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1.0 Description of the Procedure, Product, or Service

Extracorporeal shock wave lithotripsy (ESWL) is a technique for treating stones in the kidney and ureter that does not require surgery. High-energy shock waves are passed through the body and used to break stones into pieces as small as grains of sand. Because of their small size, these pieces can pass from the body along with the urine.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term “General” found throughout this policy applies to all Medicaid and NCHC policies)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise); or
   2. the NC Health Choice (NCHC is NC Health Choice program, unless context clearly indicates otherwise) Program on the date of service and shall meet the criteria in Section 3.0 of this policy.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary’s eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

a. Medicaid

   None Apply.

b. NCHC

   None Apply.
2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 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 beneficiary 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 practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or 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:

1. that is unsafe, ineffective, or experimental or investigational.
2. 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 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.

b. EPSDT and Prior Approval Requirements

1. 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.

2. IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing
2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within Section 3.0 of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary’s needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary’s caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

Medicaid and NCHC cover ESWL as follows:

a. for the disintegration of upper urinary tract stones in the kidney and the ureter above the true pelvis.

b. for renal calyx stones, renal pelvic stones, or upper ureteral stones only.

c. Other treatments modalities such as percutaneous lithotripsy, dissolution therapy, or conventional surgery may be used in conjunction with ESWL.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.
4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

4.1 General Criteria
Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:
   a. the beneficiary does not meet the eligibility requirements listed in Section 2.0;
   b. the beneficiary does not meet the criteria listed in Section 3.0;
   c. the procedure, product, or service duplicates another provider’s procedure, product, or service; or
   d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC
None Apply.

4.2.2 Medicaid Additional Criteria Not Covered
None Apply.

4.2.3 NCHC Additional Criteria Not Covered
   a. NCGS § 108A-70.21(b) “Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
      1. No services for long-term care.
      2. No nonemergency medical transportation.
      3. No EPSDT.
      4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection.”

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Recipients under 21 Years of Age.

5.1 Prior Approval
Medicaid and NCHC shall not require prior approval for ESWL.

5.2 Prior Approval Requirements

5.2.1 General
None Apply.

5.2.2 Specific
None Apply.
5.3 Other Requirements or Limitations

Coverage is limited to one ESWL per kidney or ureter per day. This procedure is subject to the multiple procedures policy.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All DMA’s clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).
### 8.0 Policy Implementation/Revision Information

**Original Effective Date:** October 1, 1985

**Revision Information:**

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<tr>
<th>Date</th>
<th>Section Revised</th>
<th>Change</th>
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<tr>
<td>09/01/04</td>
<td>Section 3.0</td>
<td>Added “in the kidney” and “above the true pelvis”</td>
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<tr>
<td>09/01/04</td>
<td>Section 4.0</td>
<td>Limited coverage to one ESWL per kidney per day</td>
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<tr>
<td>9/01/05</td>
<td>Section 2.0</td>
<td>A special provision related to EPSDT was added</td>
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<tr>
<td>12/1/05</td>
<td>Section 2.2</td>
<td>The web address for DMA’s EDPST policy instructions was added to this section.</td>
</tr>
<tr>
<td>12/1/06</td>
<td>Sections 2 through 5</td>
<td>A special provision related to EPSDT was added</td>
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<tr>
<td>5/1/07</td>
<td>Sections 2 through 5</td>
<td>EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age</td>
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<tr>
<td>7/1/2010</td>
<td>Throughout</td>
<td>Policy Conversion: Implementation of Session Law 2009-451, <strong>Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”</strong></td>
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<tr>
<td>3/1/2012</td>
<td>Throughout</td>
<td>To be equivalent where applicable to NC DMA’s Clinical Coverage Policy # 1S-4 under Session Law 2011-145, § 10.41.(b)</td>
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<tr>
<td>3/1/2012</td>
<td>Throughout</td>
<td>Technical changes to merge Medicaid and NCHC current coverage into one policy.</td>
</tr>
<tr>
<td>10/01/2015</td>
<td>All Sections and Attachments</td>
<td>Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.</td>
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Attachment A: Claims-Related Information

Provider(s) shall comply with the, NCTracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, DMA’s clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

   Professional (CMS-1500/837P transaction)
   Institutional (UB-04/837I transaction)

B. International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

<table>
<thead>
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<th>Code(s)</th>
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Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.
E. Billing Units
   Provider(s) shall report the appropriate code(s) used which determines the billing unit unit(s).

F. Place of Service
   Hospital, Outpatient Hospital.

G. Co-payments

H. Reimbursement
   Providers are required to bill applicable revenue codes.
   Providers shall bill their usual and customary charges.
   For a schedule of rates, see: http://www.ncdhhs.gov/dma/fee/