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1.0 Description of the Procedure, Product, or Service

Collagen implantation uses purified collagen derived from bovine hide. It may be lightly cross-linked with glutaraldehyde or noncross-linked.

Noncross-linked collagen is used to restore the natural skin contour to nonweight bearing areas which have been damaged by age, trauma, disease, congenital anomalies, or previous therapeutic procedures. Typically, supplemental implants are required for most recipients between 6- 18 months post-procedure (Collagen Corporation, 1986) due to the degeneration of the original implant.

Cross-linked collagen is proposed for use for all of the same indications in which noncross-linked collagen is used for the subdermal augmentation of soft tissues. An additional indication is subdermal augmentation beneath keratotic lesions of the foot. Enhanced durability, with less frequent need for supplementation, is the major advantage cited for cross-linked collagen implants. Another indication is periurethral (through the urethra or tube through which urine passes from the bladder to outside of the body) injection of crosslinked collagen for treatment of stress urinary incontinence (inability to control urination).

Collagen is the major protein component of the white fibers that form connective tissue, cartilage and bone in mammals.

1.1 Medical Term Definitions

- a. Augmentation: process of enlarging.
- b. Congenital anomalies: marked deviation from the normal standard, especially as a result of congenital defects.
- c. Incontinence: an inability to control the body's elimination of waste products through urination or defecation.
- d. Periurethral: around the urethra, which is the natural channel or tube through which urine passes from the bladder to outside the body.
- e. Subdermal under the skin.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are 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 recipient'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; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Collagen implantation may be covered by the NC Health Choice Program for the following indications:

- a. non-cross linked collagen is eligible for coverage to augment soft tissue when it is performed for reconstructive purposes.
- b. for the treatment of corns and callouses (Keragen implant).

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Collagen implantation is not covered by the NC Health Choice Program for any condition other than those listed in **Subsection 3.2**.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior Approval is not required for collagen implantation.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **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.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010		Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
September 30, 2011	Throughout	Policy Date of Termination

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes
11950
11951
11952
11954

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital, Outpatient Hospital and Office

G. Co-payments

Co-payment(s) may apply to covered prescription drugs and services.

H. Reimbursement

Providers must bill their usual and customary charges.