DRAFT

Therapeutic Class Code: L9P
Therapeutic Class Description: GENE THERAPY AGENTS - CONNECTIVE TISSUE DISORDERS

Medication
Zevaskyn Sheet

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.

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 beneficiary'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 beneficiary'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 Billing Guide,* sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

EPSDT provider page:

https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

Initial Approval Criteria:

- Beneficiary is ≥ 6 years of age; **AND**
- Beneficiary has a diagnosis of recessive dystrophic epidermolysis bullosa (RDEB) as established by detection of biallelic mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene on molecular testing (Note: If unable to confirm a biallelic mutation, confirmation that BOTH parents do not have any evidence of dominant disease is also acceptable); **AND**
- Beneficiary has cutaneous wound(s) which are adequate for treatment (e.g., stage 2 wounds that have an area of ≥ 20 cm^2) and have been present for ≥ 6 months; **AND**
- Beneficiary does NOT have severe hypersensitivity (e.g. anaphylaxis) to vancomycin or amikacin); **AND**
- Beneficiary does NOT show current evidence or have a history of squamous cell carcinoma (SCC) in the area to be treated); **AND**
- Will NOT be used concurrently, in the same wound, with another disease-modifying therapeutic agent indicated for dystrophic epidermolysis bullosa (e.g. birch triterpenes [Filsuvez], beremagene geperpavec-svdt [Vyjuvek]) (NOTE: this does NOT include disease/wound management incidentals like topicals, dressings, antibiotics, etc.); **AND**
- Females of childbearing potential should use an effective method of contraception to prevent pregnancy at the time of treatment with Zevaskyn.

Renewal Criteria:

- Beneficiary must continue to meet the above criteria; **AND**
- Beneficiary shows disease response to treatment as defined by improvement (healing) of treated wound sites, and/or reduction in skin infections, etc., as attested by his/her physician; AND
- Beneficiary requires continued treatment due to new expansion of pre-existing, or development of new (de novo) open wounds (Note: Zevaskyn is intended as a one-time treatment per area; re-treatment of wounds that were previously grafted would be considered investigational at this time and may not be renewed); AND

- Beneficiary has NOT experienced any treatment-restricting adverse effects (e.g., severe hypersensitivity reactions, development of new malignancies, contracting a serious infectious disease or agent);

Quantity Limit:

- Up to 12 collagen VII-expressing cellular sheets for each surgical session (supplied as three containers containing up to 4 sheets each)

Duration of Approval:

- Initial: Six months;
- Renewal: Six months.

References

1. Abeona Therapeutics Inc. Zevaskyn Package Insert. Cleveland, OH. March 2025.

NC Medicaid **Medicaid Outpatient Pharmacy**
Prior Approval Criteria **Effective Date: xx/xx/xxxx**
Zevaskyn

Criteria Change Log

Xx/xx/xxxx	Criteria effective date