

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.

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 between meals and bolus or prandial

insulin to cover food intake 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 3 days and holds up to 200 units of rapid-acting insulin. CeQur Simplicity provides an alternative delivery option for prandial insulin coverage as part of a basal-bolus regimen.

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 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.

"**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.

"**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. Has completed a comprehensive diabetes education program; **and**
 - b. Self-monitors blood glucose at least three (3) times per day, **OR** is using a continuous glucose monitor (CGM); **and**
 - c. Meets **ONE** of the following:
 - i. Has been on an insulin pump for at least the past 90 days; **or**
 - ii. 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., insulin lispro, insulin aspart) with the device;
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; **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 72 hours - 10 patches per 30 days (or 30 patches per 90-days);
 2. for members using >180 units of insulin per 72 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).

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 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; **AND**
2. The member has demonstrated improvement in glycemic control from baseline as evidenced by any **ONE** of the following:
 - a. Reduction in hemoglobin A1c; **or**
 - b. Improved time in range; **or**
 - c. Reduction in frequency or severity of hypoglycemia episodes; **or**
 - d. Reduction in diabetic ketoacidosis episodes; **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 following⁷:

- Use in patients under 21 years of age.
- Use in gestational diabetes.
- Use for delivery of medications other than rapid-acting insulin (e.g., lispro, aspart).
- Use as a standalone device without a basal insulin regimen.

⁷*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.*

References

1. American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Care in Diabetes—2024. *Diabetes Care* 1 January 2024; 47 (Supplement_1): S126–S144. <https://doi.org/10.2337/dc24-S007>
2. American Diabetes Association Professional Practice Committee; Summary of Revisions: Standards of Care in Diabetes—2024. *Diabetes Care* 1 January 2024; 47 (Supplement_1): S5–S10. <https://doi.org/10.2337/dc24-SREV>
3. Bergenstal RM, Johnson ML, Aroda VR, Brazg RL, Dreon DM, Frias JP, Kruger DF, Molitch ME, Mullen DM, Peyrot M, Richter S, Rosenstock J, Serusclat P, Vance C, Weinstock RS, Levy BL.

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4. CeQur Simplicity website. 2024. CeQur Simplicity Features [online]. Available at: <https://www.myceqursimplicity.com>
5. LifeScan Europe, a division of Cilag GmbH. "510(k) Summary for the OneTouch Via On-Demand Insulin Delivery System (K163357)." U.S. Food and Drug Administration, 7 June 2017, www.fda.gov/media/98547/download. Accessed 03/06/2024.

Clinical Guideline Revision / History Information

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Reviewed/Revised: