

PROPRIO FOOT[®]

The step-by-step guide
to a successful claim



COVERAGE AND REQUIREMENTS BY PAYER – L5973

L5973 is an established code that requires PDAC verification for Prior Authorization that describes a microprocessor ankle foot.

Coding	Description
L5973	Endoskeletal Ankle Foot System, Microprocessor Controlled Feature, Dorsiflexion and/or Plantar Flexion Control, Includes Power Source

AETNA

This expectation of functional ability information must be clearly documented and retained in the prosthetist's records. The simple entry of a K modifier in those records is not sufficient. For K3 or above functional levels, there must be documented evaluation from physical therapist to establish functional levels and activities. There must be information about the member's history and current condition that supports the designation of the functional level by the prosthetist and physical therapist.

ANTHEM

A. Selection criteria:

1. Individual has adequate cardiovascular reserve and cognitive learning ability to master the higher level technology; and
2. Individual has a functional K-Level 3 or above; and
3. The provider has documented that there is a reasonable likelihood of better mobility or stability with the device instead of a mechanical foot or ankle prosthesis; and
4. 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.

B. Documentation and performance criteria:

1. 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

Meet medical necessity requirements set forth for any K3 level or above component.

NATIONAL COVERAGE DETERMINATION (i.e. Medicare policy)

Meet medical necessity requirements set forth by LCD established for all K3 level feet.

BCBS

Includes: Georgia, Minnesota, and BlueChoice of South Carolina which cite Anthem's coverage policy.

Considered **experimental, investigational** for all other state payers.

BCBS FEDERAL

A microprocessor-controlled or powered ankle-foot is considered **investigational**.

HUMANA

Not Covered

Endoskeletal ankle foot system, microprocessor-controlled feature, dorsiflexion and/or plantar flexion control, includes power source

UNITED HEALTH CARE

L5973 Functional level is 3 or above

Medical notes documenting all of the following:

- Current prescription or order from physician
- Member's weight and height
- Co-morbidities

Medical history related to the prosthetic request:

- Date and level of amputation
- Etiology of absent limb
- Condition of residual and contralateral limb, if applicable
- Range of motion (ROM), if applicable
- Limitations to activities of daily living (ADLs), without the prosthetic
- Member's functional needs and functional potential as determined by the treating physician and prosthetist
- Environment in which the device will be used, including surfaces normally traversed

Prescribing physician notes, therapist notes (if applicable)

Prosthetist notes

If the prosthetic is new or a replacement

If it will be a preparatory or definitive device

Description of the prosthetic component(s) being requested

- Include medical justification for each component requested
- Quote to include itemized HCPCS codes and quantity requested signed by the prescribing physician
- Make and model of prosthetic, if applicable

STEP 1: INSURANCE INTAKE (“KNOW YOUR PAYER”)

Before you can do anything for new patients, you must first understand what their insurer will pay for and what the patients’ financial responsibility is. The following checklist helps verify the most essential payer information.

INSURANCE INTAKE CHECKLIST

Have you identified...	
<input type="checkbox"/> The insurance company/payer?	<input type="checkbox"/> Medicare <input type="checkbox"/> Private insurance (e.g., Aetna, United HC, BCBS) <input type="checkbox"/> Workers compensation <input type="checkbox"/> Medicaid <input type="checkbox"/> Other <input type="checkbox"/> Secondary insurance (e.g., “Medigap” policy)
<input type="checkbox"/> Policy effective date?	Policy effective: _____
<input type="checkbox"/> Patient’s payment responsibility?	<input type="checkbox"/> Deductible Deductible amount paid YTD \$ _____ <input type="checkbox"/> Co-pay (if applicable) \$ _____ <input type="checkbox"/> Coinsurance (if applicable) % _____ <input type="checkbox"/> Max. out of pocket (if applicable) \$ _____ Included in deductible? Yes No
<input type="checkbox"/> Delivery requirements?	<input type="checkbox"/> Medicare (e.g. prior authorization) <input type="checkbox"/> Private insurance (e.g. pre-authorization) <input type="checkbox"/> Deliver & bill
<input type="checkbox"/> Policy limits?	<input type="checkbox"/> Annual limit \$ _____ Amount exhausted YTD \$ _____
<input type="checkbox"/> LCD/Medical policy requirements?	<input type="checkbox"/> Medicare LCD (refer to Proprio Foot-specific LCD requirement listed in Step 2 of this Guide) <input type="checkbox"/> Private Payer Medical policy
<input type="checkbox"/> Final level of appeal?	<input type="checkbox"/> Self-insured plan (ID plan’s external review agency) <input type="checkbox"/> Employer not self-insured (final appeal usually through applicable state’s Department of Insurance)
<input type="checkbox"/> Who you spoke to?	<input type="checkbox"/> Payer representative’s employee id# _____ <input type="checkbox"/> Date & exact time of talk _____

STEP 2: THE PATIENT'S STORY (“KNOW YOUR PATIENT”)

Now that you understand the scope of your patients' insurance coverage you need to understand *them*. What's their story? What kind of life do they want to live with a prosthesis? What's their current and potential functional level? To accurately and completely tell your patient's story, you need both social and personal patient information on the one hand, and clinical information on the other. Review the following two checklists – one for the “patient story”, the other for clinical notes – to help you make sure that you get everything you need. Remember, you need both types of information to get your claim approved and to survive an audit or prepayment claim review!

PATIENT STORY CHECKLIST

Have you...	Hints/Explanations/Examples
<input type="checkbox"/> Asked only open-ended questions when interviewing patients?	<input type="checkbox"/> <i>What</i> time do you wake up? <input type="checkbox"/> <i>Where</i> is your bedroom in the house? <input type="checkbox"/> <i>Who</i> do you live with? <input type="checkbox"/> <i>When</i> do you put on your prosthesis every morning? <input type="checkbox"/> <i>Why</i> do you dislike walking to the end of your driveway? <input type="checkbox"/> <i>How</i> do you go down the stairs at your office? <input type="checkbox"/> <i>When</i> do you take the prosthesis off at night?
<input type="checkbox"/> Used the “day in a life” technique?	<p>Start by asking patients what time they wake up most mornings. Then ask them what they do next. Continue through their day until they report taking off the their prosthesis before bed.</p> <p>Listen to their answers and ask appropriate follow-up questions. For example:</p> <p>Q: What do you do after you put on your prosthesis? A: I go to the kitchen.</p> <p><i>Follow-up Q: Where is the kitchen in relation to the room where you put on your prosthesis?</i></p>
<input type="checkbox"/> Closed the loops?	<p>You should have a list of questions that you need answers to for all patients. After completing your “open-ended”/”day in a life” interview, make sure you’ve got answers to all of these questions. Only ask these questions at the end of the interview!</p> <p>Examples: How often do you fall? Do you take any prescriptions for amputation-related pain? Do you have any pain in your sound foot, ankle, knee or hip? Etc.</p>
<input type="checkbox"/> Spoken to significant others?	<p>Caregivers who attend patient appointments often have detailed and relevant information about the patient's condition. Include them in the interview process (with the patient's permission).</p>

PATIENT CLINICAL NOTES CHECKLIST

Have you...	Hints/Explanations/Examples
<input type="checkbox"/> Captured all elements of the patient interview in your clinical notes?	<p>Avoid general medical jargon!</p> <p><i>Do not</i> say that the patient “performs all ADL’s independently.” Instead, include all the specific examples of <i>this</i> patient’s ADL’s (e.g., shopping for food, maintaining their yard, walking between buildings for work, etc.).</p>
<input type="checkbox"/> Recorded video of the patient walking in her current prosthesis?	<p>Video can provide objective verification of the prosthetist’s and physician’s functional level assessment.</p>
<input type="checkbox"/> Recorded objectively-verifiable data about how the patient uses his current prosthesis?	<p>Have the patient use a pedometer to monitor their pre-Proprio Foot activity level and compare it to the data post-delivery to document patient progress.</p>
<input type="checkbox"/> Used validated tests to document the patient’s condition?	<p>For example, the AMP Pro, PEQ, Berg Balance Test, etc.</p>
<input type="checkbox"/> Listed the patient’s name on each page of clinical notes?	<p>Suppliers <i>are</i> seeing denials on this basis.</p>
<input type="checkbox"/> Signed and dated chart notes with your clinician’s credentials for every patient visit?	<p>Suppliers <i>are</i> seeing denials on this basis.</p>
<input type="checkbox"/> Documented the patient’s current K level, potential functional level, and explanation for the difference, if any?	<p>NOTE: Medicare requires that Proprio Foot users be K3 or higher patients. (See LCD for Lower Limb Prostheses.)</p>

STEP 3: MATCHING THE PATIENT & PRODUCT

Every patient has unique clinical needs. And every product offers unique clinical outcomes. Making sure that you map the two to each other is essential if you want (a) a happy and functional patient, and (b) to process your claim successfully. The next two checklists help map Proprio Foot's functional benefits to your patient's clinical needs to ensure that they're aligned.

PATIENT TO PRODUCT CHECKLIST

Patient Clinical Issue	Proprio Foot Function
<p>Comorbidity of spine or sound limb that:</p> <ul style="list-style-type: none"> <input type="checkbox"/> impairs knee function/causes pain <input type="checkbox"/> impairs ankle function/causes pain <input type="checkbox"/> impairs foot function/causes pain <input type="checkbox"/> causes spinal pain/impairs ROM <p>Comorbidity of upper body that impairs:</p> <ul style="list-style-type: none"> <input type="checkbox"/> arm function/causes pain <input type="checkbox"/> shoulder function/ causes pain 	<p>Microprocessor-controlled plantarflexion:</p> <ul style="list-style-type: none"> • allows users to walk more symmetrically when walking down ramps and hills, reducing stress on the sound limb <p>Microprocessor-controlled dorsiflexion:</p> <ul style="list-style-type: none"> • allows users to walk more symmetrically when walking up ramps and hills and on uneven terrain, reducing stress on the sound limb • permits more of the prosthetic foot to rest on the step during stair descent, promoting more symmetrical gait and reducing stress on the sound limb
<p><input type="checkbox"/> Documented fall history</p>	<p>Microprocessor-controlled plantarflexion:</p> <ul style="list-style-type: none"> • aligns the ankle-foot system appropriately when walking down ramps, helping limit premature knee flexion and increasing stability <p>Microprocessor-controlled dorsiflexion:</p> <ul style="list-style-type: none"> • gives the prosthetic foot increased toe clearance during swing phase, reducing the risk of stumbles and falls resulting from catching the foot on the ground (especially when walking up ramps and stairs) or on low-lying obstacles (e.g., curbs, rugs, grass, etc.) • permits more of the prosthetic foot to rest on the step during stair descent, increasing the users safety perception
<p><input type="checkbox"/> Inability to walk far enough without stopping</p>	<p>Microprocessor-controlled plantarflexion and dorsiflexion promote more symmetrical gait, decreasing energy expenditure resulting from gait deviations</p>

Patient Clinical Issue	Proprio Foot Function
<input type="checkbox"/> Difficulty walking up and down inclines	<p>Microprocessor-controlled plantarflexion:</p> <ul style="list-style-type: none"> aligns the ankle-foot system appropriately when walking down inclines, promoting more natural gait pattern by helping limit premature knee flexion <p>Microprocessor-controlled dorsiflexion:</p> <ul style="list-style-type: none"> gives the prosthetic foot increased toe clearance when walking up inclines, reducing the risk of catching the toe
<input type="checkbox"/> Gait deviations <input type="checkbox"/> Exaggerated hip movement during knee extension (i.e., kicking prosthetic foot forward)	<p>Microprocessor-controlled dorsiflexion:</p> <ul style="list-style-type: none"> gives the prosthetic foot increased toe clearance during swing phase, to prevent the toe from catching on the ground

PROPRIO FOOT CLINICAL RESEARCH CHECKLIST

Have you reviewed...	Key Finding(s)
<input type="checkbox"/> Rosenblatt, N. et al., <i>Active dorsiflexing prostheses may reduce trip-related fall risk in people with transtibial amputation</i> . JRRD (2014), www.rehab.research.va.gov/jour/2014/518/jrrd-2014-01-0031.html	Proprio Foot provides significantly greater toe clearance than fixed ankle-foot systems, decreasing the likelihood of tripping on an unseen obstacle.
<input type="checkbox"/> Delussu, AS, et al., <i>Assessment of the effects of carbon fiber and bionic foot during overground and treadmill walking in transtibial amputees</i> , <i>Gait Posture</i> (2013), http://dx.doi.org/10.1016/j.gaitpost.2013.04.009	Subjects showed “significant reduction” in Energy Cost of Walking after 90 days with Proprio Foot v. dynamic carbon feet on flat ground and inclines.
<input type="checkbox"/> Gailey, R. et al, <i>Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet</i> , <i>JRRd</i> (2012): pp. 597-612.	While subjects with peripheral vascular disease did not show an increase in Amputee Mobility Predictor scores with Proprio Foot, non-PVD subjects did. In addition, non-PVD subjects increased their walking speeds when using Proprio Foot, resulting in a “significant difference between groups.”
<input type="checkbox"/> Fradet, L, et al., <i>Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system</i> , <i>Gait Posture</i> (2010), doi:10.1016/j.gaitpost.2010.04.011.	While walking up ramps with Proprio Foot on, BK knee kinematics and kinetics on both prosthetic and sound side more closely resembled that of able-bodied controls than with it off. Similarly, during ramp ascent, hip flexion at heel strike and maximum hip extension power absorption was closer to able-bodied controls. On ramp descent, the data was “questionable” according to researchers, but they noted that users “mentioned they felt safer and had better support during roll over with reduced stress at the knee joint.”
<input type="checkbox"/> Agrawal, v. et al, <i>Symmetry in external work (SEW): a novel method of quantifying gait differences between prosthetic feet</i> , <i>Prosthet Orthot Int.</i> (2009), 33(2): 148-56.	Single-user study analyzing “Symmetry in External Work,” a new measure for quantifying kinetic gait differences between different prosthetic feet based on the user’s body center of mass. Results demonstrated that Proprio Foot exhibited higher symmetry between intact and prosthetic limb v. Seattle Lite and SACH foot

Have you reviewed...	Key Finding(s)
<input type="checkbox"/> Alimusaj, m. et al., <i>Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees</i> , Gait Posture (2009), doi:10.1016/j.gaitpost.2009.06.009.	Both when going up and down stairs, Proprio Foot users' kinematics and kinetics were closer to able-bodied controls than they were when Proprio Foot was turned off. The researchers labeled this a "substantial benefit in the patient group investigated."
<input type="checkbox"/> Wolf, S.I., et al., <i>Pressure characteristics at the stump-socket interface in transtibial amputees using an adaptive prosthetic foot</i> , J. clin. biomech. (2009), doi:10.1016/j.clinbiomech.2009.08.007.	During stair ascent, Proprio Foot reduced pressure in the socket to levels that normally correspond with level-ground walking. "The adapted ankle position gives a more even distribution of both peak pressure and PTI between the three sensor locations for all walking conditions although it is not always significant."

STEP 4: GET PHYSICIAN CONFIRMATION

Getting documentation from a physician confirming the prosthetist's findings and recommendations is an important Medicare requirement. A huge percentage of denied claims since 2011 result from prosthetists' failure to make sure that the physician's records validate their own. The next two checklists help you avoid that negative outcome.

PHYSICIAN EDUCATION CHECKLIST

Have you...	
Sent the prescribing physician a letter of medical necessity with <i>all</i> of your key findings? See exemplar LofMN, Exhibit A.	<input type="checkbox"/>
Confirmed that your LofMN discusses in detail each of the patient clinical issues and related Proprio Foot functions addressing those issues referenced in the previous <i>Patient to Product Checklist</i> ?	<input type="checkbox"/>
Sent the prescribing physician a Standard Written Order? (Note: SWO, when compliant with Medicare requirements and signed and dated by the MD, serves as valid prescription.) See exemplar SWO, Exhibit B.	<input type="checkbox"/>
Included a cover letter with the LofMN and SWO explaining Medicare's coverage requirements? See exemplar Cover Letter, Exhibit C.	<input type="checkbox"/>

PHYSICIAN DOCUMENTATION CHECKLIST

Have you confirmed that the physician's records* include...	
Documentation re. functional level of patient both before <i>and after</i> amputation?	<input type="checkbox"/>
Explanation of current and potential functional level, including an explanation for the difference between the two, if any?	<input type="checkbox"/>
History of present medical condition(s) and past history relevant to functional deficits?	<input type="checkbox"/>
Symptoms limiting ambulation or dexterity?	<input type="checkbox"/>
Diagnoses causing these symptoms?	<input type="checkbox"/>
Other comorbidities relating to ambulatory problems or impacting use of new prosthesis?	<input type="checkbox"/>
Documentation of ambulatory assistance (cane, walker, wheelchair, caregiver) currently being used by patient (either in addition to prosthesis or before amputation)?	<input type="checkbox"/>
Description of activities of daily living and how impacted by deficit(s)?	<input type="checkbox"/>
Physical examination that's relevant to the functional deficit(s)?	<input type="checkbox"/>
Weight and height, including any recent weight loss/gain?	<input type="checkbox"/>
Cardiopulmonary examination?	<input type="checkbox"/>
Arm and leg strength and range of motion?	<input type="checkbox"/>
Neurological examination – gait?	<input type="checkbox"/>
Neurological examination – balance and coordination?	<input type="checkbox"/>
Diagnosis, side of amputation, date of amputation?	<input type="checkbox"/>
Patient's desire to ambulate?	<input type="checkbox"/>
Identification of patient on each page of the physician's records?	<input type="checkbox"/>
Documentation confirming the patient's motivation to ambulate?	<input type="checkbox"/>
Documentation showing that the physician examined the patient recently?	<input type="checkbox"/>

*Records of other health care professionals (e.g., other physicians and PT's) can become part of the prescribing physician's medical records if attested to, signed, and dated by her.

STEP 5: FINAL REVIEW BEFORE CLAIM SUBMISSION

You've collected all the necessary patient information. You've confirmed that other health care providers' notes corroborate yours. You're ready to proceed to delivery and filing the claim for reimbursement. But you still need to verify that: (1) your patient delivery sheet contains all of the required information, and (2) you have filled out the claim form completely. The next two checklists will assist you with both.

PATIENT DELIVERY FORM CHECKLIST

Does your patient delivery form include...	
1. The patient's or patient's designee's name?	<input type="checkbox"/>
2. The delivery address?	<input type="checkbox"/>
3. The item(s) being delivered (brand name, serial number, or narrative description)?	<input type="checkbox"/>
4. The number of item(s) being delivered?	<input type="checkbox"/>
5. The delivery date?	<input type="checkbox"/>
6. The patient's or patient's designee's signature?	<input type="checkbox"/>
7. The date of signature (must be the date the patient/designee received the item(s))?	<input type="checkbox"/>

CMS 1500 FORM CHECKLIST

Have you verified that...	
1. The prescribing physician is listed in PECOS?	<input type="checkbox"/>
2. You've included the prescribing physician's NPI on the claim form?	<input type="checkbox"/>
3. You've listed the appropriate diagnosis code on the claim form?	<input type="checkbox"/>
4. You've included the correct date of service for every L code on the claim form?	<input type="checkbox"/>
5. You've selected the appropriate place of service for this patient on the claim form?	<input type="checkbox"/>
6. You've included the "L" and/or "R" modifier for every L code on the claim form?	<input type="checkbox"/>
7. You've listed the patient's K level for every L code on the claim form?	<input type="checkbox"/>
8. You've billed using Proprio Foot's Medicare-approved code? • L5973	<input type="checkbox"/>

STEP 6: THE AUDIT RESPONSE/PREPAYMENT CLAIM REVIEW RESPONSE/APPEAL

You've done everything you're supposed to do. And sometimes, despite that, you still get thrown into prepayment claim review, get subjected to an audit or receive a denial from the payer. You're now in "appeal" mode. What steps do you need to take in order to give yourself the best chance of winning? You can start with this checklist.

PATIENT DELIVERY FORM CHECKLIST

Have you...	
1. NOT written ANYTHING in response until first completing steps 2-5, below?	<input type="checkbox"/>
2. Created a list of (a) what information is being requested, or (b) the basis(es) for denial?	<input type="checkbox"/>
3. Gone through the relevant records below and located responsive information? <input type="checkbox"/> Your records <input type="checkbox"/> MD's records <input type="checkbox"/> PT's records <input type="checkbox"/> Other HCP's records <input type="checkbox"/> Clinical studies	<input type="checkbox"/>
4. Organized the evidence appropriately? <input type="checkbox"/> For claims where the payer requests multiple pieces of information, organize consistent with the order of items requested. <input type="checkbox"/> For claims denied on not medically necessary or experimental grounds, organize from your strongest argument to your weakest.	<input type="checkbox"/>
5. Used language that someone who doesn't understand prosthetics can comprehend?	<input type="checkbox"/>
6. Stated the main issue(s) immediately in your appeal?	<input type="checkbox"/>
7. Attached all necessary exhibits to your appeal?	<input type="checkbox"/>
8. Used footnotes in the appeal to refer the reader to your exhibits?	<input type="checkbox"/>

CONCLUSION

We hope you have found this guide on how to file a successful Proprio Foot claim useful. For more information on how to properly document your claims and file successful appeals, please go to [Össur R&R](#) for a list of upcoming Össur reimbursement seminars or to access online versions of those courses.

EXHIBIT A: EXEMPLAR LETTER OF MEDICAL NECESSITY

When writing to a physician to obtain a prescription for Proprio Foot, you should include a detailed letter of medical necessity. This letter should explicitly describe not only the functional characteristics of Proprio Foot, but how those features will help your patient.

Dear Dr. Smith:

I am the prosthetist treating our mutual patient, Veronica Jones. I examined Ms. Jones on July 16, 2012. Based upon my findings, detailed below, Ms. Jones requires a new prosthetic foot. For ease of reference, I have broken this letter of medical necessity and request for prescription into the following sections:

1. Ms. Jones' Clinical History
2. Clinical Findings
3. Ms. Jones' Medical Needs
4. Requested Prescription

1. Ms. Jones' Clinical History

Ms. Jones is a 54 year-old below-the-knee amputee. She lost her left leg below the knee 8 years ago as a result of cancer. Since she began receiving treatment from me 5 years ago, she has demonstrated a consistent and demonstrated ability to successfully utilize and prosthesis and be a fully functional, contributing member of society.

Ms. Jones is currently a regional sales manager at Optimum Enterprises, a position she has held since before her amputation. In that capacity, she oversees a sales force in 4 different states. She travels, on average, one week per month, almost always by plane. She therefore walks through airports, to and from rental car facilities, and to and from hotels on a regular basis in connection with her work.

In addition, Ms. Jones is the primary caretaker for her mother, who is 81 years old and suffers from severe arthritis and diabetes. When not traveling, Ms. Jones visits her mother every evening. She regularly does her mother's laundry, carrying clothes and sheets from her mother's bedroom on the second floor to the washing machine in the basement. In addition, on weekends she maintains her mother's quarter-acre yard, including mowing the grass and weeding the patio.

2. Clinical Findings

Ms. Jones reports that she has fallen on uneven terrain 4 times in the last 90 days, something that has never happened to her before. One of these falls occurred when walking down the 5 concrete steps at her mother's house. As a result, she has suffered a sprained right ankle and ligament damage to her right wrist. She notes that the injury is particularly painful when she tries to push herself up out of her office chair while at work.

In addition, she complains that she has experienced increased difficulty navigating inclines and declines that she regularly confronts in airports (i.e., ramps) while traveling for business. She also reports stumbling regularly while tending her mother's property because she keeps catching the toe of her current prosthetic foot on the ground. She complains of left knee pain that worsens throughout the day.

Visual observation of Ms. Jones (video available for review) reveals that she is experiencing premature knee flexion at heel strike. While that could be addressed by adjusting the alignment of the prosthesis to account for the heel height of her work shoes, previous efforts in that regard resulted in an altered gait and complaints of IT band pain as a result of the jarring knee extension she experienced when wearing sneakers after work and on weekends.

3. Medical Needs

Ms. Jones has multiple complaints arising out of the inadequacy of her current prosthetic foot: increased falls; decreased stability; and difficulty navigating uneven terrain both at work and at her mother's home. None of these symptoms can be addressed by giving her yet another fixed ankle, mechanical foot like her current device. In order for her to function safely both at work and at home, she requires a microprocessor-controlled ankle foot system.

Microprocessor-controlled lower limb joints are not new. Multiple companies brought microprocessor-controlled lower limb joints to the United States in the mid-1990's. Medicare created a code for one of these knee devices in 2001, and specifically for an ankle-foot system (Proprio Foot) in 2009. According to its own guidelines, Medicare does not pay for experimental or investigational devices, so the creation of the code describing the microprocessor-controlled ankle-foot component implicitly shows its non-experimental/non-investigational nature.

I recommend that Ms. Johnson use the Proprio Foot, a device that samples foot position to adjust plantarflexion and dorsiflexion in real time. This produces 5 key advantages that she will benefit from.

First, Proprio Foot measures the gradient of the surface being walked on during stance phase. It then provides appropriate foot and ankle position for the next step based upon that data. This will allow Ms. Johnson to walk with a more symmetrical and efficient¹ gait on ramps², stairs³, and uneven ground, all of which are presenting her with increasing problems in her current foot. The ability of Proprio Foot to adapt in real time to the underlying terrain will ensure that it is optimally aligned for the changes that currently destabilize Ms. Jones.

In contrast, her current foot is optimized for walking on level ground only. It cannot provide terrain-specific adjustments in real time. This leads to gait deviations, undue stress on Ms. Jones' left knee, unnecessary energy expenditure, and pressure inside the socket⁴ that can contribute to breakdown, discomfort and pain. Proprio Foot will help forestall those comorbidities.

Second, because Proprio Foot detects when the prosthetic toe leaves the ground and dorsiflexes, it creates greater toe-ground clearance at mid-swing phase than fixed-ankle feet⁵. As a result, Ms. Jones will be better able to navigate curbs, uneven terrain, stairs, and other environmental barriers with greater ease and a reduced risk of tripping and/or falling. When ascending stairs, this extra toe clearance can help prevent dangerous falls like the ones Ms. Jones reports.

Third, the ability of Proprio Foot to plantarflex at heel strike increases stability, particularly when walking down ramps and stairs. The user can place the entire prosthetic foot on the ground when descending a staircase, rather than only the heel as a non-microprocessor-controlled foot requires. This increases traction, reduces the risk of falls, and limits the strain on Ms. Jones' sound limb. The fall at her mother's house that injured her wrist occurred when the heel of her prosthetic foot slipped off a wet surface, which is the direct result of her inability to place anything other than the heel of her current foot on steps during stair descent.

¹ Gailey, R. et al, Application of self-report and performance-based outcome measures to determine functional differences between four categories of prosthetic feet, *JRRD* (2012): pp. 597-612.

² Fradet L, et al. Biomechanical analysis of ramp ambulation of transtibial amputees with an adaptive ankle foot system. *Gait Posture* (2010), doi:10.1016/j.gaitpost.2010.04.011.

³ Alimusaj, M. et al. Kinematics and kinetics with an adaptive ankle foot system during stair ambulation of transtibial amputees. *Gait Posture* (2009), doi:10.1016/j.gaitpost.2009.06.009.

⁴ Wolf, S.I. et al., Pressure characteristics at the stump/socket interface in transtibial amputees using an adaptive prosthetic foot, *J. Clin. Biomech.* (2009), doi: 10.1016/j.clinbiomech.2009.08.007.

⁵ Rosenblatt, N. et al., Active dorsiflexing prostheses may reduce trip-related fall risk in people with transtibial amputation. *JRRD* (2014), www.rehab.research.va.gov/jour/2014/518/jrrd-2014-01-0031.html

Fourth, Proprio Foot dorsiflexes when the patient sits, permitting the sole of the foot to rest squarely on the ground while being placed underneath the chair the patient is sitting in. Given Ms. Jones' difficulty exiting chairs as a result of the wrist injury she suffered from her falls, Proprio Foot will minimize the risk of additional injury by permitting her to more equally load both feet when transitioning from sit to stand and reduce the reliance on her arms to push herself out of her chair. This will also reduce chronic overuse syndromes affecting the sound knee, ankle, and foot.

Finally, because Proprio Foot aligns itself based upon the underlying gradient, it permits a normal rollover pattern on widely varying terrain. In contrast, a fixed ankle-foot system can only accommodate level ground walking. When walking up a hill with such a foot, the patient experiences knee hyperextension due to the foot's misalignment, while walking downhill produces destabilizing premature knee flexion, forcing the patient to catch herself. But Proprio Foot's automatic alignment calibration will allow Ms. Jones to walk both up and downhill in an anatomically correct manner, protecting her sound side, spine, and hips from trauma.

This same feature also addresses the problem caused when Ms. Jones transitions from work shoes to sneakers. The automatic alignment will accommodate both scenarios, giving her alignment that minimizes her risk of falls. Ms. Jones already suffers from right knee pain, so taking measures to forestall an additional damage to that joint is important.

4. Requested Prescription

The facts and findings listed in sections 1-3 demonstrate why Ms. Jones requires the Proprio Foot. I am therefore requesting

1. That you perform a detailed physical examination of Ms. Jones, confirm that the history and findings in sections 1-2 are accurate, and document that in your medical records; and
2. The following prescription from you:
 - Endoskeletal ankle foot system, microprocessor-control feature, dorsiflexion and/or plantarflexion control, includes power source (Proprio Foot)

Very truly yours,

EXHIBIT B: EXEMPLAR STANDARD WRITTEN ORDER

Under established Medicare policy, “[s]omeone other than the physician [i.e., the prosthetist] may complete the SWO. However, the treating physician must review the SWO and personally sign and date the order to indicate agreement.”

Standard Written Order: Proprio Foot	
DATE: ____ / ____ / ____ Patient Name: _____ Medicare #: _____ Address: _____ Code: _____ Phone #: _____ DOB: _____ Email: _____	O&P Inc. 123 Green Street Somewhere, USA 12345 (123) 456-7890 Federal Tax #: _____ NPI: _____

Patient Height: _____	Place of Service: _____
Patient Weight: _____	Diagnosis (ICD-9): _____

HCPCS Code:	Narrative Equipment Description
L5973	ÖSSUR PROPRIO FOOT, ANKLE FOOT SYSTEM, WITH MICROPROCESSOR CONTROLLED ACTION <div style="text-align: right;"><input type="checkbox"/> Check here if additional items are listed on attached pages</div>

Physician Attestation
Physician's Name, Address & Telephone <div style="text-align: right;">UPIN #: _____</div> <div style="text-align: right;">NPI: _____</div> (____) ____ - _____
I certify that I am the physician identified above. I have received this Standard Written Order, including a full narrative description with HCPCS code and pricing. I certify that the diagnosis information shown above is to the best of my knowledge true and accurate and justifies the medical necessity of the item(s) shown.
PHYSICIAN'S SIGNATURE _____ DATE _____

You must have the signed SWO in your file before delivering Proprio Foot to your patient.

EXHIBIT C: EXEMPLAR COVER LETTER

The Medicare Program Integrity Manual, the MAC “Dear Physician” letters from September, 2011, and the LCD for Lower Limb Prosthetics outline documentation details that are required in both the prosthetist’s and physician’s records. It is important that you explain to the physician the need for his/her records to corroborate the patient’s medical history, functional level and desire to ambulate.

Dear [doctor name]:

I am the prosthetist who treats [patient name], a Medicare beneficiary. Medicare has recently set forth specific requirements regarding physician documentation for prosthetic devices. Without that documentation, I cannot deliver medically necessary care and treatment to our mutual patient, [patient name]. The purpose of this letter is to give you a quick summary of Medicare’s latest requirements so that we can together work for the benefit of [patient name].

Generally speaking, Medicare wants to see that your medical records corroborate my findings/recommendations. Your records can be in the form of previous chart notes and/or a full, current patient physical evaluation. At a minimum, Medicare requires that the physician notes contain the following information:

1. Documentation supporting

- a. [patient name]’s functional abilities, including your specific findings regarding whether [patient name] has the potential to ambulate with variable cadence and has a lifestyle that demands more than simple locomotion;
- b. [patient name]’s past history, including prior prosthetic use and other assistive device use (if applicable);
- c. [patient name]’s current condition, including the status of [his/her] residual limb;
- d. the nature of any other medical problems [patient name] has; and
- e. [patient name]’s desire to ambulate.

2. Your signature and the date of that signature on the attached Standard Written Order.

If you deem it appropriate or necessary, [patient name] can be referred to a PM&R specialist and/or a physical therapist for a full evaluation and report. Once a report from either of those specialists is sent to you, reviewed, acknowledged by you in the form of your signature on the report, and placed in the medical records, it constitutes appropriate documentation based upon Medicare’s guidance.

If I can answer any questions you may have about Medicare’s documentation requirements for prosthetic care, please do not hesitate to contact me directly. Otherwise, thank you in advance for providing the Medicare-required documentation that will permit me to deliver [patient name] the medically necessary prosthetic care and treatment [he/she] requires in a timely fashion.

Very truly yours,