



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/21/19
LAST REVIEW DATE: 11/21/19
LAST CRITERIA REVISION DATE:
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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

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.



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/21/19
LAST REVIEW DATE: 11/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

INSULIN PUMPS:

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

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

Insulin Pumps (Insulet / Medtronic / Tandem Pumps)

Section A. Type 1 Diabetes Mellitus:

- **Criteria for Initial and Continuation of 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 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:
 - **For Omnipod Dash:** 2 years of age or older
 - **For Omnipod:** Adults and children
 - **For MiniMed 530G System:** 16 years of age or older
 - **For MiniMed 630G System:** 16 years of age or older
 - **For MiniMed 670G System:** 7 years of age or older
 - **For T:Flex:** 12 years of age or older
 - **For T:Slim:** 12 years of age or older
 - **For T:Slim X2:** 6 years of age or older
 4. Has failure, contraindication or intolerance to an age appropriate **Tandem insulin pumps (i.e. T:Slim X2)**

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 specializing in diabetes or is in consultation with an Endocrinologist



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/21/19
LAST REVIEW DATE: 11/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

INSULIN PUMPS:

Insulet: Omnipod and Omnipod Dash

Medtronic MiniMed: 530G, 630G, 670G

Tandem: T:Flex, T:Slim, T:Slim X2

2. Individual has a confirmed diagnosis of type 2 diabetes mellitus
3. Individual is requesting one of the following:
 - **For T:Flex:** 12 years of age or older
 - **For T:Slim:** 12 years of age or older
 - **For T:Slim X2:** 6 years of age or older
4. Individual has HgA1c of greater than 10%
5. Individual is using greater than 400 units of insulin per day

Initial approval duration: 12 months

➤ **Criteria for continuation of coverage (for type 2 diabetes mellitus) (renewal request):** Insulin Pump for type 2 diabetes mellitus with a Tandem Insulin Pump **only** 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 specializing in diabetes or is in consultation with an Endocrinologist
2. Individual has a confirmed diagnosis of type 2 diabetes mellitus
3. Uses an external insulin infusion pump system
4. Tandem Insulin pumps are the only ones covered for 2 diabetes mellitus
5. Individual's condition responded while on therapy
 - Response is defined as **THREE** of the following:
 - Achieved and maintains HgA1C of 7% or 8% for elderly
 - 50% reduction in daily insulin dose required
 - There has been a reduction in recurrent, unexplained, unexpected hypoglycemic episodes
 - There is no hypoglycemia unawareness
 - There is no post-prandial hyperglycemia
 - There has been a reduction in diabetic ketoacidosis

Renewal duration: 12 months



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/21/19
LAST REVIEW DATE: 11/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

INSULIN PUMPS:

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

-
- 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.

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.

Benefit Type:

Pharmacy Benefit:

Insulet: Omnipod Dash

Medical Benefit:

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

Resources:

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



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/21/19
LAST REVIEW DATE: 11/21/19
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

INSULIN PUMPS:

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

Cengiz E and Tamborlane WV. A tale of two compartments: interstitial versus 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, Chellappa 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

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.
