PAVET™ [1]
Patient Assessment Validation Evaluation Test

Process

The PAVET protocol evaluates the patient in each of 4 separate categories. The questions in each category rank the patient score on a scale of 0-4. The categories are:

1. ***Activities of Daily Living***
   ADL identifies specific activities the patient is expected to perform, or that the patient presently does on a day-to-day basis. This score will provide an indicator as to the specific needs the patient will have and therefore will indicate the specific style and type of prosthetic device required.

2. ***Functional Requirements***
   Functional requirements evaluate and qualify the functional abilities and capabilities of the patient as related to the Medicare functional level (or K-level) requirements. This score will provide an indicator as to the specific abilities or potential of the patient to accomplish specific ambulatory functions as related to the Medicare functional levels.

3. ***Physical Capabilities***
   Physical capabilities score will provide an indicator of the patient's physical condition related to strength and mobility of the primary joints and limbs required to ambulate with a prosthetic device.

4. ***Special Considerations***
   Special Considerations score is designed to provide additional points to the patient's overall score to take into consideration special conditions or challenges the patient may have that would require higher levels of security, stability or function from a prosthetic device to enable the patient to accomplish activities of daily living.

[1] Patent Pending

Category Scoring

It is imperative to establish that the scoring of the PAVET™ protocol is determined by the accumulated score of all four categories. Evaluating or determining the patient's score based upon a single question or category will not provide an appropriate and global evaluation of the patient and therefore will not provide an appropriate evaluation of the patient's abilities or needs.

ADL Score

ADL Scoring determines the specific activities the patient presently does or will need as a part of their daily living. Each question is scored on a scale of 0-4 based upon the following scale:

ADL Score	***Rating***	***Designates:***
0	Never	Microprocessor Knee not required
1	Rarely	Microprocessor Knee potential
2	3-4 Times a Month	Microprocessor Knee considered beneficial
3	3-4 Times a Week	Microprocessor Knee recommended
4	Daily	Microprocessor Knee indicated

The ADL category is comprised of 10 separate questions for a total ADL score range of 0-40. Each question relates to a specific activity of daily living that relates to the functional capabilities of a microprocessor knee.

ADL Question	**Justification and Rationale**
1. Walk with variable cadence (change walking speeds) *Cadence Score Question*	The speed of the microprocessor knee servomotor allows it to close the flexion and extension valves very rapidly in response to the microprocessor commands, which are sent 50 times per second. When the valves are nearly closed the microprocessor knee dampening force becomes very high, making rapid walking and even running possible. This ability to "tune" microprocessor-controlled prosthetic knees to the individual's unique gait pattern has been shown to result in the widest range of cadences available in any prosthetic knee, and to increase amputee confidence, comfort and functional levels.
2. Walk a distance greater than 400 yards *Cadence Score Question*	Scientific studies have suggested that the resulting gait with a microprocessor knee is more natural, symmetric, and therefore more energy efficient. This reduction of energy consumption will greatly prolong the time it takes the amputee's muscles to fatigue. This creates a positive effect by maintaining greater muscle strength and resulting control of the prosthesis for a longer period of time.
3. Walk on uneven terrain (gravel, grass, curbs)	The microprocessor knee servomotor readjusts the hydraulic flexion resistance from maximum powerful stance flexion resistance to nearly effortless knee bending to initiate pre-swing in less than 120 thousandths of a second. This feature offers secure stumble-recovery capabilities by ensuring optimum knee resistance and stability in the event of a mis-step or stumble.

ADL Question	Justification and Rationale
4. Walk up and down stairs	The stance flexion-yielding rate can be used to decelerate the prosthesis while descending stairs. The microprocessor stance control and stumble recovery settings provide optimum resistance for decelerating knee flexion to enable step-over-step descending of stairs. The advanced stumble recovery sensor provides maximum stance and stability control to eliminate premature knee flexion for ascending stairs.
5. Walk up and down ramps	The advanced stumble recovery sensor combined with the stance flexion design enables the wearer to initiate heel strike during the gait cycle with the knee in a natural and flexed position. This "stance-flex" feature with "flexion dampening" mimics the normal gait cycle of the anatomical knee. The flexion at mid-stance reduces stress and strain to the hip and lower back while maintaining a smooth transitional pathway for the body's center of gravity to reduce energy consumption while providing optimal stability and security to ascend and descend ramps.
6. Carry or lift items (i.e. books, infant, groceries etc.)	Independent software-modulated control of swing phase extension resistance, adjusted 50 times per second, means that the artificial limb is fully extended just prior to initial contact every time, with no conscious effort by the amputee, regardless of the gait speed or ground conditions. Independent scientific studies have shown that such optimized swing phase timing translates into greater confidence in the prosthesis, reduced risk of stumbling, and a more energy-efficient gait.
7. Walk in public areas or crowds *Cadence Score Question*	With the onboard computer continually assessing the amputee's gait and walking conditions, there is significantly reduced stress and anxiety for the patient, as he/she does not need to continuously and consciously control all movements of the knee with muscular control. This contributes to a significant reduction in overall energy consumption.
8. Get in and out of a car	The microprocessor knee is designed to allow the individual to bear weight on the prosthesis while it is in a flexed position. This unique feature enables optimal resistance to knee flexion while entering and exiting a car. This resistance to knee flexion on a bent knee greatly increases the security and stability of the knee and significantly reduces strain and stress on the lower back and sound limb, and also reduces the dependence on the upper limbs to support the body while entering or exiting a car.
9. Bend, kneel or stoop	The microprocessor knee is designed to allow the individual to bear weight on the prosthesis while it is in a flexed position. This unique feature enables optimal resistance to knee flexion while bending the knee to achieve a seated position. This resistance greatly reduces the stress and strain on the sound limb and lower back as the wearer is able to use both lower limbs to achieve a seated position.
10. Walk, stand or work in confined areas (i.e. push a vacuum cleaner, cook in a kitchen, work in a workshop, behind a desk or in a laboratory)	The electronically controlled flexion valve, adjusted 50 times per second, is automatically fully opened during pre-swing. As a result, the microprocessor knee is extremely easy to flex at slow speeds and in confined areas.

Functional Score

Functional Scoring determines the specific functional abilities the patient has the potential or is capable of accomplishing. Each question is scored on a scale of 0-4 based upon the following scale:

ADL Score	*Rating*	*Designates:*
0	Not Possible	Microprocessor Knee not required
1	Potential	Microprocessor Knee potential
2	Exhibits ability to accomplish	Microprocessor Knee considered beneficial
3	Can Accomplish	Microprocessor Knee recommended
4	Presently does on a daily basis	Microprocessor Knee indicated

The Functional category is comprised of 5 separate questions for a total Functional Score range of 0-20. Each question relates to a specific functional capability that the patient has the potential to accomplish or has demonstrated. These functional abilities are directly related to the Medicare functional levels that are utilized to determine the K level or functional level of a prosthetic wearer. The functional level category for the PAVET™ protocol determines the patient's ability to:

Functional Question	Justification and Rationale
11. Transfer without assistive devices	The ability to transfer without assistive devices is a fundamental requirement that a patient must be able to demonstrate to be considered a candidate for prosthetic rehabilitation.
12. Ambulate on level surfaces at fixed cadence	The electronically controlled flexion valve, adjusted 50 times per second, is automatically fully opened during pre-swing. As a result, the microprocessor knee is extremely easy to flex at slow speeds and at a fixed cadence.
13. Traverse low level environmental barriers	The microprocessor knee servomotor continuously adjusts the hydraulic flexion resistance and stance flexion resistance to enable the knee to immediately engage a knee stability stance setting in the event of a slip or loss of balance. This feature will ensure the knee is always stabilized in the optimum setting to prevent the knee from collapsing in rapid flexion while negotiating environmental barriers such as curbs, steps and debris.
14. Ambulate with variable cadence *Cadence Score Question*	The swing phase control characteristics of the microprocessor knee reduce the amount of excess effort the amputee must expend to walk a given distance. The adjustable "dynamic factor" allows the microprocessor knee to be optimized for all gait patterns from the very casual "strolling" style to very aggressive "athletic" movements.
15. Ambulate at a faster than baseline rate *(fast walk or jog)* *Cadence Score Question*	The enhanced stance phase control, combined with the superior swing function increases the amputee's confidence and functional capabilities in the prosthesis. Outcome studies have indicated that microprocessor knee wearers have increased their activity level and range of activities.

Prosthetic Reliance Score

The Prosthetic Reliance score indicates the patient's level of dependence on the prosthesis for stability and function based upon physical strength and condition of key joints and muscles required to control a prosthetic device. Scoring for this category provides higher scores for patients with lower physical strength capabilities. This scoring criterion is based upon the rationale that those individuals with stronger limbs and joints will have a reduced need to rely on the prosthesis for stability and function. Those individuals with weak joints and muscles will have a higher prosthetic reliance score, as they will require enhanced levels of prosthetic stability, security and function to accomplish activities of daily living.

Each question is scored on a scale of 0-4 based upon the following scale:

Prosthetic Reliance Score	***Rating***	***Designates:***
0	Normal	Microprocessor Knee not essential
1	Good	Microprocessor Knee potential
2	Fair	Microprocessor Knee considered beneficial
3	Poor	Microprocessor Knee recommended
4	Trace	Microprocessor Knee indicated

The Prosthetic Reliance category is comprised of 5 separate questions for a total Prosthetic Reliance score range of 0-20. Each question relates to a specific strength of key muscles and joints required to control and function with a prosthetic knee. The prosthetic reliance category for the PAVET™ protocol determines the patient's limb and joint strength for:

Prosthetic Reliance Question	**Justification and Rationale**
16. Amputated side hip extension *(Bilateral AK patient, score as a Left side hip extension)*	Determines the patient's ability to maintain the prosthetic knee in extension during stance phase, as well as the ability to prevent the knee from initiating premature flexion. A high prosthetic reliance score indicates a limited ability to control the knee, which signifies a need for a prosthetic knee that will provide a high degree of stability and stumble recovery. The microprocessor knee servomotor readjusts the hydraulic flexion resistance from maximum powerful stance flexion resistance to nearly effortless knee bending to initiate pre-swing in less than 120 thousandths of a second. This feature offers secure stumble-recovery capabilities to ensure optimum knee resistance and stability in the event of a mis-step or stumble.
17. Sound side hip extension *(Bilateral AK patient, score as a Right side hip extension)*	Determines the patient's strength and control of the contralateral hip, which is an indicator of the patient's overall balance and ability to transfer weight to the contralateral side. A high prosthetic reliance score indicates a limited ability to control the hip and suggests limited overall balance capabilities which signify a need for a prosthetic knee that will provide a high degree of stability and stumble recovery.
18. Sound side knee extension *(Bilateral AK patient, score 4)*	Determines the patient's strength and control of the contralateral knee, which is an indicator of the patient's overall balance and ability to transfer weight during gait from the amputated side to the contralateral side. A high prosthetic reliance score indicates a limited ability to control the contralateral knee from premature flexion at heel strike, which will reduce stability and security during normal gait. This signifies a need for a prosthetic knee that will provide a high degree of stability and optimum stumble recovery during gait weight transfer. If the patient is a bilateral AK amputee, he/she will have no contralateral knee and therefore score 4 points.

Prosthetic Reliance Question	Justification and Rationale
19. Sound side Ankle Plantar/Dorsi Flexion *(Bilateral AK or AK/BK patient, score 4)*	Determines the patient's strength and control of the contralateral ankle, which is an indicator of the patient's overall balance, stability and ability to transfer weight during gait from the amputated side to the contralateral side. A high prosthetic reliance score indicates a limited ability to control the contralateral foot and ankle at heel strike, which will reduce stability and security during normal gait. This factor signifies a need for a prosthetic knee that will provide a high degree of stability and optimum stumble recovery during gait weight transfer. If the patient is a bilateral lower limb amputee, he/she will have no contralateral ankle or foot and therefore score 4 points.
20. Upper Extremity Strength	Determines the patient's overall strength and control of their upper limbs, which is an indicator of the patient's overall balance, stability and ability to function with ambulation aids (crutches, canes, walker). A high prosthetic reliance score indicates a limited ability to control the ambulation aids, which signifies a need for a prosthetic knee that will provide a high degree of stability and optimum stumble recovery.

Special Consideration Score

The Special Consideration score provides a weighted value for unique and special conditions a patient may exhibit. Each condition is weighted to a score of 1, 2 or 3 depending upon the severity of the condition and its subsequent effect on the patient's stability and ability to accomplish activities of daily living.

Special Consideration Score	Score	Justification and Rationale
21. Hip Replacement (either side)	1	Affects hip strength, control and balance which will impact overall balance and ability to transfer weight during gait.
22. Unilateral Upper Extremity Amputation	1	Affects overall balance and weight transfer during gait as well as limits the ability to utilize ambulatory aids (crutches, cane(s), walker, etc.).
23. Neuropathy on sound side	1	Affects overall balance and weight transfer during gait due to the lack of sensory feedback on the sound side.
24. Asthma	1	Affects energy consumption and stress to the lungs and potentially impacts the heart and blood pressure. Patient requires optimum efficiency in gait to reduce energy consumption.
25. Short Transfemoral amputation *(less than 5" femoral length)*	1	Creates added stress to the lower back and increases the amount of energy and concentration for the patient to maintain control of the socket and prosthesis. The short residual limb reduces the patient's ability to maintain the prosthetic knee in extension during stance phase requires increase energy to prevent the knee from premature flexion.
26. Low Back or Hip Pain	1	Impacts ability to initiate symmetrical weight transfer during gait, which in turn increases energy consumption. Patient requires a prosthesis that will minimize stress and strain to the lower back to initiate weight transfer during the gait cycle as well as reduce overall energy consumption.
27. Normal or Long Transtibial on contra lateral side *(greater than 5" tibial length)*	2	Impacts overall balance and weight transfer during gait due to the lack of sensory feedback and voluntary control of the sound side ankle and foot.
28. Hip disarticulation or Hemipelvectomy on affected side	2	Affects voluntary control of the prosthetic knee due to lack of residual limb and inability to control femoral flexion and extension.
29. Impaired Vision	2	Affects balance and influences ability to avoid objects during gait. Patient requires additional support for stability and stumble recovery.
30. Heart disease	2	Affects energy consumption and stress to the heart and lungs. Patient requires optimum efficiency in gait to reduce energy consumption.
31. Short Transtibial on contra-lateral side *(less than 5" tibial length)*	3	Impacts overall balance and weight transfer during gait due to the lack of sensory feedback and voluntary control of the sound side ankle and foot. The short trans-tibial residual limb also reduces control of the contra-lateral knee during weight transfer, which reduces overall stability.
32. Transfemoral on contralateral side (bilateral AK)	3	Impacts overall balance and weight transfer during gait due to the lack of sensory feedback and voluntary control of the knee, ankle and foot.
33. Bilateral Upper Extremity Amputation	3	Affects balance and weight transfer during gait as well as significantly limits the ability to utilize ambulatory aids (crutches, cane(s), walker). Patient must rely on the prosthetic devices for balance and stability as he/she has no protection against injury in the event of a fall due to the lack of upper limbs to prevent or catch him/herself.

PAVET™ Application for MPK

Patient Assessment Validation Evaluation Test

Score	PAVET™ STATUS	Rationalization
<40	Not a Candidate Microprocessor Knee not required	A PAVET™ Score under 40 would indicate a low ADL and Functional score in addition to a lack of sufficient Special Consideration points to justify a microprocessor knee. A score below 40 would suggest the patient is sedentary and lacks the ability to perform specific functions to achieve a high level of activities of daily living utilizing an MPK.
40-49	MPK Stance indicated • Otto Bock Compact	A PAVET™ score between 40 and 49 would indicate a median score for ADL's, Function, and Prosthetic Reliance. This score would suggest the patient requires a higher activity level to accomplish ADL's and also displays the ability to perform the required functions. Typically a score between 40-49 will indicate the patient requires the microprocessor knee to provide maximum stability and security to enable the patient to accomplish activities of daily living (ADL's).
50-59	MPK Knee Indicated Cadence score[2] 14 and below • Otto Bock Compact Cadence score 15 and above • Otto Bock C-Leg • Ossur Rheo Knee	A PAVET™ score between 50 and 59 would indicate the patient has above average ADL and Functional scores and below median prosthetic reliance scores. This patient may also score additional points for special consideration. This patient presents as a good candidate for a microprocessor knee as he/she demonstrates the functional and physical ability to require this technology to accomplish activities of daily living. The indicator to provide additional MPK Swing phase control is determined by the patients cadence score on select PAVET questions focusing on long range walking and the ability for variable cadence and to exceed faster than baseline rate of walking.
60-72	MPK Swing & Stance Indicated • Otto Bock C-Leg • Ossur Rheo Knee • Endolite Adaptive	PAVET™ between 60 and 72 would indicate the patient is an excellent candidate for a microprocessor knee in both Swing and Stance. This score would suggest the patient has a high ADL and Functional score and a below median Prosthetic Reliance score. That would indicate that the patient requires a microprocessor knee to enable him/her to achieve an active lifestyle in achieving activities of daily living.
72>	Score over 72 indicates a possible discrepancy in scoring and the PAVET™ should be re-evaluated.	A PAVET™ Score above 72 is highly unlikely. If ADL score were 40 and Functional score were 20, this would indicate a strong and active individual and therefore the Prosthetic Reliance score should be low to mid range (0-10). It is exceedingly unlikely that a highly active (ADL=40) and highly functional patient (FL=20) would also score very high on the special consideration and Prosthetic Reliance category. Any score over 72 should be audited and re-evaluated to ensure compliance and evaluation accuracy.

[2] Cadence score is determined by the total of PAVET™ questions #1, #2, #7, #14 & #15.