BionicPower™

Agilik™

REIMBURSEMENT GUIDE:

Agilik™ Smart Orthosis

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Reimbursement Guide: Agilik™ Smart Orthosis

Disclaimer

This Agilik™ Smart Orthosis reimbursement guide (Guide) has been prepared by O&P Insight to provide general information and reference material for qualified healthcare professionals involved in the prescription, fitting, or billing of the Agilik™ Smart Orthosis, a powered microprocessor knee-ankle-foot orthosis (MKAFO). This Guide is provided to assist in understanding the reimbursement process for this specific medical device. It is not intended to replace the judgment of healthcare Suppliers, nor does it constitute legal, clinical, or billing advice.

Purpose of the Guide

The Guide is designed to outline documentation considerations and payer engagement strategies that support reimbursement claims for the Agilik™ Smart Orthosis. The information herein reflects O&P Insight's best understanding of public and private payer policies and reimbursement practices as of the publication date.

The Guide is intended for informational use only and should not be interpreted as a guarantee of coverage or payment by any payer, including Medicare, Medicaid, or commercial insurers.

Limitations of Liability

O&P Insight disclaims all warranties, express or implied, as to the completeness, accuracy, or reliability of the information contained in this Guide. While reasonable efforts have been made to ensure the information is accurate at the time of publication, payer policies and coding guidelines are subject to frequent changes and may vary by region, plan, or patient condition.

Use of this Guide and the information it contains is entirely at the user's discretion and risk. O&P Insight does not assume any responsibility or liability for claim outcomes, denials, or decisions made by payers or third-party administrators.

Responsibilities of the Supplier

The prescribing clinician, orthotist, or billing supplier remains solely responsible for:

- selecting and applying accurate coding based on the specific clinical context and device configuration;
- documenting medical necessity in accordance with payer guidelines and accepted clinical practice;

- verifying the applicable reimbursement requirements with the patient's health plan prior to delivery;
- ensuring compliance with all local, state, and federal regulations, as well as payer-specific policies.

Any sample codes or documentation suggestions included in this Guide are provided solely for reference and must be evaluated by the Supplier in the context of the specific case.

Nothing in this Guide should be interpreted as legal, regulatory, or billing advice. Suppliers should consult with their own legal counsel, billing experts, or payer representatives to ensure compliance with applicable laws, regulations, and contractual obligations. The Guide does not constitute a professional-client relationship between O&P Insight or any of its affiliates and you.

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Clinical Overview

Patient Population

The Agilik™ Smart Orthosis MPKAFO is designed to assist individuals with lower-limb weakness and gait impairments who demonstrate knee instability during ambulation. The device is particularly effective for individuals requiring dynamic knee assistance to achieve more functional, energy-efficient walking patterns. It is suitable for both pediatric and adult populations.

Indications

The product is intended for patients with lower extremity weakness resulting in gait pathology, such as but not limited to crouch gait from a diagnosis of cerebral palsy, muscular dystrophy, spina bifida, incomplete spinal cord injury, or post-stroke hemiparesis.

Patients must:

- Be ≥ 5 years old with body weight > 20 kg (44 lbs) and < 125 kg (276 lbs)
- Be able to understand and follow simple directions
- Be able to walk at least 3 meters (10 feet) without stopping, with or without a walking aid
- Be able to initiate swing
- Have sufficient length in the femur to accommodate the Agilik joint (approximately 260mm or 10 ½ inches)

Clinical Characteristics

Patients who may benefit from the Agilik™ Smart Orthosis typically present with:

- Knee instability during stance, primarily in the sagittal plane, but retain some intrinsic ability to stabilize the limb during weight-bearing
- Inability to achieve adequate knee extension due to weakness, poor motor control, or neuromuscular dysfunction
- Adequate hip and ankle range of motion, and no more than 20° total fixed flexion contracture across the hip and knee
- Cognitive and physical capacity to operate a powered orthotic system, as well as follow instructions for app-based mode switching

Pediatric Etiologies

Children and adolescents with the following conditions may be appropriate candidates:

- Cerebral palsy (CP),
- Spina bifida

- Pediatric traumatic brain injury or other developmental neuromotor disorders

Adult Etiologies

The device is also indicated for adults experiencing gait limitations due to:

- Cerebrovascular accident (CVA/stroke)
- Post-polio syndrome
- Multiple sclerosis (MS)
- Incomplete spinal cord injury
- Progressive neuromuscular disorders
- Traumatic brain injury (TBI)

Clinical Benefits

Improved upright posture and knee control

Many individuals with excessive knee flexion during gait struggle to achieve an upright posture, leading to inefficient, tiring movement patterns and further knee flexion contracture.

- The Agilik™ Smart Orthosis provides targeted torque during stance and swing phase, assisting users in maintaining knee alignment and reducing crouch gait.
- Powered support is timed using real-time inputs from a Force Sensitive Resistor (FSR) in the foot plate and Inertial Motion Unit (IMU) in the knee.
- The system dampens eccentric movement and amplifies concentric muscle activity, enabling more energy-efficient and confident ambulation.

Reduced fatigue and improved gait efficiency

Fatigue from compensatory gait patterns often limits community mobility and rehabilitation outcomes.

- The Agilik™ Smart Orthosis delivers assistance, reducing fatigue and optimizing the position in which muscles are activated.
- Torque, timing, and fade-out parameters are fully configurable, allowing personalized support that matches the user's endurance profile and gait strategy.
- Improved mechanical efficiency allows users to sustain walking for longer periods with reduced energy expenditure.

Functional versatility in daily environments

Beyond level walking, individuals often face difficulty with common transitional tasks that require more muscle power, such as standing from a chair or navigating stairs.

- The Agilik™ Smart Orthosis includes dedicated modes for sit-to-stand, stair and ramp descent, each optimized to support limb control during the demands of vertical movement.
- These functions are easily accessed via a Bluetooth-connected mobile app, empowering users to adjust the device to different environments.

This versatility allows the Agilik™ Smart Orthosis to be integrated into daily life activities beyond clinical walking scenarios.

Evidence-Based Summary

The Agilik™ Smart Orthosis is based on more than a decade of peer-reviewed research in powered knee-ankle-foot orthoses developed at the U.S. National Institutes of Health (NIH). Most clinical studies to date have focused on children and adolescents with cerebral palsy or similar neuromotor conditions, as these populations represented the initial target of the Agilik™ Smart Orthosis technology.

Results from these pediatric studies establish a strong foundation of safety, feasibility, and meaningful functional improvement, which are now being translated to adult indications (e.g., stroke, multiple sclerosis, post-polio, incomplete spinal cord injury). Practice-based clinical experience and early case evidence already support comparable biomechanical and functional effects in adults, and formal studies are being planned to expand this evidence base.

Improved upright posture and knee control

- Immediate biomechanical improvements were shown in early feasibility work.
    - Lerner et al. (2016) demonstrated +18° of knee extension during stance and +21° of total knee range of motion in a child with spastic diplegia using a powered KAFO, with no reduction in quadriceps activity, resulting, according to the authors, in a trajectory closer to that of normal walking.
    - Lerner et al. (2017, IEEE TNSRE) confirmed in a 7-participant pediatric cohort that powered assistance increased peak stance knee extension by ~12° and hip extension by ~8°, while decreasing biological knee extensor moments by up to 76 % in late stance (for 6 of them). The results show that the powered orthosis promotes upright posture and controlled extension without inducing dependency.
- Progressive gains with practice were reported by Bulea et al. (2022), where multi-session training produced incremental improvements in knee extension and posture—implying adaptation and motor learning.

- Systematic evidence synthesis (Hunt et al., 2022) across robotic gait-training devices concluded that pediatric exoskeletons increase knee and hip extension in stance, supporting better posture and stability when torque timing is individualized.

Reduced fatigue and improved gait efficiency

- Lower mechanical effort. Lerner et al. (2017) observed that powered assistance reduced biological knee extensor moment by 35–76% (for early and late stance, respectively), redistributing load between user and device.
- Metabolic efficiency. The Hunt et al. (2022) review reported average reductions of ~19 % in metabolic cost across pediatric robotic assistance studies, reflecting more efficient gait patterns when torque is phase-specific.
- Functional carry-over is under investigation. The randomized cross-over trial by Taylor et al. (2024) is currently evaluating 12 weeks of overground use of the pediatric Agilik exoskeleton, with outcomes including knee extension, gait speed, endurance (6-Minute Walk Test), and gross motor function (GMFM-66). A 6-week post-use follow-up will determine whether improvements persist without device wear, directly addressing long-term efficiency and endurance.

Maintained Engagement & Neuromuscular Activation

- Active participation during assistance:
  - Bulea et al. (2016) combined the exoskeleton with an exercise video game and found that children maintained or increased quadriceps EMG activity during assisted movement and exhibited continued cortical activation on EEG—demonstrating preserved volitional drive.
- Capacity for selective motor learning:
  - Bulea et al. (2017) showed that children with unilateral cerebral palsy retain independent neural adaptation in each limb, supporting the rationale for targeted, side-specific exoskeleton training.

Key Takeaway

The Agilik™ Smart Orthosis technology was originally conceived and validated in pediatric populations, where multiple NIH-led studies have demonstrated improved knee extension, upright posture, and functional gait performance achieved without loss of voluntary muscle activity.

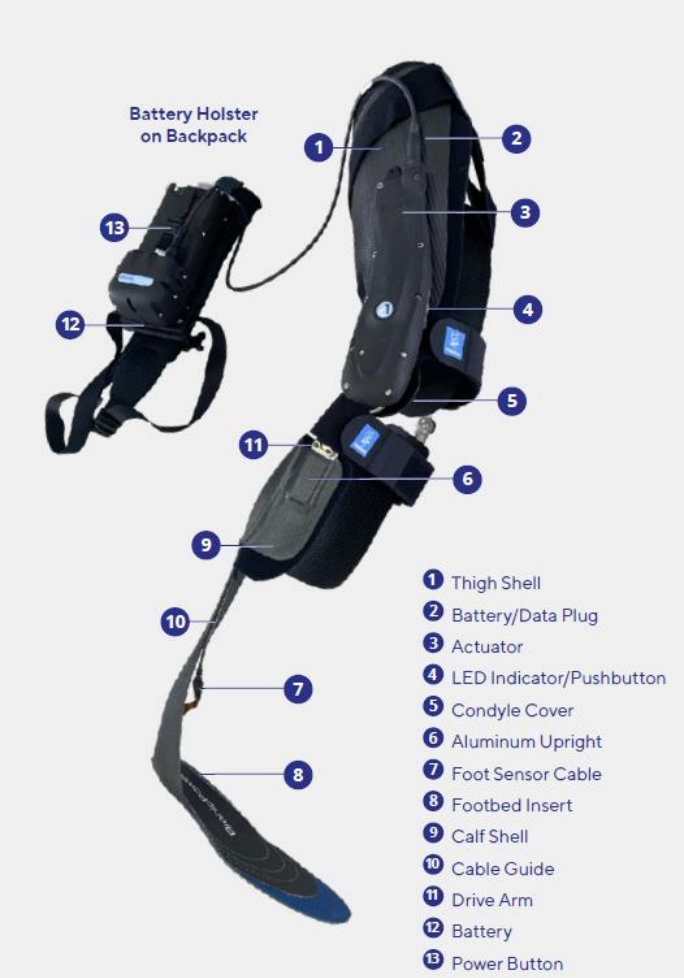
Clinical experience now indicates similar biomechanical benefits in adults with neuromotor weakness, supporting the extension of these principles to broader

contexts. Future clinical studies will formalize this transition, strengthening the evidence base for adult reimbursement and coverage decisions.

Technology Summary

Device Description

The Agilik™ Smart Orthosis can assist or resist motion independently in each gait phase. It can be used as a pair or as a single-joint orthosis on one or both legs, according to the configuration. The device can apply up to 12 Nm across the knee joint in the direction of either flexion or extension. The system consists of an orthosis for each leg, a battery, a carry pack, cabling, and application software running on a computer or cellular phone.



The orthosis consists of an electromechanical actuator with integrated electronics that is attached as a lateral hinge on a conventional, patient-specific, custom-molded KAFO. A foot pressure sensor is embedded in the footbed of the KAFO and connected to the actuator.

The foot sensor detects the patient's gait phase and communicates with the motor controller to provide a unique torque for each phase. The torque can be modified in the Agilik Care app to cater to individual patients by assisting or resisting motion during their gait. This allows the clinician working with the patient to adjust the device settings for the patient's needs.

Agilik Gait State Machine Overview

The Agilik™ Smart Orthosis uses a Gait State Machine to identify and respond to the current phase of gait in real time.

Transitions between gait phases are triggered by either:

- detection of (Stance + or Swing -)
- reaching a defined angular velocity threshold

If no transition event occurs within a given period, the system automatically returns to a waiting state.

Note: The Agilik™ Smart Orthosis follows the convention of negative angles and angular velocities for extension, and positive values for flexion.

The zero angle corresponds to the user's personalized "zero knee angle," as defined in the application's calibration function.

Gait Phases

- ***Early Stance (Loading Response):*** Early Stance begins at initial contact. In non-pathological gait, the knee moves from near full extension to a loading response flexion of up to ~15°, absorbing shock and aiding stability. The phase ends when the knee transitions back into extension following the loading response, typically covering the first 10–20% of the gait cycle.
- ***Mid-Stance:*** Mid-Stance corresponds to the period of stance when the knee is in or near full extension. This phase typically spans 20–45% of the gait cycle.

The transition from Early to Mid-Stance occurs when angular velocity changes from flexion (positive) to extension (negative) — generally set to a small negative threshold.

- ***Late Stance (Pre-Swing Flexion):*** Late Stance marks the flexion movement at the end of stance, as the body prepares for swing. It usually occurs between 45–60% of the gait cycle. The transition into this phase happens when angular velocity shifts from extension to flexion, crossing a small positive threshold.
- ***Early Swing:*** Early Swing begins at toe-off, detected by the foot sensor, and continues through the flexion phase of swing. This typically represents 60–80% of the gait cycle. During this period, the knee flexes to provide foot clearance.
- ***Late Swing:*** Late Swing encompasses the extension movement of the knee as the leg prepares for the next initial contact. It usually spans 80–

100% of the gait cycle. The transition into Late Swing occurs when angular velocity changes from flexion to extension, crossing a small negative threshold.

State Transitions

- Initial contact from any swing state transitions the system to Early Stance.
- Toe-off from any stance state transitions the system to Early Swing.
- A timeout in any state triggers a return to the waiting state.

The next initial contact or toe-off event will exit the waiting state and resume gait progression in the appropriate stance or swing phase.

Warranty

Bionic Power Inc. grants a warranty of up to two years from the date of purchase. An optional extended warranty is available at the time of purchase for up to 4 years.

The standard warranty covers defects in materials or workmanship and/or functional failures of the Goods, Products, and/or the Components. Typical and customary wear and tear, as well as theft and loss, are not covered by this warranty. Typical and customary wear and tear items include FSR assemblies (unless damaged by incorrect installation or trimming by the fabricator/lab).

The Agilik™ Smart Orthosis requires a mandatory annual maintenance inspection and software update check by a certified orthotist to ensure optimal performance.

Regulatory

Under the FDA's regulations, the Bionic Power Agilik™ Smart Orthosis is a Class I medical device exempted from the pre-market notification [510(k)] requirements. Given the low risk of Class I medical devices, the FDA determined that General Controls are sufficient to provide reasonable assurance of the device's safety and effectiveness.

The Bionic Power Agilik™ Smart Orthosis is appropriately FDA registered under Registration Number 3011363045, Classification: Orthosis, Limb Brace, Regulation Number 890.3475; Product Code IQI.

Coverage Criteria & Authorization Process

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Fee Schedule and Allowed Amounts

The Pricing, Data Analysis, and Coding (PDAC) Contractor has reviewed the Bionic Power Agilik™ Smart Orthosis and has approved the listed Healthcare Common Procedure Coding System (HCPCS) code(s) L2006, effective 12/08/2023.

The Centers for Medicare & Medicaid Services (CMS) has assigned a national allowable fee schedule amount for L2006, typically ranging from approximately $38,600 to $44,500, depending on the state of residence. While this provides a benchmark for Medicare reimbursement, it is important to note that not all commercial or Medicaid payers have adopted or published a fee schedule for this code. Some plans, especially Medicaid programs, may still require case-by-case pricing or individual consideration.

Suppliers should verify both code recognition and the associated allowable amount directly with the payer prior to claim submission. This includes confirming whether the code is considered active, manually priced, or non-covered by that payer.

Review Pertinent Payer Coverage Policies

Before pursuing authorization or delivering services, Suppliers should review the payer's official clinical coverage criteria related to microprocessor-controlled KAFO technology. This includes searching payer policy portals, medical necessity determinations, and any posted prior-authorization lists.

When available, locate and review medical policy language specific to L2006 – Microprocessor-Controlled Knee-Ankle-Foot Orthosis, including indications, required documentation, functional expectations, and exclusions. If policy language does not exist, request a pre-determination of orthotic coverage.

Review the Patient's Summary Plan Description (SPD)

Thorough review of the patient's benefits documentation is necessary to understand coverage specifics, limitations, and cost-share obligations. Key areas to review include:

- Orthotic and Durable Medical Equipment (DME) Coverage terms and definitions
- Applicable exclusions, limitations, and benefit caps, including frequency limits and prior-use restrictions
- Out-of-network requirements or special utilization rules, if applicable

Confirm whether the benefit category is treated under DME, prosthetics/orthotics, or rehabilitative services, as rules may differ between categories.

Prior Authorization Requirements

Although Medicare does not currently require prior authorization for L2006, many commercial and managed care payers do require authorization before delivery. Failure to secure authorization when required may result in denial regardless of medical necessity.

Suppliers should:

- Verify pre-service authorization requirements for each plan.
- Request and maintain documentation of approval validity periods.
- Ensure medical necessity evidence aligns with payer criteria and the approved request.
- If prior authorization is not required, a pre-determination is recommended.

Documentation Requirements

Medicare guidance specifies that products coded as L2006:

- Require PDAC coding verification
- Face-to-face evaluation by the prescribing physician is recommended
- Written order prior to delivery is recommended
- Do not have any allowed Add-On codes

Modifiers:

- KX – use only when all LCD coverage criteria are fully documented.
- RT/LT – indicate side(s); submit separate lines for bilateral claims (RT and LT each × 1).

Typical ICD-10 (NON-EXCLUSIVE LIST):

- L2006 is classified as a Group 1 code; however, CMS does not specify a particular diagnosis code for this HCPCS code per Policy Article A52457
- Pediatric: G80.x series (CP) including Spina Bifida (Q05.9)
- Adult: G83.x, G35, I69.351, etc.

Basic Coverage Criteria

To qualify for reimbursement and meet medical necessity expectations, documentation must clearly demonstrate that the device is required to restore, maintain, or improve functional mobility and safety. At a minimum, the record should show that the patient:

1. Is ambulatory or expected to achieve/maintain ambulation and will derive functional improvement through use of the orthosis.

2. Has a clinically significant weakness or deformity of the foot, ankle, and/or knee that interferes with safe ambulation.
3. Requires knee stability not achievable with an AFO or traditional KAFO configuration, including stance control limitations or instability in multiple planes.

Custom Fabrication Criteria

Documentation must include justification for custom fabrication when billing for custom-made orthoses. One or more of the following must be met:

- The patient cannot be appropriately fit using any prefabricated orthosis.
- The patient's condition is permanent or long-term (expected duration greater than six months).
- The orthosis is required to control the limb in multiple anatomical planes (e.g., sagittal and coronal).
- The patient's skin integrity, circulatory status, orthopedic deformity, or limb shape necessitates custom fabrication to prevent injury or device failure.

Clinical notes should reference gait assessment, stability needs, functional goals, and supporting evaluations.

Replacement Criteria: Same or Similar Rule

When requesting replacement of a device, the Supplier should address Medicare's Same/Similar (RUL) guidelines or comparable commercial plan rules.
Documentation must specify the reason for replacement, such as:

- Irreparable damage unrelated to misuse or neglect
- Physiological change (e.g., weight loss, growth, progression of condition)
- Non-functional or inadequate technology that no longer meets safety or functional criteria

Confirm the device's original delivery date and the applicable RUL intervals prior to submitting for replacement.

Physician Documentation Requirements

The treating physician's medical record must clearly establish medical necessity, functional need, and justification for the selection of a custom-fabricated microprocessor-controlled swing and stance KAFO (L2006). Documentation should be detailed, patient-specific, and reflect current clinical status.

a/ History of Present Condition Requiring Orthosis

The medical record should describe the clinical condition that necessitates orthotic intervention, including:

- Confirmed medical diagnoses supported by examination and diagnostic testing
- Identification of affected side(s) (unilateral or bilateral involvement)
- Description of symptoms and patient-reported complaints, including pain, weakness, instability, fatigue, or unsafe gait mechanics
- Overview of the clinical course, including onset, progression, and prior or ongoing management efforts

b/ Functional Deficits and Mobility Goals

Documentation must relate impairments to functional limitations and measurable mobility goals. The physician should provide:

- A description of how the condition affects current functional activities, such as walking, transfers, community engagement, stair use, workplace or school demands, and safety
- Identification of comorbidities that may influence orthosis selection or expected outcomes (e.g., cardiovascular disease, pulmonary impairment, cognitive limitations, contralateral limb involvement)
- Description of any existing ambulatory aids used with or without orthoses, such as a cane, walker, wheelchair, or crutches

c/ Prior Interventions and Outcomes

The physician should document all previously attempted interventions and their results, demonstrating enduring functional need. This may include:

- Prior orthoses, including AFOs or traditional KAFOs, and specific problems or limitations (e.g., knee buckling, fatigue, gait inefficiency, pain, poor terrain tolerance, inability to safely manage stairs)
- Situations or environments where ambulation occurs that require enhanced safety and stability, such as uneven surfaces, stairs, ramps, community ambulation, prolonged distances, or variable terrain
- Documentation of a trial with a microprocessor-controlled KAFO, when available, and associated improvements in stability, gait efficiency, energy expenditure, safety, or confidence
- Previous or current physical or occupational therapy participation, goals, and outcomes

d/ Physical Examination

The medical examination should support the clinical need for an advanced stance-and-swing-controlled device. Findings may include:

- Current ambulatory status and potential for improvement

- Objective manual muscle testing values for the hip, knee, and ankle
- Presence and degree of spasticity, tone abnormalities, contractures, or other neuromotor deficits

e/ Assessment and Clinical Rationale

The assessment must clearly describe the functional deficits and the medical need for stabilization and microprocessor technology. The physician should address:

- Specific, realistic functional benefits expected with use of the microprocessor-controlled KAFO (e.g., improved safety, reduced falls, enhanced mobility, endurance, community participation, job-related, etc.)
- Precise description of knee, ankle, and foot weakness, instability, deformity, or neuromuscular deficit
- Underlying diagnosis driving functional limitations
- Clinical justification for requiring stabilization
- Explain the functional deficits remaining untreated by typical AFO or KAFO
- If replacement, rationale for why the current or prior orthosis is no longer appropriate or safe
- Statement confirming that the condition is permanent or expected to persist beyond six months
- Prognosis, including estimated timeframe for achieving goals and whether physical therapy will be required to achieve optimal benefit

f/ Prescription

The physician must issue a valid order for the orthosis. The prescription should specify:

- Custom-fabricated microprocessor-controlled swing and stance KAFO (L2006)
- Indication of laterality (left, right, or bilateral)

Physical or Occupational Therapy Documentation

Involving a PT/OT in documenting the medical necessity of an Agilik™ Smart Orthosis is critical. PT/OT documentation should complement the physician's record and may include:

- Level of assistance required for transfers and ambulation, with and without the device
- Clear statement of why the device is necessary for safe, functional mobility
- Documentation of training provided to the individual and/or caregiver on donning, doffing, adjusting, charging, and operating the device

Orthotist/Clinician Documentation

a/ Physician Prescription

Prior to billing, a physician-signed Standard Written Order (SWO) must be obtained. The SWO must be signed and dated before billing.

Required SWO Elements:

- Beneficiary name
- Physician name
- Physician NPI
- Order date
    - If created by the supplier, both the order date and signature date must be included
- Detailed description of item (including HCPCS code and narrative)
- Physician signature and signature date

Optional SWO Elements:

- Date of birth
- Diagnosis and ICD-10 codes
- Medical justification

b/ Physician Record

The physician is responsible for establishing medical necessity. Per Section 50402 of the Bipartisan Budget Act of 2018, orthotists' and prosthetists' clinical notes are considered part of the patient's medical record and may be used to support documentation provided by the treating physician or eligible practitioners described in Section 42 USC 1848(k)(3)(b).

Suppliers should:

- Compare physician documentation to required elements
- Request addendum / amendment or additional visits if information is incomplete
- Review PT/OT and other eligible clinical records to support medical necessity

c/ Comprehensive Orthotist Evaluation

Medical Documentation Summary Guidance

Documentation must demonstrate medical necessity and functional need, not device preference. Maintain consistent terminology throughout ("microprocessor-controlled KAFO, L2006"). Strong records typically include:

- Diagnosis, clinical deficits, ambulatory status, history of falls or instability

- Prior therapy or orthosis trials and reasons for failure or incomplete benefit
    - Test drive fittings are strongly recommended for all patients and required by some payers
- Justification for microprocessor-controlled stance and swing technology
- Functional goals and anticipated mobility improvements
- The orthotist's independent documentation should include, at a minimum: Baseline gait assessment, including deviations, safety risks, and endurance

Clinicians should tie clinical impairments to the device's functional benefits, such as improved stance stability, swing clearance, terrain management, fall reduction, and fatigue management.

Suggested Note:

1. Diagnosis and baseline function
2. Prior management and outcome limitations: define the unmet need(s) specific to the individual beneficiary (i.e., ability to negotiate stairs or ramps due to their vocation, etc.)
3. Justification for L2006 microprocessor-controlled KAFO
    - Why is the MPKAFO the least costly, most effective orthosis to achieve the outcome(s)?
4. Plan and follow-up, including custom fabrication criteria

Supporting Clinical Outcomes

Collect objective outcome measures pre- and post-delivery over 2–8 weeks. Examples include:

- Mobility: 10-Meter Walk Test, TUG, 6-Minute Walk Test
- Balance or confidence: Berg Balance Scale, ABC Scale
- Patient-reported outcomes: fatigue rating, falls record, goal achievement, or satisfaction

These measures support ongoing coverage and replacement justification.

Practical Checklist

Before fabrication:

- Confirm medical and functional criteria are met.
- Record measurements and justification for custom fabrication.
- Record baseline outcomes and goals (with current intervention, with no intervention if possible, and with test drive)
- Obtain a signed SWO with L2006 clearly listed.

During fitting:

- Keep configuration files (parquet) and patient education notes.

At delivery:

- Have POD signed.
- Bill base code L2006 with correct modifiers (KX, RT/LT).

Follow-up (2–8 weeks) :

- Reassess functional outcomes using the same tests.
- Add a short note linking improvements to daily function (e.g., “patient now walks 150 m farther without rest”).

Device Trial and Clinical Evaluation Documentation

Results from a device trial, test drive, or temporary fitting should be documented to demonstrate functional benefit, safety, and clinical appropriateness of a microprocessor-controlled KAFO (MP-KAFO). Documentation should include:

1. **Trial Results and Observations:** The clinical record should summarize the outcomes observed during the device trial, including gait quality, safety, energy efficiency, stability, confidence, and tolerance. Specific feedback from both clinician and patient should be included to substantiate benefit or improvement compared to baseline function.

2. **Adjustment and Tuning Notes:** The record should reflect any device programming, alignment modifications, or biomechanical tuning performed during the trial. This includes:
    - Specific settings and parameter adjustments used
    - Patient response to each modification
    - Any reduction in gait deviations, fatigue, or safety concerns
    - Session-to-session changes when multiple trials are conducted

Where available, include quantitative measures (timed walks, endurance metrics, balance scoring, or step counts) to validate observed improvements.

Justification to Rule Out Less Costly Devices

To demonstrate medical necessity for a microprocessor-controlled solution, the documentation should clearly show why less expensive and lower-level orthotic alternatives cannot provide adequate functional benefit or safety. This analysis should address the following device categories:

- ***Locked KAFO (traditional or stance-locked):*** Provide rationale showing that a locked system results in functional limitations such as reduced safety, difficulty navigating stairs or uneven surfaces, increased fatigue or energy expenditure, or inability to ambulate efficiently.
- ***Stance-Control KAFO (mechanical / non-microprocessor):*** Explain why mechanical stance-control technology does not sufficiently meet the individual's needs. Examples may include delayed or unreliable engagement, poor performance on variable terrain, insufficient stance security, or inability to manage multi-environment ambulation demands.
- ***Ankle-Foot-Orthosis (FRAFO, Articulated AFO, Solid AFO, etc.):*** Explain why the AFO is insufficient to control the knee. An example would be that there is an inherent knee instability in the coronal plane, or the AFO cannot generate or control unwanted sagittal-plane forces, resulting in knee hyperextension and/or knee flexion collapse.

Clinical documentation should directly connect the patient's functional requirements to features that only microprocessor control can provide.

Education and Training Documentation

Records should demonstrate that proper device education and training were provided prior to and at the time of delivery. Training documentation should reflect instruction to:

- The patient/operator on donning, doffing, charging, maintenance, cleaning, safe operating procedures, troubleshooting, and emergency procedures
- Caregivers or support personnel, when applicable, to ensure safe home and community use
- The orthotist or clinical team, confirming hands-on training and professional competency with software, adjustments, and technology management

If the orthotist provides authorization for the patient to adjust device controls independently, documentation must reflect informed consent and acknowledgement that the patient is responsible for maintaining the required technology, such as a mobile device, app access, data connection, and/or software updates.

Potential Supporting Attachments

Additional materials may be included as supporting evidence when required or appropriate. Examples include:

- Letters of Medical Necessity (LMN) Note: An LMN may be rejected in an MCR claim as inadmissible documentation if it is not in the medical records and is a separate note
- Therapy progress notes or treatment reports
- Formal gait analysis or movement evaluation reports
- Photographs or videos demonstrating gait pattern or instability (only when requested by payers and compliant with privacy/security policies—videos may not be permitted in certain appeals)

Proof of Delivery (POD)
At the time of final delivery, a **signed Proof of Delivery** must be obtained from the patient or authorized representative. The POD must clearly identify:

- Patient name
- Item(s) delivered
- Delivery date
- Signature and printed name of the recipient
- Contact information and confirmation that delivery was completed

POD documentation must be retained in the medical record as part of final billing and audit compliance.

Denials & Appeals Guidance

The purpose of this section is to assist Suppliers, clinicians, and billing staff in understanding common denial reasons and developing a clear, evidence-based strategy for responding to them. Appeals should be fact-based, patient-specific, and aligned with payer policy language, contractual requirements, and documented medical necessity.

Common Denial Reasons & Recommended Response Strategy

Payers may deny coverage for a microprocessor-controlled KAFO (L2006) for several reasons. The response should directly address the payer's stated rationale and reference medical records, applicable benefit language, and supporting documentation. Below are common denial categories and recommended response approaches.

"Not Medically Necessary"
If the denial cites lack of medical necessity, the response should:

- Identify and reference the Medical Necessity definition in the member's Summary Plan Description (SPD), which takes priority over policy language.

- If not defined in the SPD, reference the payer's own medical necessity definition or relevant clinical coverage guideline.
- Respond to each bullet or required element and demonstrate where in the clinical record the requirement is met, supplemented by objective measures where possible.
- Include a concise case summary describing functional deficits, failed alternatives, and expected measurable benefits.

"Alternative Device Adequate"
If the denial states that a less costly device, such as a locked KAFO, mechanical stance-control KAFO, or AFO, is sufficient, the appeal must:

- Demonstrate that all lesser alternatives were considered, trialed when appropriate, and proven inadequate for this patient.
- Reference clinical documentation or trial outcomes showing ongoing limitations such as knee buckling, fatigue, gait asymmetry, inability to manage varied terrain, or safety risk.
- Reinforce that microprocessor technology uniquely addresses both stance & stability and swing-phase assistance, enabling functional goals that lesser devices cannot meet.

"Experimental, Investigational, or Unproven"
If the denial indicates that the device is experimental or lacks sufficient evidence, the response should:

- Locate the payer's specific definition of Experimental/Investigational in the SPD or policy.
- Respond point-by-point to each element, demonstrating how the device does not meet the definition.
- Provide supporting material such as published peer-reviewed literature, regulatory status, clinical evidence summaries, and documented functional outcomes.

Other Potential Denial Reasons
Examples may include:

- Insufficient documentation or missing elements
- Benefit exclusions or benefit maximums
- Reimbursement limitations based on same/similar rules
- Filing or authorization timing errors

For these, the appeal should provide clarification, missing documentation, or request reconsideration based on compliance, clinical need, or contractual rights.

Appeal Letter and Appeal Packet Requirements

An appeal must be constructed in a clear, professional, and evidence-based manner. The Appeal Packet generally includes the following components:

Required Forms and Submission Format

- Use required payer-specific appeal forms or online portals when applicable.
- Follow submission timelines, format, and routing instructions.

Appeal Cover Letter Structure

A comprehensive appeal letter generally includes:

- Identity of the appellant (Supplier or authorized patient representative)
  - If a representative is filing on behalf of the patient, include completed Appointment of Representative form
- Date and method of denial (Explanation of Benefits, pre-service denial letter, or portal entry)
- Confirmation of timely filing compliance
- Direct restatement of the denial rationale
- Clear explanation of all reasons for disagreement with supporting evidence
- Citations from:
  - SPD benefit language
  - Medical necessity definitions
  - Coverage guidelines
  - Clinical records and objective outcome measures
  - Peer-reviewed or regulatory evidence, if applicable
- A specific request, such as overturning denial, authorization approval, or medical director review
- Supplier's signature, credentials, and contact information

Required Attachments

Typical contents of a complete Appeal Packet include:

- Appeal cover form (if required)
- Signed appeal letter
- Appointment of representative form (if applicable)
- Copy of prior authorization approval (if issued)
- Copy of denial (letter or EOB)
- Relevant clinical evidence or published literature
- Complete medical records, including:
  - Physician orders (SWO or prescription)
  - Physician chart notes

    - OT/PT or other qualified Supplier notes
    - Orthotist/prosthetist evaluation and progress notes
    - Device trial documentation
    - Objective measures and gait assessment
    - Proof of Delivery (for post-service appeals)
- ABN or liability waiver (when relevant)

Supporting Documentation for Appeal

If the documentation submitted before denial was incomplete, consider adding additional evidence as part of the appeal. Examples include:

- Updated or more detailed Letter of Medical Necessity (LMN)
- Clinical outcome measures collected after delivery or during a trial phase
- Gait analysis reports or biomechanical assessments
- Patient affidavits or caregiver statements identifying safety concerns or daily functional barriers
- Clarifying supplier addenda when needed to complete the medical narrative

Documentation added at this stage must be fact-based, contemporaneous, and compliant with payer requirements.

Documenting Clinical Outcomes

The purpose of this section is to guide clinicians and billing personnel in the accurate interpretation, selection, and application of clinical outcome measures. These outcomes are essential for demonstrating value-based care and for providing objective evidence of the therapeutic effectiveness of the treatment plan utilizing the Agilik™ Smart Orthosis MPKAFO.

User Satisfaction with Agilik™ Smart Orthosis

- OPUS-Satisfaction With Device Score

Endurance

- 2-Minute Walk Test (2MWT)
- 6-Minute Walk Test (6MWT)

Balance & Fall Risk

- Berg Balance Scale (BBS)
- Timed Up and Go (TUG)

Quality of Life

- Assessment of Quality of Life - 8 Dimensions

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GAIT Parameters

- Before/after gait parameters (speed, symmetry, knee angle)

Individualized Outcome Involving Goal Selection & Scaling

- Goal Attainment Scale (GAS)

Support & Contact Resources

O&P Insight
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www.oandpinsight.com
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