Cigna Medical Coverage Policy

Coverage Policy

Cigna covers computerized gait analysis as medically necessary when BOTH of the following criteria are met:

- A child or adolescent has a diagnosis of cerebral palsy.
- The procedure is performed as part of a preoperative assessment, and the results will be used in surgical planning.

Cigna does not cover gait analysis for any other indication, because it is considered experimental, investigational or unproven.

General Background

Gait analysis, also referred to as motion analysis, is the systematic evaluation of the dynamics of gait. It is a process of measuring and evaluating the walking patterns of patients with specific gait-related problems. Observational gait analysis, the standard method of evaluating gait, refers to the visual assessment of a patient’s gait, with specific attention to hips, knees and ankles. Gait analysis by observer assessment does not use any specialized equipment, can adequately assess most conditions, and is used to note gross abnormalities in gait.

Gait analysis may also be performed in a gait analysis laboratory using specialized technology. This is also referred to as computerized gait analysis, quantitative gait analysis or clinical gait analysis. This procedure has been used to understand the etiology of gait abnormalities and as part of the treatment decision-making in...
patients with complex walking problems. It has been most often used for patients with neuromuscular conditions, primarily as part of the surgical decision-making process when all conservative measures have been exhausted and surgical intervention is being considered. Computerized gait analysis is a process by which gait characteristics are measured, abnormalities are identified, causes are suggested and treatments are proposed. It is not intended to replace the clinical examination, but rather serves as an adjunct to understand the impairment better. The treatment decision should be made in the total context of the patient’s condition, physical examination and medical history.

The technologies involved in clinical gait analysis include:

- Specialized computer-interfaced video cameras that measure patient motion. An initial videotape is recorded to provide documentation of how a patient walks and the patient's gait pattern.
- Passive reflective markers are placed on the surface of a patient's skin, aligning with specific bony landmarks and joints. As the patient walks along a straight pathway in the laboratory, the locations of the markers are monitored with a three-dimensional motion data-capture system comprising five or six special video cameras, all interfaced with a central controlling computer. An infrared light is reflected from the markers back to the cameras. Marker position data allow for the computation of the angular orientation of particular body segments as well as of the angles between segments (joint angles); these data are collectively referred to as kinematics.
- Multicomponent force platforms imbedded in the walkway provide measurement of reaction between foot and ground as the patient walks. The data are assessed directly or used to calculate the load in and across the joints. The joint load is referred to as kinetics.
- Electrodes placed on the surface of the skin or inserted as fine wires into specific muscles allow the muscle to be monitored as the patient walks. This is referred to as dynamic electromyography (EMG). This technique measures the electrical potential generated by a muscle when it is activated. This information, along with joint kinematic and kinetic results, is used to assess the gait abnormalities.

An extensive physical examination of the patient at rest should be performed. This information may then be correlated with the gait data. The gait analysis will usually take two to four hours to complete. In order to perform gait analysis, the patient must be ambulatory with or without assistive devices for a minimum of 10 consecutive steps. The patient must also be able to follow directions and be cooperative during the procedure. The gait analysis data are often interpreted by a team that includes the orthopedic surgeon; the physical therapist or kinesiologist who collected the data; and, at times, the engineer who collected data or the biomechanical engineer who developed the mathematical models used for processing the data. The information from the gait analysis is used along with results of the clinical examination to identify gait deviations, determine potential causes and determine treatment.

The most frequent application of gait analysis is in the treatment of children and adolescents with cerebral palsy, when surgical treatment is being considered. The orthopedic difficulties encountered in children with cerebral palsy are frequently a result of high muscle tone, spasticity and rigidity that prevent normal growth of muscle and cause contractures. Treatment of this condition includes physical therapy, occupational therapy, casting, orthotics and medication. Surgery is often recommended when contractures are severe enough to cause movement problems. Gait analysis may be utilized to determine if surgery is necessary and to determine which surgical procedure is appropriate. There are several published studies regarding the use of gait analysis to provide objective information in the surgical planning process for this condition.

**Literature Review—Cerebral Palsy Treatment Planning**

There have been several prospective and retrospective studies that have been published regarding the utilization of gait analysis in the surgical decision-making process in children and adolescents with cerebral palsy (Gough, et al., 2008; Lofterod, et al., 2008; Filho, et al., 2080; Lofterod, et al., 2007; Molenaers, et al., 2006; Kawamura, et al., 2006; Desloovere, et al., 2006; Chang, et al., 2006; Cook, et al., 2003; Kay, et al., 2000; DeLuca, et al., 1997). These studies have demonstrated that the use of gait analysis alters the decision making and changes the treatment that these patients receive, including confirming clinical indications for surgery, and for excluding or delaying surgery that was clinically proposed.

A retrospective study evaluated the effect of gait analysis on the amount of surgery children with cerebral palsy undergo (Wren, et al., 2009). The study involved 313 children who received gait analysis and 149 children who received not gait analysis before their initial surgery. After adjusting for differences in age and severity of
functional problems, it was found that the gait analysis group had more distinct procedures during the initial surgery than the non-gait analysis group. However, only 11% of the gait analysis children needed additional surgery in contrast to 32% of the non-gait analysis group. The study indicated that use of gait analysis was associated with a lower incidence of additional surgery.

Wren et al. (2011a) conducted a randomized controlled trial to determine the effects of gait analysis on surgical decision-making in 178 children with cerebral palsy (CP) who were being considered for lower extremity orthopedic surgery. They underwent gait analysis and were randomized into one of two groups: gait report group (N = 90), where the orthopedic surgeon received the gait analysis report, and control group (N = 88), where the surgeon did not receive the gait report. Data regarding specific surgeries were documented by the treating surgeon before gait analysis, by the gait laboratory surgeon after gait analysis, and after surgery. Agreement between the treatment done and the gait analysis recommendations was then compared using the 2-sided Fisher’s Exact test. When a procedure was planned initially and also recommended by gait analysis, it was performed more often in the gait report group (91% vs. 70%, p<0.001). When the gait laboratory recommended against a planned procedure, the plan was changed more frequently in the gait report group (48% vs. 27%, p=0.009). When the gait laboratory recommended adding a procedure, it was added more frequently in the gait report group (12% vs. 7%, p=0.037). The authors conclude that the results provide a stronger level of evidence demonstrating that gait analysis alters treatment decision-making and also reinforces decision-making when it agrees with the surgeon’s original plan.

A randomized, controlled trial was conducted to examine the impact of gait analysis on surgical outcomes in 156 ambulatory children with cerebral palsy (CP) (Wren, et al., 2013a). The children were randomized into two groups: Gait Report group (N = 83), where the referring surgeon received the patient’s gait analysis report; and, Control group (N = 73), where the surgeon did not receive the gait report. Outcomes were assessed pre- and 1.3±0.5 years post-operatively. Outcome measures included the Gillette Functional Activity Questionnaire (FAQ), Gait Deviation Index (GDI), oxygen cost, gross motor function measure, Child Health Questionnaire (CHQ), Pediatric Outcomes Data Collection Instrument (PODCI), and Pediatric Evaluation and Disability Inventory. It was found that the outcomes that differed significantly between groups were change in health from the CHQ, which was rated as much better for 56% (46/82) of children in the Gait Report group compared with 38% (28/73) in the Control group (p=0.04), and upper extremity physical function from the PODCI. Gait outcomes (FAQ and GDI) improved when over half of the recommendations for a patient were followed or the recommended extent of surgery (none, single, or multi-level) was done (p=0.04). On average only 42% of the recommendations were followed in the Gait Report group, compared with 35% in the Control group (p=0.23). This is less than the >85% reported in previous studies and the authors theorized that this may account for the lack of differences between groups for some of the outcome measures.

A secondary analysis of the above study was completed with the aim to determine if gait analysis improves correction of a specific problem, excessive hip internal rotation in ambulatory patients with spastic cerebral palsy (Wren, et al., 2013b). The analysis included all participants whose gait report recommended external femoral derotation osteotomy (FDRO). One-year postoperative, and pre- to postoperative change in femoral anteversion, mean hip rotation in stance, and mean foot progression in stance were compared between groups and in subgroups based on whether the recommendation for FDRO was followed. Outcomes did not differ between the group which received a gait report (n=39; 19 males, 20 females; mean age 10y 4mo; hemiplegia, 3; di/triplegia, 28; quadriplegia, 8; Gross Motor Function Classification System (GMFCS): level I, 5; level II, 12; level III 19; level IV, 3) and the control group (n=26; 14 males, 12 females; mean age 9y 5mo; hemiplegia, 1; di/triplegia, 21; quadriplegia, 4; GMFCS: level I, 4; level II, 1; level III, 9; level IV, 2; all p values >0.29), but improved more in the gait report subgroup in which the FDRO recommendation was followed than in the control group and the gait report subgroup in which FDRO was not performed. The gait analyses identified appropriate candidates for FDRO, and these individuals benefited when the recommended FDRO was performed. Postoperative measures became normal only in the gait report subgroup in which the recommended FDRO was performed.

Literature Review—Other Conditions
Gait Analysis has been proposed for various other conditions. There is insufficient evidence in the published, peer-reviewed scientific literature that supports the use of gait analysis for other conditions.

Radler, et al. (2010) conducted a prospective study to investigate the correlation of femoral torsion and tibial torsion as measured by using computed tomography with transverse plane gait data for patients with rotational
malalignment of the lower extremities in 26 patients (26 limbs). Calculation of Pearson correlations showed that increase of femoral anteversion resulted in increase of pelvic range of motion. A very weak correlation between femoral torsion and hip rotation (determination coefficient, R²=0.22) was found in a linear regression model, whereas tibial torsion and knee rotation showed a strong correlation (determination coefficient, R²=0.71). The correlation between the foot progression angle and tibial torsion was higher than between the foot progression angle and femoral torsion. The investigators concluded that there is a considerable dynamic influence of mechanisms of compensation, especially in the hip, that should be considered when evaluating the torsional profile. The investigators recommended that three-dimensional instrumented gait analysis be conducted for patients undergoing surgical correction of rotational malalignment. The authors note that further studies are needed to define more accurate methods for assessment of transverse plane rotation and the relationship of the joint partners during walking. The study was limited with a small number of subjects and that it was not randomized.

A systematic review was conducted by Ornetti et al. (2009) that examined gait analysis as a quantifiable outcome measure in hip and knee osteoarthritis (OA). The review included 30 reports (19 knee OA studies, 11 hip OA studies) studying 781 knee OA patients and 343 hip OA patients. It was found that gait analysis presents various feasibility issues and there was limited evidence regarding reliability (three studies, 67 patients). Discriminant capacity demonstrated significant reduction of gait speed, stride length and knee flexion in OA patients compared to healthy subjects. There was few data available concerning construct validity (three studies, 79 patients). Responsiveness of gait speed was moderate to large with effect size ranging respectively from 0.33 to 0.89 for total knee replacement, and from 0.50 to 1.41 for total hip replacement. The authors concluded that available data concerning validity and reliability of kinematic gait analysis are insufficient to date to consider kinematic parameters as valuable outcome measures in OA and further studies evaluating a large number of patients are needed.

Sankar et al. (2009) evaluated 35 patients (56 feet) with recurrent clubfoot in a retrospective study. According to the investigators, after quantitative gait analysis there were 28 changed procedures in 19 of 30 patients (63%) compared to pre-study surgical plans. Study limitations include small study size, retrospective design and the study did not address how computerized gait analysis affects patient outcomes.

Williams et al. (2008) investigated objective measures to compare gait before and after cerebrospinal fluid (CSF) drainage and shunt surgery. Gait abnormalities are an early clinical symptom in normal pressure hydrocephalus (NPH) and subjective improvement in gait after temporary removal of CSF is often used to decide to perform shunt surgery. The study included 20 patients and nine controls. Quantitative gait measures were obtained at baseline, after three days of controlled CSF drainage, and after shunt surgery. The decision to perform surgery was based on response to drainage, and the subjects were assigned to shunted or unshunted groups for comparison. There was no improvement after CSF drainage in the unshunted group (n=4). In the shunted group (n=15) velocity, double-support time, and cadence improved significantly after drainage, and improved further after shunt surgery. The degree of improvement after drainage appeared to correlate to the degree of improvement post-shunt for velocity, double support time, cadence, and stride length. The authors concluded that there are significant, quantifiable changes in gait after CSF drainage that corresponds to improvement after shunt surgery for patients with NPH. Use of objective gait assessment may improve the process of identifying these candidates when response to CSF removal is used as a supplemental prognostic test for shunt surgery. These findings require confirmation in a larger study.

Professional Societies/Organizations
National Institute of Neurological Disorders and Stroke (NINDS): NINDS notes regarding treatment options for cerebral palsy that orthopedic surgery is often recommended when spasticity and stiffness are severe enough to make walking and moving about difficult or painful. Surgical procedures may include lengthening of muscles and tendons that are proportionately too short, which can improve mobility and lessen pain. Tendon surgery may help the symptoms for some children with cerebral palsy but may also have negative long-term consequences. The orthopedic surgeries may be staggered at times appropriate to a child's age and level of motor development. Surgery may also be performed to correct or greatly improve spinal deformities in people with CP. Surgery may not be indicated for all gait abnormalities and the surgeon may request a quantitative gait analysis before surgery (NINDS, 2014).

Use Outside of the US
National Institute for Health and Clinical Excellence (NICE) (United Kingdom) published guidelines for spasticity in children and young people with non-progressive brain disorders. The guidelines note that, “The decision to perform orthopaedic surgery to improve gait should be informed by a thorough pre-operative functional assessment, preferably including gait analysis.” It is included in the guidelines that, gait analysis is defined as, “A detailed approach to analysing the component phases of walking using instrumentation or video analysis in addition to clinical observation. This is undertaken to evaluate a child or young person’s ability and style of walking and to plan or assess treatment.” (NICE, 2012).

Summary
The published peer-reviewed scientific literature indicates that clinical gait analysis may be an effective tool in the surgical decision-making process for children and adolescents with cerebral palsy. It may be performed to assist in determining if surgery is necessary and to determine which surgical procedure is appropriate. There is insufficient evidence in the published, peer-reviewed scientific literature to conclude that gait analysis has a role in the diagnosis or management of other medical conditions. Well-designed clinical trials are needed to demonstrate the clinical benefit of this procedure for other medical conditions.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement
3) ICD-10-CM Diagnosis Codes are for informational purposes only and are not effective until 10/01/2014.

Covered when medically necessary:

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<th>CPT® Codes</th>
<th>Description</th>
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<tr>
<td>96000</td>
<td>Comprehensive computer-based motion analysis by video-taping and 3-D kinematics</td>
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<tr>
<td>96001</td>
<td>Comprehensive computer-based motion analysis by video-taping and 3-D kinematics; with dynamic plantar pressure measurements during walking</td>
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<tr>
<td>96002</td>
<td>Dynamic surface electromyography, during walking or other functional activities, 1-12 muscles</td>
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<tr>
<td>96003</td>
<td>Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle</td>
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<td>96004</td>
<td>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</td>
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<tr>
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<tr>
<td>343.0</td>
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343.9  Infantile cerebral palsy, unspecified

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Experimental/Investigational/Unproven/Not Covered:

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References


