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## **1.0 Definition of the Procedure**

Bone morphogenic protein-2 (BMP-2) is a bioengineered osteoinductive protein that plays an important role in bone growth. Two products have currently received FDA approval and are implanted during spinal infusion surgery.

### **1.1 InFuse Bone Graft/LT-Cage (Lumbar Tapered)**

This device consists of three components split between two parts: a metallic tapered spinal fusion cage known as the (LT-cage lumbar tapered fusion device), and InFuse Bone Graft. InFuse Bone Graft is a bone graft substitute which consists of genetically engineered human protein (rrBMP-2) along with a carrier/scaffold for the protein (manufactured from bovine Type 1 (collagen) that is placed inside the fusion.

### **1.2 OP-1 implant**

This product treats long bone non-unions where autograft is not feasible and other treatments have failed. It is made of a manufactured human protein powder and bovine bone collagen that is mixed with a sterile saline solution to form a paste. The paste is then placed between the broken ends of the bone during surgery.

## **2.0 Eligible Recipients**

### **2.1 General Provisions**

Medicaid eligible individuals with a need for this specialized treatment confirmed by a licensed physician are eligible as long as they meet individual eligibility requirements. Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

### **2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age**

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 recipients 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 will correct or improve or maintain the recipient'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 recipient 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.

**Basic Medicaid Billing Guide:** <http://www.ncdhhs.gov/dma/medbillcaguide.htm>

**EPSDT provider page:** <http://www.ncdhhs.gov/dma/EPSDTprovider.htm>

### 3.0 When the Procedure Is Covered

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for coverage. The N.C. Medicaid program covers bone morphogenic protein allograft for patients who meet the following criteria:

- a. Tapered lumbar fusion cages in single level anterior lumbar spine fusion
- b. Long bone nonunion, when an autograft is not feasible and other treatments have failed

#### 4.0 When the Procedure Is Not Covered

**IMPORTANT NOTE:** EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are **medically necessary health care services** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem]; that is, documentation shows how the service, product, or procedure will correct or improve or maintain the recipient'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 DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED.** For additional information about EPSDT and prior approval requirements, see **Section 2.0** of this policy.

The N.C. Medicaid program does not cover bone morphogenic protein when one of the following conditions exists (not all inclusive):

- a. Fusions of the thoracic or cervical spine
- b. Multiple level lumbar fusions
- c. Augmentation of bone auto grafting
- d. Craniofacial surgery and fracture nonunions of other sites
- e. Restorative dental surgery
- f. History of or active substance abuse - must have documentation of substance abuse program completion plus six months of negative sequential random drug screens.

**Note:** To satisfy the requirement for sequential testing as designated in this policy, the Division of Medical Assistance (DMA) must receive a series of test (alcohol and drug) results spanning a minimum six-month period, allowing no fewer than a three-week interval and no more than six-week interval between each test during the given time period. A complete clinical packet for prior approval must include at least one documented test performed within one month of the date of request to be considered.

- g. Psychosocial history that would limit the ability to comply with medical care pre- and post-transplant.
- h. Current patient and/or caretaker non-compliance that would make compliance with a disciplined medical regime improbable.

Each recipient's condition is evaluated on an individual basis. There may be other conditions that are indications for non-coverage.

#### 5.0 Requirements for and Limitations on Coverage

All applicable N.C. Medicaid policies and procedures must be followed in addition to the ones listed in this procedure.

All procedures must be prior approved by DMA.

## 6.0 Providers Eligible to Bill for the Procedure

Physicians enrolled in the N.C. Medicaid program who perform this procedure may bill for this service.

## 7.0 Additional Requirements

FDA approved procedures, products, and devices for implantation must be utilized.

Implants, products, and devices must be used in accordance with all FDA requirements current at the time of surgery.

A statement signed by the surgeon certifying that all FDA requirements for the implants, products, and devices must be retained in the recipient's medical record and made available for review upon request.

## 8.0 Policy Implementation/Revision Information

**Original Effective Date:** January 1, 1994

### Revision Information:

Date	Section Revised	Change
7/1/05	Entire Policy	Policy was updated to include coverage criteria effective with approved date of State Plan amendment 4/1/05.
9/1/05	Section 2.2	The special provision related to EPSDT was revised.
12/1/05	Section 2.2	The web address for DMA's EDPST policy instructions was added to this section.
12/1/06	Sections 2.2	The special provision related to EPSDT was revised.
12/1/06	Sections 3.0 and 4.0	A note regarding EPSDT was added to these sections.
5/1/07	Sections 2 through 4	EPSDT information was revised to clarify exceptions to policy limitations for recipients under 21 years of age.
5/1/07	Attachment A	Added the UB-04 as an accepted claims form.
3/1/12	Throughout	Policy Termination

### **Attachment A: Claims-Related Information**

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

**A. Claim Type**

Providers bill professional services on the CMS-1500 claim form.

Hospitals bill for services on the UB-92 or UB-04 claim form.

**B. Diagnosis Codes**

Providers must bill the ICD-9-CM diagnosis code to the highest level of specificity that supports medical necessity.

**C. Procedure Codes**

The covered code is 22851.

**D. Reimbursement**

Providers must bill their usual and customary charges.

Date of termination 03.01.2012