BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

INSULIN PUMPS:
Beta Bionics: iLet
Insulet: Omnipod
Medtronic MiniMed
Tandem: Mobi, T:Slim X2
Sequel Med Tech: Twiist

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/or 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.

Medical Necessity Requirements for INSULIN PUMPS

Section A. Type 1 Diabetes Mellitus

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a physician or other prescriber specializing in diabetes or in consultation with an Endocrinologist

Indication
- Type 1 diabetes mellitus

Brand Specific Request
- Request is for **ONE** of the following insulin pumps:
  - Beta Bionics iLet
  - Omnipod
  - Medtronic MiniMed
  - Tandem Mobi or T:Slim X2
  - Twiist

Baseline Clinical Evaluation
- Completed or enrolled in a diabetes self management education program
- Treatment includes at least three insulin injections per day with frequent self adjustments of insulin dose
- Blood glucose self testing on average of at least four times per day OR documented use of a therapeutic factory calibrated CGM during the one month prior to initiation

Initial Therapy Criteria Approval Duration
- Omnipod; Twiist: 12 months OR end of plan year
- Beta Bionics: iLet; Medtronic: MiniMed; Tandem: Mobi, T:Slim X2: Onetime only

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Criteria for Continuation of Therapy (renewal therapy) (Omnipod Only):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification
- Continues to be seen by a physician specializing in diabetes or is in consultation with an Endocrinologist

Indication
- Type 1 diabetes mellitus

Clinical Response
- Positive clinical response defined as **THREE** of the following:
  - Achieved and maintains HgA1C of 7 percent or less OR 8 percent or less for age 65 and older
  - Reduction in recurrent, unexplained, unexpected hypoglycemic episodes
  - No hypoglycemia unawareness
  - No post prandial hyperglycemia
  - Reduction in diabetic ketoacidosis

Documentation Requirements
- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration (Omnipod only)

- 12 months OR end of plan year

Section B. Type 2 Diabetes Mellitus

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a physician or other prescriber specializing in diabetes or in consultation with an Endocrinologist

Indication

- Type 2 diabetes mellitus

Brand Specific Request

- Request is for:
  - Tandem Mobi or T:Slim X2

  Note: *Omnipod and Medtronic are only available for Type 1 diabetes mellitus.*

Baseline Clinical Evaluation

- HgA1c greater than 7 percent with two consecutive HbA1c
- Currently on multi regimen diabetes treatment including GLP 1 and SGLT 2
- Using greater than 220 units of insulin per day
- Completed a diabetes self management education program
- Treatment includes at least three insulin injections per day with frequent self adjustments of insulin dose for at least three months
- 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

Initial Therapy Criteria Approval Duration

- Tandem: Mobi, T:Slim X2: Onetime only

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

Criteria for Replacement:

Prescriber Qualifications

- Evaluation by an endocrinologist managing diabetes within the last six months with recommendation supporting continued use of a replacement device

Indication

- Diabetes mellitus any type

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Baseline Clinical Evaluation

- Pump/component is not functioning, cannot be repaired, and no longer under warranty
  OR current insulin pump has been in use for 5 years

Additional Requirements

- **Type 2 Diabetes**: Has a positive clinical response defined as **THREE** of the following:
  - Achieved and maintains HgA1C of 7 percent or less OR 8 percent or less for age 65 and older
  - Reduction in recurrent, unexplained, unexpected hypoglycemic episodes
  - No hypoglycemia unawareness
  - No post prandial hyperglycemia
  - Reduction in diabetic ketoacidosis
- **What is Not Covered: EACH** of the following is considered a convenience item and ***not medically necessary***:
  - 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)
  - 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*** such 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:
  - Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  - Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  - Insufficient evidence to support improvement of the net health outcome; or
  - Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  - Insufficient evidence to support improvement outside the investigational setting
  - These indications include but are not limited to:
    1. Treatment with dosing, frequency, or duration outside the FDA approved dosing, frequency, and duration

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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.)
Sequel Med Tech: Twiist

Medical Benefit:

Beta Bionics: iLet
Medtronic Minimed: 630G, 770G, 780G

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INSULIN PUMPS

Tandem: Mobi, T:Slim X2

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 2025. Topic last updated December 02, 2025. Accessed December 15, 2025.

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 2025. Topic last updated August 26, 2024. Accessed December 15, 2025.

Durnwald C. Gestational diabetes mellitus: Glucose management, maternal prognosis, and follow-up. In: UpToDate, Nathan DM, Werner EF, Barss VA. (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2025. Topic last updated July 01, 2025. Accessed December 15, 2025.

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 15, 2025.

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. Re-evaluated December 15, 2025.

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

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