Clinical Policy Title: Arthroscopic anterior cruciate ligament surgery — skeletally immature

Clinical Policy Number: 14.03.08

Effective Date: May 1, 2017
Initial Review Date: April 19, 2017
Most Recent Review Date: April 19, 2017
Next Review Date: April 2018

Related policies:

CPI 14.03.03 Treatment of leg length discrepancy

ABOUT THIS POLICY: AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of arthroscopic anterior cruciate ligament (ACL) reconstruction in skeletally immature members to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Skeletally immaturity confirmed with both:
  - Anterior-posterior left hand and wrist radiography.
  - Tanner stage II or III.
- Documentation of:
  - ACL injury or associated knee injury on clinical examination and imaging; magnetic resonance imaging (MRI) is preferred.
  - Knee laxity.
  - Functional impairment (e.g., Lysholm Knee Scoring scale).
  - Activity level (e.g., Tegner activity level scale).
- One of the following clinical indications:
- Unresponsive to at least six weeks of conservative therapy (See Alternative covered services).
- Concomitant repairable meniscal tear.
- Significant or recurring knee instability.

Limitations:

- All other uses of arthroscopic ACL reconstruction in skeletally immature members are not medically necessary.
- Diagnostic arthroscopy as an isolated diagnostic procedure is not medically necessary. It may be medically necessary to check for associated intra-articular injuries (such as meniscal tears and chondral surface injuries) during surgical intervention for a correctable ACL lesion.

Alternative covered services:

- Activity modification.
- Functional bracing.
- Non-steroidal anti-inflammatory drug therapy.
- Instruction in self-directed exercises to strengthen the quadriceps and hamstring muscles.
- Range-of-motion exercises.
- Proprioceptive exercises.

Background

The ACL is one of four ligaments critical to stabilizing the knee joint. It restrains forward motion of the tibia and stabilizes angulation and rotation at the knee joint. Injury to the ACL is most frequently sports-related (e.g., when pivoting or landing from a jump), but injury can occur as a result of nonsport-related trauma, disease, and rough play (American Academy of Orthopaedic Surgeons [AAOS], 2014).

Treatment for an ACL injury depends upon the patient’s individual needs and injury severity. ACL injury is graded on a severity scale from 1 to 3. A grade 1 sprain has mild damage and the knee joint is still stable. A grade 2 sprain is a partial tear with the ligament stretched and damaged. A grade 3 sprain is a complete tear of the ligament, and it is the most common (AAOS, 2014). Nonsurgical treatment (e.g., bracing, physical therapy, and self-directed exercises) may be effective for patients with a stable knee or a very low activity level. The duration of treatment depends on objective evidence of functional progress.

Surgically, ACL tears cannot be repaired or sewn together but must be replaced with a tissue graft to restore stability to the knee joint. A patellar tendon, hamstring tendon, cadaver graft, or, sometimes, quadriceps tendon can be used. Grafts are held in place with a fixation device (often a screw) by tunneling a hole in the femur and one in the tibia. ACL reconstruction can be performed arthroscopically or via open arthrotomy (AAOS, 2014).
The number of ACL injuries in children and adolescents has increased over the past 20 years (Leathers, 2015; Mall, 2014). Contributors to this trend include greater participation in organized activities, greater awareness, improved diagnostic imaging, obesity, previous injury, and decreased neuromuscular control of the trunk and lower extremities (LaBella, 2014). ACL injury rates increase sharply during puberty, especially for girls (LaBella, 2014). An ACL injury in a child can result in months of rehabilitation, time lost from school and activity participation, and, if not properly treated, more and often permanent damage to the knee.

Previously, ACL reconstruction was limited to skeletally mature individuals, because early growth plate closure or alignment deformities could result from ACL surgery in a child who has not reached skeletal maturity (Kocher, 2002). However, knees that are unstable as a result of ACL tears have a high chance of meniscus tears and cartilage injury that could result in permanent damage if the ACL is not fixed (Accadbled, 2010). New ACL reconstruction techniques eliminate the need to drill tunnels across the growth plate (physeal-sparing) or keep the primary fixation away from the growth plate (e.g., transphyseal), and can be customized to the growing child’s age (Leathers, 2015; Mall, 2014; Accadbled, 2010).

**Searches**

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 30, 2017. Search terms were: "Anterior Cruciate Ligament Reconstruction"(MeSH), "Adolescent"(MeSH), "Child"(MeSH), "Anterior Cruciate Ligament"(MeSH), "Anterior Cruciate Ligament Reconstruction"(MeSH), "Anterior Cruciate Ligament Injuries"(MeSH), and "Arthroscopy"(MeSH).

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.
Findings

We identified five systematic reviews and meta-analyses (Dunn, 2016; Ramski, 2014; Vavken, 2011; Kaeding, 2010; Frosch, 2010), two evidence-based guidelines (AAOS, 2014; LaBella, 2014) and no economic studies for this policy. Current evidence consists of surgical case series and a limited number of cohort studies comparing early ACL surgery (open physes) to either delayed surgery (closed physes) or conservative treatment.

While there is no universally accepted measure of knee ligament integrity, studies integrated subjective examination techniques, objective instrumented devices, and advanced imaging in orthopedic examination. Examples included objective measurement of knee stability (e.g., the Lachman test), subjective knee function scores, and Tegner activity scores. Studies defined skeletal immaturity by Tanner stages, hand and wrist radiographs, and other parameters, in addition to chronological age, which reflects the lack of consensus in the literature and further complicates direct comparisons across studies. In general, studies included physically active children with sustained knee laxity that limited activity participation or activities of daily living. Potential harms of early ACL surgery were rare and included physeal injury, graft failure, and surgical complications.

The evidence is sufficient to recommend early ACL reconstruction in skeletally immature patients (e.g., Tanner stage II or III) with complete ACL tears and knee instability that restricts function and activity levels. The strongest evidence from direct comparisons suggests that, compared to conservative or delayed treatment, early ACL reconstruction in skeletally immature patients with complete ACL tears will result in improved knee stability, knee function, activity levels, and prevention of secondary injury without affecting the growth plates or causing growth disturbances. Indirect comparisons among case series derived similar findings. Many patients initially selected for conservative treatment suffered from secondary damage and crossed over to surgical stabilization.

Guidelines from the AAOS and the American Academy of Pediatrics support ACL reconstruction for skeletally immature patients with high activity demands, who do not respond to medical treatment, with a concomitant repairable meniscal tear, or with significant or recurring instability (AAOS, 2014; LaBella, 2014). Reconstructive surgery should be performed within five months following an isolated ACL injury to avoid further knee damage, but earlier intervention may be needed for concomitant injury to multiple ligaments or the menisci. Conservative or delayed surgical treatment should be reserved for very compliant patients with joint stability, low demands, and no other pathologies. Rehabilitation should focus on returning motion to the joint and surrounding muscles, strengthening the surrounding muscles to protect the new ligament, and returning function tailored to the patient’s needs.

The evidence is insufficient to assess the relative effectiveness of various surgical techniques or types of grafts. Three types of surgical procedures are presented in the current literature: intra-articular, transphyseal, transosseous reconstruction; intra-articular, physeal-sparing, transosseous reconstruction; and combined intra- and extra-articular, physeal-sparing, extraosseous stabilization (Vavken, 2011). Evidence from direct and indirect comparisons suggest no differences in patient-reported outcomes,
anterior-posterior laxity, leg-length discrepancy, or angular deformities between physeal-sparing and transphyseal reconstruction.

Policy updates:

None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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| AAOS (2014) Guideline: Management of ACL injuries | **Key points:**  
  - Surgical reconstruction is recommended for torn ACL based on evidence from one low and two very low strength studies that demonstrated a significant advantage over non-operative treatment in objective knee stability, subjective knee function scores, and Tegner activity score without a clinically significant valgus deformity or limb length discrepancy.  
  - Limited evidence supports non-surgical management for less active patients with less laxity.  
  - When ACL reconstruction is indicated, moderate evidence supports reconstruction within five months of injury to protect the articular cartilage and menisci. |
| LaBella (2014) for the AAP Guideline: ACL injuries: diagnosis, treatment, and prevention | **Key points:**  
  - Lachman test is the most accurate clinical test for acute ACL injury. MRI may be helpful when physical examination is difficult to perform because of pain, swelling, and lack of cooperation and for surgical planning.  
  - Patient’s skeletal age, measured by an anteroposterior radiograph of the left hand and wrist, and Tanner stage help the physician decide the most appropriate treatment of an ACL tear in a skeletally immature athlete.  
  - Activity level and laxity should be determined.  
  - Patients with open physes at Tanner stage III and skeletal age < 14 in girls and < 16 in boys can be offered the option of activity modification, functional bracing, rehabilitation, and careful follow-up.  
  - Indications for early ACL surgery in the skeletally immature patient:  
    - Additional repairable meniscal injury or multiple torn ligaments.  
    - Failed conservative care.  
    - Inability to participate in his or her chosen sport or instability that affects activities of daily living.  
    - Unwilling to comply with activity restrictions and bracing.  
  - Choice of surgical procedure is based on the patient’s skeletal and physiologic age. |
| Dunn (2016) Early operative vs. delayed or non-operative treatment of ACL | **Key points:**  
  - Systematic review and meta-analyses of six cohort studies comparing non-operative vs. operative treatment, and five cohort studies comparing early reconstruction (shortly after injury with open physes) vs. delayed reconstruction (closed physes).  
  - Overall quality: low with high risk of bias due to lack of randomization and statistical
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<td>• Results favor early operative treatment (initiated shortly after injury with open growth plates) over delayed (closed growth plates) or non-operative treatment.</td>
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<tr>
<td>Ramski (2014)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Non-operative vs. operative treatment of ACL</td>
<td>• Systematic review and meta-analysis of six cohort studies (217 total patients) comparing operative to non-operative treatment, and five cohort studies (353 total patients) comparing early to delayed surgery.</td>
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<td>• Overall quality: low with high risk of bias and inconsistently reported outcomes.</td>
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<td>• Post-treatment instability/pathological laxity: 13.6% in the operative group vs. 75% in the non-operative group (three studies; P &lt; .01).</td>
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<td>• Patients were more than 12 times more likely to have a symptomatic medial meniscal tear after non-operative vs. operative treatment (35.4% vs. 3.9%, respectively; two studies; P = .02).</td>
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<td>• There was a significant difference in patient-reported outcome scores favoring operative treatment in one of two studies reporting International Knee Documentation Committee scores (IKDC; P = .002) and in one of two studies reporting Tegner scores (P = .007).</td>
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<td>• None of the patients in the non-operative groups returned to their previous level of play compared with 85.7% of patients in the operative groups (two studies; P &lt; .01).</td>
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<td>Vavken (2011)</td>
<td><strong>Key points:</strong></td>
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<td>ACL treatment in skeletally immature patients</td>
<td>• Systematic review of 39 case series, six cohort studies comparing surgical to non-surgical treatment, and three cohort studies comparing different surgical treatments of complete ACL tears with &gt; six months follow up (1,217 total patients; median study size nine patients [range 1 to 129 patients]).</td>
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<td>• Overall quality: low, mostly single cohorts without controls or randomization and lacking statistical power. Various definitions used for skeletal immaturity.</td>
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<td>• Average follow up 44.7 ± 18.7 months; average age 13.3 ± 1.2 years. Criterion for immaturity = radiologically-confirmed open physes in all but two studies, and 16 studies included Tanner score. Knee stability reported in 44 studies.</td>
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<td>• Conservative treatment resulted in poorer clinical outcomes and a higher incidence of secondary defects, including meniscal and cartilage injury.</td>
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<td>• Studies with the highest level of evidence unanimously reported significantly improved clinical scores and knee laxity after surgical ACL reconstruction vs. conservative treatment (Tanner II and III), with no significant difference in the risk of growth disturbances. Limited but similar results for Tanner I.</td>
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<td>• Immediate treatment (open physes) offered superior outcomes to delayed treatment.</td>
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<td>• No specific surgical treatment showed clearly superior outcomes, yet studies using physeal-sparing techniques reported no growth disturbances.</td>
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<td>Kaeding (2010)</td>
<td><strong>Key points:</strong></td>
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<td>Surgical techniques and outcomes after ACL reconstruction in skeletally immature patients</td>
<td>• Systematic review of 13 case series. Skeletal immaturity defined as having ≥ one of the following criteria: chronologic age &lt; 15 years in boys or &lt; 14 years in girls; bone age &lt; 15 years in boys or &lt; 14 years in girls; Tanner stage I, II, or III; and &lt; 10 cm of total growth after the reconstruction.</td>
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<td>• Both physeal-sparing and transphyseal reconstructions can produce excellent clinical outcomes with a very low incidence of growth complications in Tanner stage II and III.</td>
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Citation | Content, Methods, Recommendations
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Frosch (2010) | Key points:
- Systematic review and meta-analysis of 55 case series (935 total patients) (median age, 13 years; range 1.5 to 16 years; median follow-up of 40 months (range, 14 to 89 months).
- Overall quality: low. No comparative studies included.
- Excellent or good function of all knees on IKDC (grade A or B 84.2%, 95% CI 75.8% to 92.6%) and Lysholm scores (average 96.3, 95% CI 95.5 to 97.2).
- Overall low rates of leg-length differences or axis deviations (1.8%, 95% CI 0% to 3.9%) and re-ruptures (4.8%, 95% CI 2.9% to 6.7%).
- Risk of leg-length differences or axis deviations:
  - Bone-patellar tendon-bone grafts vs. hamstrings (3.6% vs. 2.0%, relative risk [RR] 1.82, 95% CI 0.66 to 5.03).
  - Transphyseal reconstruction vs. physeal-sparing techniques (1.9% vs. 5.8%, RR 0.34, 95% CI 0.14 to 0.81); risk of re-rupture (4.2% vs. 1.4%; RR, 2.91; 95% CI, 0.70 to 12.12).
- Sutures resulted in no growth disturbances, with a weighted re-rupture rate of 4.6% (95% CI 2.6 to 6.7).
- Fixation far from the joint line had a lower re-rupture rate than close fixation (1.4% vs. 3.2%, RR 0.42, 95% CI 0.09 to 1.93).

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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