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

American Association of Clinical Endocrinologists (AACE)

The 2010 Clinical Practice Guidelines for the Management of Diabetes 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
- 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, sterile, 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
E08.10-E08.11 Diabetes mellitus due to underlying condition with ketoacidosis
E08.21-E08.29 Diabetes mellitus due to underlying condition with kidney complications
E08.311-E08.319 Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy
E08.3211-E08.3219 Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema
E08.3291-E08.3299 Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema
E08.3311-E08.3319 Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy with macular edema
E08.3391-E08.3399 Diabetes mellitus due to underlying condition with moderate nonproliferative diabetic retinopathy without macular edema
E08.3411-E08.3419 Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy with macular edema
E08.3491-E08.3499 Diabetes mellitus due to underlying condition with severe nonproliferative diabetic retinopathy without macular edema
E08.3511-E08.3519 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with macular edema
E08.3521-E08.3529 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula
E08.3531-E08.3539 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment not involving the macula
E08.3541-E08.3549 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with combined traction retinal detachment and rhegmatogenous retinal detachment
E08.3551-E08.3559 Diabetes mellitus due to underlying condition with stable proliferative diabetic retinopathy
E08.3591-E08.3599 Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy without macular edema
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
E08.39 Diabetes mellitus due to underlying condition with other diabetic ophthalmic complication
E08.40-E08.49 Diabetes mellitus due to underlying condition with neurological complications
E08.51-E08.59 Diabetes mellitus due to underlying condition with circulatory complications
E08.610-E08.618 Diabetes mellitus due to underlying condition with diabetic arthropathy
E08.620-E08.628 Diabetes mellitus due to underlying condition with skin complications
E08.630-E08.638 Diabetes mellitus due to underlying condition with oral complications
E08.641-E08.649 Diabetes mellitus due to underlying condition with hypoglycemia
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

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E08.9 Diabetes mellitus due to underlying condition without complications
E10.10- E10.11 Type 1 diabetes mellitus with ketoacidosis
E10.21-E10.29 Type 1 diabetes mellitus with kidney complications
E10.311-E10.319 Type 1 diabetes mellitus with unspecified diabetic retinopathy
E10.3211-E10.3219 Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy with macular edema
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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

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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