



Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

Children's Medical Services Health Plan (CMS Health Plan)

Staywell of Florida

WellCare (Alabama, Arizona, Arkansas, California, Connecticut, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maine, Michigan, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New York, North Carolina, Ohio, South Carolina, Tennessee, Texas, Washington)

WellCare Heritage Health

WellCare TexanPlus

WellCare Prescription Insurance

Pediatric Insulin Pumps

Policy Number: HS-286

Original Effective Date: 3/5/2015

Revised Date(s): 3/3/2016; 3/2/2017;
2/1/2018; 2/7/2019; 3/10/2020

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Diabetes mellitus is characterized by hyperglycemia due to impaired pancreatic insulin secretion or inefficient use of insulin by the body. Members with insulin-dependent (type 1) diabetes require chronic treatment with exogenous insulin. To calculate the insulin dose needed to manage their blood glucose levels, these members perform self-monitoring of blood glucose (SMBG) using samples obtained by finger sticks; however, frequent SMBG may not detect all significant deviations in blood glucose, particularly in members with rapidly fluctuating glucose levels. As a result, some members who perform multiple daily finger sticks may fail to detect blood glucose excursions above or below the desired range, especially when glucose fluctuations occur at night.¹

Diabetes cannot be cured, and treatment is focused on self-management education and training that is centered on self-care behaviors such as healthy eating, physical activities, and monitoring blood glucose to improve health outcomes and the patient's quality of life. Self-management education improves HbA1c levels, and increased contact time with educators enhances the positive effect. It is a collaborative process in which diabetes educators help patients and those who are at risk for diabetes to gain the knowledge, problem-solving, and coping skills that are needed to successfully self-manage the disease and its related conditions.²

Guidelines published by the American Association of Clinical Endocrinologists (AACE) state that advances in blood glucose monitoring and continuous monitoring of interstitial glucose, along with the introduction of "smart" insulin pumps, provide clinicians and patients with powerful tools to monitor and adjust treatment regimens. The guidelines recommend arranging for continuous glucose monitoring for patients with type 1 diabetes with unstable glucose control and for patients unable to achieve an acceptable HbA1c level; continuous glucose monitoring is particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia.³

POSITION STATEMENT

Applicable To:

- Medicaid – All Markets (excluding KY)
- Children's Medical Services Health Plan (CHIP)
- Medicare – All Markets

External insulin pumps **are considered medically necessary** if the Member:

1. Has a diagnosis of insulin dependent type I diabetes mellitus; **AND**
2. Completed a comprehensive diabetes education program. (This may include, but is not limited to, leading the Member to demonstrate the ability and commitment to comply with the regimen of pump care, frequent self-monitoring of blood glucose, and careful attention to diet and exercise, and has received appropriate training on pump usage); **AND**
3. Has been on a program of multiple daily injections of insulin (e.g., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump; **AND**
4. Member has been on an external insulin infusion pump prior and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to enrollment; **AND**
5. Has an endocrinologist or physician experienced in providing insulin infusion therapy orders the insulin pump and states that he/she will monitor the members status while he/she uses the pump; **AND**
6. Has Provider documentation of a history of poor glycemic control on multiple daily injections of insulin, including a persistently elevated glycosylated hemoglobin level (HBA1C>7.0%). Additional history of poor control may be documented in the medical record, including but not limited to:
 - Widely fluctuating blood glucose levels before bedtime, **OR**
 - History of severe hypoglycemia (<60 mg/dL) or hyperglycemia (>300 mg/dL), **AND/OR**
 - Treatment of secondary diabetic complications requiring more extensive blood glucose control

Replacements

Medicaid. Insulin pumps must have a total coverage repair or replacement warranty for four (4) years. After four (4) years Medicaid will allow a request for a replacement.

Medicare. Replacement insulin pumps **are included in coverage** when there is documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria (1 - 5) while on the multiple injection regimen:

- Glycosylated hemoglobin level (HbA1C) greater than 7 percent
- History of recurring hypoglycemia
- Wide fluctuations in blood glucose before mealtime
- Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL

History of severe glycemic excursions

CODING

CPT®* Codes – No applicable codes.

Covered HCPCS Codes

- A4225** Supplies for external insulin infusion pump, syringe type cartridge, sterileing , each
- A4230** Infusion set for external insulin pump, non-needle cannula type
- A4231** Infusion set for external insulin pump, needle type
- A4232** Syringe with needle for external insulin pump, sterile, 3 cc (non-covered by Medicare)
- A9274** External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories (non-covered by Medicare)
- E0784** External ambulatory infusion pump, insulin
- S9145** Insulin pump initiation, instruction in initial use of pump (pump not included) (non-covered by Medicare)

Covered ICD-10 CM Diagnosis Codes

- E08.00-E08.01** Diabetes mellitus due to underlying condition with hyperosmolarity with coma (E08.01)
- E08.10-E08.11** Diabetes mellitus due to underlying condition with ketoacidosis with coma (E08.11)
- E08.21-E08.29** Diabetes mellitus due to underlying condition with kidney complications (E08.29)
- E08.311-E08.319** Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema (E08.319)
- E08.3211-E08.3219** Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye (E08.3211)
- E08.3291-E08.3299** Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema , right eye (E08.3291)
- E08.3311-E08.3319** Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema, right eye (E08.3311)
- E08.3391-E08.3399** Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema, right eye (E08.3391)
- E08.3411-E08.3419** Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema, right eye (E08.3411)
- E08.3491-E08.3499** Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema, right eye (E08.3491)
- E08.3511-E08.3519** Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema, right eye (E08.3511)
- E08.3521-E08.3529** Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye (E08.3521)
- E08.3531-E08.3539** Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula, right eye (E08.3531)
- E08.3541-E08.3549** Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment, right eye
- E08.3551-E08.3559** Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy Unspecified eye (E08.3559)
- E08.3591-E08.3599** Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema, right eye (E08.3591)
- E08.36** Diabetes mellitus due to underlying condition with diabetic cataract
- E08.37X1-E08.37X9** Diabetes mellitus due to underlying condition with diabetic macular edema, resolved following treatment treatment, right eye (E08.37X1)
- E08.39** Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication
- E08.40-E08.49** Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified (E08.40)
- E08.51-E08.59** Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy without Gangrene (E08.51)

E08.610-E08.618	Diabetes mellitus due to underlying condition with diabetic neuropathic arthropathy (E08.610)
E08.620-E08.628	Diabetes mellitus due to underlying condition with diabetic dermatitis (E08.620)
E08.630-E08.638	Diabetes mellitus due to underlying condition with periodontal disease (E08.630)
E08.641-E08.649	Diabetes mellitus due to underlying condition with hypoglycemia with coma (E08.641)
E08.65	Diabetes mellitus due to underlying condition with hyperglycemia
E08.69	Diabetes mellitus due to underlying condition with other specified complication
E08.8	Diabetes mellitus due to underlying condition with unspecified complications
E08.9	Diabetes mellitus due to underlying condition without complications
E10.10- E10.11	Type 1 diabetes mellitus with ketoacidosis with coma (E10.11)
E10.21-E10.29	Type 1 diabetes mellitus with diabetic nephropathy (E10.21)
E10.311-E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema (E10.311)
E10.3211-E10.3219	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema Right eye (E10.3211)
E10.3291-E10.3299	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema Right eye (E10.3291)
E10.3311-E10.3319	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy with macular edema Unspecified eye (E10.3319)
E10.3391-E10.3399	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema Unspecified eye (E10.3399)
E10.3411-E10.3419	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy with macular edema Right eye (E10.3411)
E10.3491-E10.3499	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema Unspecified eye (E10.3499)
E10.3511-E10.3519	Type 1 diabetes mellitus with proliferative diabetic retinopathy with macular edema Unspecified eye (E10.3519)
E10.3521-E10.3529	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment involving the macula right eye (E10.3521)
E10.3531-E10.3539	Type 1 diabetes mellitus with proliferative diabetic retinopathy with traction retinal detachment not involving the macula unspecified eye (E10.3539)
E10.3541-E10.3549	Type 1 diabetes mellitus with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment right eye (E10.3541)
E10.3551-E10.3559	Type 1 diabetes mellitus with stable proliferative diabetic retinopathy unspecified eye
E10.3591-E10.3599	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema Unspecified eye (E10.3599)
E10.36	Type 1 diabetes mellitus with diabetic cataract
E10.37X1-E10.37X9	Type 1 diabetes mellitus with diabetic macular edema, resolved following treatment Right eye (E10.37X1)
E10.39	Type 1 diabetes mellitus with other diabetic ophthalmic complication
E10.40-E10.49	Type 1 diabetes mellitus with diabetic neuropathy, unspecified (E10.40)
E10.51-E10.59	Type 1 diabetes mellitus with diabetic peripheral angiopathy without gangrene (E10.51)
E10.610-E10.618	Type 1 diabetes mellitus with diabetic neuropathic arthropathy (E10.610)
E10.620-E10.628	Type 1 diabetes mellitus with diabetic dermatitis (E10.620)
E10.630-E10.638	Type 1 diabetes mellitus with periodontal disease (E10.630)
E10.641-E10.649	Type 1 diabetes mellitus with hypoglycemia with coma (E10.641)
E10.65	Type 1 diabetes mellitus with hyperglycemia
E10.69	Type 1 diabetes mellitus with other specified complication
E10.8	Type 1 diabetes mellitus with unspecified complications
E10.9	Type 1 diabetes mellitus without complications

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. National Institute for Health and Clinical Excellence Web site. <https://www.nice.org.uk/guidance/ng18>. Published August 2015. Updated November 2016. Accessed February 10, 2020.
2. Implantable insulin pumps. Hayes Directory Web site. <http://www.hayesinc.com>. Published June 7, 2011 [archived August 17, 2015]. Accessed February 10, 2020.
3. American Association of Clinical Endocrinologists medical guidelines for clinical practice for developing a diabetes mellitus comprehensive plan. American Association of Clinical Endocrinologists Web site. <https://www.aace.com/files/dm-guidelines-ccp.pdf>. Published 2011. Updated April 2015. Accessed February 10, 2020.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
3/10/2020, 2/7/2019, 2/1/2018, 3/2/2017	<ul style="list-style-type: none">• Approved by MPC. No changes.
3/3/2016	<ul style="list-style-type: none">• Approved by MPC. Coding changes only.
3/5/2015	<ul style="list-style-type: none">• Approved by MPC. New.