NC Medicaid **Medicaid and Health Choice**
Outpatient Pharmacy **Effective Date:**
Prior Approval Criteria
Therapeutic Continuous Glucose Monitoring Systems (CGM) and Related Supplies

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Therapeutic Class Code: Y9A
Therapeutic Class Description: Continuous Glucose Monitoring Systems and Supplies

Medications	Generic Code Number(s)	NDC Number(s)
Dexcom Continuous Glucose Monitoring System and Supplies- G5 mobile and G6 Therapeutic Products	TBD	
FreeStyle Libre Continuous Glucose Monitoring System and Supplies- Therapeutic Products	TBD	

Eligible Beneficiaries
NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.
EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to

correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

a. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide,* sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:** https://medicaid.ncdhhs.gov/

EPSDT provider page: https://medicaid.ncdhhs.gov/

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

A typical Continuous Glucose Monitoring (CGM) system continuously measures glucose values in the interstitial fluid and consists of a glucose sensor, transmitter and receiver. Only CGM systems classified by the FDA as therapeutic will be considered for coverage under Outpatient Pharmacy Criteria. Coverage criteria for non-therapeutic CGM systems can be found at NC Medicaid Clinical Coverage Policy 5A-3 (Durable Medical Equipment benefit (DME)).

Therapeutic CGMs are approved by the FDA for use as non-adjunctive devices to replace information obtained from standard BGMs in making diabetes treatment decisions.

Criteria:

- **Initial prior authorization:** Beneficiary must meet criteria one through six (1-6) or one and seven (1 and 7).

1. the beneficiary has a diagnosis of insulin-dependent diabetes; and,
2. the beneficiary has been using a standard BGM (blood glucose monitor) or non-therapeutic CGM and testing four (4) or more times daily; and,
3. the beneficiary requires three (3) or more insulin injections daily; and,
4. the beneficiary's insulin treatment regimen requires frequent adjustment based on standard BGM or non-therapeutic CGM testing; and,
5. the beneficiary or caregiver(s) is willing and able to use the therapeutic CGM system as prescribed; and,
6. the beneficiary has had a face-to-face encounter with the treating practitioner to evaluate the beneficiary's glycemic control and determine that criteria one through five (1-5) above have been met, within six months of the initial authorization

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request; **or,**

7. the beneficiary uses an external insulin pump which communicates with a CGM.

The initial prior authorization period must not exceed six months.

- **First reauthorization:** After the initial authorization period, the first reauthorization request must include documentation that:

1. the beneficiary has been using the CGM system as prescribed; and,
2. the beneficiary has been able to improve glycemic control; or,
3. the beneficiary continues to use an external insulin pump.

Reauthorization must not exceed 12 months.

Subsequent reauthorizations: After the initial authorization and first reauthorization periods, each subsequent reauthorization request for a therapeutic CGM and related supplies must include documentation that:

1. the beneficiary has had a face-to-face encounter with the ordering practitioner to evaluate the efficacy of the CGM system no more than three (3) months prior to submission of the reauthorization request; and,
2. the beneficiary has been using the CGM system as prescribed; and,
3. the beneficiary has been able to maintain or further improve glycemic control; or,
4. the beneficiary continues to use an external insulin pump.

Reauthorization must not exceed twelve (12) months.

Note: The beneficiary must meet the FDA age limits and other requirements for the specific device prescribed.

Note: Simultaneous coverage for more than one therapeutic CGM system is not permitted.

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Coverage criteria for non-therapeutic continuous glucose monitoring systems can be found at

References

1. Dexcom Provider Website: https://provider.dexcom.com/
2. FreeStyle Libre Provider Website: https://www.myfreestyle.com/provider/?source=www.freestylelibre.us

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Criteria Change Log

	Criteria effective date