Oscar Clinical Guideline: CeQur Simplicity Insulin Delivery System (PG192, Ver. 3)

CeQur Simplicity Insulin Delivery System

- CeQur Simplicity Inserter
- CeQur Simplicity Patch

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Diabetes mellitus is a chronic metabolic disorder characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both. Inadequate glycemic control can lead to serious complications including cardiovascular disease, nephropathy, retinopathy, and neuropathy. The goal of diabetes management is to maintain blood glucose levels as close to the normal range as possible to prevent or delay complications. Diabetes is classified into two main types:

- Type 1 diabetes mellitus (T1DM): The pancreas produces little or no insulin.
- Type 2 diabetes mellitus (T2DM): The body's cells do not respond effectively to insulin, and sometimes the pancreas does not produce enough insulin.

Insulin therapy is essential for all individuals with type 1 diabetes and many with type 2 diabetes to achieve optimal glycemic control. Intensive insulin therapy aims to mimic normal physiologic insulin secretion through the use of basal insulin for control of glucose throughout the day and bolus or prandial insulin to cover food intake during mealtime and correct hyperglycemia. This is most often accomplished through multiple daily injections (MDI) using basal and rapid-acting insulins or continuous subcutaneous insulin infusion (CSII) via an insulin pump.

However, despite advances in insulin formulations and delivery systems, many individuals fail to reach glycemic targets. Adherence to insulin regimens is often suboptimal due to the burden of multiple daily injections. Insulin pumps, while allowing for more precise insulin delivery, require extensive training and are not acceptable to all patients.

The CeQur Simplicity insulin delivery device is a wearable patch that provides mealtime bolus insulin dosing in 2-unit increments with the push of a button. It can be worn for up to 4 days and holds up to 200 units of rapid-acting insulin (e.g., Novolog [insulin aspart] or Humalog [insulin lispro]). CeQur Simplicity provides an alternative delivery option for prandial insulin coverage as part of a basal-bolus regimen. Cequr Simplicity insulin delivery device is approved for those 21 years of age and older, and has been studied in those with type 2 or type 1 diabetes.

Definitions

"Basal insulin" refers to the low, steady infusion or injection of insulin to control blood glucose between meals and overnight. It mimics the background insulin normally produced by the pancreas.

"Basal-bolus regimen" is an insulin regimen that includes both long-acting basal insulin for control of glucose between meals and bolus doses of rapid-acting insulin (see "bolus insulin") to cover food intake and correct hyperglycemia.

"Bolus insulin" refers to the administration of insulin to cover food intake and correct hyperglycemia. It is typically given before meals or snacks.

"Continuous subcutaneous insulin infusion (CSII)" is a method of insulin delivery using an insulin pump to provide a continuous infusion of rapid-acting insulin subcutaneously. The basal rate is programmed and the user administers bolus doses for meals or corrections. The rate is typically determined by the individual's provider and is unique to their particular insulin needs.

"Diabetes mellitus" refers to a group of metabolic disorders characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.

"Glycemic variability" refers to the fluctuations or swings in blood glucose levels over hours or days. Higher glycemic variability may be associated with increased risk of diabetes complications.

"Hemoglobin A1c (HbA1c)" refers to a form of hemoglobin that is bound to glucose. The HbA1c test reflects average blood glucose levels over the past 2 to 3 months. It is used to monitor overall glycemic control in diabetes management.

"Hyperglycemia" is excessive blood glucose. Fasting hyperglycemia is blood glucose above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten.

"Hypoglycemia" is a condition that occurs when one's blood glucose is lower than normal, usually less than 70 mg/dL. Signs include hunger, nervousness, shakiness, perspiration, dizziness or lightheadedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness. Hypoglycemia is treated by consuming a carbohydrate-rich food such as a glucose tablet or juice. It may also be treated with an injection of glucagon if the person is unconscious or unable to swallow.

"Multiple daily injections (MDI)" refers to an insulin regimen involving the administration of basal insulin once or twice daily and separate bolus injections of rapid-acting insulin with meals and snacks. It aims to mimic normal physiologic insulin secretion.

"Time in range (TIR)" is the percentage of time that a person's blood glucose levels are within the target range, typically 70-180 mg/dL. It is a metric of glycemic control often assessed through continuous glucose monitoring.

"Type 1 diabetes" is a form of diabetes mellitus caused by autoimmune destruction of the insulin-producing beta cells of the pancreas, leading to absolute insulin deficiency.

"Type 2 diabetes" is a form of diabetes mellitus characterized by insulin resistance and relative insulin deficiency. It is often associated with obesity and may be managed with lifestyle changes, oral medications, and/or insulin.

Medical Necessity Criteria for Initial Authorization

The Plan considers CeQur Simplicity Insulin Delivery System and its components medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an endocrinologist or diabetes specialist; *AND*
2. The member is 21 years of age or older; *AND*
3. The member has a confirmed diagnosis of type 1 or type 2 diabetes mellitus; *AND*
4. The member meets ALL of the following:
    a. The member has a documented diabetic treatment plan in place and the member or caregiver can be trained to use a CeQur Simplicity Insulin Delivery System.*and*
    b. The member requires blood glucose checks daily OR is using a continuous glucose monitor (CGM); *and*
    c. The member meets ONE of the following:
        i. The member has been on an insulin pump for at least the past 90 days*; or*

ii. The member has been on a basal-bolus insulin regimen using multiple daily injections (with insulin pens or syringes) for at least the past 90 days, AND meets ONE of the following:
    1. Has tried and failed to achieve glycemic control with traditional insulin delivery methods (pens or syringes)*; or*
    2. Has a contraindication, intolerance, or inability to use traditional insulin delivery methods due to physical limitations, visual impairment, or needle phobia/aversion; *and*

d. Will use a rapid-acting insulin analog (e.g., Humalog [insulin lispro], Novolog [insulin aspart]) with the device for the purpose of meal-time only bolus dosing; *AND*

5. The member has suboptimal glycemic control despite adherence to their current insulin regimen, as evidenced by any ONE of the following:
    a. "Dawn phenomenon" with fasting blood glucose frequently > 200 mg/dL; *or*
    b. Frequent hypoglycemia; *or*
    c. Hemoglobin A1c > 7.0%; *or*
    d. Recurrent diabetic ketoacidosis; *or*
    e. Significant glucose variability (i.e., fluctuations) based on self-monitoring or continuous glucose monitoring (CGM) data; *or*
    f. Hypoglycemic episodes requiring third-party assistance (e.g., seizure, loss of consciousness, glucagon administration, transport to an emergency room, hospitalization)*; or*
    g. Wide swings in blood glucose values before meal time (e.g., regular fluctuations of preprandial blood glucose to levels <70 mg/dL and/or >140 mg/dL); *or*
    h. Pregnancy or planning for pregnancy; *or*
    i. *Complications of inadequate glycemic control (e.g., neuropathy, nephropathy, retinopathy) indicative of more intensive insulin regimens; AND*
6. The requested quantity of CeQur Simplicity meets ONE of the following:
    a. Is being prescribed for use within the Plan's Quantity Limit of:
        i. Starter Kit - 1 Kit per 365 days; *or*
        ii. Patch Refills:
            1. for members using ≤180 units of insulin per 96 hours - 10 patches per 30 days (or 30 patches per 90-days); *or*
            2. for members using >180 units of insulin per 96 hours - 30 patches per 30-days (or 90 patches per 90 days); *or*
    b. If the requested quantity exceeds the Plan's Quantity Limit, a valid clinical rationale is provided demonstrating medical necessity (e.g., for more frequent patch changes due to high insulin requirements).

<u>If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.</u>

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12-months will be granted if the member has recent (within the last 6 months) clinical chart documentation demonstrating ALL of the following criteria:

1. The member continues to meet the applicable Initial Authorization criteria
2. The member has demonstrated improvement in glycemic control from baseline as evidenced by any ONE of the following:
    a. Reduction in hemoglobin A1c; *and/or*
    b. Improved time in range; *and/or*
    c. Reduction in frequency or severity of hypoglycemia episodes; *and/or*
    d. Reduction in diabetic ketoacidosis episodes; *and/or*
    e. Improvement in glycemic variability.

Experimental or Investigational / Not Medically Necessary

CeQur Simplicity insulin delivery device for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following[*]:

- Use in those under 21 years of age. The safety and efficacy in those 21 years of age and younger has not been adequately studied.
- Use in gestational diabetes. While Cequr requires the use of a rapid-acting insulin product (e.g., Humalog [insulin lispro] or Novolog [insulin aspart]), which are both approved in the setting of gestational diabetes, the Cequr Simplicity insulin delivery device has not been studied in this population.
- Use for delivery of medications other than rapid-acting insulin (e.g., Humalog [insulin lispro], Novolog [insulin aspart]).
- Use as a standalone device without a basal insulin regimen. Cequr Simplicity insulin delivery device has only been studied in those who require both basal and bolus insulin.

[*]*NOTE: The safety and effectiveness of CeQur Simplicity have not been established in these situations. The device is only FDA-cleared for use in adult patients with type 1 or type 2 diabetes who require bolus insulin as part of a basal-bolus regimen. Any off-label use of CeQur Simplicity is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Coverage is limited to the FDA-approved indications when the medical necessity criteria outlined in this policy are met.*

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Clinical Guideline Revision / History Information

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