Protocol for Receiving Authorization for a Plié® 3 MPC Knee

The following is a suggested protocol when pursuing an authorization for a Plié 3 Microprocessor Knee unit.

1. Utilize the Lower Extremity Evaluation Form — This form facilitates a thorough patient evaluation, provides all the necessary information for your records, and organizes the patient's vital information in such a manner that it facilitates the transfer of this information into a well-written Letter of Medical Necessity.
2. Verify with your patient's insurance provider that wording does not exist within the plan that specifically identifies that a microprocessor controlled device is not covered. These insurance policies do exist and a Letter of Medical Necessity will not change the policy.
3. Obtain from the ordering Physician the most recent patient evaluation documentation which should identify the medical necessity of the prosthetic device as well as the patient's functional capabilities (K-level).
   a. It is acceptable for the prosthetist to evaluate the patient's functional level utilizing an assessment tool such as the Amputee Mobility Predictor, a validated and peer-reviewed functional level assessment tool. This evaluation can be incorporated into a letter and returned to the referring physician. Once obtained by the physician it can be dated and included in the patient's medical records.
4. Utilizing the patient information from the Lower Extremity Evaluation Form, draft a synopsis of the client's history and prosthetic devices used in the past. In this brief history section, identify the known limitations of the current prosthetic device, the patient's vocation and avocation(s), work and home environment, goals, identified number of falls and stumbles over a fixed period of time, past component inadequacies, and other relative information shared. With this information, generate a custom letter which highlights the benefits of a Plié 3 microprocessor knee, making sure to specifically identify the benefit of each feature (code) that the knee provides. (See the provided sample Letters of Medical Necessity.)
5. It will also be necessary to obtain from the prescribing physician a detailed written order. The order is a document drafted by the prosthetist that must be signed and dated by the physician and included in the patient's documentation located in the prosthetic clinic. It must be signed and dated prior to submitting for the prosthesis to the insurance provider.
   a. This document must contain the patient's name on each page, ICD-9 Code, start date of the order, patient's functional level, detailed description of what is being provided (description of each code), all of the physician's relevant information (name, credential, address, phone #) and a dated signature from the referring physician.
6. It is important to note that insurance companies will occasionally generate an initial denial in attempt to reduce the number of claims that are paid out. Industry surveys have identified that up to 30% of all denied claims are not resubmitted by the prosthetic facility, thereby fulfilling the desired outcome of the insurance provider.
   a. If a denial is received from the provider, it is essential to identify why the submittal was denied.
      i. What has been denied – the whole claim or specific codes included in the claim?
      ii. What is the one reason for denial?
      iii. Make sure to obtain the provider's definition of denial. For example, if they state they do not cover an "experimental device", obtain the provider's definition of "experimental".
   b. The attached peer-reviewed published research can be utilized to refute reasons for denial in your appeal documentation.
7. If desired (and time permits) you can implement the "Plié 3, A Difference You Can Measure" test series to provide Evidence-Based Practice in your submitted documentation which will strongly strengthen your initial request. This can provide insight into the actual claims of why this technology is being requested for your patient, as well as demonstrate the cost savings related to falls and other limitations of a lesser technology.
   a. For more details, review the "Plié 3, A Difference You Can Measure" packet.

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FREEDOM INNOVATIONS

Lower Extremity Prosthetic Evaluation Form

FREEDOM INNOVATIONS

Name: ______________________ Date: ______________________

D.O.B.: ______________________ Practitioner: ______________________

Height: ________ Weight: ________ Sex: ☐ M ☐ F Assistant: ______________________

Amputation Date: ______________________ Physician: ______________________

Skin Tone: ______________________ Secondary: ______________________

Involvement: ☐ Left ☐ Right ☐ Bilateral Therapist: ______________________

Location of Patient Evaluation	☐ Office ☐ Nursing Home	☐ Home ☐ Rehab. Hospital	☐ Skilled Nurse Facility ☐ Outpatient Facility	☐ Acute Hospital ☐ ________
Physical Therapy	☐ Ongoing	☐ Needed	☐ Patient would like a referral	☐ N/A
Living Status	☐ Alone	☐ Home w/Assistant	☐ LTCF	☐ ________
Living Conditions	☐ Level Surfaces	☐ Level with Steps	☐ Uneven Surfaces	☐ Uneven w/Steps
Patient's Vocation		Seated _____%	Standing _____%	Variable Cadence _____%
Recreation	☐ Bicycling ☐ Swimming ☐ Baseball	☐ Jogging ☐ ________ ☐ ________	Specialty Prosthesis Needed ☐ Yes ☐ No Type: ________	
Current Medication				
Cognitive Abilities	☐ Normal ☐ Impaired	Explain:		
Current Assistive Devices Used	**Devices** ☐ Handrails Present (home) ☐ Ramps present (home) ☐ Walker ☐ Crutch ☐ Cane ☐ Wheelchair	**Type** ________ ________ ________ ________ ________ ________		
Reason for Amputation	☐ Trauma ☐ Vascular ☐ Heart	☐ Diabetic ☐ Congenital ☐ ________	☐ Other Medical Conditions:	
Desire to Walk or Run (Potential)		Pre-Amputation Ambulatory Status:		

Prosthesis Longevity and Patient Wearing Schedule	Number of years patient has worn a prosthesis: __________ year(s) Age of current prosthesis: _________ month(s) or ________ year(s) Daily wearing schedule: ________ hours per day	
Heart Health		
Skin Condition	Invaginated Scars	Adherent Scar Tissue
Upper Extremity Involvement	ROM at Shoulders	Hand Dexterity
Vision		
Prosthetic History and/or Current Problems to Resolve		

Additional Information

Goals & Why Goals Cannot Be Accomplished	
Household Chores to be completed	
Work Environment	☐ Small Spaces ☐ Wet Environment ☐ Obstacles ☐ Other______________
Environmental Barriers Encountered	☐ Ramps/Slopes ☐ Stairs ☐ Curbs ☐ Grass ☐ Gravel ☐ Other: ______________________________
Transportation Utilized	☐ Train Stations ☐ Airports ☐ Buses ☐ Other______________

Strength and Range of Motion Measurements

(Test both Sides) Amputation is on: ☐ **Right** ☐ **Left** ☐ **Bilateral**

Contractures	R	✓	R	✓	Degree	L	✓	L	✓	Degree
Ankle	Y		N			Y		N		
Hip	Y		N			Y		N		
Knee	Y		N			Y		N		

ICD-9	✓	Level	ICD-9	✓	Level
ICD.9 895.0		Toe	ICD-9 897.2		Transfemoral
ICD.9 896.0		Partial Foot	ICD-9 897.4		Hip Disarticulation
ICD.9 896.0		Ankle Disarticulation	ICD-9 897.4		Pelvic Disarticulation
ICD.9 897.0		Transtibial	ICD-9 897.4		Not Otherwise Specified
ICD.9 897.4		Knee Disarticulation	ICD-9 897.6		Bilateral Any Level

Strength	Nothing				Trace				Poor				Fair				Good				Normal			
Ankle		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓
Dorsiflexion	R		L		R		L		R		L		R		L		R		L		R		L	
Plantar Flexion	R		L		R		L		R		L		R		L		R		L		R		L	
Inversion	R		L		R		L		R		L		R		L		R		L		R		L	
Eversion	R		L		R		L		R		L		R		L		R		L		R		L	
Knee		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓
Flexion	R		L		R		L		R		L		R		L		R		L		R		L	
Extension	R		L		R		L		R		L		R		L		R		L		R		L	
Hip		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓
Flexion	R		L		R		L		R		L		R		L		R		L		R		L	
Extension	R		L		R		L		R		L		R		L		R		L		R		L	
Abduction	R		L		R		L		R		L		R		L		R		L		R		L	
Adduction	R		L		R		L		R		L		R		L		R		L		R		L	
Internal Rot	R		L		R		L		R		L		R		L		R		L		R		L	
External Rot	R		L		R		L		R		L		R		L		R		L		R		L	

Residual Limb Health

Length Overall	____________ ☐ inches ☐ cm
Tissue Consistency	☐ Soft ☐ Medium ☐ Firm

	Where
☐ Distal Loading	____________
☐ Bulbous	____________
☐ Discoloration	____________
☐ Scarring	____________
☐ Delayed Healing	____________
☐ Drainage	____________
☐ Neuroma	____________
☐ Bony Prominences	____________
☐ Adhesions	____________
☐ Phantom Pain / Sensation	____________
☐ M/L Instability	____________

Additional Comments:

Functional Level Assessment

- ☐ **0** No ability or potential to ambulate or transfer.
- ☐ **1** Ability or potential to transfer or ambulate on level surfaces at fixed cadence.
- ☐ **2** Ability or potential for ambulation with ability to traverse low level barriers.
- ☐ **3** Ability or potential to ambulate with variable cadence.
- ☐ **4** Ability or potential to ambulate which exceeds basic ambulation skills.

CURRENT Functional Level – K ______ **EXPECTED Functional Level – K** ______

Type of Service

New Patient	☐ Yes	☐ No		
Replacement	☐ Entire	☐ Socket Only	☐ Components ____________________	
Replacement Due To:	☐ Change In Residual Limb ☐ Weight Gain or Loss	☐ Functional Activity Level ☐ Irreparable Damage	☐ Wear and Tear ☐ Other ____________________	
Type of Prosthesis	☐ IPOP/EPOP ☐ Prep./Temp	☐ Definitive ☐ Sport	☐ Cosmetic ☐ Endoskeletal	☐ Exoskeletal

Other Details:

Plan

Plan to cast/measure for the prosthesis: ☐ **This Visit** ☐ **Next Visit**

When the residual limb is: ☐ **Ready** ☐ **Other** ____________________

A test/diagnostic procedure (if necessary) will be scheduled on the following visit ____________________

Dynamic alignment will be scheduled after: ☐ **Casting** ☐ **Test Socket**

☐ **Other** ________________________________

Final delivery will be scheduled in approximately __________ **days.**

Practitioner Signature ________________________________ **Date** ____________________

Patient Signature ________________________________ **Date** ____________________

Sample: Letter of Medical Necessity
(Edit As Needed)

May 29, 2020

Medicare
SS# 555-55-5555-A

Re: Mr. A. Jones

To Whom It May Concern:

(Patient Introduction and Medical History)

Mr. Jones is a *57-year-old male* who is *5' 8" tall and weighs 138 lbs*. In *February of 2004, he suffered a heart attack and minor stroke while having exploratory surgery through the femoral vein and the removal of a tumor in his leg. He ultimately underwent a right transfemoral amputation on October 28th 2004, secondary to a chondrosarcoma. In addition to Mr. Jones's amputation, he has a history of surgery and tumor resection within his lungs. The resulting compromises to his pulmonary efficiency will require every effort to lower the energy cost during ambulation.*

(Vocational and Recreational Lifestyle)

Mr. Jones was employed as a *Project Manager for a construction company* before the amputation. As a *Project Manager,* he was required to walk for long periods of time, climb stairs, negotiate inclines and declines, as well as step over debris on the ground. His recreational activities included *golfing five times a week, making stained glass, flying Cessna airplanes, walking 2-5 miles a day for exercise, rebuilding computers, range shooting, and collecting coins.* His goals are to resume work and participate in the above mentioned leisure activities.

(Prosthetic Assessment)

Mr. Jones currently ambulates at a K3 level, using his current prosthesis. ***See attached Cadence Report*** *(attach report)* generated by the Plié Control Software. He has demonstrated the ability to ambulate at various speeds using his prosthesis; however he has not been able to return to work due to problems he has been experiencing with the limitations of his current prosthetic componentry, as well as secondary health problems. His reasons for requiring a new prosthesis at this time are to correct an ill fitting socket due to limb maturation, as well as providing a prosthetic knee solution which will address problems outlined below.

(Plié 3 Rational & Justification)

Mr. Jones potential return to his previous employment, as well as being able to negotiate various terrains he currently encounters, requires a high-activity prosthetic solution. This has traditionally been accomplished through the use of hydraulic knee mechanisms which allow for controlled flexion and extension of the knee in both the stance and swing phase of gait. Mr. Jones's current knee unit utilizes this traditional technology. Such hydraulic knee systems regulate knee motion through control valves that are manually set to limit the flow of hydraulic fluid inside of the knee unit by the prosthetist. Once the control valves are set they remain static regardless of *Mr. Jones's* gait pattern, the terrain on which he is ambulating and whether or not he is falling. To change the metering of the internal hydraulic ports, *Mr. Jones* must stop what he is doing, bend over at the waist, reach around to the back of the knee unit, and manually rotate a dial. Because his changes in walking speeds occur within fractions of a second, his traditional hydraulic knee unit can not change resistance with the efficiency and speed necessary, ultimately causing an unstable knee which limits *Mr. Jones's* activities and reduces the chances of his return to work. Additional design limitations require *Mr. Jones* to expend more energy and tire quickly during walking due to the inherent resistance within the hydraulic knee unit.

Mr. Jones is now seeking to be fit with a prosthesis which will address the chronic condition outlined above. Given his goals, active lifestyle, and decreased lung capacity, it is essential that any new prosthetic intervention addresses his need for stability in various terrains and slopes, accommodate his different speeds of ambulation, and do so with minimal energy costs.

To address the limitations outlined with his current hydraulic knee system, it will be necessary to utilize a microprocessor-controlled knee. The specific knee is a Freedom Innovations Plié 3 MPC Knee. The Plié 3 MPC Knee is a single-axis prosthetic knee joint system that provides hydraulic control of both the swing and the stance phase of gait. The stance phase control is assisted by sophisticated in-frame sensors that allow the microprocessor to control the resistance necessary to manage stance and determine when to send a message to enable a modification to the fluid management system, resulting in a change in torque about the knee center necessary for swing in 10 milliseconds. Sophisticated software has been developed and incorporated to allow adjustment for each user's walking style and personal preferences. Both the swing flexion and stance extension adjustments are independently optimized and utilize a sophisticated hydraulic system that reduces swing flexion and extension resistance, thereby reducing *Mr. Jones's* overall energy consumption. The hydraulic cylinder is also capable of providing stance flexion for level ground walking as well as stair and ramp descent. Stance extension has been engineered into the hydraulic cylinders capabilities as well. An extension assist is also incorporated into the design to compliment the amputee's hip extension movement and reduce effort to extend the shank. This ensures optimal stability for increased safety and efficiency when walking on level ground, uneven ground, and descending ramps and stairs, all of which *Mr. Jones* encounters on a daily basis. Finally, a removable lithium ion battery is utilized as the power source for the knee, and each knee will come complete with two batteries and a charger.

A microprocessor-controlled knee has been proven to reduce falls and increase the user's confidence. In the Plié 3 MPC knee, this is accomplished through advance stumble-recovery programming parameters. These parameters ensure that the knee unit is providing a high resistance to movement when *Mr. Jones* needs high torques around the knee for stability, and low resistance around the knee when *Mr. Jones* is in the swing phase of gait. The advanced stumble-recovery parameters read the position, speed, and moment around the knee a thousand times per second, making a decision and then changing the resistance of the knee in ten milliseconds. These unique features will increase *Mr. Jones's* confidence in his prosthesis and allow him to negotiate uneven ground and avoid environmental obstacles, significantly reducing the risk of a fall and incurring additional costly medical expenses.

A recent study by Brian J. Hafner PhD, published in the *Journal of Rehabilitation and Research* has shown that transfemoral amputees who use an MPC (microprocessor-controlled) knee have shown significant improvement in descending stairs and hills and improved sound side step length when compared to the mechanical knee. Users also reported a decrease in frequency of stumbling and falls.

Hopefully, this extensive history of *Mr. Jones's* prosthetic goals and lifestyle requirements will give you a clear picture of what he must deal with on a day-to-day basis. The efficacy of microprocessor knees has been proven as evidenced by the Veterans Administration providing this type of knee to returning war veterans, including those veterans that have comorbidities. Also, the new research performed by Hafner shows the overwhelming benefits provided by microprocessor knees when included in the prosthetic prescription. It has been demonstrated that *Mr. Jones* has extensive requirements that makes this type of prosthesis not only medically necessary but the least costly, most functional prosthesis available. It is our belief that we have provided you all of the information necessary to make a coverage review and provide prior authorization within 48 hours.

Sincerely,

Prosthetist XX, CPO.

Sample: Letter of Medical Necessity
(Edit As Needed)

May 28, 2020

Medicare
SS# 666-66-6666-A

Re: Joe Smith

To Whom It May Concern:

Mr. Smith is a 60-year-old, 148 pound, white male who underwent an above knee amputation of his right limb on December 06, 2006, secondary to diabetes. This amputation was a revision surgery from an April of 2005 below-knee amputation. His recovery was difficult due to the complications he experiences from CREST disease. The term CREST is an acronym derived from the five most prominent features:

C - Calcinosis - The accumulation of calcium below the outer layer of the skin. Many parts of the body can be affected such as: fingers, arms, feet and knees. Pressure on the skin from these deposits can cause severe pain, ulcerations and infection if the calcium protrudes.

R - Raynaud's phenomenon - A vascular disturbance affecting the extremities, primarily the hands. Spasms of the small blood vessels (capillaries) cause color changes varying from white to blue to red. Exposure to cold or emotional stress can intensify the problem; and there may be pain, tingling, numbness or a burning sensation.

E - Esophageal dysfunction - The loss of normal motility of the lower esophagus. This causes difficulty swallowing. A common complaint is acid reflux, with resulting heartburn.

S - Sclerodactyly - A condition in which the skin of the fingers becomes taut, thin and shiny. Fingers and toes may not bend or may become fixed in a flexed or less functional position.

T - Telangiectasia - The appearance of capillaries near the surface of the skin. They will blanch on pressure. These capillaries become dilated and visible appearing chiefly on the face, lips, tongue, fingers and palms.

The combination of diabetes and CREST has caused multiple problems for Mr. Smith. The calcium build-up on the left side knee has affected the muscle strength and stability of the knee. The scleroderma has reduced the elasticity of the skin on his hands, and the combination of diabetes and CREST has led to partial finger amputations on all four digits and thumb of the left hand. Additionally, arthritis and CREST have caused pain and stiffness in his lower back and shoulders and knee. However, according to his physician, these joints function better when Mr. Smith is mobile and spends less time in the wheelchair.

Mr. Smith led an active lifestyle prior the above-knee amputation, and desires to return to the same activity level. His activities include walking for exercise, taking care of grandchildren, shopping and working around the house. His leisure activities include bowling, throwing darts, and traveling. His activities of daily living will have Mr. Smith encountering a multitude of different surfaces and difficult situations which will challenge his stability while using a prosthesis. Airports are an area which present challenges to the person who wears a prosthesis. Walking from the car to the airport terminal with baggage will require Mr. Smith to encounter broken and cracked concrete, debris on the ground as well as larger objects that must be stepped over. Once in the airport, Mr. Smith will have to walk for long distances at varying speeds. He will have to stand in lines, taking small steps as he progresses forward. Inclines and declined surfaces have to be negotiated through the airport and while boarding and exiting the aircraft. The tight spaces within the airplane will require Mr. Smith to take small controlled steps and sit in a confined space. Once seated in these confined spaces, Mr. Smith will encounter further difficulty transitioning back to a standing posture. His other activities mentioned above will require the same amount of concentration to stabilize the prosthesis due to the uneven surfaces, slopes and stairs he will encounter. When encountering the various terrains and surfaces, Mr. Smith will need the sound-side leg to be strong and stable. However, with his limited strength and stability of the left leg, the prosthetic knee will have to act as the stable side so Mr. Smith has a "sound side" or stable side which will provide confidence and stability while walking.

Mr. Smith currently ambulates with crutches bilaterally at a K3 level, demonstrating multiple cadences or speeds of ambulation while negotiate various surfaces. His upper body is strong, secondary to his activity level before the amputation. However, Mr. Smith has to use his wheelchair when his left leg fatigues. The sound-side leg problem requires Mr. Smith to use a prosthesis to initiate load-bearing on the right side, while relieving his left lower extremity and his upper body from constant load-bearing. Once he is able to shift weight onto his lower extremities, Mr. Smith will be able to facilitate greater use of his upper extremities during activates of daily living.

Mr. Smith's active lifestyle alone (with the limitations of his left leg) requires a prosthetic solution which will provide stability during varying cadence and uneven ground. This has traditionally been accomplished through the use of hydraulic knee mechanisms which allow for controlled flexion and extension of the knee in both the stance and swing phase of gait. This is achieved through manually setting control valves that limit the flow of hydraulic fluid inside of the knee unit by the prosthetist. Once the control valves are set they remain static regardless of Mr. Smith's gait pattern, the terrain on which he is ambulating and whether or not he is falling. The hydraulic unit settings established in a clinical setting will accommodate a limited range of speeds, but are insufficient to accommodate the demands of an active individual on uncertain terrains. If he were a less active individual with a more sedentary lifestyle, such technology might be more appropriate, however, given that his lifestyle requires him to traverse over such varied and unpredictable terrains, the static settings found in traditional knee mechanisms are inadequate. In addition, traditional high-activity hydraulic knee units allow for the system to be locked, preventing any flexion from occurring. While this has some value as a safety feature, this function would have to be manually set each time Mr. Smith chooses to use it. This is a manual feature and he is not always able to take advantage of this feature. This safety feature prevents knee buckling when carrying heavy or bulky objects and reduces the likelihood of a fall when prolonged standing is anticipated. However, this limits its value as a safety feature in real-world situations and environments. The stumbles and falls that will occur in Mr. Smith's day-to-day life happen without warning (not after the safety feature is thoughtfully engaged). While this set-up is considered a high-activity system, the fact that the control valves are set manually is an impractical limitation from a functional and safety standpoint.

Essentially this means that once these valves are set by the Prosthetist, the metering of the hydraulic fluid through the system is set regardless of how fast or slow Mr. Smith is walking and regardless of the angle or undulation of the terrain. This requires Mr. Smith to constantly be aware of what he is currently walking on and what he is about to walk on so that he can alter his muscle activity inside of the socket to prevent inadvertent buckling of the knee. If this occurs, the knee will buckle at a rate established by the metering valves as if he were still in a walking mode rather in a safe mode. Because of this uncertainty, he must err on the safe side and constantly exert excessive muscle activity to keep the knee in a safe mode. This also requires that his walking is always a very conscience act, rather than subconscious, which diverts his attention from the task at hand. This is a real concern as his focus will be on not falling rather than negotiating the terrain which is in front of him. The potential risk of additional injury is more probable than possible in this circumstance.

Mr. Smith is now seeking to be fit for a prosthesis which will address the chronic condition outlined above. Given his goals, arthritic lower back, weak sound side knee and his CREST disease, it is essential that any new prosthetic intervention address his need for stability in various terrains and slopes, accommodate his different speeds of ambulation, and do so with minimal additional energy costs.

Since the foundation of any prosthesis is the limb-socket interface, this should be addressed first. Mr. Smith's high activity level will require a prosthetic socket which provides superior suspension, control of the remaining femur, and stability around the pelvis while taking into account that he has limited use of his left hand. The double-wall socket design provides the best suspension while allowing easy donning through the use of a suction inner socket attached to an outer frame by a pin lock. The inner socket will be held on to the residual limb through the use of a suction sleeve rolled onto the proximal thigh and then attached to the rigid inner socket. Once applied, this inner socket will be held on the residual limb by suction and can be applied with one hand. Once the inner socket is donned, the limb and inner socket is slid into the outer frame where the pin lock is engaged before Mr. Smith has to stand. This system gives him the superior suspension of suction while allowing application while in a seated position. Stability, superior suspension and reduced fatigue of the left leg are the benefits of this two-socket system.

Another beneficial component within the socket is a flexible brim along the outer socket. This will allow Mr. Smith to sit on various seating surfaces and increase the range of motion around the hip joint by lowering the trim lines of the rigid material. In conjunction with the socket system, a silicone liner will be used as the limb-socket interface. This will limit shear forces on the skin and reduce the chances of skin breakdown with the prosthetic socket. With Mr. Smith's diabetes and CREST disease it is paramount that the skin is protected since both diseases restrict blood flow to the small arteries of the limbs which can lead to multiple skin problems. To achieve the required intimate fit around the pelvis, distal femur control and protecting the skin within the socket, three test sockets will need to be fit. During the initial fittings, every attempt will be made to make adjustments directly to the test sockets to achieve the desired result. In some instances, this requires additional modifications be made to the initial mold and a subsequent new test socket be fabricated.

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The following is a detailed list of codes that we are asking to be prior authorized with further medical necessity rationale for each code:

L5321 – Above knee, molded socket, open end, SACH foot, endoskeletal system, single axis foot. This is the base procedure code and describes only the very basic components to describe a transfemoral prosthesis. The “L” coding system is an add-on system to more fully describe the specific prosthesis required.

L5624 x3 – Addition to lower extremity, test socket, above knee. As previously mentioned, the test socket fitting procedure ensures an optimal fit and function. These sockets are fabricated out of clear thermoplastic, allowing visual inspection of the limb tissues inside of the socket. This is necessary when suction is used for suspension to ensure that the tissue tension is correct. This is determined by tissue coloration as compared to the sound limb. Too much tension and the skin blanches whereas too little tension causes the skin to become reddish or purple in color. In either case, an improper fit will result in tissue damage.

L5631 – Addition to lower extremity, above knee or knee disarticulation, acrylic socket. This not an additional socket, rather it is defining the type of material that the socket is made from as compared to the standard material included in the base code. The acrylic material is far lighter and stronger than the polyester material. Due to the inner and outer socket design, a stronger material is indicated. In addition, to reduce energy consumption, the lighter socket weight will further reduce stress on Mr. Smith’s lower back.

L5649 – Addition to lower extremity, ischial containment/narrow M-L socket. Again, this is not another socket, rather it describes the shape of the socket as opposed to the standard quadrilateral design included in the base code. This socket design is necessary to better control the femur by containing the ischial tuberosity. Given the distal musculature is not attached to the bone, it is imperative that the proximal pelvic structure is secured inside of the socket so that the lateral socket wall can help stabilize the distal femur. This design also decreases stress on the tissues of the perineal area. In a quadrilateral socket, the ischial tuberosity sits on top of the socket, relying on firm perineal tissues to stabilize the socket on the limb. Stabilization of the femur is not possible inside of the soft distal tissues.

L5650 – Addition to lower extremity, total contact, above knee or knee disarticulation socket. This is a procedure that is done to establish that distal contact is established inside of the clear test socket. This is necessary when suction is used to prevent a condition called verrucose hyperplasia.

L5652: Addition to Lower Extremity, Suction Suspension, Above Knee or Knee Disarticulation Socket. Suction and pin lock will both be utilized with the two socket design described above. The inner socket is held on the residual limb by suction. This is the primary suspension which attaches the prosthesis to the limb. The secondary suspension will hold the limb and inner socket inside the outer frame. Both suspension mechanisms are needed to complete the system.

L5671: Addition to Lower Extremity, Below Knee/ Above Knee Suspension Locking Mechanism (Shuttle, Lanyard or Equal), Excludes Socket Insert.
The locking mechanism allows the residual limb and inner socket to be attached to the outer frame, knee and foot components. Once the suction is achieved between the residual limb and the inner socket, the pin lock will connect the two part system firmly together, allowing Mr. Smith to ambulate safely. This two-part system will alleviate the distal pull on Mr. Smith’s residual limb while allowing superior suspension and simple application with one hand.

L5679 X 2: Addition to Lower Extremity, Below Knee/Above Knee, Custom Fabricated From Existing Mold or Prefabricated, Socket Insert, Silicone Gel, Electrometric or Equal, Not For Use With Locking Mechanism.
These are prefabricated liners which are custom-fit to measurement. The liners are used to distribute pressures evenly over the entire limb, allowing the use the total contact socket theory. These elastomer liners have creep and flow characteristics that allow the material to move from a high-pressure area to a lower-pressure area, giving relief in the socket. The silicone or elastomer material from which the liners are fabricated will absorb torsion, shock,

and shear forces that occur at every step in a prosthesis. As the heel strikes the ground, the above-mentioned forces that are normally absorbed through an ankle are now transferred up to the residual limb. The reduction of the above mentioned forces will produce a healthier limb by reducing the forces that create sores and open wounds. Mr. Smith needs two liners for hygiene purposes. One liner is worn while the other is washed. Two alternating liners will increase the longevity of the liners as well as the healthiness of the skin by placing a clean liner against the skin. With these liners, we have had a decrease in skin problems on the residual limb as well as a higher acceptance rate in the patient's ability to wear the prosthetic device for longer periods of time.

L5685: Addition to Lower Extremity Prosthesis, Below Knee, Suspension/Sealing Sleeve, With or Without Valve, Any Material Each.
These are the suction seals which create the suction between the residual limb and the inner socket. These seals are attached to the top of the inner socket, and are rolled onto the upper portion of the thigh, creating the suction seal. These soft goods have the tendency to be damaged during everyday activities. We will provide three sleeves. These are integral to the suction system. Without these, suction will not exist. Suction suspension allows very little pistoning between the residual limb and the socket. During the swing phase of gait, distally directed forces will pull at the prosthesis, making it more inclined to come off. Suction holds the prosthesis on the residual limb with little to no movement off the leg.

L5651 – Addition to Lower extremity, above knee, flexible inner socket, external frame. This describes the definitive outer-socket design that consists of two parts. The inner portion of the outer socket is made from a flexible thermoplastic material that is housed inside of a rigid frame to make a complete outer socket unit. The flexible material is necessary so that it will conform to a variety of seating surfaces that Mr. Smith is required to sit on. The posterior portion of the inner socket is exposed and will conform to the different seating surfaces. The standard socket configuration is a hard exoskeletal shell that causes tissue impingement. In addition, the proximal brim area will flex during bending to allow increased range of motion.

L5828 – Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control. This describes the base code of the knee system. The metering valves regulate the rate at which the knee can bend during swing and stance phases of gait. Increased weight on the heel during stance phase will allow Mr. Smith to load the knee and maintain stability with varying degrees of knee flexion. Decreased friction during early swing phase will allow the knee to flex with little effort and delivers an energy efficient, symmetric and more natural gait over a wide range of walking speeds. The increased stability and ease of initial knee flexion will allow Mr. Smith to reduce the stress level on his lower back and allow him to reduce the stress on his sound-side arthritic knee.

L5845 – Addition, endoskeletal knee-shin system, stance flexion feature, adjustable. Stance flexion allows for controlled flexion up to 15 degrees during the initial stance phase of gait. Stance flexion limits the rise of the center of gravity, absorbs the initial impact of heel contact, and reduces energy consumption. This will allow Mr. Smith to walk foot-over-foot down stairs and to walk down hills or ramps without the fear of the knee buckling under him.

L5856 Endoskeletal knee shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type. The Plié microprocessor controlled knee measures input parameters 1000 times a second. The new sensor suite measures total load, bending moment at the bottom of the knee, knee joint angle, knee joint angle rate and time throughout the entire gait cycle (both stance and swing.) The microprocessor control logic is always active and determines transitions from stance into swing and from swing into stance. An extensive stumble recovery and stability system has been implemented in this configuration. Once the microprocessor control logic decides to enter swing, return to stance is blocked for 20ms (this time is variable in the control system and may change within small limits). After this delay, the stumble recovery system can command return to stance at any time and the transition occurs in less than 10ms. The stumble recovery logic monitors terminal stance and the entire swing cycle for appropriate changes in the measured parameters. Any deviation from allowable bands or progression timing triggers return to stance.

The control system displays knee angle, knee angle rate, moment and load throughout the gait cycle to aid the practitioner in establishing optimum gait and alignment. In the enhanced design, the transition from swing flexion mode back to stance flexion mode is now controlled by the microprocessor. The spool valve is now held open during swing flexion by a message sent from the microprocessor. Using data from the new position sensor, the microprocessor determines when swing flexion ends and swing extension begins. At that instant in time, the microprocessor sends a message to the solenoid allowing the spool valve to close which puts the cylinder back in stance flexion as the leg comes forward. In addition, because the spool valve is held open by the solenoid and not a mechanical latch, the microprocessor can now switch the cylinder from swing flexion mode to stance flexion mode any time the microprocessor deems that this is necessary.

L5848 – Addition to endoskeletal, knee-shin system, hydraulic stance extension, dampening feature, adjustable. This feature describes the portion of gait that occurs directly after terminal stance flexion as the knee begins to move back into full extension. Without an adjustable dampening feature, the knee would abruptly move back into an extended position, jarring the limb and interrupting the gait cycle. This jerky type of gait would cause an increase in energy expenditure.

L5920 – Addition endoskeletal system, above knee or hip disarticulation, alignable system. This code describes the overall componentry that allows the prosthesis to be aligned to Mr. Smith's individual gait pattern. A non-alignable system would increase the energy expenditure, causing additional stress to his lower back and sound-side limb.

L5950 - Addition, endoskeletal system, above knee, ultra light material (titanium, carbon fiber, or equal). This is a global code used to describe any materials that would be used in the general fabrication of the prosthesis that reduce the overall weight thus increase the energy efficiency of the prosthesis for Mr. Smith.

L5981: All Lower Extremity Prostheses, Flex-Walk System or Equal.
This is a carbon fiber type of foot that allows activity at a rate which is faster than a self selected walking speed. A reduction of O_2 consumption is seen at higher cadences when the carbon fiber feet are used. Additionally, these carbon fiber feet also have a long toe lever. This is very important during late stance when the sound side is in swing and he is rolling onto the toe of the prosthesis. With the longer carbon fiber toe plates, Mr. Smith can stay on the prosthetic toe for a longer period of time, allowing him to have a normal sound-side step length. As he rolls over the carbon plate during late stance, it will deflect, causing posterior-directed ground reaction forces against the knee, thereby, stabilizing the knee at late stance. Along with knee stability, this foot also has energy-storing capabilities. As the foot plate deflects in late stance, it will want to go back to its natural position. When the weight is transferred off the carbon toe plate, the plate will push back and release energy and help propel Mr. Smith forward. A SACH or a non-carbon fiber footplate has a much shorter keel length. The keel length affects the sound side step length through its lack of a sufficient anterior lever arm. The foot does not apply the proper ground reaction forces against the prosthetic knee causing the sound side limb to take a quick, short step in attempt to stabilize the prosthetic knee.

L5986 – All lower extremity prosthesis, multi-axial rotation unit (MCP or equal). The multi-axial rotation unit is essential to prevent shear forces inside of the socket from causing skin ulceration and to allow for the normal axial rotation that occurs with ambulation. This will help to normalize Mr. Smith's gait, which translates to greater symmetry and decreased metabolic costs.

Hopefully, this extensive history of Mr. Smith's prosthetic goals and lifestyle requirements will give you a clear picture of what he must deal with on a day-to-day basis. The efficacy of microprocessor knees has been proven as evidenced by the Veterans Administration providing this type of knee to returning veterans from Iraq. Also, the new research performed by Hafner shows the necessity of the microprocessor knees in prosthetics. It has been demonstrated that Mr. Smith has extensive requirements that makes this type of prosthesis not only medically necessary but the least costly, most functional prosthesis available. It is our belief that we have provided you all of the information necessary to make a coverage review and prior authorization within 48 hours.

Sincerely,

Prosthetist XX, CPO, LPO.

Microprocessor Knee Literature Review

FREEDOM INNOVATIONS

The following articles were reviewed in an effort to understand where the research in Microprocessor Knees (MPK) has been focused and to determine where significant outcomes exist. These articles can be utilized within your initial Letter of Medical Necessity or could be used in refuting an appeal.

Many different measures have been evaluated to tease out the perceived benefits of the microprocessor. Metabolic energy expenditure, temporal parameters, symmetry of gait, distances covered, swing phase characteristic, balance, improved joint angles, and others.

The research has been able to show that the user feels more stable on stairs, inclines, and uneven terrain, while reducing the cognitive demand required for walking. These outcomes have been identified using self-reported questionnaires (PEQ—Prosthesis Evaluation Questionnaire) and timed walks on varying terrains. These questionnaires also identified that the user experiences less stumbles and falls while expressing a higher level of satisfaction and stability with MPKs.

Evaluation of Function, Performance, and Preference as Transfemoral Amputees Transition from Mechanical to Microprocessor Control of the Prosthetic Knee
Brian J. Hafner, PhD, Laura L. Willingham, BS, Noelle C. Buell, MSPT, Katheryn J. Allyn, CPO, Douglas G. Smith, MD,
Arch Phys Med Rehabil Vol 88, February 2007
Results: Stair descent score, hill descent time, and hill sound-side step length showed significant ($P<.01$) improvement with the C-Leg. Users reported a significant ($P<.05$) decrease in frequency of stumbles and falls, frustration with falling, and difficulty in multitasking while using the microprocessor knee.
Anecdotal reports suggest that microprocessor control is most beneficial in functional activities outside of level walking. Improvement in stair descent, ramp or hill descent, and walking on uneven terrain are commonly noted by users after transitioning to microprocessor stance control.

VA TECHNOLOGY ASSESSMENT PROGRAM PROJECT REPORT – Patient Summary on Computerized Lower Limb Prostheses.
http://www4.va.gov/vatap/patientinfo/prosteticlimb.htm
What are the benefits of a computerized lower limb prosthesis?
The main supposed benefit is improved stability of the knee while walking. This means the amputee may have a more natural walk and may be able to walk stairs, inclines, uneven terrain, or when it is hard to see. Other benefits may be increased confidence in the prosthesis; fewer stumbles and falls; and participation in sports for veterans who were active athletes prior to their injury.
Biomechanical analysis of stair ambulation in lower limb amputees
Thomas Schmalz a,*, Siegmar Blumentritt a, Bjo¨rn Marx b, **Gait & Posture 25 (2007) 267–278**
Department of Research, Otto Bock Health Care, Duderstadt, Germany
Institute of Physiology, Georg-August-University, Go¨ttingen, Germany
Results showed that kinetics and kinematics of the microprocessor control knee were closer to the normal knee and produced a significantly ($P<.01$) reduced maximum sound-side weight-acceptance force and increased ($P<.01$) maximum knee flexion moment when compared with mechanical control knees.

Gait and balance of transfemoral amputees using passive mechanical and microprocessor-controlled prosthetic knees
K.R. Kaufman a,*, J.A. Levine b, R.H. Brey c, B.K. Iverson a, S.K. McCrady b, D.J. Padgett a, M.J. Joyner d
Gait & Posture 26 (2007) 489–493
When the patients used the mechanical prosthesis, they walked in a way that maintained the ground reaction force in front of the knee, which caused knee hyperextension and locked the knee in order to maintain a mechanically stable environment. When the patients changed to the microprocessor controlled knee, they changed to a more normal walking pattern resulting in knee flexion during loading response. The knee moment changed from an internal flexion moment when using the mechanical prosthesis to an internal extension moment when using the microprocessor-controlled prosthesis. The change in the dynamic environment required the prosthetic knee to support the loading in a more natural fashion. These gait changes were statistically significant ($p < 0.01$). Balance improved significantly when using the microprocessor-controlled knee ($p < 0.01$). All six conditions of the sensory organization test demonstrated improvements in equilibrium score. The composite score also was significantly improved.

Energy expenditure during walking in amputees after disarticulation of the hip
A MICROPROCESSOR-CONTROLLED SWING-PHASE CONTROL KNEE VERSUS A MECHANICAL-CONTROLLED STANCE-PHASE CONTROL KNEE
T. Chin, S. Sawamura, R. Shiba, H. Oyabu, Y. Nagakura, A. Nakagawa
THE JOURNAL OF BONE AND JOINT SURGERY, VOL. 87-B, No. 1, JANUARY 2005 117
An energy expenditure comparison between a mechanical- controlled stance-phase control knee (Otto Bock 3R15) and the Intelligent Prosthesis was studies with three unilateral hip disarticulation patients. During walking paces faster than self selected, the IP knee showed less oxygen consumption compared to the 3R15.

Comparison of nonmicroprocessor knee mechanism versus C-Leg on Prosthesis Evaluation Questionnaire, stumbles, falls, walking tests, stair descent, and knee preference
Jason T. Kahle, CPO, LPO; 1 M. Jason Highsmith, DPT, CP; 1–2* Sandra L. Hubbard, PhD, OTR/L, ATP3–4, JRRD,
Volume 45, Number 1, 2008
We found that use of the C-Leg improved function in all outcomes: (1) Prosthesis Evaluation Questionnaire scores increased 20% ($p = 0.007$), (2) stumbles decreased 59% ($p = 0.006$), (3) falls decreased 64% ($p = 0.03$), (4) 75 m self selected walking speed on even terrain improved 15% ($p = 0.03$), (5) 75 m fastest possible walking speed (FPWS) on even terrain improved 12% ($p = 0.005$), (6) 38 m FPWS on uneven terrain improved 21% ($p < 0.001$), (7) 6 m FPWS on even terrain improved 17% ($p = 0.001$), (8) Montreal Rehabilitation Performance Profile Performance Composite Scores for stair descent increased for 12 subjects, and (9) the C-Leg was preferred over the NMKM by 14 subjects.

Energy Expenditure and Activity of Transfemoral Amputees Using Mechanical and Microprocessor-Controlled Prosthetic Knees
Kenton R. Kaufman, PhD, PE, James A. Levine, MD, PhD, Robert H. Brey, PhD, Shelly K. McCrady, MS,Denny J. Padgett, PT, Michael J. Joyner, MD,
Arch Phys Med Rehabil Vol 89, July 2008
Main Outcome Measures: Objective measurements of energy efficiency and total daily energy expenditure were obtained. The Prosthetic Evaluation Questionnaire was used to gather subjective feedback from the participants. Results: Subjects demonstrated significantly increased physical activity–related energy expenditure levels in the participant's free-living environment ($P=.04$) after wearing the microprocessor-controlled prosthetic knee joint. There was no significant difference in the energy efficiency of walking ($P=.34$). When using the microprocessor-controlled knee, the subjects expressed increased satisfaction in their daily lives ($P=.02$).

Does Having a Computerized Prosthetic Knee Influence Cognitive Performance During Amputee Walking?
Rhonda M. Williams, PhD, Aaron P. Turner, PhD, Michael Orendurff, MS, Ava D. Segal, BAS, Glenn K. Klute, PhD, Jan Pecoraro, RN, Joseph Czerniecki, MD.
Arch Phys Med Rehabil Vol 87, July 2006
Main Outcome Measures: Objective cognitive performance measures included verbal fluency (Controlled Oral Word Association Test, Category Test), attention and working memory (serial subtraction), and walking speed during cognitive tasks. Measures of perceived cognitive burden included subjective attentional requirements of walking and cognitive tasks and subjective general cognitive burden of prosthesis. Results: There were no significant differences in objective cognitive performance on any task between prostheses, nor did walking speed vary by prosthesis during the free-speed walk. Participants reported that walking required less attention while wearing the C-leg and that the C-leg was less of a cognitive burden than the noncomputerized prosthesis

The Impact of C-Leg® on the Physical and Psychological Adjustment to Transfemoral Amputation
Daniel J. Bunce, PhD, James W. Breakey, PhD, CP.
JPO Journal of Prosthetics and Orthotics, Volume 19 • Number 1 • 2007
The C-Leg becomes an instrument that transforms the amputee's body and thus returns a sense of connectedness with the world. Indeed, patients find that their sense of self in relation to their surroundings and others transforms when using it. They feel stable, able confident and normal.

A comparative evaluation of oxygen consumption and gait pattern in amputees using Intelligent Prostheses and conventionally damped knee swing-phase control
Dipak Datta, Ben Heller John Howitt. **Clinical Rehabilitation 2005; 19: 398_/403**
Main outcome measures: Oxygen consumption while walking at different speeds on a treadmill, video-recording of gait assessed by a panel and temporal_/spatial parameters of gait whilst walking at slow, fast or normal speeds in a gait laboratory. Results: Mean oxygen cost for all subjects at 0.69 m/s was 0.33 ml/kg.m with the conventional limb and 0.30 ml/kg.m with the Intelligent Prosthesis (p_/0.01). At 1.25 m/s the mean oxygen cost for the conventional limb was 0.24 ml/kg.m and for the Intelligent Prosthesis was 0.22 ml/kg.m (not significant). The ANOVA analysis showed that oxygen cost was similar at normal walking speeds but increased more at lower speeds for the pneumatic swing-phase control leg compared to the Intelligent Prosthesis (pB/0.02). There were no significant differences in subjective gait evaluation or temporal and spatial gait parameters.