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.

<table>
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<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 09/01/2019</th>
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<tr>
<td>Policy Number: 0397</td>
<td>Effective Date:</td>
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<tr>
<td>Policy Name: Knee Ligament Arthrometer Testing</td>
<td>Revision Date:</td>
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**Type of Submission – Check all that apply:**

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

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

**CPB 0397 Knee Ligament Arthrometer Testing**

Clinical content was never revised. Additional non-clinical updates were made by Corporate since the last PARP submission, as documented below.

**Update History since the last PARP Submission:**

07/23/2019-This CPB has been updated with additional background information and references.

Name of Authorized Individual (Please type or print): 

Signature of Authorized Individual:

Revised July 22, 2019
Knee Ligament Arthrometer Testing

Number: 0397

Policy

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

Aetna considers knee ligament arthrometer testing experimental and investigational for evaluating ligament laxity in the knee or for other indications because the peer-reviewed medical literature does not support the clinical value of this testing.

Background

There are a number of commercially available knee arthrometers. These devices provide computerized measurements of knee laxity. Knee ligament arthrometer testing can not replace the need for a physical examination and/or magnetic resonance imaging (MRI).

According to the manufacturer of one of the commercially available arthrometers, the KT1000™ (MEDmetric® Corporation, San Diego, CA) was developed to provide objective measurement of the sagittal plane motions of the tibia relative to the femur. This motion, sometimes referred to as drawer motion, occurs when an examiner applies force to the lower limb or when the muscles of the quadriceps are contracted. Although the KT1000 (or KT2000) and other knee ligament
arthrometers have been employed for research purposes for quantifying outcomes of anterior cruciate ligament reconstruction, the peer-reviewed medical literature does not support its reliability, reproducibility, and clinical utility in the general clinical setting.

Spindler et al (2004) performed a evidence-based systematic review of randomized controlled trials assessing patellar tendon versus hamstring tendon autografts. Objective and subjective outcome measures included surgical technique, rehabilitation, instrumented laxity, isokinetic strength, patello-femoral pain, return to pre-injury activity, as well as Tegner, Lysholm, Cincinnati, and International Knee Documentation Committee-1991 scores. Slight increased laxity on arthrometer testing was observed in the hamstring population in 3 of 7 studies. Pain with kneeling was greater for the patellar tendon population in 4 of 4 studies. Only 1 of 9 studies reported increased anterior knee pain in the patellar tendon group. Frequency of additional surgery seemed to be related to the fixation method and not graft type. No study showed a significant difference in graft failure between patellar tendon and hamstring tendon autografts. Objective differences (e.g., range of motion, isokinetic strength, arthrometer testing) were not detected between groups in the majority of studies, suggesting that their sensitivity to detect clinical outcomes may be limited.

Papannagari et al (2006) stated that recent follow-up studies have reported a high incidence of joint degeneration in patients with anterior cruciate ligament (ACL) reconstruction. Abnormal kinematics after ACL reconstruction have been thought to contribute to the degeneration. These investigators hypothesized that ACL reconstruction, which was designed to restore anterior knee laxity under anterior tibial loads, does not reproduce knee kinematics under in-vivo physiological loading conditions. In a controlled laboratory study, these researchers examined both knees of 7 patients with complete unilateral rupture of the ACL with magnetic resonance image, and constructed 3D models from these images. The ACL of the injured knee was arthroscopically reconstructed using a bone-patellar tendon-bone autograft. Three months after surgery, the kinematics of the intact contralateral and reconstructed knees were measured using a dual-orthogonal fluoroscopic system while the subjects performed a single-legged weight-bearing lunge. The anterior laxity of both knees was measured using a KT-1000 arthrometer. The anterior laxity of the reconstructed knee as measured with the arthrometer was similar to that of the intact contralateral knee. However, under weight-bearing conditions, there was a statistically significant increase in anterior translation of the
reconstructed knee compared with the intact knee at full extension (approximately 2.9 mm) and 15 degrees (approximately 2.2 mm) of flexion. Furthermore, there was a mean increase in external tibial rotation of the ACL-reconstructed knee beyond 30 degrees of flexion (approximately 2 degrees at 30 degrees of flexion), although no statistical significance was detected. The authors concluded that the data showed that although anterior laxity was restored during KT-1000 arthrometer testing, ACL reconstruction did not restore normal knee kinematics under weight-bearing loading conditions.

Wiertsema et al (2008) examined the reliability of the KT1000 arthrometer and the Lachman test in patients with an ACL rupture. A total of 20 patients with a complete tear of the ACL were examined in a single session each. During the assessment, 2 physical therapists measured the anterior-posterior translation of the knee using both the KT1000 arthrometer and the Lachman test. One examiner performed a repeated measurement of each test for determination of intra-rater reliability. The examiners were blinded to the findings of their colleague. The intraclass correlation coefficient (ICC) was used to describe the degree of reliability of the measurements. High ICCs were found for the intra-rater reliability and the inter-rater reliability of the Lachman test (ICC = 1.0 and 0.77). For the KT1000 arthrometer both ICCs were clearly lower (ICC = 0.47 and 0.14). The KT1000 arthrometer showed inadequate reliabilities, even when measurements are repeated within a single measurement session. Contrastingly, the Lachman test is a reliable measurement to determine the anterior-posterior laxity of the ACL deficit knee. The results of the present study suggested good within-session intra-rater reliability as well as inter-rater reliability for the Lachman test.

An UpToDate review on “Anterior cruciate ligament injury” (Friedberg, 2013) states that “The KT-1000 knee ligament arthrometer is a device that provides an objective measurement of anterior-posterior translation and is often used in studies evaluating ACL tears. This machine is seldom used in clinical practice because physical examination is generally reliable. Due to the high sensitivity of the Lachman and the high specificity of the pivot shift, we suggest performing both tests to confirm an ACL rupture. The combination of a positive Lachman and a negative pivot shift can mean the ACL is partially torn”.

Lustig and colleagues (2012) noted that the KneeKG™ system was developed with the objective of providing high reliability movement analysis. These researchers reviewed the technical details, clinical evidence, and potential applications of this
system for evaluation of rotational knee laxity. A comprehensive review of the MEDLINE database was carried out to identify all clinical and biomechanical studies related to KneeKG™ system. The KneeKG™ system non-invasively quantifies knee abduction/adduction, axial rotation, and relative translation of the tibia and femur. The average accuracy of the acquisition is 0.4° for abduction/adduction, 2.3° for axial rotation, 2.4 mm for antero-posterior translation, and 1.1 mm for axial translation. This clinical tool enables an accurate and objective assessment of the tri-planar function of the knee joint. The measured biomechanical parameters are sensitive to changes in gait due to knee osteoarthritis and ACL deficiency. The authors concluded that the KneeKG™ system provided reliable movement analysis. They stated that this system has the potential to improve understanding the biomechanical consequences of trauma or degenerative changes of the knee as well as more accurately quantify rotational laxity as detected by a positive pivot-shift test.

Lorbach et al (2012) summarized the development of a simple, objective, and non-invasive measurement device, the Rotameter, for tibio-femoral rotation to assess static rotational knee laxity. The device is based on the dial test with the patient lying prone and the knee flexed to 30°. From measurements of 30 healthy participants, the device achieved high inter- and intra-observer reliability and showed a high correlation of the measured results with the contralateral knees of the participants. Measurements of the device were also performed in a human cadaver study and revealed highly correlated results when compared to the simultaneous measurements of a knee navigation system, which was used as an invasive standard method to assess tibial rotation. In human cadaver specimens, it was shown that a simulated tear of the postero-lateral bundle as well as a complete ACL tear led to a significant increase in isolated tibio-femoral rotation compared to the intact ACL. A retrospective case series investigated the clinical results as well as knee laxity measurements after ACL surgery in-vivo. Rotational, as well as antero-posterior, knee laxity was objectively assessed in 52 patients at a mean post-operative follow-up of 27 months by comparing the measured results with the results of the contralateral unaffected knee in each patient. The clinical results were comparable to the results reported in the literature. Moreover, rotational laxity was successfully restored after ACL reconstruction, whereas anterior-posterior (AP) laxity showed significant differences compared to the contralateral knees although they were defined as clinically successful according to the International Knee Documentation Committee (IKDC) classification. The authors concluded that a
A non-invasive and objective knee rotational measurement device has been developed, which offers good potential for objective quality control in knee ligament injuries and their treatment.

Mouton et al (2012) evaluated the influence of individual characteristics on rotational knee laxity in healthy participants and examined if the contralateral knee of patients with a non-contact ACL injury presents greater rotational knee laxity than a healthy control group. A total of 60 healthy participants and 23 patients having sustained a non-contact ACL injury were tested with a new Rotameter prototype applying torques up to 10 Nm. Multiple linear regressions were performed to investigate the influence of gender, age, height and body mass on rotational knee laxity and to establish normative references for a set of variables related to rotational knee laxity. Multiple analyses of co-variance were performed to compare the contralateral knee of ACL-injured patients and healthy participants. Being a woman was associated with a significantly (p < 0.05) higher rotational knee laxity, and increased body mass was related to lower laxity results. In the multiple analyses of co-variance, gender and body mass were also frequently associated with rotational knee laxity. When controlling for these variables, there were no differences in measurements between the contralateral leg of patients and healthy participants. The authors concluded that in the present setting, gender and body mass significantly influenced rotational knee laxity. Furthermore, based on these preliminary results, patients with non-contact ACL injuries do not seem to have excessive rotational knee laxity.

Ahlden et al (2012) stated that studies have reported that knee kinematics and rotational laxity are not restored to native levels following traditional ACL reconstruction. This has led to the development of anatomic ACL reconstruction, which aims to restore native knee kinematics and long-term knee health by replicating normal anatomy as much as possible. These researchers reviewed current dynamic knee laxity measurement devices with the purpose of investigating the significance of dynamic laxity measurement of the knee; gait analysis was not included. The subject was discussed with experts in the field in order to perform a level V review. MEDLINE was searched according to the discussions for relevant articles using multiple different search terms. All found abstracts were read and scanned for relevance to the subject. The reference lists of the relevant articles were searched for additional articles related to the subject. There are a variety of techniques reported to measure dynamic laxity of the knee. Technical development of methods is one important part toward better understanding of knee kinematics.
Validation of devices has shown to be difficult due to the lack of gold standard. Different studies used various methods to examine different components of dynamic laxity, which makes comparisons between studies challenging. The authors concluded that several devices can be used to evaluate dynamic laxity of the knee. At the present time, the devices are continuously under development. Moreover, they stated that future implementation should include primary basic research, including validation and reliability testing, as well as part of individualized surgery and clinical follow-up.

Barcellona et al (2013) stated that the KT1000 and KT2000 knee joint arthrometers (MEDmetric Corp, San Diego, CA) have been shown to over-estimate the measurement of knee joint sagittal laxity. These investigators examined the accuracy of the KT arthrometers as measures of anterior and posterior linear displacement. The anterior and posterior linear displacements of 3 KT arthrometers (2 KT1000 arthrometers and 1 KT2000 arthrometer) were compared with the simultaneous displacement measured by a precision linear Vernier Dial Test Indicator (Davenport Ltd, London, U.K.). The displacement calculated using the analog output of the KT2000 was also compared with the values on the KT2000 displacement dial. Compared with the Vernier Dial Test Indicator, the KT arthrometers over-estimated anterior linear displacement by between 22 % and 24 %. True anterior displacement for all 3 arthrometers, as recorded by the Vernier Dial Test Indicator, was found by multiplying the KT value by 0.79. When compared with the Vernier Dial Test Indicator, the KT arthrometers under-estimated posterior linear displacement by between 18 % and 19 %. True posterior displacement, as recorded by the Vernier Dial Test Indicator, was found by multiplying the KT1000 value by 1.17 and the KT2000 value by 1.16. The authors concluded that the internal apparatus of the KT2000 and KT1000 knee joint arthrometers over-estimated anterior displacement and under-estimated posterior displacement with a predictable relative systematic error. Moreover, they stated that future validation studies should use these correction equations to assess the accuracy of the KT arthrometers; and sagittal plane knee laxity measured with the KT devices requires systematic correction for optimal accuracy.

Vauhnik et al (2014) evaluated the inter-rater reliability of the GNRB® knee arthrometer. Knee anterior laxity in both knees was tested in a group of young, uninjured subjects (n = 27, 13 females) by 2 examiners. Knee anterior laxity was calculated at test forces of 134N and 250N with values presented for the
unstandardized and standardized conditions (relative to patellar stabilization force). The ICCs ranged from 0.220 to 0.424. The authors concluded that the inter-rater reliability of the GNRB® knee arthrometer is low.

Jang and colleagues (2014) determined objective factors involved in returning to sports following ACL reconstruction. Based on the inclusion criteria of a minimum 2-year follow-up, pre-injury sports activity level of Tegner 5 or greater, these researchers retrospectively evaluated 67 patients who underwent ACL reconstruction. The patients were divided into "return-to-sports" (n = 51) and "non-return" groups (n = 16) by surveying participants using a questionnaire. Comparisons between the 2 groups were made using pre-operative and post-operative International Knee Documentation Committee questionnaires (IKDC), Lysholm score, and KT-2000 arthrometer. Flexor and extensor muscle strength, and functional performance tests (1-leg-hop test, co-contraction, shuttle run, and carioca tests) were used for assessment. Overall clinical results, including IKDC score, Lysholm score, and KT-2000 arthrometer, improved in all patients post-operatively and no significant difference was seen between the 2 groups (p > 0.05). Although there was no significant difference in flexor or extensor deficits, 1-leg-hop test, or shuttle run test, "return-to-sports" group obtained significantly better scores in the co-contraction and carioca tests (p < 0.05). The authors concluded that tests that assess rotational stability showed statistically significant differences between the 2 groups. Moreover, they stated that further prospective studies with larger cohort are needed to determine the factors associated with returning to sports after ACL reconstruction.

In a cross-sectional study, Kievit et al (2013) evaluated the degree of osteoarthritis (OA), degree of laxity, and quality-of-life (QOL) scores in primary and revision ACL reconstruction. A total of 25 patients who had undergone revision ACL reconstruction with allografts were identified and compared with 27 randomly selected primary ACL reconstruction patients operated on in the same hospital in the same period with the same technique. The main outcome measure was the IKDC radiographic OA sum score, and secondary outcome measures were Knee Injury and Osteoarthritis Outcome Score, IKDC functional outcome measures, anterior laxity, and QOL at follow-up. The median follow-up was 5.3 years for revision reconstruction patients and 5.1 years for primary reconstruction patients. Radiographic IKDC sum scores for OA were found to be significantly worse in revision patients, with a median of 4, compared with primary patients, with a median of 1 (p = 0.016). Differences were found in meniscal injury (p = 0.02) and...
cartilage status (p < 0.001) before or at the index operation. Significantly worse outcomes were found in the following subscores of the Knee Injury and Osteoarthritis Outcome Score: pain (median, 92 versus 97; p = 0.032), symptom (median of 86 versus 96; p = 0.015), activities of daily living (median of 94 versus 100; p = 0.020), sport (median of 50 versus 85; p = 0.006), and QOL (median of 56 versus 81; p = 0.001). International Knee Documentation Committee functional outcome measures were the same in both groups except for the pivot-shift test (p = 0.007). No differences were found in anterior drawer, Lachman, or KT-1000 arthrometer testing. Present-day health scores on the EQ-5D were worse for revision reconstruction patients (median of 70 versus 80; p = 0.009). The authors concluded that revision reconstruction patients have more signs of OA and worse QOL than primary reconstruction patients, even though they have comparable IKDC success rates and KT-1000 arthrometer laxity test results.

UpToDate reviews on “Approach to the athlete or active adult with knee pain.” (Beutler and Fields, 2015) and “Physical examination of the knee” (Beutler and Alexander, 2015) do not mention the use of arthrometry/arthrometer testing as a management tool.

Rolimeter

Ericsson and colleagues (2017) examined the test-retest reliability of the Rolimeter measurement procedure in the acute time phase, following a substantial knee trauma. A total of 15 subjects with acute knee trauma were examined by 1 single observer at 3 different time-points with the Rolimeter using a maximum force. The selected time-points were: baseline (0 to 7 days after the trauma), mid-point (3 to 4 weeks after the trauma), and end-point (6 to 8 weeks after the trauma). The AP displacement was recorded where the end-point evaluation was used as the reference value. The mean anterior laxity scores remained constant over the measurement time-points for both knees, with an anterior laxity that was 2.7 mm higher (on average) in the injured than the non-injured knee (9.5 mm versus 6.8 mm). The mean difference (i.e., bias) between laxity scores, for the injured knee, measured at end-point versus baseline was 0.2 ± 1.0 mm and -0.2 ± 1.1 mm when measured at end-point versus mid-point, with average typical errors of 0.7 and 0.8 mm and intra-class correlations that were very strong (both r = ~0.93). For the same comparisons on the non-injured knee, systematic bias was close to zero (0.1 ± 0.3 and -0.1 ± 0.3 mm, respectively), and both the intra-class correlations were almost perfect (r = ~0.99). The authors concluded that the present study implicated
that repeated Rolimeter measurements were relatively reliable for quantifying anterior knee laxity during the acute time-phases following knee trauma. Hence, the Rolimeter, in combination with manual tests, appeared to be a valuable tool for identifying ACL injuries.

These researchers noted that in the present study, 15 subjects were evaluated, with 10 male and 5 female subjects, and soccer was the dominant sport in generating the injury. Although the test-retest reliability results supported the use of the Rolimeter in quantifying anterior knee laxity also during the acute phase following a substantial knee trauma, the results had to be interpreted with caution. For instance, the side-to-side difference between the injured and the non-injured knee was not displayed or discussed in the current study and related to the fact that 1 subject reported previous injury to the contralateral knee and 2 subjects to the injured knee. Moreover, the predictive value of the Rolimeter, in detecting ACL injuries, was not assessed since data on the ultimate diagnosis were not accessible and hence not possible to analyze. Finally, further research should combine acute measurements with the Rolimeter and MRI for determining and highlighting the predictive value of the Rolimeter in detecting ACL injuries in the acute phase, following a substantial knee trauma.

**GNRB Arthrometer**

Ryu and colleagues (2019) compared the accuracy of the GNRB arthrometer (Genourob), Lachman test, and Telos device (GmbH) in acute ACL injuries and evaluated the accuracy of each diagnostic tool according to the length of time from injury to examination. From September 2015 to September 2016, a total of 40 cases of complete ACL rupture were reviewed. These investigators divided the time from injury to examination into 3 periods of 10 days each and analyzed the diagnostic tools according to the time frame. An analysis of the area under the curve (AUC) of a receiver operating characteristic (ROC) curve showed that all diagnostic tools were fairly informative. The GNRB arthrometer showed a higher AUC than other diagnostic tools. In 10 cases assessed within 10 days after injury, the GNRB arthrometer showed statistically significant side-to-side difference in laxity ($p < 0.001$), whereas the Telos test and Lachman test did not show significantly different laxity ($p = 0.541$, and $p = 0.413$, respectively). The authors concluded that all diagnostic values of the GNRB arthrometer were better than
other diagnostic tools in acute ACL injuries. The GNRB arthrometer was more effective in acute ACL injuries examined within 10 days of injury. The GNRB arthrometer could be an useful diagnostic tool for acute ACL injuries.

The authors stated that this study had several drawbacks. First, the sample size was small (n = 40). Second, these researchers did not address cases of acute partial ACL injury, so a further study is needed on acute partial ACL injuries. In addition, the GNRB test was performed in 1 trial, but the radiographic tests (Lachman test and Telos test) were performed several times to obtain accurate measurements, and this might have affected knee joint relaxation and muscle tension. Finally, these investigators did not evaluate intra-observer reliability because patients received surgery immediately after diagnosis.

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>
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<td>Knee ligament arthrometer testing:</td>
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<td>CPT codes not covered for indications listed in the CPB:</td>
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<tr>
<td>95851</td>
<td>Range of motion measurements and report (separate procedure); each extremity (excluding hand) or each trunk section (spine)</td>
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<tr>
<td>97750</td>
<td>Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes</td>
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Other CPT codes related to the CPB:

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<td>collateral and cruciate ligaments</td>
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<td>27427</td>
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<td>27429</td>
<td>intra-articular (open) and extra-articular</td>
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<tr>
<td>29888</td>
<td>Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:


25. Friedberg RP. Anterior cruciate ligament injury. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2013.


34. Beutler A, Fields KB. Approach to the athlete or active adult with knee pain. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2015.


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AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0397 Knee Ligament Arthrometer Testing

There are no amendments for Medicaid.