Prosthetic Xpert Consultation

As presented at AOPA National Assembly
September 26, 2019, San Diego CA

Prosthetic Clinical Documentation
Guidelines for Timely Prior Authorization, Patient Care and Payment

Dale Berry, CP, FAAOP, LP

INTRODUCTION

Since the passing of a resolution to the social security act in Feb 2018[i], Orthotist and Prosthetist notes have become part of the medical record to support documentation of referring physicians. With this transition comes the responsibility to elevate the quality and content of the prosthetic clinical record to meet the standards and expectations of a Medical Record to establish Medical Necessity.

From a business perspective, there is a key nuance with this regulatory resolution that is critical to ensuring compliance…the regulation specifically states:

> (5) DOCUMENTATION CREATED BY ORTHOTISTS AND PROSTHETISTS. – For purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by an orthotist or prosthetist shall be considered part of the individual's medical record *to support documentation created by eligible professionals described in section 1848(k)(3)(B)."*

This makes it very clear and unambiguous that clinical notes from the O&P Provider can only be used to *support* documentation created by an *eligible professional*, which is defined by Medicare as[ii]

> A physician, A physical or occupational therapist or a qualified speech-language pathologist, a qualified audiologist, a practitioner, specifically defined as[iii] a physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse-midwife, clinical social worker, clinical psychologist or registered dietitian or nutrition professional

Regulatory standards also clearly stipulate in detail that documentation authored or generated by the O&P clinician and subsequently signed by the referring physician cannot be used to establish medical necessity. The Medicare Program Integrity Manual[iv] specifically states:

> "Certificates of Medical Necessity (CMN), DME Information Forms (DIF), supplier prepared statements and physician attestations by themselves do not provide sufficient documentation of medical necessity, *even if signed by the ordering physician*".

Lastly, it is also imperative to consider the specific and deliberate language and interpretation contained in the "Dear Physician" letter that was signed and published by the Medicare Medical Directors that clearly states;

> "Payment *may not be provided solely based on O&P documentation*, and in the absence of physician/practitioner documentation, the DME MACs may deny payment for the prosthetic."[v]

With commercial insurance companies following and adapting Medicare regulatory standards, the implications to the prosthetic provider are clear. Appropriate documentation is key to prior authorization to provide medically necessary care as well as timely payment for products and services.

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Dale Berry, CP, FAAOP, LP
612-810-1100
Dale.Berry@PXCRx.com

FIVE CS OF DOCUMENTATION

1. Clinical Evidence

Medical necessity is based upon the medical condition of the patient which in-turn is determined and verified solely upon the evidence as documented in the medical record. Clinical evidence is therefore based upon clear and concise facts as observed and documented by the referring physician and corroborate and confirmed by the treating prosthetist.

Physician Clinical Evidence

The written and published opinion of the Medicare Medical Directors[vi] states that it is the responsibility of the referring physician to do a face to face evaluation of the patient and that the medical record documentation should include:

- Patient's current functional capabilities and expected functional potential.
- History of the present condition(s) and past medical history that is relevant to functional deficits
    - Symptoms limiting ambulation or dexterity
    - Diagnoses causing these symptoms
    - Other co-morbidities relating to ambulatory problems or impacting the use of a new prosthesis
    - What ambulatory assistance (cane, walker, wheelchair, caregiver) is currently used (either in addition to the prosthesis or prior to amputation)
    - Description of activities of daily living and how impacted by deficit(s)
- Physical examination that is relevant to functional deficits
    - Weight and height, including any recent weight loss/gain
    - Cardiopulmonary examination
    - Musculoskeletal examination
    - Arm and leg strength and range of motion
    - Neurological examination
    - Gait observation/evaluation
    - Balance and coordination

It is also important to note that *"a prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record."*[vii] Regulations clearly stipulates that the Rx and Letter of Medical Necessity cannot be used to support medical necessity, the Rx and LMN must be accompanied and corroborated by clinical documentation from the physician to validate medical necessity.

Prosthetist Clinical Evidence

A key aspect for the prosthetic documentation is to clearly establish the condition of the prosthesis and explain why it needs to be replaced. Note, out of warranty or the age of a prosthesis is never a valid reason to replace a prosthesis. Replacement is based upon irreparable damage or change in the patient condition.

Validating functional level is also imperative in order to establish component selection. In addition to a full narrative description of the patient's functional capabilities and potential, it is beneficial to support a clinical opinion with combination of the following 3 validated clinical evaluation tools:

Evaluation Tool	K-PAVET™	Plus M™	AmPro™
Internet Link	**HangerClinic.com**	**Plus-m.org**	**Physio-Pedica.com**

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Compliant

A medical record, by definition, must contain specific information to establish and support medical necessity. Medical Necessity however does not have a consistent nor uniform definition and can vary depending upon the policy and contract language of each insurance provider. [viii]

Following is but one example of how policy language can directly impact medical necessity. Aetna Medical Policy for Microprocessor knees states; *"Aetna considers microprocessor-controlled leg prostheses medically necessary in otherwise healthy, active community ambulating adults (18 years of age or older) (functional level 3 or above) with a knee disarticulation amputation or a trans-femoral amputation from a non-vascular cause (usually trauma or tumor) for whom this prosthesis can be fitted and programmed by a qualified prosthetist trained to do so."*

In this scenario, two individuals working for the same company, with the same job, having the same insurance policy would be eligible for different type of prosthesis bases solely upon the cause of amputation. For the individual that lost a limb due to trauma, he would have access to a microprocessor knee, while the individual that lost a limb to vascular issues would only be approved for a mechanical knee.

Patient Age	*51*	*51*
Weight	*185*	*185*
K Level	*K3*	*K3*
Occupation	*Manager*	*Manager*
Employer	*ABC Distribution*	*ABC Distribution*
Insurance Carrier	*Aenta*	*Aenta*
Policy	*Choice POS*	*Choice POS*
Cause of Amputation	***Trauma***	***Vascular***
Prosthetic Benefit	***Microprocessor***	***Mechanical Knee***

Another example of how the language defining medical necessity can have a direct influence on the selection of a prosthetic technology can be observed with the CIGNA policy 0536 related to the application of the L5781 Residual Limb Volume.

The CIGNA policy states "HCPCS code L5781 is considered medically necessary ***to control residual limb volume*** *when there is contraindication to or failure of other socket-suspension systems".* For a patient with a CIGNA policy that presents as a candidate for a residual limb vacuum system, the documentation must clearly establish that other suspension systems are either medically contraindicated or have been applied to the patient and have either failed or been inadequate to accommodate the patient's activities of daily living.

Understanding the variations and standards for medical necessity for each payer will establish clear expectations for the practitioner and the patient as well as streamline the prior authorization process and improve efficiency and productivity.

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612-810-1100
Dale.Berry@PXCRx.com

2. Complete

The Medicare regulatory standards[ix, x] which are adopted by numerous national commercial insurance providers, spells out in detail the requirements to replace a prosthesis or any major component:

- Patient must have a face-to-face examination with the referring physician conducted within 6 months prior to the date of the prescription.
- Must be documented by the treating physician/practitioner, either on the order or in the medical record, and must fall under one of the following:
  - A change in the physiological condition of the beneficiary resulting in the need for a replacement; or
  - An irreparable change in the condition of the device; or
  - Repairs would be more than 60 percent of the cost of a replacement device.
- The prosthetist must retain documentation of the items being replaced.
- Specific reason for replacement, which can but is not limited to:
  - changes in the residual limb, functional need changes, or irreparable damage or excessive beneficiary weight or prosthetic demands of very active amputees.
- Documentation of the labor involved since the prosthesis was originally provided to the beneficiary.

3. Collaborative

Review of the medical file of the referring physician, therapist and other related health care providers will serve to identify potential inconsistencies related to care protocol, rehabilitation expectations and standards of patient care. By educating the referring physician and allied health care providers to the very specific and detailed regulatory standards serves to streamline administrative demands and ultimately provide timely and medically necessary care to the patient.

There are also helpful tools available to assist physician compliance in capturing the required information to establish medical necessity such as the "Physician Prosthetic Assessment" (PPA Form) which can be downloaded at HangerClinic.com

4. Consistent

Creating a quality medical record for a specific patient is beneficial, however creating a process and procedure to ensure each patient interaction will result in a quality medical record provides for a successful, profitable and growing business. Simply collecting and submitting the entire medical file often can make the prior authorization process more cumbersome and time consuming as the person reviewing the file will be forced to sift through pages of medical records that may not be relevant or germane to the request.

Compiling and presenting the clinical documentation and medical record in a logical and uniform process will greatly assist in communicating and interacting with payers and prior authorization professionals.

It is beneficial to assemble and submit the information in a clear and concise manner, providing a cover page to identify what is being requested and why, with an index listing with appropriate attachments of the key medical documents to support the request. Attached is a sample Prior Authorization Package that is fully compliant to address all regulatory and collaborative standards.

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CONCLUSION

Authorization and subsequent provision and payment of prosthetic devices are justified based solely upon clear and defined standards of medical necessity, all of which are based upon validation in the medical record.

The focus and goal are to establish policies, procedures and workflow that will ensure all patient files are:

1. **Clinical** in nature, providing the specific details to justify and validate medical necessity.
2. **Compliant** and conforming to the specific regulatory and contractual language of the patient's policy.
3. **Complete** and containing the required documents and details to support medical necessity.
4. **Collaborative** to confirm the medical team treating the patient have a uniform treatment plan.
5. **Consistent** to provide documentation in a clear, concise and reliable format.

Implementing and following a well-established documentation process and procedure to validate Medical Necessity will contribute to streamlined approval process resulting in timely patient care and payment for services.

About Dale Berry, CP, FAAOP, LP

Dale Allen Berry is an internationally recognized, board certified prosthetist with over 35 years of clinical care experience. Berry is the clinical advisor for Orchid Medical's comprehensive prosthetics program, Prosthetic ASSESS™. For 20 years, Berry served as vice president of clinical operations for the nation's largest provider of prosthesis with 800 clinics and 2,000 clinicians treating one million patients per year. Berry invented the advanced prosthetic assessment validation evaluation test and protocol, currently identified as the industry standard. Furthermore, he developed a clinical operational procedure resulting in the approval of advanced computerized prosthesis for over 25,000 individuals with above knee amputation. He has authored over 5,000 prosthetic life cost plans and over 25 peer-reviewed studies and editorials. Berry is certified by the American Board for Certification (ABC) in Orthotics & Prosthetics and he is a licensed prosthetist (LP) in Texas, Illinois and Minnesota. In addition, he is a member of the Fellow of the American Academy of Orthotists & Prosthetists (FAAOP).

End Notes & References

[i] Sec. 50402. Orthotist's and prosthetist's clinical notes as part of the patient's medical record. 13 section 1834(h) of the Social Security Act. (42 U.S.C. 1395m(h))

[ii] Medicare Social Security Act, Payment for Services, *1848(k)(3)(B)."* https://www.ssa.gov/OP_Home/ssact/title18/1848.htm

[iii] Medicare Social Security Act, Provisions Relating to The administration of Part B, 1842(b)(18)(C). https://www.ssa.gov/OP_Home/ssact/title18/1842.htm

[iv] Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions (Rev. 876, 04-12-19) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf

[v] Dear Physician Letter, Documentation of Artificial Limbs and Braces (O&P), Revised November 2018. https://www.cgsmedicare.com/jc/mr/pdf/dear_physician_op.pdf

[vi] Dear Physician Letter, Documentation of Artificial Limbs and Braces (O&P), Revised November 2018. https://www.cgsmedicare.com/jc/mr/pdf/dear_physician_op.pdf

[vii] Medicare Supplier Manual, Chapter 3, Summer 2019, https://www.cgsmedicare.com/jc/pubs/pdf/Chpt3.pdf

[viii] AETNA Lower Limb Policy, 07/12/2019, http://www.aetna.com/cpb/medical/data/500_599/0578.html

[ix] Medicare Supplier Manual, Chapter 3, Summer 2019, https://www.cgsmedicare.com/jc/pubs/pdf/Chpt3.pdf

[x] Local Coverage Determination (LCD): Lower Limb Prostheses (L33787), https://www.cms.gov/medicare-coverage-database/details/lcddetails.aspx?LCDId=33787&ContrId=140&ver=17&ContrVer=2&CntrctrSelected=140*2&Cntrctr=140&name=&DocType=2&bc=AAACAAQAAAAA&

Compliance O&P

We Brace'm or Replace'm

Request for Prior Authorization

Patient Name	Joe Prosthetic Wearer
Date of Birth	01/02/1960
Patient ID Number	KJE1589
Amputation Level	Left Transtibial
Request	Prior Authorization for a replacement Trans Tibial K3 Prosthesis
Enclosures	The following attachments provide supporting documentation to validate medical necessity for the requested services

Enclosure 1: Physician Medical Record

Enclosure 2: Original Rx

Enclosure 3: Detailed Written Order

Enclosure 4: Prosthetic Clinical Summary

Enclosure 5: Coding and Pricing

Thank you for reviewing this prior authorization request.

Please contact us directly should you have any questions or require any additional information

Stand Tall Orthopedics Clinical Encounter

Encounter Date: 6/23/2019

Physician I.M. Doingitright, MD

Wearer, Joe Prosthetic

DOB: 01/02/1960

Date of Injury: 2014

VITALS

Temp: 98.7 RHR: 72 Weight: 165 BP: 121/78

REASON FOR VISIT:

Patient complaining of fit of prosthesis, reports it "sort of fits" in the morning, but is much too tight by the end of the day. Reports he has fallen twice in the past few months with no injury. Balance is off and it is difficult to walk on ramps and uneven ground and can no longer walk very fast due to socket discomfort. States leg has been great the past 4.5 years or so, but with his weight gain is now having difficulties as well as low back pain and knee pain.

PHYSICAL EXAMINATION

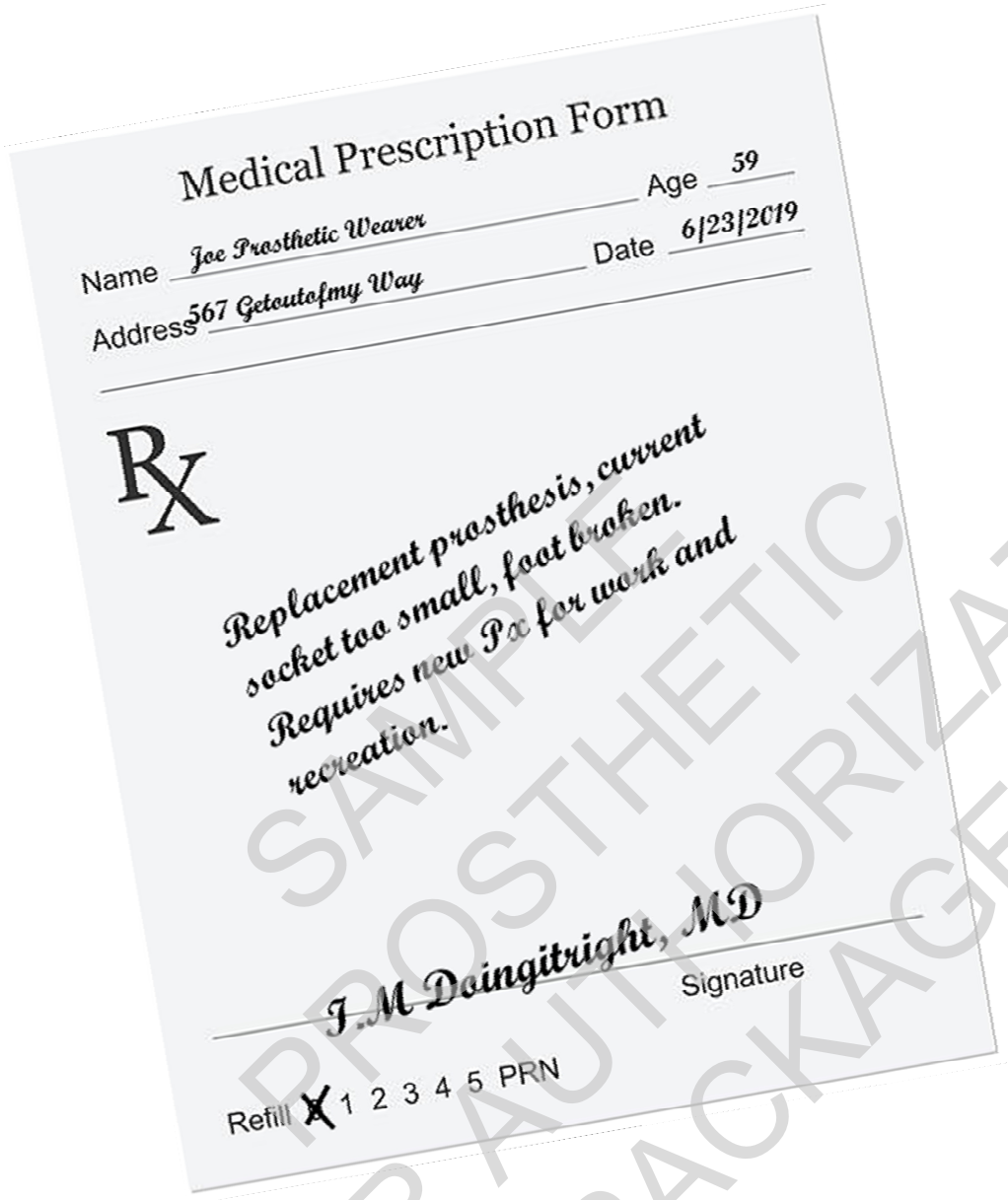
External evaluation of knees has full mobility, no progression of OA. Residual limb has signs of abrasion where the socket is not fitting properly, obviously too tight due to weight gain. Demonstrates ability to walk with prosthesis with little sign of limp. Patient weight was record as 140 lbs when last prosthesis was prescribed, indicated a gain of 25 lbs. Inspection of the prosthesis shows that the liners are torn and stretched very thin and can hear a slight clicking sound from the foot when walking Weight gain has obviously made the current prosthesis to no longer fit properly.

ASSESSEMENT AND PLAN

Write Rx for new prosthesis and complete Physician Prosthetic Assessment form and refer to Compliance O&P to be fit with new prosthesis. New prosthesis needs to accommodate the patient residual daily limb fluctuation as well as provide a prosthetic foot similar to his current design but with able to reduce stress to the knee and low back during gait.

Electronically Signed by: I.M. Doingitright, MD

Electronically Signed on: 6/23/2019



Medical Prescription Form

Name Joe Prosthetic Wearer Age 59

Address 567 Getoutofmy Way Date 6/23/2019

℞

Replacement prosthesis, current socket too small, foot broken. Requires new Px for work and recreation.

T.M Doingitright, MD

Signature

Refill X 1 2 3 4 5 PRN

DWO

Detailed Written Order

Provider	Compliance O&P 123 Walkright Street Stand Tall, USA 12345	Patient	Joe Prosthetic Wearer 567 Getoutofmy Way DOB 01/02/1960 Patient ID KJE1589
Physician	I.M. Doingitright, MD UPIN:12345678		

Prescribed Items
L5301, Below knee, molded socket, shin, SACH foot, Endoskeletal, L5620 X 2, Test Socket, Below Knee, L5629, Below Knee, Acrylic Socket, L5637, Below Knee, Total Contact, L5685 X 2, BK Suspension/Sealing Sleeve, With Or Without Valve, L5647, Below Knee Suction Socket, L5679, BK or AK Silicone Insert, Not For Use With Locking Mechanism, L5645, Below Knee, Flexible Inner Socket, External Frame, L5962, BK Flexible Protective Outer Surface Covering System, L5704, Custom Shaped Protective Cover, Below Knee, L5685X 2, BK Suspension/Sealing Sleeve, With Or Without Valve, L5781, Vacuum Pump, Volume Management & Moisture Evacuation, L5987, Shank Foot System With Vertical Loading Pylon, L5986, Multi-Axial Rotation Unit ('Mcp' Or Equal), L5910, Endoskeletal System, Below Knee, Alignable System, L5940, BK Ultra-Light Material (Titanium, Carbon Fiber Or Equal), L8400 X 6, Sheath below knee, L8420 X 6, Prosthetic sock multi ply bk, L8470X 6, Pros sock single ply bk

Physician Signature: *I.M Doingitright, MD* Date: *7/12/2019*

Enclosure 3

Patient Clinical Summary

Compliance O&P
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Patient Name	Joe Prosthetic Wearer	Eval Date	6/28/2019
Date of Birth	01/02/1960		
Pt ID Number	KJE1589		
Amputation Level	Left Transtibial		
Patient Height	5' 10"		
Patient Weight	169 Pounds		
Foot Size	28 cm		
Patient Observations			
General	Patient presents with Rx for new prosthesis. Pt has gained 28 pounds since receiving his current prosthesis 5 years ago. Weight has been adding slowly, so we have been able to accommodate adjustments to the prosthesis over the past years, socket cannot be adjusted further. Pt reporting low back pain and knee pain.		
Residual Limb	Abrasion marks on distal tibia and lateral fibular head. Bruise on Patella Tendon Bar Tenderness on mid tibial flair		
Components	Socket is too tight for patient due to increase in residual limb size Foot is delaminating due to patient weight gain and now being too heavy for the rating of current foot Liners are stretched and have minor tears.		
CURRENT PROSTHESIS			
Type	Definitive, K3 Transtibial, Pin Suspension		
Age	5 years 6 month		
Foot	Flexfoot energy storing, foot is damaged due to delamination. Patient has also gained 28 pounds since being fit with the current foot. Foot must be replaced as it cannot be repaired and is now the wrong category for his current weight.		
Socket	Total contact with pin suspension. Pt was initially fit with 5 ply of sock. Pt now has volume issues daily, in the morning with a 3 ply fit and by day end is sheath fit and cannot fully get into the socket. Limb measurements have increased by ½". Socket must be replaced, cannot be modified to accommodate change in patient condition.		
Liners	Patient has two liners that both have minor tears and stretch marks. This is due to the patient forcing himself into the socket due to his weight gain. Liners cannot be repaired and need to be replaced with the new socket.		
Knee	NA, patient is Trans Tibial Level		

Enclosure 4

Compliance O&P
We Brace'm or Replace'm

Functional Level[1]	
PAVET™ Score	68, validates K3
AmPro™ Score	44, validates as a K2 or K3
Plus-M™ T-Score	59.6, validates 83.2%
Observations	Patient takes public transit to work, deals with environmental barriers, ramps, uneven ground and stairs daily. Pt routinely cares for his grandchildren and needs to change his walking speed from slow to medium to fast at a moment notice while playing/caring from the. Also does yard work and chores and needs to carry items while walking daily.
Functional Level	K3
Prosthetic Recommendations & Justification	
Socket	Total contact with pin suspension. Patient has been wearing this system for 5 plus years without issue related to comfort and suspension, therefore will continue with familiar and functional system he currently has
Foot	Ottobock Triton Foot. Patient previously had a carbon graphite flex foot which did accommodate him in the past, however with his weight gain he is causing additional strain and stress to his residual limb, knee and lower back. Triton foot has vertical shock capabilities which will reduce strain and stress on the low back and knee during gait.
Knee	NA
Liners	Patient has significant scarring on the distal end from the original amputation as well as a small amount of adherent scar tissue on the distal tibial. Will require a custom liner to accommodate the unique shape of the residual limb.
Other	Due to change it the shape of the residual limb and patient weight gain, the patient has significant change in limb volume throughout the day, starts in the morning with a 3 ply and by day end has to reduce to a sheath fit. Therefore, medically necessary to provide a L5781 Residual limb volume management pump to control and maintain limb volume throughout the day.

Digitally Signed: IM Complaint, Certified Licensed Prosthetist

Digital Signature Date: 6/28/2019

[1] *PAVET™, Hanger Clinic, AmPro™, Bob Gailey, Plus-M™ University of Washington. Copies of evaluation forms available upon request.*

Enclosure 4

Patient Clinical Summary

Compliance O&P
We Brace'm or Replace'm

Quote for Services

Patient Name	Joe Prosthetic Wearer
Date of Birth	01/02/1960
Patient ID Number	KJE1589
Amputation Level	Left Transtibial

L Code	*Qty*	*Component Short Description*	*Price Per*	*Fair Market Value*
L5301	1	Below knee, molded socket, shin, SACH foot, endoskeletal	$3,338	$3,338.29
L5620	2	Test Socket, Below Knee	$404	$808.44
L5629	1	Below Knee, Acrylic Socket	$462	$462.06
L5637	1	Below Knee, Total Contact	$420	$420.03
L5685	2	BK Suspension/Sealing Sleeve, With Or Without Valve	$167	$334.67
L5647	1	Below Knee Suction Socket	$1,157	$1,156.55
L5679	1	BK or AK Silicone Insert, Not For Use With Locking Mechanism	$810	$809.60
L5645	1	Below Knee, Flexible Inner Socket, External Frame	$1,160	$1,160.09
L5962	1	BK Flexible Protective Outer Surface Covering System	$855	$854.61
L5704	1	Custom Shaped Protective Cover, Below Knee	$766	$765.58
L5685	2	BK Suspension/Sealing Sleeve, With Or Without Valve	$167	$334.67
L5781	1	Vacuum Pump, Volume Management & Moisture Evacuation	$5,227	$5,227.10
L5981	1	Flex-Walk System Or Equal	$4,188	$4,187.62
L5987	1	Shank Foot System With Vertical Loading Pylon	$9,398	$9,397.85
L5910	1	Endoskeletal System, Below Knee, Alignable System	$527	$526.59
L5940	1	BK Ultra-Light Material (Titanium, Carbon Fiber Or Equal)	$729	$729.31
L8400	6	Sheath below knee	$23	$137.33
L8420	6	Prosthetic sock multi ply bk	$28	$169.68
L8470	6	Pros sock single ply bk	$10	$58.21
Total				**$30,878.29**