Prior Authorization Review Panel
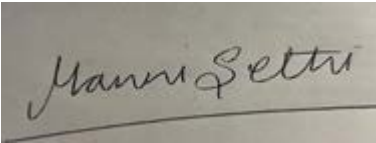## MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 3/1/2024
Policy Number: ccp.1105	**Effective Date:** 6/2014 **Revision Date:** February 1, 2024

Policy Name: Computerized gait analysis

Type of Submission – Check all that apply:

    New Policy
X Revised Policy*
    Annual Review – No Revisions
    Statewide PDL

*All revisions to the policy <u>must</u> be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

This policy was previously retired and is being reactivated.

Name of Authorized Individual (Please type or print):	Signature of Authorized Individual:
Manni Sethi, MD, MBA, CHCQM	*Manni Sethi*

Computerized gait analysis

Clinical Policy ID: CCP.1105

Recent review date: 2/2024

Next review date: 6/2025

Policy contains: Cerebral palsy; Progressive supranuclear Palsy; Parkinson's; gait dysfunction; instrumented gait analysis; quadriplegia; hemiplegia; orthopedic surgery; specialized laboratories; Spina Bifida; phenotypes.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

The use of computerized gait analysis is clinically proven and, therefore, may be medically necessary for the evaluation of musculoskeletal gait function to assess and aid in planning for orthopedic surgery or interventional neurology (e.g., nerve blocks to reduce spasticity orthotic application) in ambulatory members with certain gait dysfunctions associated with the following conditions (National Institute for Health and Care Excellence, 2016; Wren, 2020):

- Cerebral palsy.
- Spina bifida meningomyelocele.
- Traumatic brain injury.
- Incomplete quadriplegia.
- Spastic hemiplegia.
- Spastic diplegia.

For any determinations of medical necessity for medications, refer to the applicable state-approved pharmacy policy.

Limitations

All other uses of computerized gait analysis are not medically necessary.

Alternative covered services

Observational clinical gait analysis.

Background

Gait analysis is used to assess and treat individuals with conditions that affect their ability to ambulate. It's also used in sports biomechanics to improve athletic ability; to run more efficiently and to recognize and treat posture or movement-related disorders in those with previous injuries (Perry, 2010).

Gait and balance disorders are common in the elderly, in whom they significantly contribute to falls; after orthopedic surgery; and in neurodevelopmental disorders such as spina bifida and cerebral palsy (Baker, 2018). In recent years the use of instrumented gait analysis for clinical management and assessment has been increasing for cerebral palsy individuals. For the important aspects of treatment decision making, the provider must understand the ongoing relationship between orthopedic, neurological and developmental considerations related to gait (States, 2021). The clinical heterogeneity of gait disorders reflects the large and complex neuromuscular systems involved and the vulnerability of walking to neurologic disease at every level of progression.

Neurodevelopmental disorders are disruptions of the normal growth and development of the brain and central nervous system (Sontheimer, 2015). They may result from genetic causes or from conditions occurring prenatally or in infancy or childhood. These disorders have widespread effects that can impact such functions as learning, memory, and other cognitive functions, as well as voluntary muscle control (e.g., coordination, mobility, and speech articulation). Neurodevelopmental disorders are attributable to genetics, metabolic or infectious diseases, physical trauma, and toxic or other environmental exposures. Among the most common are cerebral palsy and spinal bifida.

Providers have historically diagnosed and classified gait by visual observation, but this approach yielded more generalized results lacking information on more specific causes and treatment of failing gaits, balance and stability issues, and declining performance. In a review of 34 studies of gastrocsoleus lengthening surgery, outcomes improved, and authors found observational gait analysis and video recordings can be used to measure treatment outcomes as a comparison but are subjective in nature and have validity and reliability issues (Ma, 2021). More standardized gait analyses have been developed in specialized laboratories equipped with cameras, floor sensors, and other data collecting equipment inherent in more objective data classification.

Types of gait analysis include but are not limited to: three dimensional gait analysis also known as 3DGA; optical tracking gait analysis; comprehensive computer-based motion analysis by videotaping; three-dimensional kinematics; dynamic plantar pressure measurements during walking; and dynamic surface electromyography of multiple muscles during walking or other functional activities. These analyses are used to assess, diagnose, develop a plan of care, and document treatment and surgical outcomes for multiple gait issues (Ma, 2021).

Findings

Guidelines for appropriate use of computerized gait analysis are very limited, due to the lack of homogeneity for published articles, and the large variety of conditions for which providers use the technology.

The guideline from the National Institute for Health and Care Excellence (2016) addressed care of young persons with spasticity. Specifically, it advises any decision to perform orthopedic surgery to improve gait must include a pre-operative functional assessment, preferably to include gait analysis. In addition, surgical outcomes of effects on gait should be performed one to two years post-operatively.

A scoping review of 909 studies assessed the impact of Instrumented Gait Analysis on children with cerebral palsy. Results were divided into six categories, of which 49% used Instrumented Gait Analysis as an outcome measure for treatment. Authors state the large number of studies provide a basis for developing a guideline for managing children with cerebral palsy-related gait disorders (States, 2021).

A systematic review of 2,712 articles concluded that three-dimensional instrumented gait analysis changes treatment plans, increases clinicians' confidence in treatment decisions, and increases agreement among clinicians. A small number of these studies determined patient outcomes (such as incidence of severe crouch gait) improved only when three-dimensional instrumented gait analysis were available and recommendations were followed (Wren, 2020).

Computerized three-dimensional gait analysis is recognized as a standard means of analyzing gait patterns in patients with ambulatory issues such as Parkinson's disease, cerebral palsy, spina bifida and other disorders such as flat foot (Ma, 2021). The procedure offers promise for identifying individuals in need of preventive measures regarding falls or ambulatory rehabilitation, but is a complex process producing vast amounts of data.

Research on measuring sensitivity and sensitivity of gait is still evolving for different conditions. Thus, research is limited to its technical ability to provide necessary and accurate information for individualized clinical decision making. While studies often show that gait analysis impacts decisions, many studies fail to address impacts on patient outcomes (Wren, 2011). Assessment between clinical measurements and quantitative gait analysis do not demonstrate with certainty that the data provided by gait analysis improves clinical management.

In 2016, we identified no new evidence for this policy. We found one new CMS Local Coverage Determination that covers Florida, Puerto Rico, and the U.S. Virgin Islands and is reflected in the policy for Medicare members only.

In 2017, we identified one evidence-based guideline from the National Collaborating Centre for Women's and Children's Health in the United Kingdom for this policy (National Institute for Health and Care Excellence, 2012). The routine use of computerized gait analysis remains controversial. While it can alter decision making in some cases, it is less clear if the decisions based on computerized gait analysis lead to better patient outcomes. However, in ambulatory children with certain gait dysfunction (e.g., cerebral palsy) who are candidates for orthopedic surgery, it can aid in surgical planning by identifying common patterns of muscle overactivity and deformity and determining what type of muscle, tendon, or joint surgery would be most helpful. This policy was amended to reflect this information.

In 2018, no new evidence was identified. The guideline published by National Collaborating Centre for Women's and Children's Health (National Institute for Health and Care Excellence, 2012) was updated in 2016 but the changes do not affect this coverage policy. The two Centers for Medicare & Medicaid Services Local Coverage Determinations that were previously included have both been retired.

In 2019, we updated the policy references with no change to coverage. The policy ID changed from 15.01.01 to CCP.1105.

In 2020, we updated the policy references with no change to coverage.

In 2021, we updated the policy references, removed nine references, and added five systematic reviews to the policy (Bouça-Machado, 2020; Chakravorty, 2019; Job, 2020; MIchelini, 2020; Wren, 2020). The new information confirms previous findings and warrants no change in coverage.

In 2022, we updated and added additional current references with no change to coverage.

In 2023, we updated and added additional current references with no change to coverage.

In 2024, we added the following studies:

- A systematic review of 26 studies found use of artificial intelligence methods for assessing gait in athletes was insufficient, but showed great potential for sports performance analysis (Molavian, 2023).

- A systematic review/meta-analysis on the ability of virtual reality/augmented reality to impact physical exercise in the elderly. Fourteen of these studies used instrumental measures of gait outcomes, and found an improvement, significant at $P < .006$ (Dore, 2023).

- A systematic review of 25 studies assessed instrumental evaluation of function in Chronic Obstructive Pulmonary Disease patients. Seven studies included three-dimensional gait analysis. Evaluation was hampered by lack of standardization, small sample sizes, and study design issues. Specifically, gait analysis was found to be costly, requiring dedicated space and infrastructure (Zucchelli, 2022).

- A systematic review of 12 studies of instrumental gait assessments in persons with fractured ankles concluded that these assessment can objectively characterize gait alterations. Instrumental gait assessment can be useful in clinical practice (assess patient performance) and clinical research (evaluate existing or new rehabilitative interventions (Mirando, 2022).

References

On November 8, 2023, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "gait analysis," "gait disorders, neurologic" [MeSH], "Cerebral Palsy/rehabilitation" [MeSH], "Cerebral Palsy/surgery" [MeSH], and "Spinal Dysraphism" [MeSH]. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Chakravorty A, Mobbs RJ, Anderson DB, et al. The role of wearable devices and objective gait analysis for the assessment and monitoring of patients with lumbar spinal stenosis: Systematic review. *BMC Musculoskelet Disord.* 2019;20(1):288. Doi: 10.1186/s12891-019-2663-4.

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Policy updates

5/2014: initial review date and clinical policy effective date: 6/2014

6/2016: Policy references updated.

5/2017: Policy references updated. Coverage changed.

3/2018: Policy references updated.

3/2019: Policy references updated. Policy ID changed.

2/2020: Policy references updated.

2/2021: Policy references updated.

2/2022: Policy references updated.

2/2023: Policy references updated.

2/2024: Policy references updated.