PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 2/01/2020
LAST REVIEW DATE: 2/18/2021
LAST CRITERIA REVISION DATE: 2/18/2021
ARCHIVE DATE:

INSULIN PUMPS:

- **Insulet: Omnipod and Omnipod Dash**
- **Medtronic MiniMed: 530G, 630G, 670G**
- **Tandem: T:Flex, T:Slim, T:Slim X2**

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602)

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864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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 prescribers 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 MiniMed 530G System**: 16 years of age or older
     d. **For MiniMed 630G System**: 16 years of age or older
     e. **For MiniMed 670G System**: 7 years of age or older
     f. **For T:Flex**: 12 years of age or older
     g. **For T:Slim**: 12 years of age or older
     h. **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:

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1. Prescriber is a physician or other prescribers 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, no longer under warranty and cannot be repaired
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:
    a. Response is defined as **THREE** of the following:
        i. Achieved and maintains HgA1C of 7% or 8% for elderly (65 years or older)
        ii. 50% reduction in daily insulin dose required
        iii. There has been a reduction in recurrent, unexplained, unexpected hypoglycemic episodes

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iv. There is no hypoglycemia unawareness
v. There is no post-prandial hyperglycemia
vi. 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 all other indications not previously listed is considered ***experimental or investigational*** and will not be covered when any one or more of the following criteria are met:
  1. Lack of final approval from the Food and Drug Administration;
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes;
  3. Insufficient evidence to support improvement of the net health outcome;
  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:
  a. Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration.

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.

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Benefit Type:

Pharmacy Benefit:

Insulet: Omnipod Dash

Medical Benefit:

Insulet: Omnipod
Medtronic: 530G, 630G, 670G
Tandem: T:Slim, T:Slim X2

Coding:

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

Resources:

Grunberger G, 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. (Reaffirmed 2019 Jun)

1.01.20 BCBS Association Medical Policy Reference Manual. Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid. Issue date 11/2018

1.01.32 BCBS Association Medical Policy Reference Manual. Artificial Pancreas Device Systems. Review date 12/2017

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

UpToDate: Self-monitoring of blood glucose in management of adults with diabetes mellitus. Current through Jan 2019

Cengiz E and Tamborlane WV. A tale of two compartments: interstitial verses blood glucose monitoring. Diabetes Technol Therapeutics 2009; 11 (Sup 1):11-16

Gandhi GY, Kovalaske M, Kudva Y, et al.: Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: A systematic review and meta-analysis of randomized trials. J Diabetes Sci Technol 2011 July; 5 (4):952-965

Ehrhardt NM, Chellppa M, Walker S, et al.: The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. J Diabetes Sci Technol 2011 May; 5 (3):668-675

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Vigersky RA, Fonda SJ, Chellappa M, et al.: Short and long term effects of real time continuous glucose monitoring in patients with type 2 diabetes mellitus. Diabetes Care 2012 Jan; 35:32-38

Kim SK, Kim HJ, Kim T, et al.: Effectiveness of 3-day continuous glucose monitoring for improving glucose control in type 2 diabetic patients in clinical practice. Diabetes Metab J 2014; 38:449-455

Vigersky R, Shrivastav M. Role of continuous glucose monitoring for type 2 in diabetes management and research. J Diabetes Complications. 2017 Jan;31(1):280-287.

Danne T, Nimri R, Battelino T, et al.: International consensus on use of continuous glucose monitoring. Diabetes Care 2017 December; 40: 1631-1640

Shrivastav M, Gibson W, Shrivastav R, et al.: Type 2 diabetes management in primary care: The role of retrospective, professional continuous glucose monitoring. Diabetes Spectrum 2018 Aug; 31(3): 279-287.