Policy Number	**THE803.009**
Policy Effective Date	**04/01/2025**
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Gait Analysis

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Comprehensive gait analysis **may be considered medically necessary** as an aid in surgical planning in individuals with gait disorders associated with cerebral palsy.

Comprehensive gait analysis **is considered experimental, investigational and/or unproven** for all other applications, including but not limited to:

- Surgical planning for conditions other than gait disorders associated with cerebral palsy;
- Postoperative evaluation of surgical outcomes and rehabilitation planning and/or evaluation for all conditions.

Gait analysis that is not comprehensive **is considered experimental, investigational and/or unproven** for all indications.

Policy Guidelines

Gait analysis is sometimes termed dynamic EMG and surface EMG and may be erroneously submitted on claims under EMG codes.

Description

Background

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 (EMG), assessed during walking, 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.

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 3 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 for gait analysis.

Gait analysis has been proposed as an aid in surgical planning, primarily for cerebral palsy 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, etc.

A nonprofit 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, procedures), equipment (e.g., accuracy and precision), and data management and reporting (e.g., control and clinical data sets).

Regulatory Status

In May 2003, the Peak Motus Motion Measurement System (Peak Performance Technologies) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. This system uses off-the-shelf video cameras and sensors and proprietary software to document human movement in 2- or 3-dimensional space. The FDA determined that this device was substantially equivalent to existing devices and is indicated for assessment and training of limb or body motion in gait analysis, pre- or post-rehabilitation evaluation, physical therapy, and similar applications. Product code: LXJ.

In January 2004, the Coda cx1 Motion Analysis System (Charnwood Dynamics Ltd., Rothley, Leicestershire, UK), was cleared for marketing by the FDA through the 510(k) process. The system uses infrared light sight sensors and software data analysis to measure the 3-dimensional movement of patients. The FDA determined that the device was substantially equivalent to existing devices and is indicated for analysis of the 3-dimensional motion of the limbs and body of patients who have some impairment of movement functions due to a neurologic or orthopedic cause. Product code: LXJ.

Since 2004, the FDA has cleared other systems for marketing (e.g., SMART-D, Qualisys Clinical System, Vicon Motion Systems). Refer to the FDA website for the complete updated list of systems.

Rationale

Medical policies assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Medical policies assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these policies, and credible information on technical reliability is available from other sources.

Accuracy and reliability

A systematic review of 18 studies on gait classification systems was published in 2007. (3) The review included studies that involved classification of gait impairment based on kinematic, temporal-spatial kinetic, or electromyographic (EMG) data. Fifteen studies used 3-dimensional gait analysis, 1 study used video observation analysis, and 6 studies used EMG data. The

authors assessed the overall methodologic quality of the studies as low. Many studies appeared to classify patients arbitrarily rather than use clear clinical decision-making principles. Only 2 studies evaluated the reliability of classification, and the methods for determining the validity of classification systems was found inadequate. In 2009, McGinley et al. published a systematic review of studies of intersession and interassessor reliability of 3-dimensional kinematic gait analysis that included 15 full manuscripts and 8 abstracts. (4) Similar to the Dobson systematic review, 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 et al. conducted an analysis of between-site consistency in gait analysis measurements of 1 healthy subject at 7 different laboratories. (5) The authors concluded that there was generally high concordance of segment and joint kinematics, except in the knee and the hip.

In an earlier study funded by the United Cerebral Palsy Foundation, 4 different gait analysis centers gave different treatment recommendations after evaluating the same 11 patients. (6) Thus, there appears to be inconsistency in gait analysis recommendations between some centers.

Impact on health outcomes

The ideal study design to evaluate the utility of gait analysis for surgical planning or evaluation or rehabilitation planning would be a randomized controlled trial (RCT) and would compare health outcomes in patients managed with gait analysis to patients managed using another approach.

<u>Pre- and/or postsurgical evaluation for children with cerebral palsy</u>

There is 1 RCT, published in 2012 by Wren et al., comparing postsurgery health outcomes in children with cerebral palsy who were managed with and without gait analysis. (7) 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 preoperative treatment planning. Outcomes were assessed preoperatively and approximately 1-year postsurgery. There were 3 primary outcomes: pre- to postsurgical change between groups in the walking scale of the Gillete Functional Assessment Questionnaire, the Gait Deviation Index, and the oxygen cost of walking, a measure of the energy expended while walking (oxygen, cost). A total of 156 of 186 (84%) participants returned for the follow-up examination; analysis was not intention to treat. There was not a statistically significant difference between groups in any of the 3 primary outcomes. For example, the proportion of patients improved according to the Functional Assessment Questionnaire 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 2 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.

In 2013, Wren et al. 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. (8) In the secondary analysis, the authors included the subset of children for whom the gait laboratory recommended external femoral de-rotation 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 7 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.

Previously, in 2009, Wren et al. published a retrospective, nonrandomized study comparing outcomes in patients managed with and without gait analysis. (9) The analysis included 462 children with cerebral palsy who had undergone lower-extremity orthopedic surgery at a single hospital and had at least 6 months' follow-up (n=313 had gait analysis before surgery and n=149 did not). Adjusting for baseline differences, the overall finding was that the number of procedures and costs did not differ significantly between groups. The group that received gait analysis had a mean of 2.6 procedures per person-year compared with 2.3 per person-year in

the nongait analysis group. In subanalyses, patients in the gait analysis group had significantly more initial surgical procedures (5.8 vs 4.2, $p<0.01$) than the group that did not have gait analysis. Conversely, patients in the group not managed with gait analysis had more subsequent procedures (32% vs 11%, $p<0.001$ – all respectively). Study findings suggest that gait analysis does not significantly affect overall utilization and cost. This study, however, did not specifically evaluate health outcomes. Also, since the study was not randomized, there may have been uncontrolled baseline differences that affected the number of procedures received.

In addition, several uncontrolled studies have been published in which children underwent both pre- and postoperative gait analysis. For example, in a study by Lofterod et al., 60 children with cerebral palsy were referred for gait analysis after development of an initial surgical plan based on clinical observation. (10, 11) The original surgical plans were found to have been modified in 70% of patients following multidisciplinary team gait analysis. In a follow-up report, patients were divided into 3 groups: group A: Agreement between clinical evaluation, gait analysis, and subsequent surgery; group B: Procedures performed due to gait analysis recommendations that had not been part of the initial surgical plan; group C: Procedures that were part of the initial surgical plan were not performed because they were not recommended after gait analysis. Based on gait analysis interpretation, surgery was not recommended in 11 children. Fifty-five children, including 47 who received surgery, underwent follow-up gait analysis 1 to 2 years after the initial analysis. Overall, at follow-up, there was improvement in kinematic parameters for children in groups A and B. This suggests that the change in treatment planning associated with gait analysis may have been beneficial, or at least not harmful; we do not know what the outcome would have been if the original treatment plan had been followed. Group C had fewer surgical procedures or no surgery; among children in this group, there were no statistically significant changes in any kinematic parameters at the follow-up gait analysis. Of the 8 children in group C, 4 children had clinical deterioration during more than 2 years of follow-up and were recommended to have multilevel surgery; most of their kinematic parameters were in the normal range at the time of initial evaluation. Based on this case series of patients referred for gait analysis, the authors concluded that gait analysis was useful for surgical planning.

Another study reviewed outcomes in 45 children with cerebral palsy who underwent gait analysis before and approximately 1 year after surgery that included collection of 3-dimensional motion and force-plate data. (12) The study aimed to determine whether gait analysis had a positive impact on treatment plans and whether gait analysis could predict which children would benefit from surgery. Most children had approximately 1 year between examinations. Like the Lofterod et al. study, patients were retrospectively classified into 3 groups, each with 15 children. A key outcome measure was change in the Gillette Gait Index (GGI); the article states that a change of 10% in the index is clinically significant. Based on change in the GGI, among the 15 children for whom surgery was not recommended, 7 children improved, 4 were stable, and 4 deteriorated. In the group that had surgery recommended but not performed (due to family preference or other factors), 6 of 15 children improved, 1 was stable, and 8 deteriorated. In the group for whom surgery was recommended and performed, 12 children improved and 3 remained stable. A limitation of this study is that the authors did not prospectively collect data on how treatment plans changed after the gait analysis; instead, this

was estimated by a multivariate analysis that found a significant association between the GGI and choice of treatment, which the authors believe suggests that gait data influenced the treatment decision.

Schwartz et al. published an evaluation of the role of a random forest algorithm (a statistical method used to predict an outcome for a particular observation based on a series of predictor values) that included gait analysis to predict outcomes after single-event, multilevel surgery for patients with ambulatory cerebral that either did or did not include psoas lengthening. (13) The study authors report that their random forest algorithm was able to generate criteria that are predictive of good outcomes for patients undergoing a single-event, multilevel orthopedic surgery. However, the study based on a retrospective analysis of a motion analysis center database and is thus subject to bias. 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.

In 2011, prior to the publication of the RCT just described (7), Wren et al. published a systematic review of literature on the efficacy of gait analysis. (14) The authors identified 7 studies evaluating the effect of gait analysis on patients' health outcomes; none were RCTs. The studies addressed a variety of clinical conditions, and 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.

Rasmussen et al. (2019) conducted a RCT to test the hypothesis that improvements in gait and function following individualized interdisciplinary interventions consisting of physical therapy, orthotics, spasticity management, and orthopaedic surgery using instrumented gait analysis are superior to 'usual care' in children with cerebral palsy (CP). (15) Sixty participants (mean age 6 years 10 months) with CP were randomized to interventions with or without gait analysis. 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-ups were done at 26 weeks (questionnaires) and at the primary end point of 52 weeks (all outcomes). No significant or clinically relevant between-group differences in change scores of the primary or secondary outcomes were found. The recommended categories of interventions were dominated by non-surgical interventions and were applied in 36% to 86% of the participants. Interventions using gait analysis were not superior to 'usual care' on gait, walking, or patient-reported outcomes in a sample of relatively young and independently walking children with CP not expected to need surgery. A limitation of the study is the fact that the participants (parents and children) and the local health care teams were unblinded and thus aware of their allocation. Nonetheless, data collection and the statistical analysis were performed blinded.

Section Summary

Primary results and 1 subgroup analysis from 2 RCTs have been published comparing outcomes in patients with cerebral palsy managed with and without gait analysis. The studies did not find better health outcomes in patients managed with gait analysis; however, surgeons followed only a minority of recommendations in the gait analysis reports, and trials were not definitive in ruling out a beneficial impact. Overall, there is insufficient evidence from RCTs that gait analysis prior to surgery improves health outcomes in patients with cerebral palsy.

Pre- and/or postsurgical evaluation for conditions other than cerebral palsy

In a study by Suda et al., gait analysis recommendations in 60 patients with neurogenic intermittent claudication were evaluated and compared with 50 healthy controls. (16) 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 et al. received the records of 35 children (56 feet) who had recurrent deformity after treatment of idiopathic clubfoot. (17) Gait lab recommendations were compared with surgical plans prior to gait analysis and to actual surgery received. Thirty of 35 (86%) children underwent surgery. Gait analysis resulted in changed procedures in 19 of 30 (63%) patients. Gait analysis was found to influence clinical decisions, but, like the study by Suda et al., this study does 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 [18], gait after acute stroke [19], and of frailty in older patients [20]); however, the evidence linking the use of gait analysis to outcomes in these conditions is limited.

Section Summary

There is insufficient evidence that gait analysis as part of surgical planning improves health outcomes in patients with conditions other than cerebral palsy.

Rehabilitation planning and/or evaluation

No relevant clinical studies were identified.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In 2010, BCBSA requested and received clinical input from 3 specialty societies (7 reviewers) and 2 academic medical centers (4 reviewers). The reviewers generally disagreed with the statement that gait analysis is investigational for all indications. There was agreement among the reviewers that comprehensive gait analysis (i.e., involving analysis of video recordings) may be medically necessary as an aid in surgical planning for children with gait disorders associated with cerebral palsy. Specifically, in children with cerebral palsy, reviewers consider comprehensive gait analysis to be important for planning prior to bony or muscle surgery in the lower extremities.

Summary of Evidence

Gait analysis is the quantitative assessment of coordinated muscle function. For patients with cerebral palsy undergoing surgery for gait disorders, 2 randomized controlled trials (RCTs) did not find improvement in health outcomes for patients who received gait analysis as part of surgical planning, and 1 non-RCT did not find improvement in utilization parameters. Several studies conducted among patients with cerebral palsy and other conditions suggest that gait analysis recommendations impact treatment decisions, but the impact of these decisions on health outcomes is as yet unknown. Based on input from clinical reviewers, gait analysis, when comprehensive, may be medically necessary for planning before surgery in children with gait disorders associated with cerebral palsy.

Professional Guidelines and Position Statements

National Institute for Health and Care Excellence (NICE)

In 2012, NICE published guidance on the spasticity in children and young people with non-progressive brain disorders. The NICE Guideline was updated in November 2016 and reaffirmed that the decision to perform orthopedic surgery to improve gait should be informed by a thorough pre-operative functional assessment, preferably including gait analysis (21).

Table 1: Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Date of Completion
Unpublished			
NCT00419432	Outcomes of Orthopedic Surgery Using Gait Laboratory Versus Observational Gait Analysis in Children With Cerebral Palsy	60	Dec 2023 (unknown status)
NCT04290689	Can Gait Analysis and Imaging Methods Detect Change in the Calf Musculature in Children With Cerebral Palsy? Comparison Study of Toe Walking Patients Following Serial Casting, Botulinum Toxin-A and Typically Developing Controls	20	Dec 2022 (unknown status)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	96000, 96001, 96002, 96004, [Deleted 1/2025: 96003]
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
04/01/2025	Reviewed. No changes.
04/01/2024	Document updated with literature review. Coverage unchanged. Reference 15 added, others updated, some removed.
07/01/2023	Review only. No changes.
01/01/2023	Document updated with literature review. Coverage unchanged. No new references added; some removed.
09/01/2021	Reviewed. No changes.
01/15/2021	Document updated with literature review. Coverage unchanged. References updated.
06/15/2019	Reviewed. No changes.
04/15/2018	Document updated with literature review. Coverage unchanged. Added reference 22.
03/01/2017	Reviewed. No changes.
03/01/2016	Document updated with literature review. Coverage unchanged.

07/01/2015	Reviewed. No changes.
07/01/2014	Document updated with literature review. Coverage unchanged.
06/01/2012	Document updated with literature review. Coverage unchanged, two examples of experimental, investigational and unproven applications were added. Rationale revised.
07/15/2010	Document updated with literature review. The following change was made: Comprehensive gait analysis may be considered medically necessary as a surgical planning aid for patients with gait disorders associated with cerebral palsy. Comprehensive gait analysis for any other application and gait analysis that is not comprehensive are considered experimental, investigational and unproven.
12/01/2007	Revised/Updated Entire Document
02/01/2002	Codes Revised/Added/Deleted
03/01/2000	Revised/Updated Entire Document
06/01/1998	Revised/Updated Entire Document