MEDICAL POLICY DETAILS

<table>
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<tr>
<th>Medical Policy Title</th>
<th>COMPUTERIZED MOTION DIAGNOSTIC IMAGING (CMDI)/GAIT ANALYSIS</th>
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<tbody>
<tr>
<td>Policy Number</td>
<td>2.01.13</td>
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<tr>
<td>Category</td>
<td>Technology Assessment</td>
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<tr>
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<td>07/02/99</td>
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| Product Disclaimer   | • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.  
• If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.  
• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. |

POLICY STATEMENT

I. Based on our criteria and assessment of the peer reviewed literature, Computerized Motion Diagnostic Imaging (CMDI)/gait analysis is considered medically appropriate as part of the preoperative assessment when the results will be used in surgical planning for children with a diagnosis of cerebral palsy.

II. Based on our criteria and the lack of peer reviewed literature, Computerized Motion Diagnostic Imaging (CMDI)/gait analysis is considered not medically necessary for all other applications including but not limited to:
   A. Surgical planning for conditions other than gait disorders associated with cerebral palsy.
   B. Postoperative evaluation of surgical outcomes and rehabilitation planning and/or evaluation for all conditions.

Refer to Corporate Medical Policy #8.01.12 regarding Physical Therapy (PT).
Refer to Corporate Medical Policy #8.01.17 regarding Occupational Therapy (OT).

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Computerized Motion Diagnostic Imaging (CMDI), or gait analysis, uses video recording combined with information from sensor devices, such as surface or needle electromyography or foot pressure sensing plates, to record and analyze coordinated muscle function.

This technology is proposed for surgical planning, primarily for cerebral palsy, and for evaluation of work related athletic and automobile accident injuries, and back pain.

Spinoscopy focuses on dynamic function of the muscles of the back.

RATIONALE

A number of motion analysis systems, including the Peak Motus Motion Measurement System have received FDA 510(k) clearance. The Spinex International spinoscopy device received 510(k) clearance in 1988.

Reports of single center experience suggest that gait analysis may alter decisions regarding the timing and choice of surgical interventions for children with spastic cerebral palsy. A limitation of another study is that the authors did not prospectively collect data on how treatment plans changed after the gait analysis. In addition, the complexity of the
random forest decision algorithm makes it difficult to determine the degree to which gait analysis independently predicts outcomes. There is insufficient evidence that gait analysis as part of surgical planning improves health outcomes in patients with conditions other than cerebral palsy.

An RCT, published in 2012 by Wren et al, compared post-surgery health outcomes in children with cerebral palsy who were managed with and without gait analysis. 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, but only received the gait analysis report for patients in the Gait Report group. Patients were reexamined the day before surgery (ie, following gait analysis) for preoperative treatment planning. Outcomes were assessed preoperatively and approximately 1 year post-surgery. There were 3 primary outcomes: pre- to postsurgical change between groups in the walking scale of the Gillette 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). On the Child Health Questionnaire (CHQ), there was a significant change in health between the Gait Report group (56%) and the Control group (38%). 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 a previous RCT to evaluate the impact of gait analysis on the correction of excessive internal hip rotation among ambulatory children with cerebral palsy. In the secondary analysis, the authors included the subset of children for whom the gait laboratory recommended external femoral derotational 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 anteverision, maximum hip internal and external rotation range of motion, and rotational alignment during gait. The primary outcome variables included femoral anteverision 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, and FDRO was performed in 6/26 limbs in the control group who did not have knowledge of the gait analysis recommendations. 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 anteverision (-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. The authors conclude outcomes were significantly better for limbs in the gait report group when the recommendations for FDRO were followed. Also, when the recommended FDRO was performed in the gait report group, all outcome measures were corrected to within the normal range. 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 a systematic review by Rathinam et al. (2014), the reliability and validity of pediatric gait analysis tools were examined and compared to instrumented gait analysis (IGA). In December 2012, the authors conducted a comprehensive search for any type of study reporting observational gait analysis for the pediatric population with neurological, neuromuscular, orthopaedic and other developmental delay due to genetic disorders. Nine studies related to children with Cerebral Palsy (CP) were included in this review consisting of 5 observational gait tools for children with CP. The Edinburgh Visual
Gait Score (EVGS) was found to have better reliability and validity than the other tools but none of the tools accomplished the level of IGA’s consistency. Limited studies were available for most of the gait assessment tools. The authors conclude five video-based gait assessment tools to assess children with CP were not equal in their objectivity, reliability or validity to IGA.

In 2015, Niklasch et al published a retrospective study evaluating the results of femoral derotation osteotomy (FDO) in children with cerebral palsy who were examined pre- and 1 yr post operatively with standardized clinical examination and 3D gait analysis. A total of 235 affected limbs from 138 children with a mean age of 11 years were included in this analysis. Patients were retrospectively classified into three groups by the amount of derotation in relation to the mean hip rotation (MHR) in stance during gait analysis: Group A with a derotation amount of more than 10 degrees (twice the estimated measurement error) larger than indicated by mean hip rotation in stance (n=57, excessive FDO), Group B consisting of a derotation amount within 10 degrees of gait analysis advice (n=67, moderate FDO), and Group C which includes a derotation amount more than 10 degrees less than mean hip rotation in stance (n=14, conservative FDO).

Improvement of mean hip rotation in stance was calculated by subtracting postoperative from preoperative mean hip rotation in stance. Results showed Group B had the greatest benefit with the highest ratio (86%) of good results. Group C had only 79% good results, but no case of overcorrection or worsening, and Group A had the poorest outcome with 81% good results, but 14% overcorrection and 3% worsening. The authors conclude it is less likely to have unsatisfactory outcomes if the amount of FDO is defined according to the findings of gait analysis compared with clinical examination.

In a retrospective study, Mueske et al (2018) examined the effects of gait analysis data on pathology identification and surgical recommendations in children with spina bifida. Clinical gait analysis which included range of motion and strength testing, kinematics and kinetics during walking, and dynamic EMG was performed on 43 ambulatory children with spina bifida. Data was reviewed by one pediatric orthopaedic surgeon and one therapist (kinesiologist or physical therapist) with surgical treatment recommendations and pathology identification performed both before and after gait analysis. Results showed pathology identification changed in at least 18% of cases for both surgeons and therapists after consideration of gait analysis data. Surgery was recommended before or after gait analysis in 56 cases, and the overall recommendation of whether surgery was needed changed in 18% (10/56) after consideration of gait analysis data. At least one change was made to the specific surgical recommendations for 44% of patients. The authors conclude gait analysis may be particularly helpful in identifying abnormal femoral rotation and excessive hip flexion.

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.”

According to National Institute of Neurological Disorders and Stroke (NINDS) for Cerebral Palsy, “orthopedic surgery is often recommended when spasticity and stiffness are severe enough to make walking and moving about difficult or painful. Surgery may not be indicated for all gait abnormalities and the surgeon may request a quantitative gait analysis before surgery.”

CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.
- CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

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Proprietary Information of Excellus Health Plan, Inc.
COMPUTERIZED MOTION DIAGNOSTIC IMAGING (CMDI) / GAIT ANALYSIS

Policy Number: 2.01.13
Page: 4 of 5

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<th>Description</th>
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<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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**HCPCS Codes**

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**ICD10 Codes**

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**REFERENCES**


BlueCross BlueShield Association Technology Evaluation Center. Gait analysis for pediatric cerebral palsy. 2001 Apr;16(19).


{Proprietary Information of Excellus Health Plan, Inc.}


*Key Article

**KEY WORDS**

Gait, Motion Analysis, Spinoscopy, Dynamic EMG, Electrodynagram, Gait Analysis, Surface EMG

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

Based on our review, computerized motion diagnostic imaging, gait analysis, or spinoscopy are not addressed in National or Local Medicare coverage determinations or policies.