# Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association



***Current Policy Effective Date: 7/1/23**
**(See policy history boxes for previous effective dates)**

# Title: Comprehensive Gait Analysis

## Description/Background

### Background

Gait analysis, also referred to as motion analysis, is the systematic evaluation and measurement of the dynamics of a walking pattern. The standard method of evaluating gait is by visual assessment, known as observational gait analysis. This does not use any specialized equipment and is adequate to assess most conditions affecting gait.

Comprehensive gait analysis is the quantitative assessment of coordinated muscle function. The evaluation is conducted in a laboratory and typically involves a dedicated facility and staff. The Commission for Motion Laboratory Accreditation, a nonprofit organization established in 1997, evaluates and accredits clinical motion laboratories using a set of criteria for rating quality of administration (eg, staffing, policies, procedures), equipment (eg, accuracy and precision), and data management and reporting (eg, control and clinical data sets).

Several modalities have been incorporated into a comprehensive gait analysis. For instance, visual assessment of gait is supplemented by video recordings taken 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. Dynamic electromyography assessed during walking may be an included component of gait analysis. Dynamic EMG measures timing and intensity of muscle contractions and can help determine whether a muscle's activity is normal, out of phase, continuous, or clonic. Dynamic EMG is primarily used for the optimization of athletic performance.

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. A specific protocol (the “Outwalk” protocol) has been developed to allow the use of an IMMS system for gait analysis. There is continuing research on the reliability of wearable devices for gait analysis.

Comprehensive gait analysis has been proposed as an aid in surgical planning for correction of gait abnormalities resulting from cerebral palsy. It has also been proposed for use in other conditions such as clubfoot and for planning rehabilitative strategies (ie, orthotic-prosthetic devices) for ambulatory problems related to aging, stroke, spinal cord injury, and other conditions.

Functional neuromuscular electrical stimulation is also known as Neuromuscular Electrical Stimulation (NMES). It is a technique that provides ambulation in patients with spinal cord injury, to restore upper or lower extremity function in patients with nerve damage (e.g., spinal cord injury or post stroke) to improve ambulation in patients with foot drop by congenital disorders or as a treatment of pain. The use of this technology through specific devices is also a part of a comprehensive gait analysis.  Functional neuromuscular stimulators are closed loop systems, which provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters which are required for complex activities such as walking.

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## Regulatory Status

**The following are indications for which functional neuromuscular electrical stimulation devices have received U.S. Food and Drug Administration (FDA) approval**

- Providing stimulation to trigger action potentials to allow spinal cord injured patientsi the ability to stand and walk.

To date, Sigmedics’ Parastep® Ambulation System is the only noninvasive functional walking neuromuscular stimulation device to receive PMA from the FDA. The Parastep devices is approved to “enable appropriately selected skeletally mature spinal cord injured individuals (level C6-T12) to stand and attain limited ambulation and /or take steps, with assistance if

required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of spinal cord injury." Other devices include ReWalk™, by ReWalk™ Bionics research Inc., a reciprocating gait orthosis (RGO) with electrical stimulation. The orthosis used is a hip-knee-ankle-foot device linked together with a cable at the hip joint.

- Resoring upper extremity functions such as grasp-release, forearm pronation, and elbow extension in patients with stroke, or C5 and C6 tetraplegia (quadriplegia).

Examples of these devices include: the Neurocontrol Freehand® system (no longer available), which received approval from the FDA from the PMA process and the NESS H200® (previously known as the Handmaster NMS I system), which received 510(k) clearance to provide hand active range of motion and function for patients with stroke or C5 tetraplegia.

- Improving dorsilflexion and ambulation in foot drop caused by stroke or multiple sclerosis.

Functional electrical stimulation of the peroneal nere has been suggested for these patients as an aid in raising the toes during the swing phase of ambulation. In these devices, a pressure senor detects heel off and initial contact during walking. A signal is then sent to the simulation cuff, initiating r pausing the stimulation of the peroneal nerve, which activates the foot dorsiflexors. Examples of devices used for treatment of food drop are the Innovative neurotronics (formerly NeuroMotion, inc.) WalkAide®, Bioness' radio-frequency controlled NESS L300™, MyGait (Otto Bock healthCare), and Odstock Medical Limited's Foot Drop Stimulator. All have received 510 (k) marketing clearance from the FDA and are intended to be used in patients with drop foot by assisting with ankle dorsilflexion during the swing phase of gait.

- Allowing patients with impaired function of the extremities to passively and actively exercise using cycle ergometry.

Cycle ergometers consist of motorized leg ergometer, optional motorized arm crank, and leg and optional arm electrical stimulation. Examples of cycle ergometers that have 510(k) FDA approval are the RT300 (Restroative Therapies, Inc.) and the Myocycle (Myolyn). Rowing devices have also been devised for exercise.

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.

In January 2004, the Coda cx1 Motion Analysis System (Charnwood Dynamics Ltd., Rothley, Leicestershire, UK), was cleared for marketing by 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. 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.

Since 2004, the FDA has cleared other systems for marketing (eg, SMART-D, Qualisys Clinical System, Vicon Motion Systems).

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## Medical Policy Statement

The safety and effectiveness of comprehensive gait analysis (the use of sophisticated quantitative and video capture devices) have been established. It may be considered a useful diagnostic option in specified situations.

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## Inclusionary and Exclusionary Guidelines

**Inclusions:**

Comprehensive gait analysis (ie, the use of sophisticated quantitative and video capture devices to assess coordinated muscle function) is considered established when used:

- As an aid in surgical planning in patients with gait disorders associated with cerebral palsy

**Exclusions:**

- Gait analysis that does not meet definition of comprehensive
- Gait analysis that is used for purposes other than surgical planning for individuals with cerebral palsy, including but not limited to:
  - Gait disorders associated with conditions other than cerebral palsy (eg, club foot)
  - Postoperative evaluation of surgical outcomes
  - Evaluation or planning for rehabilitation for any reason

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## CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

### *Established codes:*

96000 96001 96002 96003 96004

### *Other codes (investigational, not medically necessary, etc.):*

N/A

*Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.*

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## Rationale

The Blue Cross Blue Shield Association published a 2001 TEC Assessment on gait analysis in cerebral palsy.[3] At the time of the TEC assessment, there were no generally recognized

standards of performance and interpretation of gait analysis and only limited reference standards to use for evaluating the accuracy of gait analysis. Gait analysis had been used extensively as an outcome tool in research on gait; however, there was only 1 small, published case series addressing improved patient outcomes due to gait analysis in cerebral palsy. Gait analysis was considered investigational for all applications. Since 2001, numerous studies have been published regarding the use of gait analysis.

**Cerebral Palsy**

There have been several studies published regarding the utilization of gait analysis in the surgical decision-making process in children and adolescents with cerebral palsy.[4,5,6,7,8,9,10,11,12] The studies demonstrated that the use of gait analysis confirms the clinical indications for surgery, alters the decision-making process for surgery, and can direct appropriate treatment.

Wren et al (2009) performed a retrospective study that evaluated the effect of gait analysis on the number of surgeries children with cerebral palsy underwent at Children's Hospital Los Angeles from 1991 to 2005.[13] The study included 313 children who received gait analysis before their initial surgery and 149 children who did not. 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. A higher proportion in the non-gait analysis group (32%%) required additional surgery in contrast to the gait analysis group (11%). The authors concluded that use of gait analysis was associated with a lower incidence of additional surgery.

Wren et al (2011) conducted a randomized controlled trial to determine the effects of gait analysis on surgical decision-making in 178 children with cerebral palsy who were being considered for lower extremity orthopedic surgery.[14] 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 orthopedic 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 performed 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%, $p<.001$). When the gait laboratory recommended against a planned procedure, the plan was changed more frequently in the gait report group (48% vs. 27%, $p=.009$). When the gait laboratory recommended adding a procedure, it was added more frequently in the gait report group (12% vs. 7%, $p=.037$). 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.

**Other Conditions**

Suda et al (2002) reported on gait analysis recommendations in 60 patients with neurogenic intermittent claudication who were evaluated and compared with 50 healthy controls.[15] 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 (2009) received the records of 35 children (56 feet) who had recurrent deformity after treatment of idiopathic clubfoot.[16] Gait lab recommendations were compared with surgical plans prior to gait analysis and then to the 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 (2002), this study did not evaluate whether these changes resulted in improved health outcomes.

Chakravorty (2019) published a systematic review evaluating the accuracy and reliability of wearable devices for objective gait measurement of Lumbar Spinal Stenosis (LSS) patients.[17] 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, which limited interpretation of results. 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 needed to contribute to the body of evidence.

Gait analysis has been used in the assessment of multiple other conditions (eg, knee pain in older patients with osteoarthritis,[18] gait after acute stroke,[19] recovery after hip arthroplasty, [20] and of frailty in older patients[21]); however, the evidence linking the use of gait analysis to outcomes in these conditions is limited.

A systematic review (SR and meta-analysis published by Monte-Silva (2019 evaluated the effects of electromyogram-triggered neuromuscular electrical stimulation (EMG-NMES) on restoring wrist and hand movement in poststroke hemiplegia. [22] Twenty-six studies (N=782) were included from clinical trials comparing the effect of EMG-NMES versus no treatment or another treatment on stroke upper extremity motor recovery. Fifty percent of the studies were considered to be of high quality. Outcomes were each of the International Classification of Functioning, Disability, and health (ICF) domains. The meta-analysis showed that EMG-NMES had a robust short-term effect on improving upper limb motor impairment in the Body Structure and Function domain. EMG-NMES had a stronger effect for each ICF domain in chronic (greater than or equal to 3 months) compared to acute and subacute phases.

## SUMMARY

### Cerebral Palsy

Early studies have reported on the utility of gait analysis in the surgical decision-making process in children and adolescents with cerebral palsy. Gait analysis confirms the clinical indications for surgery, alters the decision making process for surgery, and can direct appropriate treatment. Despite the lack of randomized controlled trials, gait analysis has evolved to a standard of care for this population.

### Other Conditions

There is lack of research to support that gait analysis improves health outcomes for indications other than cerebral palsy.

Functional neuromuscular electrical stimulation is also known as neuromuscular Electrical Stimulation (NMES), Functional neuromuscular Stimulation (FNS), Electrical Neuromuscular Stimulation (ENS), or electromyography (EMG)- triggered neuromuscular stimulation. Treatment with NMES devices must be evaluated in general groups of individuals against the

existing standard of care for the condition being treated. Data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from a functional neuromuscular stimulation device provides a significant advantage over the placebo.

The principal outcome associated with use of functional neuromuscular stimulation devices includes a clinically significant improvement in functional ability, such that there is an improved ability to complete activities of daily living. As a secondary outcome, positive changes in the patient's quality of life may result from improved functional ability . Physical therapy is an important component of clinical treatment of loss of neuromuscular function. Therefore, comparisons between physical therapy with and without neuromuscular stimulation from adequately powered, blinded, RCTs are required to determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the standard of care.

NMES devices are not designed to be alternative to a wheelchair and offer, at best, limited, short-term ambulation.[23]Final health outcomes, such as improved functional performance and ability to perform activities of daily living, have not been reported. Without randomized comparisons, it is not known whether similar or improved results could be attained with other training methods.

Occurring at the same time, uses of NMES with exercise equipment has been proposed to counteract the health consequences of paralyzed limbs, including prevention of muscle atrophy, reduction of muscle spasms, improvement of circulation, improvement in range of motion, improvement in cardiopulmonary function, reduction in pressure sore frequency, and improvements in bowel and bladder function. It is not clear that the health benefits of EMG-triggered NMES exercise cannot be realized through standard passive range of motion exercise.

## SUPPLEMENTAL INFORMATION

### National Institute for Health and Care Excellence (NICE)

Spasticity in under 19s: management
Clinical Guideline [CG145], July 2012. Last Updated: November 2016

1.7 Orthopaedic surgery
1.7.7 The decision to perform orthopaedic surgery to improve gait should be informed by a thorough pre-operative functional assessment, preferably including gait analysis.

### The American Heart Association/ American Stroke Association

The American Heart Association and American Stroke Association published a guideline for adult stroke rehabilitation in 2016[25]. This guideline comments on the use of electrical stimulation form the treatment of hemiplegic shoulder pain, including NMES, with the conclusion that this modality has not been evaluated sufficiently and its efficacy for pain prevention and treatment remains inconclusive.

**Clinical Trials**
A search of clinicaltrials.gov did not reveal any current studies that would influence this review.

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## Government Regulations
## National/Local:
There is no national or local coverage determination on this topic.

The 2023 CMS Physician fee schedule has fees associated with codes 96000 through 96004. An assigned fee is not a guarantee of coverage.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

- Dynamic Posturography
- Surface Electromyography (SEMG)

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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 3/14/23, the date the research was completed.*

## Joint BCBSM/BCN Medical Policy History

| Policy Effective Date | BCBSM Signature Date | BCN Signature Date | Comments |
|---|---|---|---|
| 3/1/11 | 2/17/11 | 1/4/11 | Joint policy established |
| 1/1/13 | 10/16/12 | 10/16/12 | Routine maintenance |
| 9/1/13 | 6/19/13 | 6/26/13 | Routine maintenance. Policy reformatted to mirror BCBSA. Policy title changed from “Comprehensive Computerized Gait Analysis” to “Gait Analysis.” |
| 9/1/14 | 6/20/14 | 6/23/14 | Routine maintenance. Policy retired as established. |
| 7/1/19 | 4/16/19 | | Policy unretired |
| 7/1/20 | 4/14/20 | | Routine maintenance |
| 7/1/21 | 4/20/21 | | Routine maintenance, rationale section updated. Title changed from “Gait Analysis” to “Comprehensive Gait Analysis,” inclusions/exclusions revised. |
| 7/1/22 | 4/19/22 | | Routine maintenance |
| 7/1/23 | 4/18/23 | | Routine maintenance (jf)<br>Vendor Managed: NA<br>Added 22,23, 25 ref |

Next Review Date: 2nd Qtr, 2024

# BLUE CARE NETWORK BENEFIT COVERAGE
# POLICY: COMPREHENSIVE GAIT ANALYSIS

## I. Coverage Determination:

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|---|---|
| **Commercial HMO (includes Self-Funded groups unless otherwise specified)** | Covered; criteria applies. |
| **BCNA (Medicare Advantage)** | See Government Regulations section. |
| **BCN65 (Medicare Complementary)** | Coinsurance covered if primary Medicare covers the service. |

## II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.