Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

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Type of Submission – Check all that apply:

- [ ] New Policy
- [x] Revised Policy*
- [ ] Annual Review – No Revisions

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0220 Distraction Osteosynthesis**

Clinical content was last revised on 05/02/2014. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

Update History since the last PARP Submission:

02/04/2019-This CPB has been updated with additional background information and references.

Name of Authorized Individual (Please type or print):

Dr. Bernard Lewin, M.D.

Signature of Authorized Individual:

[Signature]
Distraction Osteosynthesis

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers the Ilizarov method for distraction osteosynthesis medically necessary for members who meet both of the following selection criteria:

I. Member has one of the following indications for the Ilizarov procedure:
   A. Angular/rotational deformities of the long bones; or
   B. Bone defects with or without an associated deformity; or
   C. Limb length discrepancies with or without an associated deformity; and

II. Any of the following selection criteria is met:
   A. Member has a leg length discrepancy of more than 6 cm; or
   B. Member has an arm length discrepancy of more than 5 cm; or
   C. Member has a fracture of a long bone that has not healed in 6 or more months, and has tried and failed electrical stimulation (see CPB 0343 - Bone Growth Stimulators (../300_399/0343.html)) and bone grafting (see CPB 0411 - Bone and Tendon Graft Substitutes and Adjuncts (../400_499/0411.html)) or

Policy History

Last Review
02/04/2019
Effective: 03/19/199
Next Review: 02/27/2020

Additional Information

Definitions
D. Member has an angular/rotational deformity of the long bones resulting in functional impairment, and has failed other treatments.

Aetna considers the use of the Ilizarov method to correct short stature as cosmetic.

Aetna considers the Ilizarov method experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established.

Aetna considers femoral shortening a medically necessary acceptable alternative treatment for persons with lower extremity length discrepancies greater than 1 inch (2.5 cm) that limit function.

Aetna considers the use of intramedullary skeletal kinetic distractor for limb lengthening experimental and investigational because its effectiveness has not been established.

Aetna considers pulsed ultrasound as an adjuvant therapy for distraction osteogenesis experimental and investigational because its effectiveness has not been established.

Aetna considers the PRECICE intramedullary limb lengthening system experimental and investigational because its effectiveness has not been established.

Aetna considers implantable magnetically activated nails (Phenix nails) experimental and investigational because their effectiveness has not been established.

**Notes:** Insertion of wires and subsequent osteotomy of the affected limb are performed in the hospital. Removal of the device can be performed in the office/clinic; thus, hospitalization to remove the device is not necessary.

See

[CPB 0549 - Distraction Osteogenesis for Craniofacial Defects](../500_599/0549.html)
**Background**

Distraction osteosynthesis refers to a technique in which a limb is gradually lengthened at a controlled rate across the osteotomy site. The original limb lengthening procedure was first described in the English orthopedic literature by Codvila (1905). In the 1960s, the Wagner method (limb lengthening with cancellous bone grafting and plating of the distraction gap) was introduced into North America, and became the mainstay of limb lengthening in the United States for many years. In this technique, an open mid-diaphyseal osteotomy is carried out across the periosteum, endosteum, and cortex resulting in a 0.5 to 1 cm diastasis; followed by the placement of an external fixation system secured by screws in both the proximal and distal metaphyses. Distraction commences immediately following placement of the fixator. The distraction rate is traditionally set at 1.5 to 2 mm per day. Following attainment of the desired distraction length, iliac crest cancellous bone is grafted into the diastasis in a second operation. The affected bone is plated, and the external distractor is removed. The operated limb does not bear weight for an extended period of time to allow for incorporation of the graft. In a third operation, the plate is removed, and the subject is put on protective weight bearing (Wagner, 1978; Hood and Riseborough, 1981).

A less invasive technique for distraction osteosynthesis was developed by a Russian orthopedist Gavriil Abramovich Ilizarov in the 1950s. His work was introduced to Italy in the 1980s as a result of the former Soviet Union's policy of glasnost, and later to the United States (Frankel et al, 1988). According to Ilizarov's principle of "tension stress", bone and soft tissue will heal and regenerate in a predictable fashion under tension. The Ilizarov procedure comprises 4 phases: (i) corticotomy (a special type of percutaneous osteotomy) and placement of an external fixation system, (ii) latency period, (iii) distraction, and (iv) consolidation. This method has been employed to treat a wide variety of bone defects including limb lengthening while correcting concurrent associated angular and rotational malalignments, transporting bone segments to fill fracture gaps, and healing non-union fractures. Compared to other alternatives such as the Wagner technique, the Ilizarov method requires only one surgical procedure and appears to have fewer complications. Additionally, the Ilizarov procedure allows for simultaneous correction of multiple deformities, early movement of adjacent joints, as well as early weight bearing (Do and Sadove, 1992; Simard et al, 1992).
Cattaneo et al (1993) described the use of the Ilizarov procedure to 97 humeri on 75 patients, with 68 lengthening in 46 patients (27 males and 19 females, average age of 16.5 years) and 29 treatments for non-union in 29 patients (17 males and 12 females, average age of 46 years). For patients who underwent humeral lengthening, results were considered excellent if the projected lengthening was attained, or in the cases of length discrepancy, less than a 3-cm length discrepancy remained, or if axial alignment was acceptable (less than 10 degrees angulation), and scars were minimal. Furthermore, pre-operative function had to be maintained. Outcomes were deemed good if there was only minimal functional loss, and poor if there was a limb discrepancy of greater than 5 cm, angulation of more than 10 degrees and significant loss of function, or a permanent neurological injury. For patients who had treatments for humeral nonunion, consolidation was considered an excellent result, whereas persistence or recurrence of nonunion was considered a poor result. Duration of treatment ranged from 5 to 14 months. Forty-two (91.3 %) of the 46 patients who had undergone humeral lengthening had excellent results, 3 (6.5 %) had good results, and the remaining 1 (2.2 %) had a poor result as a consequence of reduced shoulder motion. There were no major complications associated with this procedure. For patients who underwent treatments for humeral nonunion, 25 (86.2 %) of 29 humeri healed, and 4 (13.8 %) remained ununited. Of these, there were 3 patients aged 55, 70, and 79 years, and 1 patient with irradiated bone. Results of this study indicated that the Ilizarov procedure is effective in humeral lengthening as well as in the treatment of humeral non-union.

Cierny and Zorn (1994) compared conventional methods with the Ilizarov procedure in the treatment of 44 patients with segmental tibial defects. Patients were divided into 2 groups: (i) 21 long bone defects (segmental defects averaged 6.5 cm) were reconstituted by means of transport (part of the Ilizarov procedure that entails sliding a bone fragment internally, producing distraction osteogenesis behind the defect until it is bridged) or distraction methodologies according to the Ilizarov technique, and (ii) 23 subjects (segmental defects averaged 8.5 cm) underwent conventional treatment of reconstruction using tissue transfers and transpositions, massive cancellous grafts, and combinations of internal and external fixation. Total wound consolidation and infection arrest occurred after the first treatment in 71 % of the Ilizarov wounds, and 74 % of the conventionally treated wounds. The major complication rate for the Ilizarov group was 33 %, while that for the conventionally treated group was 60 %. The overall success rate (95 %) were the same for both groups. However, the Ilizarov group averaged 9 fewer
hours in the operating room, 23 fewer days in the hospital, 5 fewer months of disability times, and a saving of nearly $30,000 per application. These findings indicated that the Ilizarov procedure is faster, safer, and less expensive approach than conventional methods for the treatment of segmental tibial defects.

Fadel and Hosny (2005) noted that the Taylor Spatial Frame (TSF) uses the slow correction principles of the Ilizarov system but adds a 6-axis deformity analysis incorporated within a computer program. These researchers used the TSF in lengthening and deformity correction of the lower limbs to treat 22 cases from 1999 to 2001. There were 14 females and 8 males (average age of 16.5 years). Their target was lengthening in 8 cases, correction of deformities in 8 and both in 6. The results were excellent in 18 cases, good in 2, and fair in 2. Despite the cost, patient profile and a steep learning curve, the results were encouraging but less favorable than with the traditional Ilizarov external fixator.

Kristiansen et al (2006) noted that different methods and devices are used to perform lengthening and deformity reconstruction in the tibia. Recently, the TSF has been introduced as a computer-assisted and versatile external ring fixator. Lengthening index (LI) and complications are important result parameters, and the aim of this study was to review our first 20 tibial segments operated with the TSF and compared the results with those of using the traditional Ilizarov external fixator (IEF). These researchers lengthened 20 tibial segments in 20 patients with the TSF. The results were compared with those of 27 tibial segments from 27 patients that were lengthened with the IEF. All segments were operated on with monofocal osteotomies. In the overlapping zone of comparable lengthening distances between 2.4 and 6.0 cm, the LI of 2.4 and 1.8 months/cm was not significantly different between the TSF and IEF groups, respectively (p = 0.17). This non-significant difference was confirmed after adjustment for age. The authors found no difference between the TSF and IEF frames regarding LI and complication rate. However, rotational, translational, and residual deformity correction is easier to perform with the TSF.

Simpson et al (2008) stated that the TSF is a fixation device used to implement the Ilizarov method of bone deformity correction to gradually distract an osteotomized bone at regular intervals, according to a prescribed schedule. These researchers modified conventional technique by: (i) pre-operatively planning a virtual three-dimensional (3D) correction; (ii) basing the correction on the actual location of the frame with respect to the anatomy, immediately compensating for frame
mounting errors; and (iii) calculating the correction based on 3D CT data rather than measurements from radiographs. They performed a laboratory study using plastic phantoms, and a pilot clinical study involving 5 patients. In 20 tibial phantom experiments, these investigators achieved average correction errors of less than 2 degrees total rotation and less than 0.5 mm total lengthening. They observed clinically acceptable corrections with no complications in this pilot clinical study. The authors concluded that their method achieved high accuracy and precision in a laboratory setting, and produced acceptable outcomes in a pilot clinical study.

Naqui et al (2008) noted that correcting multi-planar lower-limb pediatric deformities requires complex and, in many cases, staged procedures. The TSF is a sophisticated external fixator system that can be used to treat simple to complex multi-planar and multi-apical skeletal deformities. These researchers described its use in 53 children during the last 7 years in a variety of pathologies and demonstrate its ease of use and versatility. A review of medical and physiotherapy records, radiographs, and CT scans of all patients treated with a TSF between June 1999 and December 2005 at the Booth Hall Children's Hospital was conducted. Data recorded were etiology of deformity, sex, age, number of previous operations, pre-operative deformity parameters, operative records and frame constructs, treatment regime, frame duration, follow-up protocol, post-treatment deformity, complications, and clinical and radiological outcome. Fifty-three patients between the ages of 12 months and 16 years (mean of 10.7 years) underwent correction programs for 55 limbs (44 tibia and 11 femurs). The etiology of deformity was congenital in 39 cases and acquired in 14. These investigators were able to achieve an acceptable correction of deformity (leg length discrepancy less than 15 mm, angulation less than 5 degrees) in 52 limbs. A number of complications were encountered. The authors demonstrated the TSF's ease of use for both surgeon and patient and its versatility in a variety of pathologies. The advantages of the TSF system are many. It is a simple frame construct, and application is easy. The plan and execution are structured with precise end points; it is a single-stage correction and thus avoids frame modifications. Any residual deformity can be further corrected by use of the same frame. The authors concluded that the TSF is an effective and efficient way to correct a wide variety of simple and complex often obstinate pediatric limb deformities.

Marangoz et al (2008) stated that the TSF has been used commonly in children and young adults. Its use in the tibia is more extensively studied and applied than in the femur. These researchers examined if normal alignment can be achieved with
accuracy during correction of femoral deformities while avoiding major complications in children and young adults. They retrospectively reviewed the clinical and radiographic records of 20 patients (22 limbs), aged 5.9 to 24.6 years, who underwent a TSF for femoral deformity. Etiology included a number of diagnoses of the pediatric age. Minimum follow-up was 4.5 months (mean of 15.7 months; range of 4.5 to 35 months). The mean time in frame was 6.2 months (range of 2.6 to 19 months). Frontal and sagittal plane deformities were corrected to within normal values. A mean limb lengthening of 4.9 cm (range of 1.5 to 9 cm) was performed in 8 femora; 7 of which the limb length discrepancy was a secondary concern. External fixation index in the lengthening subgroup was 2.2 months/cm. The 15 complications in 13 limbs included pin tract infection, knee stiffness, delayed union, skin irritation, and posterior knee subluxation. No complications occurred in 9 limbs. Computer-assisted femoral deformity correction with 6-axis deformity analysis and the TSF is an accurate and safe technique in children and young adults.

McCarthy and colleagues (2008) examined if a monolateral fixator, which allows for correction of angular deformity and displacement in 3 planes, can correct lower extremity deformities to within normal radiographic means (anatomic lateral distal femoral angle, anatomic medial proximal tibial angle, and tibial femoral angle). These researchers retrospectively reviewed the clinical records and radiographs of 22 consecutive patients (25 limbs) who underwent deformity correction using a new multi-axial monolateral external fixator. The patients were 4 to 16 years of age. The authors had a minimum 1.2-year follow-up (mean of 2.14 years; range of 1.2 to 3.1). Those with primary femoral and tibial deformities had improvements in the mean deviation from normal of the anatomic lateral distal femoral angle, anatomic medial proximal tibial angle and tibial femoral angle. Patients with Blount's disease had improvements in the mean anatomic medial proximal tibial angle from 59.9 masculine to 87.8 masculine. Five patients had complications (2 pin site infections, 1 premature consolidation, 1 knee flexion contracture, 1 recurrence of varus). Six patients developed secondary deformities, all of which were corrected using the primary or secondary hinge. The authors concluded that this fixator can produce satisfactory results with relatively few complications.

Wukich and Kline (2008) stated that patients with diabetes mellitus (DM) have higher complication rates following both open and closed management of ankle fractures. Diabetic patients with neuropathy or vasculopathy have higher complication rates than both diabetic patients without these co-morbidities and non-
diabetic patients. Unstable ankle fractures in DM patients without neuropathy or vasculopathy are best treated with open reduction and internal fixation with use of standard techniques. Patients with neuropathy or vasculopathy are at increased risk for both soft-tissue and osseous complications, including delayed union and non-union. Careful soft-tissue management as well as stable, rigid internal fixation are crucial to obtaining a good outcome. Prolonged non-weight-bearing and subsequently protected weight-bearing are recommended following both operative and non-operative management of ankle fractures in patients with DM.

DiDomenico et al (2009) noted that patients who have a diagnosis of DM, diabetic peripheral neuropathy, peripheral vascular disease and experience an unstable ankle fracture present as difficult case scenarios for treating physicians. In addition, patients who have DM, along with the presence of multiple co-morbidities, have been shown to have higher complication rates than patients who do not have DM. These researchers described a relatively safe alternative surgical percutaneous technique using external circular ring fixation in the vascularly compromised diabetic patient with an unstable ankle fracture. This novel technique decreases the risk for soft tissue complications in the high-risk diabetic patient and serves as a definitive method of fixation without the need for additional surgery. It allows the patient to have early and full weight-bearing when indicated in the post-operative period.

The Intramedullary Limb Lengthening Systems (e.g., the Intramedullary Skeletal Kinetic Distractor and the PRECISE)

The Intramedullary Skeletal Kinetic Distractor (ISKD) is an internal limb lengthening device consisting of a telescoping internal limb lengthener, locking screws, and an external hand-held monitor that tracks the rotation of an internal magnet on a daily basis. Implanted after osteotomy, the ISKD lengthens gradually in response to normal movements of the limb. The device allows lengthening to take place internally, thus the risk of infection and scarring from pins moving through the soft tissues is potentially reduced.

The ISKD requires a physical leg movement to "click" the device into lengthening. In this method, there is no risk of accidentally over-stretching the bone due to the lengthener being preset to the desired fully extended length. However, there is a risk of growing the bone too quickly. Bone growth is monitored by measuring changes in the magnetic field of the embedded magnet in the system. The poles of
the magnet change as the device grows. However, if the motion of the leg makes the device grow too quickly, and the magnet switches poles twice between measurements, then that growth is not recorded. This leads to overly rapid growth which can cause a number of issues such as nerve damage or causing breaks in the bone.

Potaczek and colleagues (2008) presented their findings of limb elongation method with the ISKD. Subjects consisted of 5 patients, aged 14 to 16 years, 3 boys and 2 girls, who underwent femur lengthening with the ISKD nail between 2005 and 2007. Initial shortening, surgical procedure, complications, amount of lengthening, lengthening rate, distraction index, time of treatment and mobility of adjacent joints were evaluated. Initial shortening was 4 to 11 cm. No surgical complications were observed, mean time of surgery was 145 mins, mean blood loss was 200 ml. In 3 patients difficulties with initial distraction required manipulations under general anaesthesia. Distraction was complicated in 3 cases: in 2 patients premature consolidation was noted; in 1 case the distraction rate was too high. Mean lengthening rate in the study group was 0.7 mm/day (0.6 to 0.7 mm/day). Mean distraction index was 41.7 days/cm (26.2 to 55 days/cm). Full weight bearing was allowed after mean 234 days (210 to 275 days). Transient decrease of adjacent joint mobility was observed. The authors concluded that the fully implantable, telescopic ISKD eliminated the need of external fixation and associated complications. Early results of limb lengthening with ISKD are encouraging. The authors stated that careful patient selection and pre-operative planning is required; they also noted that further studies and longer follow-up periods are also needed.

Kenawey and associates (2011a) noted that mechanically activated intramedullary lengthening nails are advantageous over external fixator. However, difficulties with the control of the distraction rate are the main drawbacks, which may in turn cause insufficient bone regenerate. These investigators reviewed the findings of of 57 lengthening procedures using ISKD nail in 53 patients (femoral = 45 and tibial = 12). Average length gain was 4.3 +/- 1.6cm. The cause of shortening was post-traumatic (n = 33), congenital (n = 20), post-tumour resection (n = 1), cosmetic femoral lengthening (n = 2) and post-correction of distal femoral varus deformity (n = 1). The desired lengthening was achieved in all patients. The mean follow-up period was 23 +/- 12 months. The healing index for patients with normal bone healing was 1.2 +/- 0.32 months/cm. Complications in femoral lengthening were superficial wound infection (n = 1), premature consolidation (n = 4) and insufficient bone regenerate (n = 11), while in the tibial lengthening, 2 developed equinus...
contractures, 1 had compartment syndrome following implantation of the nail and 1 insufficient bone regenerate. Furthermore, 9 runaway nails and 3 non-distracting nails were present in the femoral lengthening. One non-distracting nail responded to manipulation under anaesthesia, 1 required exchange nailing and accidental acute lengthening of 3 cm took place while manipulating the third nail. Patients with femoral lengthening and those with insufficient regenerate had significantly higher distraction rates (p = 0.006 and 0.003, respectively). Six out of the 9 runaway nails developed insufficient bone regenerate. In addition, 10.7-mm tibial ISKD nails were found to have lower rates of runaway nails compared with other used diameters. The authors emphasized the rule of distraction rates above 1.5 mm/day in the development of insufficient bone regenerate. Distraction problems with these nails are mostly due to dysfunction within the ratcheting mechanism, which may be related to the diameter of the nail. They stated that new designs for mechanically activated nails with a better control mechanism for the distraction rate are required.

Kenawey and co-workers (2011b) stated that control of distraction rate with an ISKD may be problematic and a high distraction rate may result in insufficient bone regenerate. These researchers analyzed 37 consecutive ISKD femoral lengthening procedures in 35 patients with a mean age 33 +/- 11 years and minimum follow-up of 12 months (average of 27 +/- 9 months; range of 12 to 55 months). The average length gain was 42.8 +/- 12.9 mm. A total of 8 patients had problems during distraction: 7 had "runaway nails" and 1 had a non-distracting nail. Insufficient bone regenerate developed in 8 patients. Important risk factors were a distraction rate greater than 1.5 mm/day (9.1 times higher risk), age 30 years or older, smoking, and lengthening greater than 4 cm. Less important risk factors identified were creation of the osteotomy at the site of previous trauma or surgery and acute correction of associated deformities. The authors proposed a radiological classification for failure of bone regeneration: partial regenerate failure (Type I) or complete failure resulting in a segmental defect subdivided according to a length of 3 cm or less (Type IIa) or greater than 3 cm (Type IIb). They concluded that distraction problems with the ISKD were related mostly to internal malfunction of the lengthening mechanism. A distraction rate greater than 1.5 mm/day should be avoided in femoral intramedullary lengthening. Furthermore, smoking should be a contraindication for femoral lengthening.

Schiedel et al (2011) reported the results of intramedullary leg lengthening conducted between 2002 and 2009 using the ISKD in 69 unilateral lengthening involving 58 femora and 11 tibiae. These investigators identified difficulties that
occurred during the treatment and examined if they were specifically due to the implant or independent of it. Paley's classification for evaluating problems, obstacles and complications with external fixators was adopted, and implant-specific difficulties were continuously noted. There were 7 failures requiring premature removal of the device, in 4 due to nail breakage and 3 for other reasons, and 5 unsuccessful outcomes after completion of the lengthening. In all, 116 difficulties were noted in 45 patients, with only 24 having problem-free courses. In addition to the difficulties arising from the use of external fixators, there was almost the same number again of implant-specific difficulties. Nevertheless, successful femoral lengthening was achieved in 52 of the 58 patients (90 %). However, successful tibial lengthening was only achieved in 5 of 11 patients (45 %).

Mahboubian et al (2012) noted that lengthening over a nail and internal lengthening nails have been developed to minimize or eliminate patients' time wearing a frame during femur lengthening. However it is unclear whether either of these 2 approaches results in faster times to union or fewer complications over the other. These investigators examined which technique better achieved: (i) the lengthening goals, (ii) the distraction rate control, (iii) quality of the regenerate bone, (iv) fewer complications, and (v) if SF-36 scores and American Academy of Orthopaedic Surgeons-Lower Limb Module (AAOS-LLM) scores differ in each treatment modality? They retrospectively reviewed the records and radiographs of 11 patients who had 12 ISKD procedures between 2002 and 2005, and 21 patients with 22 femoral lengthening performed as lengthening over nail procedures between 2005 and 2009. Details such as leg length discrepancies, operative time, time of removal of the external fixator or ISKD, and any complications encountered were recorded; SF-36 and AAOS-LLM scores also were compiled. The minimum follow-ups for the ISKD and the lengthening over nail cohorts were 62 months (average of 76 months; range of 62 to 93 months) and 13 months (average of 27 months; range of 13 to 38 months), respectively. These researchers observed no difference in achieving the lengthening goals between the 2 procedures. Distraction was not well-controlled in the ISKD group; the distraction rates were 1.7 mm per day for the fast group (distraction rate greater than 1 mm/day) and 0.84 mm per day for the slow group (less than 1 mm/day). The lengthening over nail group had an average distraction rate of 0.88 mm per day. One of 20 of the patients who had lengthening over a nail had complications requiring additional unanticipated surgeries whereas 6 of 12 patients who had femoral lengthening in the ISKD group had such complications. The authors concluded that based on
their observations, they believe the lengthening over nail technique for femoral lengthening is associated with fewer complications than the ISKD studies.

Jain and Harwood (2012) performed a systematic review to evaluate tibial lengthening procedures with the use of an intramedullary nail. These researchers investigated the hypothesis that lengthening over a nail can reduce the time spent in an external fixator and increase the rate of consolidation, thereby reducing the risk of complications and improving patient satisfaction. These investigators conducted a comprehensive literature search using the MEDLINE, EMBASE and PubMed databases using the key words 'tibia' or 'tibial lengthening' and 'nail'. This search was performed in December 2011 and repeated by both authors. Specific outcome measures were the duration of external fixation, rate of consolidation and complication rates. A total of 6 comparative studies published between 2005 and 2011 consisting of 494 procedures met the inclusion and exclusion criteria and were eligible for critical appraisal. The methodological quality of the studies was variable, and they were not homogenous enough for meta-analysis. Patients who have tibial lengthening over an intramedullary nail spend significantly less time in an external fixator. However, there is no reliable evidence to suggest that the rates of consolidation or complication were any different to those lengthened without an intramedullary nail.

Kim and associates (2012) noted that lengthening over a nail was introduced to reduce the overall complication rate in the classic Ilizarov method. Previous studies reported that an intramedullary nail could decrease the time of external fixation, prevent anatomic mal-alignment and collapse; internal friction, damage to endosteal blood supply and infection rates, however, may be higher. Whether the approach achieves its goals with acceptable complication rates is unclear. These investigators described the results and complications of tibial lengthening over a nail. They retrospectively reviewed 40 patients with 80 lengthened tibial segments over an intramedullary nail between 2004 and 2009. The average age of the patients at the time of surgery was 22 years (range of 18 to 38 years). Functional and psychological outcomes were evaluated using the questionnaires. The average lengthening achieved was 7.73 cm, 23.5% of initial length. The external fixation index was 1.1 months/cm, and bone-healing index was 1.7 month/cm. The most common complications were valgus angulations of tibia in 20 segments (25%) and equinus contracture in 58 segments (72%). Functional and psychological outcomes were satisfactory after surgery. The authors concluded that lengthening over a nail did not fully prevent axial deviation of regenerate. Equinus contracture
was the most common complication but it could be rectified by early intervention such as intramuscular recession or an additional foot frame. Limb lengthening increased functional and psychological outcomes even though there were many complications after surgery.

In a prospective RCT, El-Husseini et al (2013) compared lengthening over an intramedullary nail to the conventional Ilizarov method with regard to percentage length increase, external fixation index, consolidation index and incidence of complications. A total of 31 limbs in 28 patients were included in the study; 15 were lengthened over an intramedullary nail, and 16 limbs were lengthened conventionally. The mean duration of external fixation in the lengthening over nail group was 52.2 days compared to 180.4 days in the conventional group. There was higher incidence of complications in the conventional method group. In comparison with conventional Ilizarov lengthening, lengthening over an intramedullary nail offers a shorter period of external fixation and fewer complications overall, but there is a high incidence of deep intramedullary infection which was serious.

Konofaos et al (2012) described a novel intramedullary device (M-Bone; Phenix, Paris, France) that contains a mechanism for internal osteodistraction and bone transport in patients with segmental bone defects or limb length discrepancy after limb salvage operations. A total of 5 patients with primary bone tumors were enrolled in the study. After implantation, daily lengthening was performed in an outpatient setting either by the patient or with the help of a therapist, without the use of anesthesia. This unique device offers a totally new approach for the treatment of segmental bone defects or limb length discrepancy. It was designed to expand the remaining native bone by a magnetically activated drive system to induce new bone formation using osteodistraction and bone transport.

Thaller and colleagues (2014) stated that limb lengthening and deformity correction with fully implantable systems is becoming more and more widespread. Different actuation techniques are known and every system has its specific limitations in distraction control and/or stability. A new system with magnetic activation offers outstanding options. The mechanism of the Phenix M2 bone lengthening nail (Phenix Medical, France) is driven by a strong external magnet. The device can provide lengthening, shortening and bone transport. Between December 2011 and November 2012, these researchers applied the nail in 10 patients with an average age of 25 years (range of 15 to 40 years). There were 6 femoral and 4 tibial
procedures. The intended distraction goal was achieved in 8 of 10 patients. In 3
cases these investigators simultaneously corrected mal-alignment. Average
lengthening was 4.6 cm (range of 1.3 to 7.6cm). Average distraction index was
0.85 mm/day (range of 0.6 to 1.3 mm/day). Average weight bearing index was 27
days/cm (range of 16 to 37 days/cm). Three patients had revisions due to early
distraction arrest. The early results were comparable to those of other
intramedullary systems in the literature like the ISKD, the Albizzia or the Fitbone
system. All intramedullary procedures require accurate analysis and planning,
advanced operative technique and close follow-up. The custom-made design of
the Phenix nail with unique options for size, stroke and locking provided new
options for small bones and improved stability. The shortening option may be
helpful for soft tissue problems, joint subluxation and additional stimulation of bone
formation. Magnetic forces have to be considered and too much soft tissue around
the nail might be a limiting factor. The authors stated that magnetically activated
Phenix nail offers new therapeutic options in limb lengthening. These preliminary
findings need to be validated by well-designed studies.

Hammouda and colleagues (2017a) examined if trochanteric entry IM lengthening
nails can be used safely (no avascular necrosis (AVN) or proximal femoral
deformity) in the skeletally immature femur. A retrospective review was performed
between 2004 and 2014 to determine all skeletally immature patients younger than
18 years of age who had a reamed IM lengthening nail inserted through the greater
trochanter, with at least 1-year follow-up. A total of 31 femurs were lengthened in
28 patients (17 males and 11 females). The etiology was congenital femoral
deficiency (n = 10), achondroplasia (n = 6), post-traumatic (n = 5), hemi-
hypertrophy (n = 3), Ollier disease (n = 2), and miscellaneous (n = 5). An attending
surgeon was present for all procedures. Mean age at time of surgery was 12.9
years (range of 7 to 17 y). Mean follow-up was 3.5 years (range of 1.4 to 9 years).
The average amount of lengthening was 5.4 cm (range of 3 to 6.7 cm); 24 nails
were 10.7 mm in diameter; 7 nails were 12.5 mm in diameter. Intramedullary
skeletal kinetic distractor was used in 18 femurs and PRECICE in 13 femurs; 10
segments (7 intramedullary skeletal kinetic distractor; 3 PRECICE) experienced 13
complications. None of the patients developed AVN or proximal femoral deformity.
The authors concluded that IM lengthening nails inserted through the greater
trochanter may be utilized in skeletally immature patients without increased risk of
AVN of the femoral head or proximal femoral deformity. Moreover, they stated that
larger trials would be helpful to confirm their hypothesis; they recommended careful surgical technique with liberal use of the image intensifier to avoid trauma to the femoral head blood supply.

**PRECICE Intramedullary System**

The PRECICE intramedullary limb lengthening system is used for lengthening procedures of the tibia and femur bones. Traditional lengthening of bones occurs via an external adjustable fixation system, namely, the Ilizarov method, attached to the leg bones through openings in the tissue. The PRECICE intramedullary limb lengthening system will enable leg lengthening via non-invasive methods through remote control technology that enables adjustment of previously surgically implanted rods. The system is essentially comprised of extension rods, a magnetic actuator, and a hand-held external remote controller (ERC). Once the magnetic actuator and extension rods have been surgically implanted in a sterile fashion, the ERC can be positioned against the skin to non-invasively shorten or lengthen the rods via the magnetic system. Limb lengthening is done for medical conditions such as major fractures, congenital abnormalities, or some forms of bone cancer. This non-invasive method hopes to reduce such complications as infections by eliminating the need for deep tissue exposure while lengthening bones over time. The device was cleared for marketing by the Food and Drug Administration (FDA) in August 2011. Also, there is currently a post-market study of the Ellipse PRECICE Intramedullary Limb Lengthening System to evaluate the performance and safety of this device.

Rozbruch and colleagues (2014) noted that distraction osteogenesis has been used for more than 50 years to address limb-length discrepancy (LLD) and deformity. Intramedullary fixation has been used in conjunction with external fixation to decrease the time in the external fixator and prevent deformity and re-fracture. A new generation of motorized intramedullary nails is now available to treat LLD and deformity. These nails provide bone fragment stabilization and lengthening with reliable remote-controlled mechanisms, obviating the need for external fixation. Motorized intramedullary nails allow accurate, well-controlled distraction, and early clinical results have been positive. The authors stated that the motorized intramedullary nail is an important new tool for the management of LLD and deformity.

Paley et al (2014) stated that implantable limb lengthening using non-invasively
adjusted telescopic nails dated back to 1983. The newest technology is the PRECICE Intramedullary Limb Lengthening System. These investigators performed a retrospective study of the first 65 PRECICE nails for the treatment of LLD (unilateral) and short stature (bilateral). Successful lengthening was achieved in all patients. The authors stated that there were numerous distraction and hardware complications. Despite these, implantable limb lengthening appeared to be the direction for the future of limb lengthening. They stated that “The future for non-invasively adjusted limb lengthening devices is very exciting … Adjustable nails could eventually replace simple locking nails for trauma, allowing adjustability of length post-operatively”. 

Schiedel et al (2014) evaluated the reliability and safety of the PRECICE system. These researchers compared our preliminary results with PRECICE in 24 patients (26 nails) with the known difficulties in the use of mechanical lengthening devices such as the ISKD. They used the Paley classification for evaluation of problems, obstacles, and complications. Two nails were primarily without function, and 24/26 nails lengthened over the desired distance. Lengthening desired was 38 mm and lengthening obtained was 37 mm. There were 2 nail breakages, 1 in the welding seam and 1 because of a fall that occurred during consolidation. External remote controller usage was problematic mostly in patients with femoral lengthening. Adjustment of the ERC was necessary in 10 of 24 cases; 15 cases had implant-associated problems, obstacles were seen in 5 cases, and complications were seen in each of 4 cases. The authors concluded that the reliability of the PRECICE system is comparable to that of other intramedullary lengthening devices such as the ISKD. The motorized ERC and its application by the patients is a weak point of the system and needs strict supervision.

Kirane and co-workers (2014) evaluated the PRECICE nail in terms of:

(i) accuracy and precision of distraction, (ii) effects on bone alignment, (iii) effects on adjacent-joint range of motion (ROM), and (iv) frequency of implant-related and non-implant-related complications. These investigators reviewed medical and radiographic records of 24 patients who underwent femoral and/or tibial lengthening procedures using the PRECICE nail from August 2012 to July 2013 for conditions of varied etiology, the most common being congenital LLD, post-traumatic growth arrest, and fracture malunion. This group represented 29 % of patients (24 of 82) who underwent a limb lengthening procedure for a similar diagnosis during the review period. At each post-operative visit, the accuracy and
precision of distraction, bone alignment, joint ROM, and any complications were recorded by the senior surgeon. Accuracy reflected how close the measured lengthening was to the prescribed distraction at each post-operative visit, while precision reflected how close the repeated measurements were to each other over the course of total lengthening period. No patients were lost to follow-up; minimum follow-up from surgery was 3 weeks (mean of 14 weeks; range of 3 to 29). Mean total lengthening was 35 mm (range of 14 to 65), with an accuracy of 96 % and precision of 86 %. All patients achieved target lengthening with minimal unintentional effects on bone alignment. The knee and ankle ROM were minimally affected. Of the complications requiring return to the operating room for an additional surgical procedure, there was 1 (4 %) implant failure caused by a non-functional distraction mechanism and 6 (24 %) non-implant-related complications, including premature consolidation in 1 patient (4 %), delayed bone healing in 2 (8 %), delayed equinus contracture in 2 (8 %), and toe clawing in 1 (4 %). The authors concluded that this internal lengthening nail is a valid option to achieve accurate and precise limb lengthening to treat a variety of conditions with limb shortening or length discrepancy. Moreover, they stated that randomized, larger-sample, long-term studies are needed to further confirm the effectiveness of these devices, monitor for any late failures and complications, and compare with other internal lengthening devices with different mechanisms of operation.

Shabtai and colleagues (2014) evaluated the PRECICE nail in terms of: (i) healing index, (ii) complications, (iii) accuracy of the device's external controller, and (iv) adjacent-joint ROM. Between January 2012 and May 2013, these investigators treated 66 patients for congenital limb shortening, of whom 21 were treated using this device. During this period, general indications for using the device were patients with LLD of 2 cm or more, with intramedullary canals able to withstand rods of at least 12.5-mm diameter and 230-mm length, without active infection in the affected bone, able to comply with the need for frequent lengthening, and without metal allergies or an implanted pacemaker. These researchers included only those patients who had completed their course of treatment and were currently fully weight-bearing, leaving 18 patients (21 bone segments) available for follow-up at a minimum of 6 months after limb lengthening (mean of 14 months; range of 6 to 22). Mean age was 19 years (range of 9 to 49); 16 femurs and 5 tibias were lengthened a mean of 4.4 cm (range of 2.1 to 6.5). Mean distraction index was 1.0 mm/day (range of 0.5 to 1.8). Healing index, complications, device accuracy, and ROM were recorded. To-date, 10 of the 21 devices have been removed. This was typically done 12 to 24 months after insertion when the bone was solidly healed on
all 4 cortices. Mean healing index was 0.91 months/cm (range of 0.2 to 2.0). There were 7 complications requiring an additional unplanned surgery, including 1 hip flexion contracture, 3 femurs with delayed healing, 1 tibia with delayed healing, 1 hip subluxation/dislocation, and 1 knee subluxation. The external controller was accurate as programmed and actual lengthening amounts were consistent; ROMs of the hip, knee, and ankle were essentially maintained. The authors concluded that the PRECICE nail was completely internal, allowing for satisfactory joint motion during treatment in most patients. Lengthening was achieved in an accurate, controlled manner, and all patients reached their goal length. Complications remain a concern, as was the case with all approaches to this complex patient population. They stated that both future comparative studies and longer-term follow-up are needed. This study provided only Level IV evidence.

Schiedel and colleagues (2014) noted that the PRECICE intramedullary limb lengthening system uses a new technique with a magnetic rod and a motorized ERC with rotational magnetic field. These researchers evaluated the reliability and safety of the PRECICE system. They compared their preliminary results with PRECICE in 24 patients (26 nails) with the known difficulties in the use of mechanical lengthening devices such as the ISKD. They used the Paley classification for evaluation of problems, obstacles, and complications; 2 nails were primarily without function, and 24/26 nails lengthened over the desired distance. Lengthening desired was 38 mm and lengthening obtained was 37 mm. There were 2 nail breakages, 1 in the welding seam and 1 because of a fall that occurred during consolidation; ERC usage was problematic mostly in patients with femoral lengthening. Adjustment of the ERC was necessary in 10 of 24 cases; 15 cases had implant-associated problems, obstacles were seen in 5 cases, and complications were seen in each of 4 cases. The authors concluded that the reliability of the PRECICE system was comparable to that of other intramedullary lengthening devices such as the ISKD. The motorized ERC and its application by the patients was a weak point of the system and needed strict supervision. They noted that in view of the continuing improvements to the system by the manufacturer, current problems with the PRECICE system would probably be addressed. This was a reliability and safety study.

Paley (2015) noted that the PRECICE Intramedullary Limb Lengthening System is a remotely controlled, magnetically driven, implantable limb lengthening intramedullary nail system. It has both European Conformité Européene (CE) mark and United States FDA clearance for its 1st- (2011) and 2nd-generation (2013)
implants. It is indicated for the treatment of LLD and short stature. It has been used worldwide in over 1,000 cases. Its reported and published results in over 250 cases has been excellent with less pain and lower complication rates than with external fixation methods or previous implantable nail systems.

Landge and co-workers (2015) stated that external fixation has long been used for limb lengthening but can result in many complications, such as tethering of the soft tissues, pain, decreased joint motion, scarring, and nerve injury. Recently, a controllable, telescopic, internal lengthening nail was developed to address many of these issues and hopefully improve the overall experience for the patient. The satisfaction rates of internal and external fixation for limb lengthening were compared in 16 patients, all of whom have experienced both methods; 13 out of 16 patients responded to a limb-lengthening questionnaire, developed by the authors for this patient population. Patients preferred the internal device with respect to overall satisfaction, reduced pain, ease of physical therapy, and better cosmetic appearance. When asked which device they would prefer if another surgery was required, all patients chose the internal device. From the patients' perspective, the internal lengthening device is an improvement over the traditional external fixator. The main drawbacks of this study were: (i) small sample size (n = 16), (ii) relatively short follow-up (15 months), (iii) a lack of randomization, and (iv) the use of a non-validated questionnaire. The authors stated that future studies that include a larger group with long-term follow-up would help to confirm these initial findings.

In a retrospective, case-series study, Tiefenboeck et al (2016) determined: (i) safety of the PRECICE nail, (ii) the complication rate, and (iii) functional outcome after magnetic driven intramedullary bone lengthening with a telescopic implant. A total of 10 patients with LLD of lower extremity, treated with an Ellipse PRECICE nail, were included. The mean LLD was 4.7 cm (range of 2.5 to 7.0). In all patients, limb lengthening goals were reached within a range of ± 0.5 cm after a mean time of 53 days. However, in 2 patients, mechanical failures with unintended shortening were observed. In a further patient nail breakage occurred. Overall, 7 patients presented with complications during the follow-up period. The authors concluded that the PRECICE nail represents a new, fully implantable, magnetically driven device for limb lengthening. However, due to a high rate of complications, a close follow-up is needed to identify early implant failures and to avoid severe adverse outcomes. This study provided only Level IV evidence.

Wiebking and associates (2016) described and analyzed the complications
associated with lengthening with the PRECICE nail. These investigators retrospectively reviewed the charts of 9 patients operated between 2012 and 2013 with a PRECICE nail for a (LLD). The mean age of the patients was 32 years (range of 17 to 48). There were 5 femoral and 4 tibial procedures. The causes of LLD were post-traumatic (n = 5) and congenital (n = 4). The mean LLD was 36.4 ± 11.4 mm. The minimum follow-ups were 2 months (average of 5; range of 2 to 9). The mean distraction rate was 0.5 ± 0.1 mm/day. These researchers observed in 7 patients differences in achieving the lengthening goals (average of 1.6 mm; range of -20.0 to 5.0); average lengthening was 34.7 ± 10.7 mm. All patients reached normal alignment and normal joint orientation. An unintentional loss of the achieved length during the consolidation phase was noticed in patients with delayed bone healing in 2 cases. In the 1st case (loss of 20 mm distraction) the nail could be re-distracted and the goal length was achieved. In the 2nd case (loss of 10 mm distraction) the nail broke shortly after the diagnosis and the nail was exchanged. The authors reported of loss of achieved length after lengthening with a telescopic nail; weight-bearing before complete consolidation of the regenerate might be a risk factor for that. They stated that thorough examination of the limb length and careful evaluation of the radiographs were required in the follow-up period; and the PRECICE nail system requires the same vigilance like the other intramedullary systems too. The present study had several drawbacks: (i) small sample size is a universal problem for studies investigating uncommon procedures, such as intramedullary limb lengthening, (ii) these researchers did not consider long-term outcomes, and (iii) they did not compare this new technology with other lengthening techniques (e.g., lengthening over nail, lengthening with other intramedullary distractors). This study should be considered a preliminary report. The authors noted that the new generation nail is said to have remedied the described problems with the PRECICE nail. When ensuring proper instruction of the patients and regular monitoring of the ratio of measured and indicated lengthening, the PRECICE nail is a safe and convenient system for the correction of leg length discrepancies. Irrespective of the nail, healing delays in existing healed bone regeneration should be expected in connection with renewed callus distractions. They stated that post-marketing surveillance is very important to see if the new technology in PRECICE II Nail is safe or not, and to improve the precision and accuracy of the distraction.

Karakoyun and colleagues (2016) reported their experience with the PRECICE nail for limb lengthening in 23 patients. Records of 15 female and 8 male patients aged 14 to 38 (mean of 23.6) years who underwent lengthening of the tibia (n = 6) or
femur (n = 21) using the PRECICE nail were reviewed. The reasons for
lengthening included trauma (n = 7), hemi-hypertrophy (n = 2), focal femoral
deficiency (n = 2), Ellis-van Creveld syndrome (n = 1), hip septic arthritis sequelae
(n = 1), hereditary multiple exostosis (n = 1), club foot sequelae (n = 1), congenital
tibial pseudoarthrosis (n = 1), fibrous dysplasia (n = 1), idiopathic limb length
discrepancy (n = 7), and cosmetic (n = 1). The mean follow-up duration was 20.72
months. The mean lengthening was 48.20 mm, and the mean acute angular
correction was 15.5º. The mean time to full weight-bearing was 5.15 months, and
the mean consolidation index was 1.12 months/cm. The mean maturation index
was 0.78 months/cm. One patient had nail breakage during the consolidation
phase. The nail was replaced by an intramedullary nail until consolidation, after
which another PRECICE nail was used to treat the residual shortening; 8 patients
had over-lengthening and the nails were driven back to the desired length. No
patient had infection. The authors concluded that the PRECICE nail is a viable
option for lengthening of the femur and tibia. The authors also noted that The
PRECICE nail allows both lengthening and shortening but cannot be used in sites
containing previously applied metallic implants. It is not suitable for patients with
excessive angular deformities, infections, or inappropriate medullary canal. These
preliminary findings need to be validated by well-designed prospective studies with
larger sample size and longer follow-up.

Accadbled and associates (2016) stated that intramedullary limb lengthening
systems include mechanical systems (the Albizzia nail and the ISKD nail) as well as
motorized systems with the Fitbone (Wittenstein, Igersheim, Germany) and the
PRECISE (Ellipse Technologies, Irvine, CA) nails. These researchers
hypothesized that limb lengthening using the Fitbone nail was reliable,
reproducible, and comfortable for the patient. Between 2010 and 2013, a
prospective single-center, single-operator study was conducted on patients who
had undergone limb lengthening using the Fitbone nail. The inclusion criteria were
length discrepancy of the limbs equal to or greater than 25 mm or a short stature.
The exclusion criteria were indications for cosmetic reasons and/or growth plates
that were still open. The lengthening parameters were evaluated post-operatively
and at the last follow-up. Lengthening was considered achieved when the
lengthening objective did not differ by more than 5 mm. All complications were
noted. A statistical analysis was performed. A total of 26 Fitbone nails were
implanted in 23 patients (in the femur in 15 cases and the tibia in 11 cases). The
patients’ mean age was 22.5 years (range of 15 to 53) and the mean follow-up was
3.4 years (range of 2 to 5.3). The limb lengthening targeted was obtained in 23
cases (88 %) and the mean lengthening was 45.3 ± 18 mm (range of 20 to 80). The mean time to healing was 277 ± 167 days (range of 86 to 638). The mean healing index was 73 ± 57 days/cm for the femurs and 83.5 ± 65 days/cm for the tibias. The mean complication rate was 15.4 %. The authors concluded that the findings of this study emphasized the good short-term results of this motorized intramedullary lengthening system. Moreover, they stated that an evaluation over the longer term and with a higher number of patients remains necessary.

Laubscher and colleagues (2016) stated that patients undergoing femoral lengthening by external fixation tolerate treatment less well when compared to tibial lengthening. Lengthening of the femur with an intramedullary device may have advantages. These investigators reviewed all cases of simple femoral lengthening performed at their unit from 2009 to 2014. Cases of non-unions, concurrent deformities, congenital limb deficiencies and lengthening with an unstable hip were excluded, leaving 33 cases (in 22 patients; 11 patients had bilateral procedures) for review. Healing index, implant tolerance and complications were compared. In 20 cases (15 patients) the PRECICE lengthening nail was used and in 13 cases (7 patients) the LRS external fixator system. The desired length was achieved in all cases in the PRECICE group and in 12 of 13 cases in the LRS group. The mean healing index was 31.3 days/cm in the PRECICE and 47.1 days/cm in the LRS group (p < 0.001). This was associated with an earlier ability to bear full weight without aids in the PRECICE group. There were more complications with LRS lengthening, including pin site infections and regenerate deformity. Implant tolerance and the patients’ perception of the cosmetic result were better with the PRECICE treatment. The authors concluded that femoral lengthening with the PRECICE femoral nail achieved excellent functional results with fewer complications and greater patient satisfaction when compared with the LRS system in this cohort of patients. This was a small (n =15) retrospective study.

In a retrospective cohort study, Hammouda and colleagues (2017b) evaluated the outcomes of lengthening post-traumatic femoral segments using a recently available magnetic intramedullary (IM) lengthening system. Patients treated for post-traumatic femoral shortening at the authors’ institution between 2012 and 2015 were eligible for this study. These researchers identified 17 femurs lengthened (14 men and 3 women). The mean age was 30 years (range of 11 to 72 years). Main outcome measures were amount of lengthening achieved, consolidation index, and complications encountered. The mean follow-up was 2.2 years (range of 1 to 3.7 years); 16 patients achieved the planned lengthening, a mean of 3.8 cm (range of
2.3 to 6.0 cm). Regenerate consolidation occurred at a mean of 119 days (range of 57 to 209 days). The mean consolidation index was 32 d/cm (range of 16 to 51 d/cm); 3 patients (18 %) experienced complications. The authors concluded that their preliminary results showed that IM lengthening nails may be useful tools in the armamentarium for treatment of femoral post-traumatic injuries. No specific implant-related complications were observed in this cohort. Moreover, they stated that further trials with bigger cohorts are needed to evaluate the efficacy of lengthening nails used in conjunction with acute angular/rotational correction. Furthermore, studies on larger cohorts and other long bones should be considered to confirm these findings. This study provided level 4 evidence.

Hammouda, et al. (2017c) said that antegrade intramedullary (IM) nailing for skeletally immature femur fractures can damage the capital femoral epiphysis blood supply, leading to avascular necrosis (AVN) of the femoral head. Reported AVN rates are 2% for piriformis entry and 1.4% for trochanteric entry. The investigators noted that none of previous reports described IM lengthening nails for limb lengthening procedures. The investigators stated that they have used self-lengthening telescopic nails with a proximal Herzog bend and standard trochanteric entry for femoral lengthening in children. The purpose of this study is to determine whether trochanteric entry IM lengthening nails can be used safely (no AVN or proximal femoral deformity) in the skeletally immature femur. Hammouda, et al. (2017c) performed a retrospective review between 2004 and 2014 to determine all skeletally immature patients younger than 18 years of age who had a reamed IM lengthening nail inserted through the greater trochanter, with at least 1-year follow-up. Thirty-one femurs were lengthened in 28 patients (17 males and 11 females). The etiology was congenital femoral deficiency (10), achondroplasia (6), post-traumatic (5), hemihypertrophy (3), Ollier disease (2), and miscellaneous (5). An attending surgeon was present for all procedures. Mean age at time of surgery was 12.9 years (range, 7 to 17 y). Mean follow-up was 3.5 years (range, 1.4 to 9 y). The average amount of lengthening was 5.4 cm (range, 3 to 6.7 cm). Twenty-four nails were 10.7 mm in diameter. Seven nails were 12.5 mm in diameter. Intramedullary skeletal kinetic distractor was used in 18 femurs and PRECICE in 13 femurs. Ten segments (7 intramedullary skeletal kinetic distractor; 3 PRECICE) experienced 13 complications. None of the patients developed AVN or proximal femoral deformity. IM lengthening nails inserted through the greater trochanter may be utilized in skeletally immature patients without increased risk of AVN of the femoral head or proximal femoral deformity. Larger trials would be helpful to confirm our
hypothesis. The investigators recommended careful surgical technique with liberal use of the image intensifier to avoid trauma to the femoral head blood supply. This study provided level IV evidence.

In a retrospective study, Szymczuk and associates (2017) compared clinical outcomes of femoral lengthening utilizing mono-lateral external fixation versus a magnetically motorized intramedullary nail in patients with congenital femoral deficiency (CFD) with or without fibular hemimelia. This trial included 62 patients with femoral lengthening, 32 patients had mono-lateral external fixation (group A), 30 patients had internal lengthening nail (group B). Mean age was 9.4 ± 3.8 and 15.4 ± 4.9 years for groups A and B, respectively. Mean follow-up was 4.47 ± 2.7 and 1.86 ± 0.7 years for groups A and B, respectively. Mean lengthening achieved was 5.6 ± 1.7 and 4.8 ± 1.4 cm for group A and group B, respectively (p = 0.052). Mean distraction index was 0.7 ± 0.2 mm/d for group A and 0.7 ± 0.2 mm/d for the group B (p = 0.99). Mean consolidation index for group A was 29.3 ± 12.7 and 34.8 ± 11.2 d/cm for group B (p = 0.08). Mean arc of motion before surgery and at final follow-up were similar between groups (p = 0.35). Group A had significantly less ROM at the end of distraction (p = 0.0007) and at consolidation (p < 0.0001). Both groups had similar rates of obstacles and complications. A significant difference between groups was found in the total problems (p < 0.001) specifically with pin site/superficial infection (p < 0.0001). The authors concluded that the intramedullary nail had superior ROM during the lengthening phase and at consolidation and an overall lower problem complication rate, while maintaining similar distraction and healing indices to mono-lateral external fixation. They stated that internal lengthening nails represented a significant advance in technology for CFD lengthening. Level of Evidence = IV (this was a small [n = 30] retrospective study).

Panagiotopolou, et al. (2018) retrieved 15 PRECICE nails 13 patients following lower-limb lengthening. Seven male and three female patients underwent 12 femoral lengthenings. Three female patients underwent tibial lengthening. All patients obtained the desired length with no implant failure. Surface degradation was noted on the telescopic part of every nail design, less on the latest implants. Microscopical analysis confirmed fretting and pitting corrosion. Following sectioning, black debris was noted in all implants. The early designs were found to have fractured actuator pins and the pin and bearings showed evidence of corrosive debris. The latest designs showed evidence of biological deposits.

suggestive of fluid ingress within the nail but no corrosion. The investigators concluded that this study confirms less internal corrosion following modification, but evidence of titanium debris remains.

Fragomen and co-workers (2018) noted that bone lengthening with an internal lengthening nail (ILN) avoids the need for external fixation and requires one less surgical procedure than lengthening over a nail (LON). However, LON has been shown to be superior to femoral internal lengthening using a mechanical nail. The magnetic ILN, a remote-controlled and magnet-driven device, may have overcome the weaknesses of earlier internal lengthening technology and may be superior to LON. In a retrospective study, the authors addressed the following questions: First, is the magnetic ILN more accurate than LON for femoral lengthening? Second, does the magnetic ILN demonstrate more precise distraction rate control than LON? Third, does the magnetic ILN result in faster regenerate site healing, with more robust callus, than LON? Lastly, does the magnetic ILN result in fewer complications, including impediments to knee motion, than LON? These researchers compared records and radiographs of 21 consecutive patients with 22 femoral lengthening using LONs and 35 consecutive patients with 40 femoral lengthening using remote-controlled magnetic ILNs. Primary outcomes measured included accuracy, distraction rate precision, time to bony union, final knee ROM, regenerate quality, and complications. The minimum follow-up times for the LON and ILN cohorts were 13 and 21 months, respectively. Patients treated with ILN had a lower post-treatment residual limb-length discrepancy (0.3 mm) than those treated with LON (3.6 mm). The rate of distraction was closer to the goal of 1 mm/day and more tightly controlled for the ILN cohort (1 mm/day) than that for the LON group (0.8 mm/day; SD, 0.2). Regenerate quality was not significantly different between the cohorts. Bone healing index for ILN was not statistically significant. Time to union was shorter in the ILN group (3.3 months) than that in the LON group (4.5 months). A lower percentage of patients experienced a complication in the ILN group (18 %) than in the LON group (45 %). Knee flexion at the end of distraction was greater for ILN patients (105°) than that for LON patients (88.8°), but this difference was no longer observed after 1 year. The authors concluded that femoral lengthening with magnetic ILN was more accurate than with LON. The magnetic ILN comported the additional advantage of greater precision with distraction rate control and fewer complications. Both techniques afforded reliable healing and did not significantly affect knee motion at the final follow-up. The magnetic ILN method showed no superiority in regenerate quality and healing rate. This was a small (n = 35) retrospective study.

Iobst and colleagues (2018) described the outcomes of acute, fixator-assisted deformity correction with gradual lengthening using the retrograde femoral PRECICE nail. These investigators analyzed a retrospective series of 27 patients in whom an external fixator was combined with a PRECICE nail to correct angular or rotational deformity and limb-length discrepancy. The fixator was applied temporarily to restore normal alignment. The PRECICE nail was inserted and locked in place to hold the correction, with gradual restoration of limb length. The 27 patients (mean age of 28 years) had a mean follow-up of 13 months. Secondary deformities were mainly valgus (15 patients) and varus (10 patients). Post-operatively, 93 % of patients had correction of limb length to within 3 mm of the discrepancy (mean lengthening of 30 mm). Mechanical axis deviation was corrected to within 8 mm of neutral (i.e., zero) in 81 % of patients. The mechanical lateral distal femoral angle was corrected to a mean of 88° post-operatively. Final Association for the Study and Application of Methods of Ilizarov (ASAMI)-Paley scores were excellent for 96 % of patients. These researchers noted that the use of intramedullary lengthening nails has revolutionized the field of limb lengthening. The results of this study showed that a retrograde femoral PRECICE nail could be used safely and accurately to correct both limb-length discrepancy and deformity with minimal complications. The benefits of using this implant included the ability to maintain knee ROM during the lengthening process; and rapid bone healing allowed a relatively fast return to weight-bearing ambulation. The authors concluded that the PRECICE nail was effectively used to correct both limb-length discrepancy and deformity, with excellent overall outcomes. This surgical technique may help avoid the complications that could occur with prolonged post-operative use of an external fixator. This was a small [n = 27] retrospective study with short-term follow-up [13 months] (Level IV evidence).

An assessment of the PRECICE Intramedullary Limb Lengthening System by the Canadian Agency for Drugs and Technologies in Health (CADTH) (Young & Adcock, 2017) stated that "Overall, the evidence appeared to support the use of the PRECICE nail, which was generally favoured or considered equivalent to either limb reconstruction system external fixation or the intramedullary skeletal kinetic distractor system for the outcomes assessed. Limitations of the evidence, including variation in the length of follow-up, a study sample sizes, and a lack of randomization to treatment arms, made it difficult to draw definitive conclusions regarding the clinical effectiveness of the PRECICE nail."

The CADTH assessment (Young & Adcock, 2017) included evidence from three non-randomized studies regarding the clinical effectiveness for the use of the PRECICE intramedullary system for the correction of lower or upper limb deformities in adults and children (citing Szymczuk, et al. (2017), Hammouda, (2017) and Laubscher, et al. (2016). Only studies with a comparison group of another limb lengthening system or comparison to no treatment were included in the analysis. Uncontrolled, single-arm trials were excluded.

The CADTH assessment found that the PRECICE nail was generally favored or considered equivalent to either limb reconstruction system (LRS) external fixation or the intramedullary skeletal kinetic distractor (ISKD) system for the outcomes assessed. Regarding the mean lengthening achieved, two studies (Szymczuk, et al., 2017; Laubscher, et al., 2016) observed a higher value in the LRS group than in the PRECICE group. One study (Hammouda, et al., 2017) found the mean lengthening achieved to be higher in the PRECICE group compared to the ISKD group. However, these differences did not achieve statistical significance, and the femur lengthening goal was achieved in a large majority of patients, regardless of their treatment group. Two studies (Szymczuk, et al., 2017; Laubscher, et al., 2016) that monitored range of motion reported better movement in the PRECICE groups, although this difference was not always statistically significant. One observation made in these studies is that the PRECICE nail was less prone to pin site of superficial infections than LRS external fixation.

The assessment said that the included literature had several strengths (Young & Adcock, 2017). In the three non-randomized studies, the objective, inclusion and exclusion criteria, interventions of interest, and main outcomes were explicit and described with an appropriate amount of detail. Patient characteristics, including age, gender, patient history, and underlying etiology were also stated. Patients appeared to be recruited to both treatment groups throughout the same time period. Because these were retrospective reviews, patient populations, staff, and care settings are likely representative of those of interest, which should increase the generalizability of the results.

The CADTH assessment (Young & Adcock, 2017) stated that, due to the non-randomized nature of these studies, all three included publications were susceptible to a number of biases that may have influenced the effectiveness of their results.
For example, none of these studies considered potentially confounding characteristics when forming treatment groups or when analyzing the outcomes measured.

The CADTH assessment noted that there were differences in the time of follow-up and age of patients between treatment groups in all studies, which may have had an effect on the measurement of outcomes (Young & Adcock, 2017). The authors of one study (Szymczuk, et al., 2017) noted that the PRECICE nail was used in patients older than 9 years of age, but the limb reconstruction system (LRS) system was used in children as young as 3 years old. This approach may have resulted in the LRS group being overrepresented by potentially higher risk patients. In all three non-randomized studies, the patients and outcome assessors were aware of their treatment interventions (unblinded). In two studies (Szymczuk et al., 2017; Hammouda, et al., 2017) the characteristics of patients that were excluded from the study due to insufficient follow-up data were not described. One study (Laubscher, et al., 2016) relied on patient interviews following the completion of their treatment for data on patient pain, ability to perform activities of daily life, and patient preference to repeat their procedure with the same lengthening system. Because of the time between treatment and patient interviews, this information would be susceptible to a recall bias. Several of the authors of one study (Hammouda, et al., 2017) disclosed financial ties to companies involved with limb lengthening devices, including Ellipse Technologies, the developer of the PRECICE system. In addition, the sample sizes ranged from 22 in the Laubscher et al. (2016) study to 62 in the Szymczuk et al. (2017) study.

The assessment (Young & Adcock, 2017) concluded: "Although the results indicate favourable outcomes for patients undergoing lengthening with the PRECICE nail, decision-makers must take into consideration the limitations of these studies that were identified in this report. In addition, the authors of one study [citing Szymczuk, et al., 2017] advised that the PRECICE nail is not as practical in children with congenital femoral deficiency under the age of 9, whereas the monolateral external fixator can be used in children as young as 3 years of age. This suggests that patient characteristics must be considered when deciding on the appropriate treatment for the target population." The assessment stated: "Overall, insufficient evidence, which provided answers to our research question, was available. No relevant health technology assessments, systematic reviews, meta-analyses, or
randomized controlled trials were identified regarding the clinical effectiveness of
the use of the PRECICE intramedullary system for the correction of lower or upper
limb deformities in adults and children."

Low-Intensity Pulsed Ultrasound

In a systematic review of randomized controlled trials (RCTs), Busse and
colleagues (2009) examined the effectiveness of low-intensity pulsed ultrasound
(LIPUS) for healing of fractures. Electronic literature search without language
restrictions of CINAHL, Embase, Medline, HealthSTAR, and the Cochrane Central
Registry of Controlled Trials, from inception of the database to 10 September 2008
was performed. Eligible studies were RCTs that enrolled patients with any kind of
fracture and randomly assigned them to LIPUS or to a control group. Two
reviewers independently agreed on eligibility; 3 reviewers independently assessed
methodological quality and extracted outcome data. All outcomes were included
and meta-analyses done when possible. A total of 13 randomized trials, of which 5
assessed outcomes of importance to patients, were included. Moderate quality
evidence from 1 trial found no effect of LIPUS on functional recovery from
conservatively managed fresh clavicle fractures; whereas low quality evidence from
3 trials suggested benefit in non-operatively managed fresh fractures (faster
radiographic healing time mean of 36.9 %, 95 % confidence interval [CI]: 25.6 % to
46.0 %). A single trial provided moderate quality evidence suggesting no effect of
LIPUS on return to function among non-operatively treated stress fractures. Three
trials provided very low quality evidence for accelerated functional improvement
after distraction osteogenesis. One trial provided low quality evidence for a benefit
of LIPUS in accelerating healing of established non-unions managed with bone
graft. Four trials provided low quality evidence for acceleration of healing of
operatively managed fresh fractures. The authors concluded that evidence for the
effect of LIPUS on healing of fractures is moderate to very low in quality and
provided conflicting results. Moreover, they stated that although overall results are
promising, establishing the role of LIPUS in the management of fractures requires
large, blinded trials, directly addressing patient important outcomes such as return
to function.

In a prospective RCT, Dudda et al (2011) examined the effect of LIPUS during
distraction osteogenesis. A total of 36 patients who underwent distraction
osteogenesis (greater than 2 cm) were enrolled; 16 patients in the treatment group
received LIPUS, and 20 patients as control group did not. Ultrasound treatment
device was transcutaneously applied at the distraction gap for 20 mins daily (frequency 1.5 MHz, signal burst with 200 μs, signal repetition frequency 1.0 kHz, intensity 30 mW/cm(2)). Evaluation of patients was performed by standard radiographs every 3 weeks to 4 weeks. Average transport distance was 7.0 cm in the ultrasound group, and 6.3 cm in the control group. Mean Paley index for the ultrasound group was 1.09 months/cm and 1.49 months/cm for the control group. Mean distraction consolidation index for the ultrasound group was 32.8 days/cm and 44.6 days/cm for the control group. The calculated indices indicated no significant statistical difference between the 2 groups (p < 0.116) but the fixator gestation period could be decreased for 43.6 days in the treatment group. The authors concluded that therapeutic application of LIPUS during callus distraction constitutes a useful adjuvant treatment during distraction osteogenesis and has a positive effect on healing time with no negative effects.

Salem and Schmelz (2014) noted that LIPUS has been shown to improve callus maturation with distraction osteogenesis in animal trials. However, only few clinical studies are available to support its widespread use for the latter indication in humans. In this study, a total of 21 patients undergoing callus distraction for post-traumatic tibial defects were randomized into 2 groups: (i) the trial group (12 men; mean age of 32 years) received 20 minutes of LIPUS daily during treatment and (ii) the control group (6 men and 3 women; mean age of 29 years) with no LIPUS treatment. The Ilizarov ring fixator was used in all cases. Results were examined clinically and radiologically; callus maturation was analyzed with a computer-assisted measurement. Patients in the LIPUS group needed a mean of 33 days to consolidate every 1 cm of new bone in comparison to 45 days in the control group. The healing index was therefore shortened by 12 days/cm in the LIPUS group. This means that callus maturation was 27 % faster in the LIPUS group. The fixator time was shortened by 95 days in the LIPUS group. The overall daily increase in radiographic callus density was 33 % more in the LIPUS group than in the control group. The authors concluded that LIPUS treatment is an effective non-invasive adjuvant method to enhance callus maturation in distraction osteogenesis. With the help of this treatment, the healing time and the duration of external fixation can be reliably shortened. This was a small study (n = 12); its findings need to be validated by well-designed

In a systematic review with meta-analysis, Raza et al (2016) analyzed the available scientific literature regarding the effects of LIPUS on stimulating bone regeneration and bone maturation during distraction osteogenesis in humans and examined if
the stimulatory effect of LIPUS can effectively reduce the associated treatment time. Studies were considered for inclusion if they were randomized clinical trials that examined the effect of LIPUS on distraction osteogenesis compared to conventional distraction osteogenesis. The primary outcome was reduced treatment time. Study selection, risk of bias assessment, and data extraction were performed in duplicate. A random-effects meta-analysis model was used when more than 3 trials were eligible for a quantitative analysis and considering the expected differences in interventions and measurement tools. A total of 5 randomized clinical trials, with a moderate-to-high risk of bias, met the eligibility criteria; 4 trials examining tibial distraction osteogenesis in 118 patients were combined in a meta-analysis. A statistically significant difference for reduced treatment time between distraction osteogenesis with LIPUS and standard distraction osteogenesis was evident (mean difference, -15.236 d/cm; random-effects 95% CI: -19.902 to -10.569 d/cm; p < 0.0001). As for the mandible, only 1 clinical trial was available, which showed no significant effect of LIPUS therapy on distraction osteogenesis. The authors concluded that current available evidence suggested that LIPUS therapy may provide a reduction in the overall treatment time for tibial distraction osteogenesis. However, they stated that this conclusion should be considered with caution, given the moderate to high risk of bias in the included randomized clinical trials.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20690</td>
<td>Application of a uniplane (pins or wires in one plane), unilateral, external fixation system</td>
</tr>
<tr>
<td>20692</td>
<td>Application of a multiplane (pins or wires in more than one plane), unilateral, external fixation system (e.g., Ilizarov, Monticelli type)</td>
</tr>
<tr>
<td>20693</td>
<td>Adjustment or revision of external fixation system requiring anesthesia (e.g., new pin(s) or wire(s) and/or new ring(s) or bar(s))</td>
</tr>
<tr>
<td>20694</td>
<td>Removal, under anesthesia, of external fixation system</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>20696</td>
<td>Application of multiplane (pins or wires in more than one plane), unilateral, external fixation with stereotactic computer-assisted adjustment (eg, spatial frame), including imaging; initial and subsequent alignment(s), assessment(s), and computation(s) of adjustment schedule(s)</td>
</tr>
<tr>
<td>20697</td>
<td>exchange (ie, removal and replacement) of strut, each</td>
</tr>
<tr>
<td>27465</td>
<td>Osteoplasty, femur; shortening (excluding 64876)</td>
</tr>
<tr>
<td></td>
<td>CPT codes not covered for indications listed in the CPB:</td>
</tr>
<tr>
<td>20979</td>
<td>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)[pulsed]</td>
</tr>
<tr>
<td></td>
<td>Other HCPCS codes related to the CPB:</td>
</tr>
<tr>
<td>E0747</td>
<td>Osteogenesis stimulator, electrical, noninvasive, other than spinal applications</td>
</tr>
<tr>
<td>E0760</td>
<td>Osteogenesis stimulator, low intensity ultrasound, non-invasive</td>
</tr>
<tr>
<td>G0283</td>
<td>Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care</td>
</tr>
<tr>
<td></td>
<td>ICD-10 codes covered if selection criteria are met:</td>
</tr>
<tr>
<td>M21.051 - M21.069</td>
<td>Other acquired deformities of hip, genu valgum or genu varum</td>
</tr>
<tr>
<td>M21.151 - M21.169</td>
<td>Other specified acquired deformities of limbs</td>
</tr>
<tr>
<td>M21.20 - M21.279</td>
<td>Unequal limb length (acquired), femur, tibia, fibula</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td>----------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>M21.961 - M21.969</td>
<td>Unspecified acquired deformity of lower leg</td>
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<tr>
<td>M80.00x+ - M80.88x+</td>
<td>Malunion or nonunion of fracture</td>
</tr>
<tr>
<td>M84.311+ - M84.68x+</td>
<td>Atypical femoral fracture</td>
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<tr>
<td>S42.001+ - S42.92x+</td>
<td>Other congenital deformities of hip, congenital deformity of knee, and congenital malformation of knee</td>
</tr>
<tr>
<td>S49.001+ - S49.929+</td>
<td>Congenital genu recurvatum and bowing of long bones of leg</td>
</tr>
<tr>
<td>S52.001+ - S52.92x+</td>
<td>Congenital genu recurvatum and bowing of long bones of leg</td>
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<td>S59.001+ - S59.299+</td>
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<td>S62.001+ - S62.92x+</td>
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<td>S72.001+ - S72.92x+</td>
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<td>S79.001+ - S79.929+</td>
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<tr>
<td>S82.001+ - S82.92x+</td>
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<tr>
<td>S89.001+ - S89.399+</td>
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<tr>
<td>S92.001+ - S92.919+</td>
<td>Congenital genu recurvatum and bowing of long bones of leg</td>
</tr>
<tr>
<td>M84.750+ - M84.759+</td>
<td>Atypical femoral fracture</td>
</tr>
<tr>
<td>Q65.81 - Q65.89, Q68.2, Q74.1</td>
<td>Other congenital deformities of hip, congenital deformity of knee, and congenital malformation of knee</td>
</tr>
<tr>
<td>Q68.2 - Q68.5</td>
<td>Congenital genu recurvatum and bowing of long bones of leg</td>
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<tr>
<td>Q71.40 - Q71.93</td>
<td>Reduction deformities of upper limb involving humerus, radius, and ulna</td>
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<tr>
<td>Q72.40 - Q72.93</td>
<td>Reduction deformities of lower limb involving femur, tibia and fibula</td>
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<tr>
<td>Q74.2</td>
<td>Other congenital malformations of lower limb(s), including pelvic girdle</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
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<tr>
<td></td>
<td>ICD-10 codes not covered for indications listed in the CPB:</td>
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<tr>
<td>E23.0</td>
<td>Hypopituitarism [pituitary dwarfism]</td>
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<tr>
<td>E34.3</td>
<td>Short stature due to endocrine disorder</td>
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<tr>
<td>Q77.0 -Q77.1</td>
<td>Osteochondrodysplasia</td>
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<tr>
<td>Q77.4 - Q77.5</td>
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<tr>
<td>Q77.7 - Q77.9</td>
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<tr>
<td>Q78.4</td>
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<tr>
<td>R62.50, R62.59</td>
<td>Other and unspecified lack of expected normal physiological development in childhood</td>
</tr>
<tr>
<td>R62.52</td>
<td>Short stature (child)</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:

8. Pons JMV. Lengthening in achondroplasia [summary]. IN99003. Barcelona, Spain: Catalan Agency for Health Technology Assessment and Research (CAHTA); April 1999.


70. Public Health Wales Observatory. What is the evidence on the clinical and cost-effectiveness of the motorised intramedullary nail for the management of limb-length discrepancy and deformity (with particular


04/26/2019


AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0220 Distraction Osteosynthesis

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania updated 02/04/2019