MiniMed 670G System**: 7 years of age or older
    c. **For T:Slim X2**: 6 years of age or older

4. Individual has HgA1c of greater than 7% with 2 consecutive HbA1c

5. Individual is currently on multi-regimen diabetes treatment including GLP-1 and SGLT-2

6. Individual is using greater than 220 units of insulin per day

7. There is evidence individual has completed a diabetes self-management education program

8. Treatment program includes at least three insulin injections per day with frequent self-adjustments of insulin dose for at least three months

9. There is documentation of blood glucose self-testing of 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 ***diabetes mellitus*** when **ALL** of the following criteria are met:

    1. Documentation that the pump/component is not functioning, cannot be repaired, and no longer under warranty **OR** the current insulin pump has been in use for 5 years

    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 has responded while on therapy with response defined as **THREE** of the following:
        a. Achieved and maintains HgA1C of 7% or less **OR** 8% or less for 65 years and older
        b. There has been a reduction in recurrent, unexplained, unexpected hypoglycemic episodes
        c. There is no hypoglycemia unawareness
        d. There is no post-prandial hyperglycemia
        e. There has been a reduction in diabetic ketoacidosis

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INSULIN PUMPS

- **What is 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 of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. 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.

Benefit Type:

Pharmacy Benefit:
Insulet: Omnipod
Insulet: Omnipod 5 G6, G7
Insulet: Omnipod Dash (Omnipod Dash Kit Intro can be obtained via Insulet at 1(800) 591-3455. Pods do require prior authorization.)

Medical Benefit:
Beta Bionics: iLet
Medtronic Minimed: 630G, 670G, 770G, 780G
Tandem: T:Slim X2

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INSULIN PUMPS

Coding:

HCPCS: A9274, E0784, S1034, S1035, S1036, S1037

Description:

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:

Weinstock RS. Continuous subcutaneous insulin infusion (insulin pump). In: UpToDate, Hirsch RS, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2023. Topic last updated December 05, 2023. Accessed December 11, 2023.

Weinstock RS. Glucose monitoring in the ambulatory management of nonpregnant adults with diabetes mellitus. In: UpToDate, Hirsch RS, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2023. Topic last updated February 20, 2023. Accessed December 11, 2023.

Durnwald C. Gestational diabetes mellitus: Glucose management and maternal prognosis. In: UpToDate, Nathan DM, Werner EF, Barss VA. (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2023. Topic last updated November 16, 2023. Accessed December 11, 2023.

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. Re-evaluated December 11, 2023.

El Sayed NA, Aleppo G, Aroda VR, et al: Diabetes Technology: Standards of Care in Diabetes – 2023. Diabetes Care 2023;46 (Suppl. 1): S111–S127 | https://doi.org/10.2337/dc23-S007. Accessed December 11, 2023.

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