



Original Effective Date: 12/1/2022  
Current Effective Date: 08/23/2023  
Last P&T Approval/Version: 07/26/2023  
Next Review Due By: 07/2024  
Policy Number: C24238-A

## Insulin Patch NC

### PRODUCTS AFFECTED

CeQur Simplicity (injection device for insulin), Inserter, Starter kit

### COVERAGE POLICY

*Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.*

*This 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 Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.*

#### **Documentation Requirements:**

*Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.*

#### **DIAGNOSIS:**

Type 1 and 2 diabetes

#### **LIMITATIONS/EXCLUSIONS:**

CeQur Simplicity insulin delivery patch is considered not medically necessary for diabetes due to insufficient evidence of therapeutic or clinical value over other insulin delivery. Randomized clinical trials comparing insulin pen delivery with patch delivery found no statistical difference in clinical outcomes, including A1c lowering, between the delivery systems. There was no safety advantage (e.g., hypoglycemic events, adverse events) found for the patch over the pen.

Molina Healthcare will be continuing to evaluate and update this policy as relevant clinical evidence becomes available to determine whether CeQur Simplicity provides clear clinical benefit or is medically necessary.

#### **CONTINUATION OF THERAPY:**

N/A

## Drug and Biologic Coverage Criteria

### **DURATION OF APPROVAL:**

N/A

### **PRESCRIBER REQUIREMENTS:**

N/A

### **AGE RESTRICTIONS:**

N/A

### **QUANTITY:**

N/A

### **PLACE OF ADMINISTRATION:**

N/A

## DRUG INFORMATION

### **ROUTE OF ADMINISTRATION:**

N/A

### **DRUG CLASS:**

Needles & Syringes

### **FDA-APPROVED USES:**

N/A

### **COMPENDIAL APPROVED OFF-LABELED USES:**

None

## APPENDIX

### **APPENDIX:**

None

## BACKGROUND AND OTHER CONSIDERATIONS

### **BACKGROUND:**

It is estimated by the WHO that there are 463 million people living with diabetes worldwide. Given that there are many long-term complications of uncontrolled diabetes, many new medications and devices are being researched. While there are already disposable injectable insulin pens, as well as other insulin delivery devices, there is always a concern of proper patient education and comprehension when self-dosing insulin. Keeping track of carbohydrates and adjusting insulin dosing based on blood glucose levels are all factors that must be taken into consideration by patients who manage their diabetes. There has been a lot of reform recently regarding emphasis on patient education with injection technique, site rotation, nutrition information, and calculating insulin dosing, however the patient must be willing to follow through with these steps in order to best manage their diabetes and to maintain a healthy lifestyle. New technology has alleviated some of the burden when it comes to keeping track of blood glucose numbers, calculating insulin doses, and monitoring carbohydrate intake, however there is still much that the patient is responsible for.

CeQur Simplicity is a wearable insulin patch cleared for use in adults 21 years of age and older with type 1 or type 2 diabetes. The patches are single use, for up to 3 day wear. Patches hold 200 units of rapid acting insulin that can be dispensed in 2 unit increments on demand for mealtime needs and bolus correction. CeQur is intended for use with Humalog and Novolog U-100 insulin. The CeQur Simplicity

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## Drug and Biologic Coverage Criteria

system does not have a tracking mechanism within the dispensing patch. The insulin patch does not provide basal insulin coverage.

Study 1 compared CeQur patch with NovoLog FlexPen using aspart insulin. Study was a randomized, multicenter, open-label, parallel, two arm interventional study to compare the efficacy, safety, and self-reported outcomes in adults with type 2 diabetes on basal insulin therapy who initiated and managed mealtime insulin therapy using an algorithm-based weekly insulin dose titration. The study enrolled 278 patients aged 22-75 years. The study was conducted internationally. Patients were randomized to patch or pen for 44 weeks, then crossed over to the other treatment arm for 4 weeks to evaluate patient preference of the devices. The primary endpoint was change in HbA1c from baseline to week 24, assessing for noninferiority of the patch to the pen. The change in HbA1c from baseline to week 24 was statistically significant in both arms and the patch met non-inferiority thresholds. Improvement in glycemic control was maintained through week 44 of the study. Safety was comparable in each arm and not significantly different.

Study 2 is a substudy of Study 1 that used DexCom G4 CGM in 97 individuals to review glucose time-in-target range (70-180 mg/dL) in patch versus pen utilizers. There was a significant improvement ( $p < 0.0001$ ) in A1c and all CGM metrics at week 24, but no difference between groups.

## CODING/BILLING INFORMATION

*Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement*

HCPCS CODE	DESCRIPTION
NA	

### AVAILABLE DOSAGE FORMS:

CeQur Simplicity 2U DEVI  
CeQur Simplicity Inserter MISC  
CeQur Simplicity Starter KIT

## REFERENCES

1. Dreon, D., Hannon, T., Cross, B., Carter, B., Mercer, N., & Nguyen, J. et al. (2018). Laboratory and Benchtop Performance of a Mealtime Insulin-Delivery System. *Journal Of Diabetes Science And Technology*, 12(4), 817-827. doi: 10.1177/1932296818760633
2. Bergenstal, R., Peyrot, M., Dreon, D., Aroda, V., Bailey, T., & Brazg, R. et al. (2019). Implementation of Basal-Bolus Therapy in Type 2 Diabetes: A Randomized Controlled Trial Comparing Bolus Insulin Delivery Using an Insulin Patch with an Insulin Pen. *Diabetes Technology & Therapeutics*, 21(5), 273-285. doi: 10.1089/dia.2018.0298
3. JOHNSON, M., DREON, D., LEVY, B., RICHTER, S., MULLEN, D., & BERGENSTAL, R. (2018). Comparing Patch vs. Pen Bolus Insulin Delivery in Type 2 Diabetes Using Continuous Glucose Monitoring Metrics and Profiles. *Diabetes*, 67(Supplement\_1). doi: 10.2337/db18-73-lb
4. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2023. *Diabetes Care* 2023; 46 (Suppl. 1): S140-S157. <https://doi.org/10.2337/dc23-S009>

## Drug and Biologic Coverage Criteria

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: References	Q3 2023
NEW POLICY	Q4 2022