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Medical Policy Manual Medicine, Policy No. 107

Gait Analysis

Effective: July 1, 2021

Next Review: March 2022
Last Review: May 2021

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 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 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-dimenstional 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. There also is ongoing research on the reliability of wearable devices for the acquisition of data 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 controlled trials (RCTs) are needed to demonstrate impact of the test on the net health outcome.

ACCURACY/RELIABILITY

Systematic Reviews

A systematic review by Michelini (2020) evaluated the evidence of reliability and validity of two-dimensional motion capture systems to quantify human gait.[4] Across the 30 publications included in the analysis, the reliability was found to be highly varied, ranging from poor to excellent. In addition, validity of the approach was varied across studies. The noted limitations of the studies include heterogeneity in study/analysis protocols, instrumentation, and outcomes measured. The authors conclude that additional testing is needed to overcome the aforementioned limitations in existing data.

Rathinam (2014) published a systematic review of studies of the reliability and validity of pediatric gait analysis tools.[5] 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 accomplished 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 by Dobson in 2007.[6] 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 six 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.[7] 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.”

Nonrandomized studies

Benedetti (2013) conducted an analysis of between-site consistency in gait analysis measurements of one healthy subject at seven different laboratories.[8] The authors concluded that there was generally high concordance of segment and joint kinematics, except in the knee and the hip.

WEARABLE / PORTABLE DEVICES FOR GAIT ANALYSIS

Systematic Reviews

Petraglia (2019) published a systematic review with meta-analysis of the use of wearable or inertial sensors for gait analysis compared to traditional systems in healthy and clinical groups.[9] Sixteen studies were included in the review and seven of them were included in a meta-analysis of different gait parameters. Demographic data, tested devices, reference systems, test procedures and outcomes were analyzed. The authors report good agreement between inertial sensors and classical gait analysis for some gait parameters but specify that reliability requires the analysis must be done in a clinical setting and that clinical experience should direct treatment decisions.

Chakravorty (2019) published a systematic review evaluating the accuracy and reliability of wearable devices for objective gait measurement of Lumbar Spinal Stenosis (LSS) patients.[10] Four studies were included in the review. The objectives, methodology and quality of the studies varied, and no single gait metric was investigated in all four studies, limiting interpretability. The most relevant metrics of gait cycle, gait velocity, step length and cadence were reported in two studies and only two studies explored gait symmetry. Although demonstrable differences between LSS and healthy patients was reported, additional RCTs are required to overcome the limitations of scarce data and study design heterogeneity.

IMPACT ON HEALTH OUTCOMES

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

In 2020, Wren published an update to the 2011 systematic review on the clinical efficacy of three-dimensional instrumented gait analysis (summarized below).[11] A total of 2712 studies met inclusion criteria, which were then classified into the types of efficacy that was evaluated. Among the 2712 studies, 313 were classified as type 1 (Technical: Physical process of obtaining data, including accuracy and reliability of equipment & procedures used in data collection); 1466 as type 2 (Diagnostic accuracy: Data interpretation, including performance in classifying patients & making diagnoses, interpreting data, identifying measures predictive of good or bad outcomes for specific treatments); 927 as type 2b (Outcome prediction: Gait analysis used to evaluate the efficacy of treatments at group level); 6 as type 3−4 (Diagnostic thinking & treatment: Impact of gait analysis on treatment decision-making and the treatment actually done for individual patients), and 3 as type 5 (Patient outcome: Effect on outcomes for individual patients). Only the 9 studies classified as type 3 or higher were further evaluated. Of these, the most common quality rating (4/9 articles) was evidence level 3b which reflects a lesser quality prospective cohort study. Two studies had a high evidence level of 2a and one had an evidence level of 2b, indicating good and lesser quality controlled clinical trials, respectively. Two studies had lower evidence levels (4a and 5b). No pooled analyses were completed. Since the 2011 review, 3 new publications were identified that address the impact of gait analysis on treatment outcomes for individual patients, however 2 of these publications were from the same randomized controlled trial of children with cerebral palsy (CP). In a population-based type 5 study, the incidence of severe crouch gait dropped from 25% to 4% following practice changes including (but not specific to) the addition of 3DGA. Additional randomized controlled trials that are adequately powered and appropriately controlled are needed to determine the added benefit of this technology on health outcomes. Rasmussen (2019) published a prospective, single-blind, parallel-group, randomized controlled trial investigating the effectiveness of interventions based on the use of gait analysis in children with CP.[12] The primary outcome was gait (Gait Deviation Index) and secondary outcomes were walking and patient-reported outcome measures of function, disability, and health-related quality of life. Follow-up questionnaires were completed at 26 weeks and all outcomes were assessed at the primary end point of 52 weeks. Sixty participants with CP (39 males, 21 females, mean age 6y 10mo, SD 1y 3mo, range 5y-9y 1mo) in Gross Motor Function Classification System levels I or II were randomized to interventions with or without gait analysis. No significant or clinically relevant between-group differences in change scores of the primary or secondary outcomes were found; interventions using gait analysis were not superior to usual care on gait, walking, or patient-reported outcomes. These results are specific to relatively young and independently walking children with CP not expected to need surgery.

Wren (2011) published a systematic review of literature on the efficacy of gait analysis.[13] The authors identified seven studies evaluating the effect of gait analysis 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 gait analysis 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 gait analysis, there is a lack of evidence from RCTs on the effect of gait analysis on health outcomes.

SPECIFIC APPLICATIONS OF GAIT ANALYSIS

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

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

The following studies have been published subsequent to the 2011 systematic review summarized above.

Wren (2012) compared post-surgery health outcomes in children with cerebral palsy who were managed with and without gait analysis.[14] 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 one 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), and
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.[15] 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[16] and 2014[17], Schwartz 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 is 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.[18] 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.[19] 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[20], gait after acute stroke[21], recovery after hip arthroplasty,[22] and of frailty in older patients[23]); 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 (updated 2016) for children and young people with spasticity who plan to have orthopedic surgery.[24] 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

Codes	Number	Description
	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	

Date of Origin: *July 1998*