MEDICAL POLICY

SUBJECT: ILIZAROV METHOD OF DISTRACTION OSTEOSYNTHESIS

POLICY NUMBER: 7.01.08
CATEGORY: Technology Assessment

EFFECTIVE DATE: 10/18/01
REVISED DATE: 11/15/01, 09/19/02
ARCHIVED DATE: 08/21/03
EDITED DATE: 11/11/05, 10/19/06, 10/18/07, 12/18/08, 12/17/09, 12/16/10, 12/15/11, 12/20/12, 12/19/13, 12/18/14, 03/15/16

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• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.
• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature:

I. The Ilizarov procedure has been medically proven to be effective and is therefore medically appropriate for the following:
   A. Correction of limb length discrepancies greater than 6 cm and for correction of congenital or post-traumatic angular/rotational deformations of the long bones;
   B. Treatment of non-union or mal-union of long bone with or without bone loss or infection;
   C. When used for angular bone defects with or without deformities; or
   D. Where lengthening of an amputation stump is needed for proper fitting of a prosthesis.

II. Lengthening of upper extremities is considered not medically necessary.

III. Use of a bone lengthening device for the sole purpose of altering short stature is considered not medically necessary.

DESCRIPTION:

The Ilizarov method of distraction osteosynthesis is based on the premise that new bone and soft tissue can be generated through controlled distraction. The Ilizarov procedure uses a circular external fixator, which is attached to the underlying bone via multiple transfixion wires. A corticotomy is performed first; the transfixion wires are then inserted percutaneously. Telescopic rods on the external device allow for daily changes in the length of the apparatus, providing the distractive force necessary to promote osteosynthesis (new bone growth).

RATIONALE:

The Ilizarov device was in use in the United States before the FDA began to approve medical devices. Titanium wires received 510k approval for use with the device in 1996. There is sufficient data published in the medical literature to conclude that the Ilizarov bone lengthening technique improves health outcomes for patients with congenital or traumatic limb length discrepancies, non-union or mal-union of long bone fractures and angular bone defects, and for lengthening of amputation stumps. The procedure has been performed outside the investigational setting for many years.

CODES:

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>20690</td>
<td>Application of uniplane, unilateral, external fixation system</td>
</tr>
<tr>
<td>20692</td>
<td>Application of multiplane, unilateral, external fixation system (e.g. Ilizarov, Monticelli type)</td>
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Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
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20693 Adjustment or revision of external fixation system requiring anesthesia
20694 Removal, under anesthesia, of external fixation system
20696 Application of multiplane (pins or wires in more than one plane), unilateral, external fixation with stereotactic computer-assisted adjustment (spatial frame), including imaging; initial and subsequent alignment(s), assessment(s), and computations(s) of adjustment schedule(s)
20697 exchange (ie, removal and replacement) of strut, each

HCPCS: No code(s)

ICD9:
733.81 Malunion of fracture
733.82 Nonunion of fracture
736.81 Unequal leg length (acquired)
755.69 Congenital angulation, leg

ICD10: M21.751-M21.769 Unequal limb length (code range)
Q72.70 Split foot, unspecified lower limb
Q74.2 Other congenital malformation of lower limb(s), including pelvic girdle

Multiple diagnosis codes for malunion and nonunion of fracture

REFERENCES:

KEY WORDS:
Ilizarov

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Ilizarov method of distraction osteosynthesis is not addressed in National or Regional Medicare coverage determinations or policies.