MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Computerized Motion Diagnostic Imaging (CMDI)/Gait Analysis**
Policy Number	**2.01.13**
Category	**Technology Assessment**
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Product Disclaimer	• *Services are contract dependent; 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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer reviewed literature, computerized motion diagnostic imaging (CMDI)/gait analysis has been medically proven to be effective and, therefore, 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 upon our criteria and the lack of peer-reviewed literature, CMDI/gait analysis has not been medically proven to be effective and, therefore, 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; and
   B. Post-operative evaluation of surgical outcomes and rehabilitation planning and/or evaluation for all conditions.

III. Based upon our criteria and assessment of the peer-reviewed literature, other forms of CMDI/gait analysis have not been medically proven to be effective and, therefore, are considered **investigational**. Examples include but are not limited to the following;
   A. DARI Health functional motion analysis;
   B. Surface mechanomyography (sMMG) (e.g., FIGUR8)

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

Refer to Corporate Medical Policy #8.01.12 Physical Therapy (PT)

Refer to Corporate Medical Policy #8.01.17 Occupational Therapy (OT).

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. Recently, markerless systems have entered the market.

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

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

DARI Health (Scientific Analytics, Inc.) was approved by the U.S. Food and Drug Administration (FDA) on March 7, 2019, and marketed as the "world's first and only technology that delivers validated 3D kinematic and kinetic motion analytics without sensors, markers or force plates". The system uses basic cameras, computers and proprietary DARI Health Software (consisting of DARI Connect, DARI Capture plug-in, DARI Insight engine, and DARI Report Engine) to collect, quantify, and document patient movement. It was granted approval based on its substantial equivalence to the predicate device, Peak Motus.

The Figur8 company started as a collaboration between scientists at the Massachusetts Institute of Technology, Massachusetts General Hospital Orthopedics and the Boston Red Sox, a professional baseball team. The shared goal was to develop ways to better diagnose and treat injuries. The resulting device, which is also known as FIGUR8, is a wearable skin surface multi- sensor technology. It is currently being used in clinical trial in several hospitals in the United States and is advertised as a data solution for worker's compensation claims. Inertial measurement unit (IMU) sensors are placed over the patient's bony landmarks and specific muscle groups. The patient performs functional activities such as sit to stand, and gait. The FIGUR8 is reported to assess joint motion, muscle function, and produces a report to diagnose and treat injuries.

RATIONALE

A number of motion analysis systems, including the Peak Motus Motion Measurement System, have received Section 510(k) clearance from the U.S. Food and Drug Administration (FDA). The Spinex International spinoscopy device received Section 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. 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 that was 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 (the "gait report group") 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 re-examined on 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: pre- to post-surgical 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 three primary outcomes. For example, the proportion of patients who 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 gait report 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 derotation osteotomy (FDRO) to correct excessive passive and active internal hip rotation and who had both pre- and post-operative 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 (the "gait report 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 sub-analysis 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 post-surgery and change in variables pre- to post-surgery were compared between the gait report group and the control group, with additional analyses based on whether patients in the gait report group had had the gait report recommendations followed. This sub-analysis included 44 children (65 limbs) in whom FDRO was recommended. FDRO was performed on seven of 39 limbs when it was recommended in the gait report group, and FDRO was performed on six of 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 gait report group who had FDRO performed (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 (7) of 39 recommended FDROs were performed in the gait report group. The authors concluded that 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, orthopedic, and other developmental delay due to genetic disorders. Nine (9) studies related to children with cerebral palsy (CP) were included in this review, consisting of five 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 concluded that five video-based gait assessment tools to assess children with CP were not equal to IGA in their objectivity, reliability or validity.

In 2015, Niklasch et al. published a retrospective study evaluating the results of femoral derotation osteotomy (FDO) in children with CP who were examined pre- and one-year 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 had 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 had a derotation amount within 10 degrees of gait analysis advice (n=67, moderate FDO); and Group C had 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 post-operative from pre-operative mean hip rotation in stance. Results showed that 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 concluded that 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 were reviewed by one pediatric orthopedic 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 concluded that gait analysis may be particularly helpful in identifying abnormal femoral rotation and excessive hip flexion.

The National Institute for Health and Clinical Excellence (NICE) (United Kingdom) has published guidelines for spasticity in children and young people with non-progressive brain disorders. The guidelines note that, "The decision to perform orthopedic surgery to improve gait should be informed by a thorough pre-operative functional assessment, preferably including gait analysis." The guidelines define gait analysis as "[a] detailed approach to analyzing 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."

Markerless motion capture has been reported to reduce data collection, processing time and soft tissue artifact errors compared to marker-based methods. However, the current scientific evidence for computerized motion diagnostic imaging using DARI Health is limited. There are no identified reports of well-designed investigations that have been reproduced by non-affiliated, authoritative sources with measurable results, backed up by the positive endorsements of national medical bodies or panels regarding its scientific efficacy and rationale.

There is currently no published, peer-reviewed literature providing conclusive evidence that use of the Figur8 device has a definite positive effect on health outcomes. Available whitepapers were developed and written by affiliated sources. The Figur8 has not received approval by the United States Food and Drug Administration (FDA), as a medical device, and there for the evidence has not demonstrated that it is reasonably safe and effective for its particular use. Peer-reviewed, scientific studies are warranted.

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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
96000	Comprehensive computer-based motion analysis by videotaping and 3-D kinematics
96001	with dynamic plantar pressure measurements during walking
96002	Dynamic surface electromyography, during walking or other functional activities, 1–12 muscles
96003	Dynamic fine wire electromyography, during walking or other functional activities, 1 muscle

Code	Description
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
0693T **(E/I)**	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report (e.g., DARI Health)
0778T **(E/I)**	Surface mechanomyography (sMMG) with concurrent application of inertial measurement unit (IMU) sensors for measurement of multi-joint range of motion, posture, gait, and muscle function (e.g., FIGUR8)

HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
G80.0-G80.9	Cerebral palsy (code range)

REFERENCES

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*Key Article

KEY WORDS

Motion Analysis, Spinoscopy, Dynamic EMG, Electrodynagram, Gait Analysis, Surface EMG, markerless motion capture, surface mechanomyography, Figur8, DARI Health

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, computerized motion diagnostic imaging is not addressed in National or Regional Medicare coverage determinations or policies, however, there is a Local Coverage Article related to Lower Limb Prosthesis (A52496) that contains information regarding gait analysis.

[https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52496&ver=46&keyword=gait+analysis&keywordType=starts&areaId=s41&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD%2C6%2C3%2C5%2C1%2CF%2CP&contractOption=all&sortBy=relevance&bc=1] accessed 07/01/24.