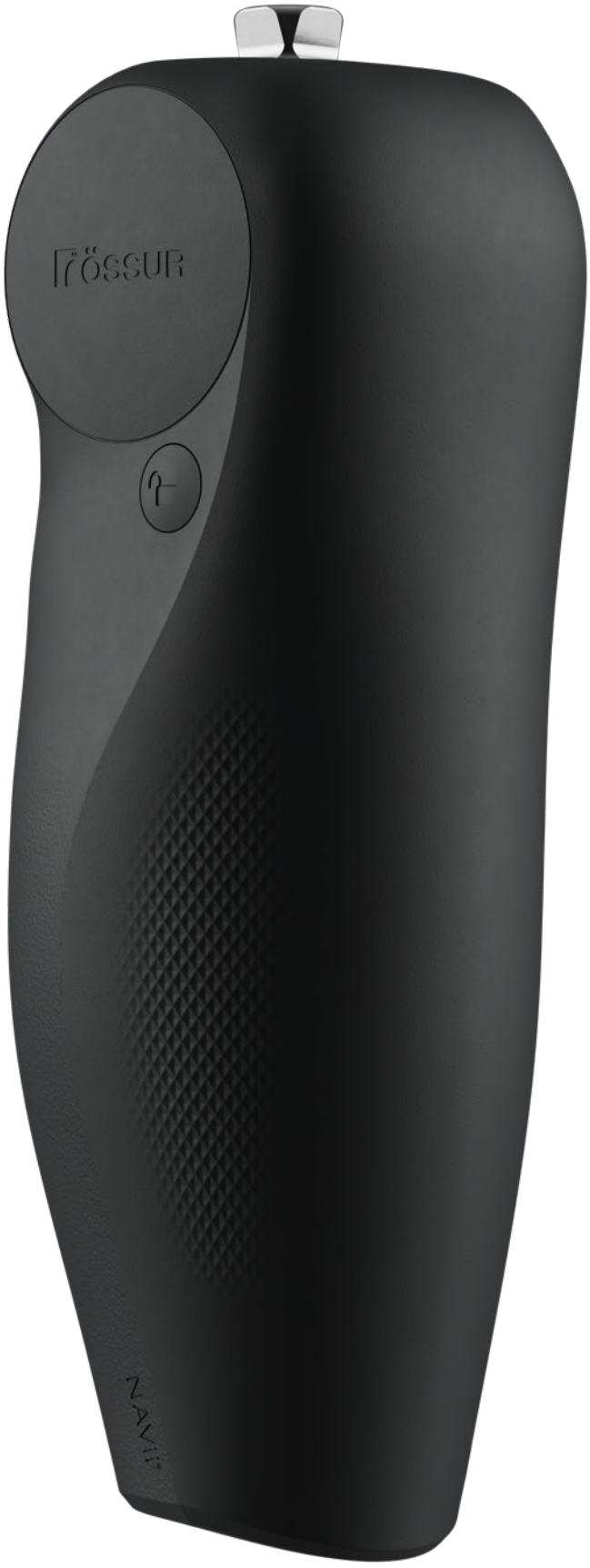

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Navii®

Reimbursement Guide

V.012025

Coding and Coverage

CODING

Navii is PDAC-verified for the following HCPCS codes:

L5856	addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5828	addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5845	addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848	addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability
L5850	addition, endoskeletal system, above knee or hip disarticulation, knee extension assist
L5925	addition, endoskeletal system, above knee, knee disarticulation or hip disarticulation, manual lock

COVERAGE

Medicare - Local Coverage Determination

Covered for patients whose functional level is 3 or above; OR
Covered for patients whose functional level is 2 when ALL the following criteria are met and documented:

- The beneficiary had a clinical evaluation to determine their functional level; AND
- Supporting documentation in the medical record outlines, in the context of the beneficiary's overall medical health, the rationale for selection of an electronic/microprocessor-controlled knee, including (at minimum) how the selected knee will:
  - Improve the beneficiary's functional health outcomes (e.g., fall reduction, injury prevention, lower energy expenditure); AND
  - Help the beneficiary accomplish their activities of daily living (ADLs); AND
- Lower-level knee systems (e.g., knee systems which exclude use of fluid, pneumatic, or microprocessor) have been considered and ruled out based on the beneficiary's specific functional and medical needs.
- The electronic/microprocessor knee is indicated for functional level 2; AND
- The electronic/microprocessor knee has integrated technology that allows the knee to detect when the user trips or stumbles and can automatically adjust to stabilize the knee unit (e.g., stumble recovery); AND
- The beneficiary is able to make use of a product that requires daily charging; AND
- The beneficiary is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

Aetna Clinical Policy Bulletin 0578

Covered for otherwise healthy, active community ambulating members (K3 or higher) with a transfemoral or knee disarticulation amputation from a non-vascular cause.

Anthem Clinical UM Guideline CG-OR-PR-08
Covered for transfemoral and knee disarticulation amputees when all the criteria below have been met: • Individual has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology; and • Individual has a functional level K3 or above; and • The provider has documented that there is a reasonable likelihood of better mobility or stability with the device instead of a mechanical knee prosthesis; and • There is documented need for ambulation in situations where the device will provide benefit (for example, regular need to ascend/descend stairs, traverse uneven surfaces or ambulate for long distances (generally 400 yards or greater cumulatively); and • Complete multidisciplinary assessment of individual including an evaluation by a trained prosthetic clinician. The assessment must objectively document that all of the above selection criteria have been evaluated and met.
Cigna Medical Coverage Policy 0536
Criteria identical to Medicare LCD if the specific Cigna policy offers coverage for a microprocessor-controlled lower-limb prosthesis.
Humana Medical Coverage Policy HUM-0331-036
Criteria identical to Medicare LCD
United Healthcare Medical Policy 2024T0645E
No specific criteria listed. UHC Medical Policy does state, however that: (1) "[T]here is ample clinical literature to support the efficacy of microprocessor knees with community ambulators [K3 functional level]"; and (2) "If more than one prosthetic device can meet the member's functional needs, benefits are available only for the prosthetic device that meets the minimum specifications for the member's needs."

In addition to satisfying the coverage criteria for the largest U.S. health plans listed above, you should always explain how unique Navii functions - i.e., functions that do not exist in any non-microprocessor controlled mechanical knee - solve specific clinical issues that limit your patient's mobility or safety. This will help establish that (1) no other prosthetic solution can meet your patient's clinical needs, and (2) the medical necessity of your recommended intervention.

Please note that you should always verify the exact medical policy that applies to your patient. The information in the above table is current as of January 9, 2025. ***This is not a representation of insurance coverage for your patient by Össur and should not be relied upon as such.*** *It is possible that your patient's medical policy may differ from those listed in the table above even if your patient is covered by one of the health plans in that table.*

Clinical Evidence Supporting Navii

Clinical Challenge	Supporting Research
Asymmetrical gait/sound-side comorbidities	Magnetorheologic knees provide more natural/symmetrical gait compared to non-MPKs.[1, 2, 3, 4] Magnetorheologic knees reduce compensatory motions.[1] Users show less vaulting at slower walking speeds.[1]
Documented fall history	MPKs produced significant reduction in falls compared to non-MPKs (study included functional level K2 Magnetorheologic knee patients).[5] Magnetorheologic knees prevent uncontrolled flexion.[6]
Fatigue	MPKs produce lower energy cost at all walking speeds than non-MPKs and Magnetorheologic knees offer the lowest energy cost of all MPKs, including C-Leg, at all walking speeds.[7]
Difficulty commencing gait initiation phase of the gait cycle	Magnetorheologic knees allow patients to initiate swing phase more easily than other MPK's.[3, 8, 9]

[1] Prinsen EC, Nederhand MJ, Sveinsdóttir HS, Prins MR, van der Meer F, Koopman HFJM, Rietman JS. *The influence of a user-adaptive prosthetic knee across varying walking speeds: A randomized cross-over trial.* Gait Posture. 2017 Jan;51:254-260. doi:10.1016/j.gaitpost.2016.11.015. Epub 2016 Nov 9. PMID: 27838569.

[2] Uchytil J, Jandacka D, Zahradnik D, Farana R, Janura M. *Temporal-spatial parameters of gait in transfemoral amputees: Comparison of bionic and mechanically passive knee joints.* Prosthet Orthot Int. 2014 Jun;38(3):199-203. doi:10.1177/0309364613492789. Epub 2013 Jul 3. PMID: 23824546.

[3] Johansson JL, Sherrill DM, Riley PO, Bonato P, Herr H. *A clinical comparison of variable-damping and mechanically passive prosthetic knee devices.* Am J Phys Med Rehabil. 2005 Aug;84(8):563-575. doi:10.1097/01.phm.0000174665.74933.0b. PMID: 16034225.

[4] HerrH,WilkenfeldA.*User-adaptivecontrolofamagnetorheologicalprostheticknee.*IndRobot.2003;30(1):42-55.doi:10.1108/01439910310457706.

[5] Kaufman KR, Bernhardt KA, Symms K. *Functional assessment and satisfaction of transfemoral amputees with low mobility (FASTK2): A clinical trial of microprocessor-controlled vs. non-microprocessor-controlled knees.* Clin Biomech (Bristol, Avon). 2018 Oct;58:116-122. doi:10.1016/j.clinbiomech.2018.07.012. Epub 2018 Jul 19. PMID: 30077128.

[6] Thiele J, Schöllig C, Bellmann M, Kraft M. Designs and performance of three new microprocessor-controlled knee joints. Biomedical Engineering/ Biomedizinische Technik. 2019 Feb 25;64(1):119-26.

[7] Li S, Cao W, Yu H, Meng Q, Chen W. *Physiological parameters analysis of transfemoral amputees with different prosthetic knees.* Acta Bioeng Biomech. 2019;21(3):135-142. PMID: 31798017.

[8] Bellmann M, Köhler TM, Schmalz T. *Comparative biomechanical evaluation of two technologically different microprocessor-controlled prosthetic knee joints in safety-relevant daily-life situations.* Biomed Tech (Berl). 2019 Aug 27;64(4):407-420. doi:10.1515/bmt-2018-0026. PMID: 30540556.

[9] Lechler K, Ikelaar L, Sigurthorsson S, Sverrisson R. *The effect of a design change of a microprocessor-controlled knee on quality of life and performance-based measures of mobility.* Presented at: OT-World; May 13-16, 2014; Leipzig, Germany. Poster 4997, Abstract 1418.

Required Physician Documentation

Medicare has issued guidance to physicians detailing the type of documentation that they must include in their medical records in order for a patient to receive prosthetic or orthotic care. Medicare requires physicians to document the following findings for people with limb loss/difference:

- The patient's *current* functional capabilities, *expected* functional potential, and an explanation for the *difference* between the two if there is one.

  NOTE: For individuals with limb loss, functional capabilities are described by 5 "K-levels." The physician's notes must contain patient-specific information supporting K-level designation (see the FUNCTIONAL LEVEL CHARACTERISTICS section in the Lower Limb Prostheses Policy Article for an expanded list of K-level specific activities).

  K0: Cannot walk/transfer - would not benefit from a prosthesis

  K1: Ability or potential to use prosthesis for walking/transfers in the home only

  K2: Ability or potential to use prosthesis for limited community walking

  K3: Ability or potential to use prosthesis for variable cadence walking in the community without limitation

  K4: Ability or potential to use prosthesis beyond basic ambulation (e.g., child, active adult, or athlete).

- The patient's motivation to ambulate.
- Other ambulatory assistance currently used, if any
- Description of ADL's and how they are impacted by the identified deficits
- Musculoskeletal exam (arm and leg strength/ROM)
- Neurological exam
  - Gait
  - Balance and coordination

In addition, if the physician has reviewed the prosthetist's medical record for their mutual patient and is in agreement with his/her findings, a statement of concurrence with the prosthetist's findings is both appropriate and helpful in ensuring that their mutual patient receives timely and appropriate prosthetic care.

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