

Gait Analysis

Effective: June 1, 2019

Next Review: March 2020

Last Review: April 2019

IMPORTANT REMINDER

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

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

DESCRIPTION

Gait analysis (GA) is the quantitative assessment of coordinated muscle function; evaluation is conducted in a laboratory and typically involves a dedicated facility and staff. A visual assessment of walking is supplemented by video recording. Videos can be observed from several visual planes at slow speed, allowing detection of movements not observable at normal speed. Joint angles and various time-distance variables, including step length, stride length, cadence, and cycle time, can be measured. Electromyography (EMG), assessed during walking, may be an included component of gait analysis and measures timing and intensity of muscle contractions. This calculation allows determination of whether a certain muscle's activity is normal, out of phase, continuous, or clonic.

MEDICAL POLICY CRITERIA

Note: Surface electromyography (SEMG) may be included as a component of gait analysis. See Medical Policy, Medicine No. 73, Surface Electromyography (SEMG) Including Paraspinal SEMG for specific criteria regarding SEMG.

- I. Gait analysis may be considered **medically necessary** in children and adolescents with cerebral palsy to select surgical or other therapeutic interventions for gait improvement.

II. All other indications for gait analysis are considered **investigational**.

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

LIST OF INFORMATION NEEDED FOR REVIEW

REQUIRED DOCUMENTATION:

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

- History and physical/chart notes
- Indication for Gait Analysis

CROSS REFERENCES

1. [Surface Electromyography \(SEMG\) Including Paraspinal SEMG](#), Medicine, Policy No. 73

BACKGROUND

Gait analysis has been proposed as an aid in surgical planning, primarily for cerebral palsy (CP), but also for other conditions such as clubfoot. In addition, gait analysis is being investigated as a means to plan rehabilitative strategies (i.e., orthotic-prosthetic devices) for ambulatory problems related to cerebral palsy, aging, stroke, spinal cord injury, and other conditions.

Kinematics is the term used to describe movements of joints and limbs such as angular displacement of joints and angular velocities and accelerations of limb segments. The central element of kinematic assessment is some type of marker system that is used to represent anatomic landmarks, which are then visualized and quantitatively assessed by videotaped observations or optoelectronic data. Movement data are compiled by computer from cameras oriented in several planes, and the movement data are processed so that the motion of joints and limbs can be assessed in three dimensions. The range and direction of motion of a particular joint can be isolated from all the other simultaneous motions that are occurring during walking. Graphic plots of individual joint and limb motion as a function of gait phase can be generated.

Inertial and magnetic measurement systems (IMMSs) are under investigation for the assessment of joints and limbs in 3-dimensions.^[1,2] Rather than videotaped or optoelectronic calibration of markers placed on anatomic landmarks, IMMS systems involve sensor units that are comprised of miniaturized 3-dimensional accelerometers, gyroscopes, and magnetometers that are attached to body segments. The 3-dimensional orientation of each sensor is measured in relationship to an earth-based coordinate system through the use of computerized algorithms. One protocol, the "Outwalk" protocol, has been developed to allow the use of an IMMS system for gait analysis.

A non-profit organization established in 1997, the Commission for Motion Laboratory Accreditation evaluates and accredits motion laboratories within clinical facilities. A multidisciplinary team uses a set of criteria to evaluate laboratories in the areas of administration (e.g., staffing, policies, and procedures), equipment (e.g., accuracy and precision), and data management and reporting (e.g., control and clinical data sets).

REGULATORY STATUS

Gait analysis devices, approved through the FDA 510(k) process include but are not limited to the Peak Motus Motion Measurement System, the Coda cx1 Motion Analysis System, KneeKG and Smart.^[3]

EVIDENCE SUMMARY

Assessment of a diagnostic technology typically focuses on three parameters: 1) technical feasibility; 2) diagnostic performance (sensitivity, specificity, and positive [PPV] and negative predictive value [NPV]) in appropriate populations of patients; and 3) demonstration that the diagnostic information can be used to improve patient outcomes (clinical utility).

Technical feasibility of a device is typically assessed with two types of studies, those that compare test measurements with a gold standard and those that compare results taken with the same device on different occasions (test-retest). Demonstration of technical feasibility should include an assessment of its reproducibility and precision.

Diagnostic performance is evaluated by the ability of a test to accurately diagnose a clinical condition in comparison with the gold standard. The sensitivity of a test is the ability to detect a disease when the condition is present (true-positive), while specificity indicates the ability to detect patients who are suspected of disease but who do not have the condition (true-negative). Evaluation of diagnostic performance, therefore, requires independent assessment by the two methods in a population of patients who are suspected of disease but who do not all have the disease.

Evidence related to improvement of clinical outcomes with use of this testing assesses the data linking use of a test to changes in health outcomes (clinical utility). While in some cases, tests can be evaluated adequately using technical and diagnostic performance, when a test identifies a new or different group of patients with a disease; randomized trials are needed to demonstrate impact of the test on the net health outcome.

ACCURACY/RELIABILITY

Rathinam (2014) published a systematic review of studies of the reliability and validity of pediatric gait analysis tools.^[4] Five observational gait tools were identified in nine studies of children with CP and one for children with Down's syndrome. None of these observational gait tools the level of consistency found in instrumented gait analysis (IGA). While the Edinburgh Visual Gait Score (EVGS) was found to have better reliability and validity than the other observational tools, the limited studies available were insufficient to determine their impact on clinical outcomes.

A systematic review of 18 studies on gait classification systems was published in 2007.^[5] The review included studies that involved classification of gait impairment based on kinematic, temporal-spatial kinetic, or electromyographic (EMG) data. Fifteen studies used three-dimensional gait analysis, one study used video observation analysis and 6 studies used EMG data. The authors assessed the overall methodological quality of the studies as low. Many studies appeared to classify patients arbitrarily rather than using clear clinical decision-making principles. Only two studies evaluated the reliability of classification, and the methods for determining the validity of classification systems were inadequate.

McGinley (2009) published a systematic review of studies of intersession and interassessor

reliability of 3-dimensional kinematic gait analysis that included 15 full manuscripts and eight abstracts.^[6] Similar to the 2007 systematic review summarized above, the authors noted variability in methodologic quality across the studies, but concluded that most studies demonstrated interassessor error of between 2 and 5 degrees of measurement, which the authors considered was “reasonable but may require consideration in data interpretation.”

Benedetti (2013) conducted an analysis of between-site consistency in gait analysis measurements of one healthy subject at seven different laboratories.^[7] The authors concluded that there was generally high concordance of segment and joint kinematics, except in the knee and the hip.

IMPACT ON HEALTH OUTCOMES

The ideal study design to demonstrate the clinical utility of gait analysis is a randomized controlled trial (RCT) comparing treatment decisions and health outcomes in patients managed with and without gait analysis.

Wren (2011) published a systematic review of literature on the efficacy of GA.^[8] The authors identified seven studies evaluating the effect of GA on patients’ health outcomes; none were RCTs. The studies addressed a variety of clinical conditions, so the authors were not able to pool findings. The systematic review also identified studies evaluating other aspects of GA including technical accuracy, diagnostic accuracy, and societal efficacy (i.e., impact on number and cost of procedures). The authors concluded that, although there is lower-level evidence (e.g., case series, case-control studies) supporting GA, there is a lack of evidence from RCTs on the effect of GA on health outcomes.

SPECIFIC APPLICATIONS OF GAIT ANALYSIS

In addition to the literature addressing gait analysis in general, several studies evaluate specific indications for GA.

Pre- and/or Post-Surgical Evaluation for Children with Cerebral Palsy

Two reports from one randomized controlled trial were published after the 2011 systematic review summarized above.

Wren and colleagues compared post-surgery health outcomes in children with cerebral palsy who were managed with and without gait analysis.^[9] This was a single-center, single-blind study. The trial included 186 ambulatory children with cerebral palsy who were candidates for lower extremity surgery to improve their gait. All participants underwent gait analysis at a gait laboratory. Patients were randomized to a treatment group in which the surgeon received the gait analysis report or a control group in which the surgeon did not receive the report. The reports included a summary of test results and treatment recommendations from the gait laboratory physician. The same surgeons treated the intervention and control patients i.e., they received gait reports for half of the patients. Patients were re-examined the day before surgery (i.e., following gait analysis) for pre-operative treatment planning. Outcomes were assessed pre-operatively and approximately 1 year post-surgery. There were three primary outcomes:

- 1) pre- to post-surgical change between groups in the walking scale of the Gillete Functional Assessment Questionnaire (FAQ),
- 2) the Gait Deviation Index (GDI), and
- 3) the oxygen cost of walking, a measure of the energy expended while walking.

A total of 156 of 186 (84%) participants returned for the follow-up examination; analysis was not intention to treat. There was no statistically significant difference between groups in any of the three primary outcomes. For example, the proportion of patients improved according to the FAQ was 31% in the intervention group and 25% in the control group ($p=0.38$). There were significant differences between groups at the $p=0.05$ level for two of 19 secondary outcome variables; p values were not adjusted for multiple comparisons. The authors noted that physicians followed only 42% of recommendations in the gait analysis report for patients in the treatment group, which may partially explain the lack of significant differences between groups in the primary outcomes and most of the secondary outcomes. They further noted that there was a positive relationship between gait outcomes and following gait analysis recommendations. Wren (2013) published a secondary analysis of data from the RCT previously described to evaluate the impact of gait analysis on the correction of excessive internal hip rotation among ambulatory children with cerebral palsy.^[10] In the secondary analysis, the authors included the subset of children for whom the gait laboratory recommended external femoral derotation osteotomy (FDRO) to correct excessive passive and active internal hip rotation and who had both pre- and postoperative data available. As in the primary study, the intervention was receipt of the gait analysis report by the treating orthopedic surgeon for participants in the intervention group; in this subset of patients, all patients had had FDRO recommended by the gait analysis report, but the decision to actually perform surgery was up to the treating surgeon. Physical measurements for this subanalysis included femoral anteversion, maximum hip internal and external rotation range of motion, and rotational alignment during gait. The primary outcome variables included femoral anteversion and mean hip rotation and foot progression in the stance phase of gait. Outcomes postsurgery and change in variables pre- to postsurgery were compared between intervention and control groups, with additional analyses based on whether patients in the gait report (intervention) group had had the gait report recommendations followed.

This subanalysis included 44 children (65 limbs) in whom FDRO was recommended. FDRO was performed in 7/39 limbs in which it was recommended in the gait report (intervention group); it is not clear how many children in the control group for whom FDRO was recommended received surgery. There were no significant differences in outcomes between the gait report and control groups on intent-to-treat analysis. However, among children in the intervention group who had FDRO done ($n=7$ limbs), the limbs demonstrated greater improvements in femoral anteversion (-32.9° vs -12.2° ; $p=0.01$), dynamic hip rotation (-25.5° vs -7.6° ; $p=0.001$), and foot progression (-36.2° vs -12.4° ; $p=0.02$) than limbs in the control group. The discrepancy between the intent-to-treat and per-protocol results may be related to generally poor compliance with the gait report recommendations, as only seven of 39 recommended FDROs performed in the gait analysis group. Interpretation of this study's significance is limited by its subgroup analysis design and the small number of patients who received gait analysis and FDRO.

In 2013^[11] and 2014^[12], Schwartz et al. published two retrospective analyses to evaluate the role of a random forest algorithm in children with cerebral palsy using data from a motion analysis center database. The random forest algorithm was a statistical method used to predict an outcome for a particular observation based on a series of predictor values. The algorithm included gait analysis to predict outcomes after single-event, multilevel surgery for children with ambulatory cerebral palsy. The study authors reported that their random forest algorithm was able to generate criteria that were predictive of good outcomes for patients undergoing a single-event, multilevel orthopedic surgery. However, methodological limitations, such as the potential bias inherent in studies based on retrospective analysis of a motion analysis center

database, make interpretation difficult. In addition, the complexity of the random forest decision algorithm makes it difficult to determine the degree to which gait analysis independently predicts outcomes.

Pre- and/or Post-Surgical Evaluation for Conditions Other Than Cerebral Palsy

In a study by Suda (2002), gait analysis recommendations in 60 patients with neurogenic intermittent claudication were evaluated and compared with 50 healthy controls.^[13] The authors concluded that gait analysis provided useful quantitative and objective information to evaluate postsurgical treatment. However, the study does not address how the gait analysis influenced treatment decisions or affected health outcomes.

Sankar (2009) reviewed the records of 35 children (56 feet) who had recurrent deformity after treatment of idiopathic clubfoot.^[14] Gait lab recommendations were compared to surgical plans prior to gait analysis, and then to the actual surgery received. Thirty of 35 (86%) of children underwent surgery. GA resulted in changed procedures in 19 of 30 (63%) patients. GA was found to influence clinical decisions, but, like the study by Suda et al, this study did not evaluate whether these changes resulted in improved health outcomes.

Gait analysis has been used in the assessment of multiple other conditions (e.g., knee pain in older patients with osteoarthritis^[15], gait after acute stroke^[16], and of frailty in older patients^[17]); however, the evidence linking the use of gait analysis to outcomes in these conditions is limited.

PRACTICE GUIDELINE SUMMARY

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE (NICE)

The National Institute for Health and Care Excellence (NICE) provided guidance in July 2012 for children and young people with spasticity who plan to have orthopedic surgery.^[18] The NICE clinical guideline CG145 revised in 2016 states that “the decision to perform orthopaedic surgery to improve gait should be informed by a thorough pre-operative functional assessment, preferably including gait analysis”.

SUMMARY

Despite the lack of research, gait analysis has evolved to a standard of care for select surgical or other therapeutic interventions for children and adolescents with gait disorders associated with cerebral palsy. Therefore, gait analysis may be considered medically necessary in this population.

There is not enough research to show that gait analysis improves health outcomes for indications other than cerebral palsy. No clinical guidelines based on research recommend gait analysis for any other indication. Therefore, gait analysis is considered investigational for indications other than cerebral palsy.

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CODES

Codes	Number	Description
CPT	96000	Comprehensive computer-based motion analysis by video-taping and 3-D kinematics
	96001	Comprehensive computer-based motion analysis by video-taping and 3-D kinematics; with dynamic plantar pressure measurements during walking
	96002	Dynamic surface electromyography, during walking or other functional activities, 1 to 12 muscles
	96003	Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle
	96004	Review and interpretation by physician or other qualified health care professional of comprehensive computer-based motion analysis, dynamic plantar pressure measurements, dynamic surface electromyography during walking or other functional activities, and dynamic fine wire electromyography, with written report
HCPCS	None	

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