



NOTE: This policy is not effective until January 1, 2027

Medical Policy Manual

Surgery, Policy No. 29

Bone Lengthening (Distraction Osteogenesis)

Effective: January 1, 2027

Next Review: August 2027

Last Review: August 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Bone lengthening, also known as distraction osteogenesis, procedures can be used to treat limb length discrepancies, limb deformities, nonunion or malunion, amputation stump lengthening, and bone defects.

MEDICAL POLICY CRITERIA

Notes:

- Member contracts have specific language regarding covered reconstructive services and excluded cosmetic procedures. Specific member contract language takes precedence over medical policy.
- Clinical documentation to support criteria is required (See Required Documentation)

Medically Necessary

- I. Bone lengthening procedures may be considered **medically necessary** when both of the following Criteria (A. and B.) are met:
 - A. Either of the following (1. or 2.):

1. For correction of congenital or post-traumatic limb length discrepancies; or
2. For correction of angular deformities of the limb (arm, forearm, thigh or leg); and

B. One or more of the following:

1. The individual has fracture nonunion or malunion of the long bone, with or without bone loss or infection, documented by both of the following Criteria (a. and b.):
 - a. At least 3 months have passed since the date of injury or treatment; and
 - b. Radiographic evidence on at least 2 serial imaging studies during the most recent 3-month period showing evidence of nonunion or malunion;
2. Lengthening of an amputation stump is needed for the individual to ensure the proper fitting of a prosthesis; or
3. Bone lengthening is needed to equalize leg length discrepancy greater than 6 cm; or
4. Correction of any congenital limb length discrepancy or post-traumatic angular-rotational deformations of the long bones; or
5. Bone lengthening is being used for bone defects with or without deformities.

Not Medically Necessary

- II. Bone lengthening is considered **not medically necessary** for congenital or post-traumatic limb length discrepancies, or correction of angular deformities of the limb (arm, forearm, thigh or leg) when Criterion I. is not met and all indications other than short stature.

Cosmetic

- III. Bone lengthening for the sole purpose of altering short stature is considered **cosmetic**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

REQUIRED DOCUMENTATION

It is critical that the documentation listed below is submitted to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and Physical/Chart Notes
- Description of congenital, trauma, or angular deformity causing limb length discrepancy, including amount of discrepancy
- For fracture nonunion or malunion:
 - Documentation of fracture nonunion or malunion location
 - Date of injury or previous fracture treatment
 - Serial radiographs documenting no progressive signs of healing over most recent three months
- For lengthening post amputation:
 - Description of length discrepancy and the plan for post procedure prosthesis

CROSS REFERENCES

1. [Electrical Bone Growth Stimulators \(Osteogenic Stimulation\)](#), Durable Medical Equipment, Policy No 83.11
2. [Ultrasonic Bone Growth Stimulators \(Osteogenic Stimulation\)](#), Durable Medical Equipment, Policy No. 83.12

BACKGROUND

Lower extremity reconstruction may be needed for a range of causes including trauma, chronic wounds, infection, degenerative conditions, cancer-related resection, and congenital abnormalities.

For congenital lower-extremity conditions, reconstruction focuses on supporting continued growth and minimizing future limb-length differences. Severe defects may be managed with limb-lengthening procedures, while amputation with prosthetic reconstruction is another option but has limitations such as infection risk and lack of growth potential.

Bone lengthening, or distraction osteogenesis, is a surgical method used to lengthen or rebuild bone. During surgery, the bone is cut and a device is used to slowly move the bone ends apart. New bone grows in the space between the bone ends over time. This process may take several months and allows for gradual correction of bone length or position.

REGULATORY STATUS

The Monticelli Spinelli External Fixation System (Howmedica Corp.) received 510(k) premarket approval by the U.S. Food and Drug Administration (FDA) in 1986.^[1]

The Ilizarov External Fixation System (Smith+Nephew) received 510(k) premarket approval by the FDA in 1996.^[2] This system utilizes a circular external fixator system. It is designed for patients with the following indications: open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of bony or soft tissue defects.

The Hoffmann® LRF System (Stryker) received initial 510(k) premarket approval by the FDA in 2012 with the most recent approval in 2025.^[3] The approval indications include treating various bone and joint conditions including fractures (open/closed), joint contractures, non-union of bones, limb lengthening, and correction of bone/soft tissue deformities and defects. Additionally, the device can be used in pediatric (2 through 21 years of age) and adult patients.

The PRECICE® Intramedullary Limb Lengthening System (Ellipse Technologies, Incorporated) received 510(k) premarket approval by the FDA in 2015.^[4] This system is indicated for limb lengthening of the tibia and femur. The implantable device uses an external remote controller and implanted magnets to precisely adjust limb length.

EVIDENCE SUMMARY

ANGULAR DEFORMITY

Agrawal (2022) conducted a retrospective case series evaluating compression-distraction osteogenesis using the Ilizarov apparatus for managing post-traumatic cubitus varus deformity.^[5] The researchers analyzed 32 patients with cubitus varus deformity of $\geq 10^\circ$ at the elbow who underwent mini-incision subperiosteal osteotomy followed by Ilizarov frame application. Clinical and radiological follow-up was performed at regular intervals until union

was achieved and yearly thereafter. Mean time to union was 11 weeks. Using the Oppenheim grading system, results were excellent in 25 cases (78.1%), good in 2 cases (6.3%), and poor in 5 cases (15.6%). The mean Humerus Elbow Wrist (HEW) angle improved from 20° of varus preoperatively to 6° of valgus at final follow-up. Mean flexion/extension improved from 121°/-3° preoperatively to 125°/-4° at final follow-up. Complications included superficial pin-tract infections (3 cases), lateral condylar prominence (1 case), loss of terminal flexion (3 cases), and valgus over-correction (1 case). The study limitations include the retrospective case series design, potential selection bias from single-center data, and lack of standardized preoperative deformity assessment.

BONE TUMOR

McCoy (2013) conducted a retrospective case series evaluating the Ilizarov method for bone tumor reconstruction in patients with musculoskeletal tumors facing large bone deficiency, deformity, and nonunion.^[6] The researchers reviewed 20 patients (9 females and 11 males) with a range of musculoskeletal tumors requiring surgical treatment, with a mean age of 22.6 years (range 8 to 58 years) and mean follow-up of 81.7 months (range 26 to 131 months). The mean bone deficiency was 7.9 cm (range 1.2 to 18.0 cm). Mean lengthening achieved was 7.1 cm (range 3.5 to 18.0 cm) over an external fixation index (EFI) of 33.5 days/cm (range 9.5 to 58.3 days/cm). Treatment resulted in 10 excellent and 3 good Association for the Study and Application of Methods of Ilizarov (ASAMI) bone scores, 10 excellent and 3 good ASAMI function scores, a mean lower extremity Musculoskeletal Tumor Society (MSTS) score of 93%, and a mean upper extremity MSTS score of 87%. Treatment resulted in 2 complications, 18 obstacles, and 6 problems. The study's limitations include a small sample size, retrospective design, heterogeneous patient population with various tumor types and locations, extended time required in external fixation, inability to assess the method's effectiveness with concurrent chemotherapy or radiotherapy as no patients received these treatments simultaneously, and potential selection bias from single-center experience.

CONGENITAL DESCRIPANCIES

Takagi (2014) conducted a study evaluating five radial club hands (Bayne type I or II) treated with a novel procedure involving radius lengthening.^[7] External fixation was used to support the radial side of the wrist and combined with temporary external fixation between the ulna and metacarpals. Assessment included radial deficiency deformity recurrence from anteroposterior radiographs and passive range of wrist motion using a goniometer before surgery and at final follow-up. The healing index of the radius ranged from 72.2 to 298.9 days/cm (mean 176.8 days/cm), and mean radial/ulnar deviation improved from 84.0°/-14.0 degrees before surgery to 37.0°/13.0 degrees at final follow-up, with no correction loss detected during follow-up. All patients were able to hold and bring an object to the mouth after surgery, with no postoperative infections or cases of nerve palsy. Study limitations include the very small sample size, lack of control group, no specification of follow-up duration, retrospective design without randomization, single-center experience, and limited assessment of functional outcomes.

Catagni (2011) conducted a retrospective case series examined 32 patients with Type III fibular hemimelia treated with successive lower limb lengthening and deformity correction using the Ilizarov method as an alternative to amputation.^[8] The patients underwent a total of 56 tibia lengthenings and 14 ipsilateral femoral lengthenings, with a mean age of 6.7 years and mean functional leg-length discrepancy of 6.2 cm at initial treatment. The mean number of surgeries was six per case, with a healing index of 44.9 days/cm. Complications were

observed during 60 lengthenings (82%), though most were managed with the Ilizarov system. Nearly equal limb length and a plantigrade foot were achieved in 16 patients (50%), while two patients (6%) required Syme's amputation. The outcome was considered satisfactory in 17 patients (53%) and relatively good in eight patients (25%). Limitations include the retrospective design, lack of a control group for comparison with amputation outcomes, absence of validated outcome measures, no long-term follow-up data, and the high complication rate which may affect treatment feasibility and patient selection.

LOWER EXTREMITY

Systematic Reviews

Frost (2021) conducted a systematic review examining complications associated with externally controlled motorized intramedullary bone lengthening nails (FITBONE and PRECICE) in lower limb lengthening procedures.^[9] The researchers identified 41 studies meeting inclusion criteria for final analysis. The review included 983 lengthened segments in 782 patients (age 8-74 years), with 214 FITBONE nails, 747 PRECICE nails, and 22 unspecified nails. Lengthening was completed for various indications including congenital shortening (208), acquired limb shortening (305), short stature (111), and unidentified etiology (158). A total of 332 complications occurred in 34% of segments, categorized as Type I (minimal intervention) in 11% of segments, Type II (substantial change in treatment plan) in 15% of segments, Type IIIA (failure to achieve goal) in 5% of segments, and Type IIIB (new pathology or permanent sequelae) in 3% of segments. Device and bone complications were the most frequent types observed. The study's limitations include the absence of a standardized reporting method for complications across the included studies, heterogeneous reporting in small case series, and potential variability in surgical techniques and patient selection criteria across the included studies.

Nonrandomized Studies

Frost (2023) conducted a retrospective multicenter cohort study examining complications and risk factors associated with intramedullary bone lengthening nails in 314 segments across 257 patients at two hospitals.^[10] The study included only lower limb lengthening procedures using FITBONE (75% of cases) and PRECICE nails, with most lengthenings performed in the femur (80%). Complications occurred in 53% of patients, with 269 total complications identified across 175 segments in 144 patients. Device-related complications were most frequent at 0.3 complications per segment, followed by joint complications at 0.2 complications per segment. Modified Poisson regression analysis revealed increased relative risk for complications in tibial lengthening compared with femoral lengthening and in patients aged 30 years and above compared with the 10-19 years age group. The study's limitations include the retrospective design, lack of a control group for comparison, potential selection bias from the two-center cohort, absence of standardized complication reporting methods across institutions, heterogeneous patient population with varying indications for lengthening, and inability to establish causality between identified risk factors and complications.

Radler (2022) conducted a retrospective study investigating the efficacy and safety of intramedullary limb lengthening with Precice nails in children and adolescents 18 years and younger using the Precice nail.^[11] The procedure was performed between March 2013 and March 2020, with radiologic and clinical outcome data obtained from a prospective database and minimum post-implantation follow-up of 12 months. Of 161 patients who underwent limb lengthening with a Precice nail, 76 patients met inclusion criteria, with 84 nails used (68 femurs

and 16 tibias). The mean lengthening was 33 mm (range 14 to 80 mm), with additional acute axial or rotational malalignment correction in 16 segments. At last follow-up (mean 2.1 years, range 1 to 5 years), all regenerates had healed and all patients were mobile with full weight-bearing. Complications necessitating surgical revision occurred in 6 patients (8%), desired lengthening was not achieved in 2 patients, and post-lengthening malalignment occurred in 4 patients (5 tibial nails). The weight-bearing index was a mean of 45 days/cm (range 7 to 127 days/cm). The study's limitations include the retrospective design despite data collection from a prospective database, lack of a control group, heterogeneous patient population with varying ages and lengthening goals, and relatively short follow-up period which may not capture long-term complications or outcomes.

Sangkaew (2008) conducted a study evaluating a new technique of distraction osteogenesis using conventional monolateral Association for the Study of Internal Fixation (ASIF) external fixator for femoral lengthening in 51 femora of 50 patients with limb-length discrepancy.^[12] Participants had a mean age of 21.9 years (range 5-48) and average follow-up of 24.6 months after fixator removal (range 6-120 months). The length of 51 femora was increased by an average of 4.4 cm (range 1-13) or 12% (range 2.5-40.9%), with average healing index of 50.5 days/cm (range 22.5-110.6), and 22 femora had associated axial or rotational deformities corrected with average gradual angular correction in coronal plane of 20.4 degrees (range 10-45) in 14 femora, average acute correction in sagittal plane of 17 degrees (range 10-20) in 5 femora, and average acute derotation of 24.2 degrees (range 10-60) in 6 femora. A total of 61 complications occurred (26 problems, 18 obstacles, 17 sequelae) for an overall rate of 1.2 per femur, including 15 femora with delayed consolidation (healing index greater than 54 days/cm) and 3 nonunions. A significant negative parabolic relationship was noted between healing index and amount of length gained ($R=-0.47$, $p=0.004$), and a significantly positive exponential relationship between age and healing index ($R=0.51$, $p<0.001$), with greater amount of length gained associated with complications, while acute deformity correction and level of osteotomy had no significant effect on healing index. Study limitations include a single center with a single surgeon experience, lack of control group, variable follow-up periods, retrospective design, and absence of validated outcome measures beyond healing index and complication rates.

Noonan (1998) performed a retrospective case series reviewed distraction osteogenesis outcomes in 114 femora and 147 tibiae lengthened using monolateral external fixation to treat various diagnoses.^[13] Femora were lengthened an average of 11 cm (range 3.5-17.0 cm) or 48% (range 8-86%) of original length, with average total treatment time of 257 days (range 105-420 days), resulting in 114 complications requiring 87 additional operations. Tibiae were lengthened an average of 9 cm (range 3.0-15.6 cm) or 41% (range 9-100%) of original length, with average total treatment time of 268 days (range 110-497 days). There were 196 complications requiring 219 additional operations. Femoral lengthenings for limb-length discrepancy had higher complication rates ($p=0.010$) and additional operations ($p=0.023$) per percentage of length gained compared to those for skeletal dysplasias. Patients aged 14 years or older had higher femoral complication rates ($p=0.047$), tibial joint-related problems ($p=0.044$), and femoral healing indices ($p=0.002$) compared to younger patients. Metaphyseal femoral lengthening showed higher complication rates ($p=0.031$) and additional operations ($p=0.042$) per percentage gained versus diaphyseal lengthening. Limitations include the retrospective design, heterogeneous patient population, lack of standardized outcome measures, absence of a control group, and inability of healing scores to accurately predict future problems or patient recovery results.

METATARSAL

Li (2024) conducted a retrospective study of 11 patients (10 females, 1 male, mean age 24.6 ± 4.5 years, range 16-31) with 17 shortened fourth metatarsals treated by metatarsal lengthening using Orthofix external fixator mini track.^[14] Mean follow-up was 55 ± 10.8 months, with mean preoperative fourth metatarsal length of 49.9 ± 2.9 mm, mean metatarsal shortage of 18.8 ± 3.1 mm, and mean lengthening achieved of 19.8 ± 3.3 mm with lengthening ratio of $39.7\% \pm 6.6\%$, and lengthened callus ossified completely at 3-4 months postoperatively. American Orthopedic Foot and Ankle Society lesser metatarsophalangeal-interphalangeal scores improved from 83.7 ± 4.2 preoperatively to 93.2 ± 2.7 postoperatively ($t=-10.27$, $p<0.001$), with all patients satisfied with lengthening results. Complications included 1 patient with traumatic metatarsophalangeal joint subluxation treated by joint reduction and Kirschner wire fixation, 1 patient requiring metatarsophalangeal joint release and Kirschner wire fixation for flexion contracture, and 6 patients with pin tract infections controlled by wound care and antibiotics, while no patients experienced nonunion, toe necrosis, or sensory disturbance. Study limitations include the retrospective design, small sample size, lack of control group, predominance of female patients limiting generalizability, single-center experience, and relatively homogeneous patient population with only fourth metatarsal involvement.

NONUNION

Systematic Reviews

Yin (2015) conducted a systematic review and meta-analysis examining the efficacy of Ilizarov methods for treating infected nonunion of the tibia and femur.^[15] The researchers performed a comprehensive literature search of major databases from January 1995 to August 2015 and include 24 studies with 590 patients. The study found a bone union rate of 97.26% across all included studies. Poor bone results occurred in 8% of cases (95% confidence interval [CI] 0.04-0.12; $I^2 = 44.1\%$, $p=0.065$), and poor functional results occurred in 10% of cases (95% CI: 0.05-0.14; $I^2 = 34.7\%$, $p=0.121$). Complication rates included refracture (4%), malunion (7%), infectious recurrence (5%), knee stiffness (12%), amputation (4%), limb edema (13%), and peroneal nerve palsy (13%). The study's limitations include high heterogeneity of the included studies, potential publication bias, exclusions of non-English language studies, reliance on observations study designs for all included studies, and variability in treatment protocols and outcome measures.

Nonrandomized Studies

Zhang (2017) conducted a retrospective analysis of 41 patients with femoral nonunion and segmental bone defects greater than 6 cm (range 6-17 cm) treated by distraction osteogenesis.^[16] The monolateral external fixation was applied by a single surgeon at a trauma center between January 2010 and January 2014, evaluating bone union, duration of distraction osteogenesis, time to consolidation, external fixation index, complications, and additional surgical interventions using modified ASAMI criteria. All patients achieved healing with no recurrence or newly developed infection, and average time needed for healing was 13 months. Complications included 3 cases of axial deviation, 5 cases of docking site nonunion, 23 cases of pin-tract infection, 14 cases of knee joint stiffness or declined joint mobility, 2 cases of insufficient osteogenesis in the distraction area, 1 case of refracture, and 2 cases of loose external fixation pins. Fracture healing evaluations were excellent in 30 patients, good in 6 patients, fair in 5 patients, and poor in 0 patients, while postoperative function evaluations were excellent in 21 patients, good in 9 patients, fair in 7 patients, and poor in 4 patients. Study limitations include the retrospective design, lack of control group, single-surgeon and single-

center experience, absence of standardized outcome measures beyond modified ASAMI criteria, variable bone defect sizes (6-17 cm) creating heterogeneous patient population, no specification of follow-up duration, and potential selection bias in patient inclusion criteria.

Xu (2015) conducted a retrospective review of 12 patients (mean age 46.5 years) treated for hypertrophic nonunion presented with two-plane angular deformities (mean 19 degrees and 23.5 degrees in sagittal and frontal plane respectively) and limb-length discrepancy (mean 3.8 cm).^[17] The Ilizarov apparatus was used to simultaneously treat the nonunion, malalignment, and limb-length discrepancy. Bone union was achieved in all cases within an average of 8 months after a single surgery without need for additional procedures, and no patients had recurrence of limb-length discrepancy or malalignment during the mean follow-up duration of 42 months after apparatus removal. Complications of superficial pin-tract infections and mild Achilles tendon contracture were observed but resolved over time, and all patients were satisfied with the surgical outcome. Study limitations include the retrospective design, small sample, lack of control, absence of validated outcome measures, potential selection bias, and single-institution experience.

Vukasinovic (2012) conducted a multicenter observation study evaluating the Ilizarov method for 16 patients in the treatment of infected tibial nonunions.^[18] Bone and functional results were classified as excellent, good, fair, or poor, with a mean total follow-up period of 48.77 ± 41.57 months. Fifteen cases (93.75%) achieved successful bone union and resolution of local infection based on laboratory findings of inflammation. Lower limb length inequality was corrected through new bone formation with an average length of 5.75 ± 3.29 cm. Poor results occurred in one patient (6.25%). Patient satisfaction was scored at 3.73 ± 1.33 and physician satisfaction at 4.33 ± 1.11 . The study's limitations include the small sample size, non-randomized observational design, absence of standardized outcome measures, potential selection bias, and wide variability in follow-up duration.

PRACTICE GUIDELINE SUMMARY

No clinical practice guidelines were identified which addressed bone lengthening for individuals with any condition, including congenital limb length discrepancies, post-traumatic limb length discrepancies, and correction of angular deformities of the limb (arm, forearm, thigh or leg).

SUMMARY

Medically Necessary

There is enough research to show that bone lengthening improves health outcomes for individuals with congenital or post-traumatic limb length discrepancies, and correction of angular deformities of the limb (arm, forearm, thigh or leg). Therefore, bone lengthening may be considered medically necessary when policy criteria are met.

Not Medically Necessary

For all other indications, excluding short stature, and for individuals who do not meet policy criteria, bone lengthening for congenital or post-traumatic limb length discrepancies, and correction of angular deformities of the limb (arm, forearm, thigh or leg) has not been shown to improve health outcomes and therefore is considered not medically necessary.

Cosmetic

Bone lengthening for the sole purpose of altering short stature, in the absence of limb length discrepancy or deformity, is considered cosmetic.

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CODES

Codes	Number	Description
CPT	0594T	Incision of upper arm bone and insertion of bone-lengthening device in marrow cavity
	20690	Placement of single direction external bone stabilizing device to arm or leg
	20692	Placement of multiple direction external bone stabilizing device to arm or leg
	20693	Revision of external bone stabilizing device under anesthesia
	20696	Placement of multiple direction external bone stabilizing device to arm or leg using imaging
	20697	Placement of multiple direction external bone stabilizing device to arm or leg using imaging guidance
	24420	Reconstruction of upper arm bone
	25391	Lengthening of one of the forearm bones with patient-derived bone graft
	25393	Lengthening of both bones of forearm with patient-derived bone graft
	27458	Incision of thigh bone and insertion of bone-lengthening device in marrow cavity
	27466	Lengthening of thigh bone
	27713	Incision of lower leg bone and insertion of bone-lengthening device in marrow cavity
	27715	Lengthening or shortening of lower leg bones
HCPCS	None	

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