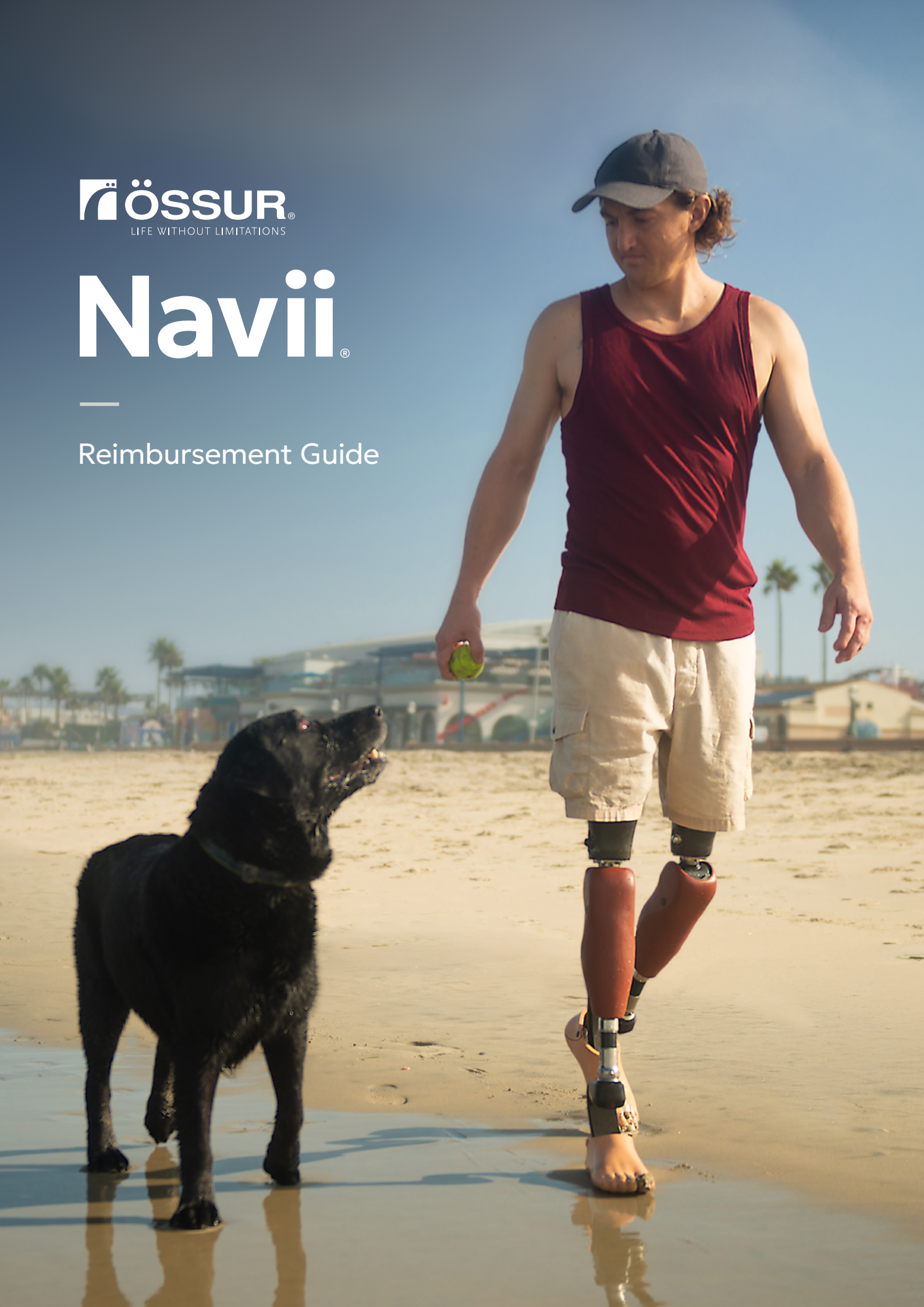
ÖSSUR®
LIFE WITHOUT LIMITATIONS

Navii®

Reimbursement Guide



Indications and Features

INDICATIONS		
Medical Indication:	Lower limb loss, amputation or deficiency	
Functional Level:	K2, K3, K4	
Impact Level:	Low to moderate	High
Maximum User Weight:	136 kg	110 kg
User Goals:	• No limitations with mobility; everyday life and adventuring • Participation in water-based activities (shower, river, beach, pool)	
Other:	Compatible with bone-anchored prostheses[1]	

FEATURES

The Navii knee is a microprocessor-controlled prosthetic knee suitable for unilateral and bilateral transfemoral, knee disarticulation, and hip disarticulation users. It is safe to use as part of a transfemoral bone-anchored prosthesis. Navii is fully waterproof (IP68) and corrosion-resistant, enabling users to shower and submerge their prosthesis in the pool or ocean.

Navii supports cadence-responsive walking, directional changes, and safe backwards stepping. It identifies quiet standing, increasing stance resistance. It provides controlled yielding for sitting down, stair and ramp descent, and activity-specific features like automatic cycling detection, running capability, and step-over-step stair ascent.

Navii features a clamped actuator design and utilises improved magnetorheologic fluid technology to create an electronic brake where resistance continuously adapts to the user's needs and situation, optimising safety and efficiency. Magnetorheologic technology eliminates fluid drag and is highly responsive to cadence changes. Higher maximum and minimum torque outputs provide stronger braking force through stance flexion range and a lighter, freer-feeling swing. Effortless swing initiation enables a smoother gait, even in crowds and confined spaces. Advanced control features continually monitor and adapt resistance levels.

Navii provides variable mechanical ratcheting lock positions (0°, 10°, and 20° flexion) for additional support and functionality in activities like golf, gym training, and yoga, or for safety in challenging environments such as steep or loose terrain. Navii can be personalised with five different colored standard covers featuring a natural shape and volume, with longer black covers available for a more filled-out leg shape when wearing pants.

Navii has eight functional training exercises available in the Össur Logic app to help users optimise their functionality. The battery lasts up to 72 hours, and the service life is six years, with a three-year warranty included, extendable to a maximum of six years.

[1] Frossard, L., Laux, S., Geada, M., Heym, P.P., & Lechler, K. (2021). Load applied on osseointegrated implant by transfemoral bone-anchored prostheses fitted with state-of-the-art prosthetic components. *Clinical Biomechanics, 89*, 105457. DOI: 10.1016/j.clinbiomech.2021.105457

Mobility Benefits

Mobility Benefit	Supporting Research
Reduced Risk of Falling	Kaufman, K.R., Bernhardt, K.A., & Symms, K. (2018). Functional Assessment and Satisfaction of Transfemoral Amputees with Low Mobility (FASTK2): A Clinical Trial of Microprocessor-Controlled Knees vs. Non-Microprocessor-Controlled Knees. *Clinical Biomechanics, 58*,116-122. DOI: 10.1016/j.clinbiomech.2018.07.012 Thiele, J., Schöllig, C., Bellmann, M., & Kraft, M. (2019). Designs and performance of three new microprocessor-controlled knee joints. Biomedizinische Technik. *Biomedical engineering,* 64(1), 119–126. https://doi.org/10.1515/bmt-2017-0053
Improved Mobility, Reduced Metabolic Cost	Howard, C.L., Wallace, C., Perry, B., & Stokic, D.S. (2018). Comparison of Mobility and User Satisfaction between a Microprocessor Knee and a Standard Prosthetic Knee: A Summary of Seven Single-Subject Trials. *International Journal of Rehabilitation Research, 41*(1), 63–73, DOI: 10.1097/MRR.0000000000000267 Johansson, J.L., Sherrill, D.M., Riley, P.O., Bonato, P., & Herr, H. (2005). A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. *American Journal of Physical Medicine & Rehabilitation, 84*(8), 563–575. DOI: 10.1097/01.phm.0000174665.74933.0b Lechler K., Ikelaar, L., Sigurthorsson, S. & Sverrisson R. (2014, May 13-16). The effect of a design change of a microprocessor-controlled knee on quality of life and performance-based measures of mobility. Poster presented at OT World Congress, Leipzig. *Unpublished*
Improved Gait Symmetry, Reduced Compensatory Motion	Prinsen, E., Nederhand, M.J., Sveinsdóttir, H.F., Prins, M.R., van der Meer, F., Koopman, H.F.J.M., & Rietman, J.S. (2017). The influence of a user-adaptive prosthetic knee across varying walking speeds: A randomized cross-over trial. *Gait & Posture, 51*(1), 254-260. DOI: 10.1016/j.gaitpost.2016.11.015
Easier Swing Initiation, Lightness in Swing Phase	Bellmann, M., Köhler, T.M., & Schmalz, T. (2019). Comparative Biomechanical Evaluation of Two Technologically Different Microprocessor-Controlled Prosthetic Knee Joints in Safety-Relevant Daily-Life Situations. *Biomedizinische Technik (Berl), 64*(4), 407–420. DOI: 10.1515/bmt-2018-0026 Johansson, J.L., Sherrill, D.M., Riley, P.O., Bonato, P., & Herr, H. (2005). A clinical comparison of variable-damping and mechanically passive prosthetic knee devices. *American Journal of Physical Medicine & Rehabilitation, 84*(8), 563–575. DOI: 10.1097/01.phm.0000174665.74933.0b Lechler K., Ikelaar, L., Sigurthorsson, S. & Sverrisson R. (2014, May 13-16). The effect of a design change of a microprocessor-controlled knee on quality of life and performance-based measures of mobility. Poster presented at OT World Congress, Leipzig. *Unpublished*

Outcome Measures

Outcome measures are used by health care professionals to help determine the user's baseline function and progression throughout rehabilitation and beyond. They are an important tool to utilise to provide credible and reliable justification for treatment and reimbursement. This table outlines examples of validated outcome measures used in practice to determine function, trial outcomes, progress, and treatment efficacy.

OUTCOME MEASURES	USE	REFERENCE
Performance Based		
6 Minute Walk Test (6MWT)	General Mobility	Cooper, K.H. (1968). A Means of Assessing Maximal Oxygen Intake Correlation Between Field and Treadmill Testing. *Journal of the American Medical Association, 203*(3), 201–204. DOI: 10.1001 jama.1968.03140030033008
Amputee Mobility Predictor (AMP)	Amputee Function	Gailey, R.S., Roach, K.E., Brooks Applegate, E., Cho, B., Cunniffe, B., Licht, S., Maguire, M. and Nash, M.S. (2002). The amputee mobility predictor: an instrument to assess determinants of the lower-limb amputee's ability to ambulate, *Archives of Physical Medicine and Rehabilitation, 83*(5), 613–27. DOI: 10.1053/ampr.2002.32309
Timed Up and Go (TUG)	Falls Risk	Podsiadlo, D. and Richardson, S. (1991). The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *Journal of the American Geriatrics Society, 39*(2), 142–8. DOI: 10.1111/j.1532-5415.1991.tb01616.x
L-Test	Falls Risk	Deathe, A.B. and Miller, W.C. (2005). The L test of functional mobility: measurement properties of a modified version of the timed "up & go" test designed for people with lower-limb amputations. *Physical Therapy, 85*(7), 626-35.
Self Report		
Activities-Specific Balance Confidence Scale (ABC)	Balance, Confidence	Powell, L.E. and Myers, A.M. (1995). The Activities-Specific Balance Confidence (ABC) Scale. The Journals of Gerontology. Series A, *Biological Sciences and Medical Sciences, 50A*(1), M28–34. DOI: 10.1093/gerona/50a.1.m28
Prosthesis Evaluation Questionnaire – Mobility Section (PEQ-MS)	Prosthetic Function and Satisfaction	Franchignoni, F., Giordano, A., Ferriero, G., Orlandini, D., Amoresano, A. and Perucca, L. (2007). Measuring mobility in people with lower limb amputation: Rasch analysis of the mobility section of the prosthesis evaluation questionnaire. *Journal of Rehabilitation Medicine, 39*(2), 138–44. DOI: 10.2340/16501977-0033

Outcome Measures

OUTCOME MEASURES	USE	REFERENCE
Self Report		
Trinity Amputation and Prosthesis Experience Scales – Revised (TAPES-R)	Prosthetic Function and Satisfaction	Gallagher, P. Franchignoni, F., Giordano, A. and MacLachlan, M. (2010). Trinity amputation and prosthesis experience scales: a psychometric assessment using classical test theory and Rasch analysis. *American Journal of Physical Medicine and Rehabilitation, 89*(6), 487–96. DOI: 10.1097/PHM.0b013e3181dd8cf1
Locomotor Capabilities Index (LCI)	Prosthetic Use	Grise, M.C., Gauthier-Gagnon, C. and Martineau, G.G. (1993). Prosthetic profile of people with lower extremity amputation: Conception and design of a follow-up questionnaire. *Archives of Physical Medicine and Rehabilitation, 74*(8), 862-70. DOI: https://doi.org/10.1016/0003-9993(93)90014-2
Oswestry Disability Index	Lower Back Pain	Fairbank, J.C.T. and Pynsent, P.B. (2000). *The Oswestry Disability Index. Spine, 25*(22), 2940–53.
Western Ontario and McMaster Osteoarthritis Index (WOMAC)	OA in Hip or Knee	McConnell, S., Kolopack, P. and Davis, A.M. (2001). The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): A Review of Its Utility and Measurement Properties. *Arthritis Care and Research, 45*(5), 453-61.
Socket Fit Comfort Score (SFCS)	Socket Fit	Hanspal, R.S., Fischer, K. and Nieveen, R. (2003). Prosthetic Socket Fit Comfort Score, *Disability Rehabilitation, 25*(22), 1278–80. DOI: 10.1080/0963828031000160398 3
Prosthetic Limb Users Survey – Mobility (PLUS-M)	Mobility	Morgan, S.J., Amtmann, D., Abrahamson, D.C., Kajlich, A.J. and Hafner, B.J. (2014). Use of cognitive interviews in the development of the PLUS-M item bank. *Quality of Life Research, 23*(6), 1767–75. DOI: 10.1007/s11136-013-0618-z

Warranty and Maintenance

A 3-year warranty is included with Navii. A 3-year warranty extension is available to bring the warranty period to the maximum of 6 years. Service life of Navii is 6 years. There is one mandatory service required at 40 months. Should any additional maintenance or repair be required during the warranty period, a loaner unit can be supplied free-of-charge by Össur for this time if requested. Navii is not field serviceable.

Further Information

PRODUCT CARE AND SUPPORT	
Product Information	
Website:	ossur.com/en-au/prosthetics/knees/navii
Further Resources:	go.ossur.com/NaviiANZ
Recommended Treatment Pathway and Resources	

A Navii trial unit may be requested by the treating Prosthetist and set up for the user to test for up to four weeks. Please contact the Össur Customer Care team for loaner unit availability and the Clinical Specialist Prosthetist team to arrange training and a trial.

Clinical support from and training with an Össur Clinical Specialist Prosthetist is required for your first experience with Navii set up and trial. Please refer to the AOPA Endorsed Education event details for Navii: https://www.aopa.org.au/events/event/ossur-navii-knee.

Engaging with a Physiotherapist trained in prosthetic rehabilitation is also encouraged, to provide the user with appropriate training and support through their Navii trial. It is recommended that the physiotherapist be in attendance for the user's first Navii trial appointment. This enables gait training to begin immediately, encouraging the user to load and control their prosthesis effectively and confidently, to optimise their gait and functionality.

A minimum of six physiotherapy sessions is recommended for experienced prosthetic walkers who are transferring from a mechanical knee joint to Navii. A minimum of twelve physiotherapy sessions is recommended post-amputation, for users who are undergoing initial prosthetic rehabilitation. Functional training exercises to optimise Navii use are available in the Össur Logic app.

Scan or Click the QR Code to access essential support materials, including connection guides, fitting instructions, user videos, and app tools.

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