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| Case Number: | CM14-0117380 | | |
| Date Assigned: | 09/22/2014 | Date of Injury: | 01/17/2007 |
| Decision Date: | 10/23/2014 | UR Denial Date: | 06/23/2014 |
| Priority: | Standard | Application Received: | 07/26/2014 |

HOW THE IMR FINAL DETERMINATION WAS MADE

MAXIMUS Federal Services sent the complete case file to an expert reviewer. He/she has no affiliation with the employer, employee, providers or the claims administrator. The expert reviewer is Board Certified in Orthopedic Surgery and is licensed to practice in California. He/she has been in active clinical practice for more than five years and is currently working at least 24 hours a week in active practice. The expert reviewer was selected based on his/her clinical experience, education, background, and expertise in the same or similar specialties that evaluate and/or treat the medical condition and disputed items/services. He/she is familiar with governing laws and regulations, including the strength of evidence hierarchy that applies to Independent Medical Review determinations.

CLINICAL CASE SUMMARY

The expert reviewer developed the following clinical case summary based on a review of the case file, including all medical records:

The patient is a 35 year old male who sustained an industrial injury on 1/17/2007. He was standing in a loading area and was struck by a forklift resulting in a crush injury to the left lower extremity, and he underwent an about the knee amputation of the left lower extremity in 2007. Diagnoses include phantom limb pain, chronic lumbar pain, depression/anxiety. The patient had a prosthetic assessment on 1/21/2014. The patient scored 65 on K level (activity level) Pavet score, his potential is at a slightly higher than normal K3. He does not use any assistive devices with his prosthesis and has unlimited community ambulatory ability. His prosthesis is not waterproof, must be removed in a dry area. The C-leg is not rated as a high-impact knee for activities such as extended jogging, running, or basketball on regular basis. Walking backwards with the C-leg can be done with training. The patient trialed the Genium, which is the non-waterproof version of an X-3. It is felt the patient has the potential to exceed the abilities of the C-leg. It is recommended he be provided a new socket, X-3 system, and waterproof foot. A prior request for new prosthesis was non-certified on 10/16/2012 as he had a prosthesis that was less than 2 years old. A request for a waterproof prosthesis for the purpose of swimming was non-certified on 5/6/2013. The patient had a running prosthesis certified in 2011. A prosthetic refitting was certified on 1/3/2013. A prior peer review on 6/23/2014 non-certified the request for prosthetic limb parts: left above knee prosthesis endo skeletal system, ischial containment narrow ML socket total contact with a suction suspension system, ultralight material, Ottobock X3 microprocessor controlled knee, a flex foot system, with a multiaxial rotation unit; Total price [REDACTED]. Comprehensive review of current peer-reviewed literature indicates no documented research studies indicating that the Ottobock X3 prosthesis is superior to the C leg microprocessor prosthesis except that it is water proof. Peer review documents the patient can perform all his mobility and ADLS with the AKA prosthetic components and design. The AKA

prosthesis with the Ottobock X3 microprocessor knee is not medically necessary as the additional/components are not required for the effective use of the device and evidence for functional improvement is insufficient and inadequate. According to the 9/29/2014 applicant's position letter regarding X-3 parts, patient was provided the C-leg, which at the time was state of the art prosthetic. The C-leg only allowed for safe forward walking. The C-leg did not allow for safe backward ambulation or ambulation on uneven ground and is not water-proof. The applicant's counsel learned that the waterproof X-3 leg allowed for safe showering, safe backward ambulation, ambulation on uneven surfaces and various rigorous activities.

IMR ISSUES, DECISIONS AND RATIONALES

The Final Determination was based on decisions for the disputed items/services set forth below:

Prosthetic limb parts: OTTOBOCK X3 microprocessor controlled knee prosthesis: Upheld

Claims Administrator guideline: The Claims Administrator did not base their decision on the MTUS. Decision based on Non-MTUS Citation ODG (Official Disability Guidelines): Prosthesis 2014

MAXIMUS guideline: The Expert Reviewer did not base their decision on the MTUS. Decision based on Non-MTUS Citation Official Disability Guidelines (ODG) Knee and leg, Prostheses (artificial limb); Microprocessor-controlled knee prostheses

Decision rationale: Recommended as indicated below. A prosthesis is a fabricated substitute for a missing body part. Lower limb prostheses may include a number of components, such as prosthetic feet, ankles, knees, endoskeletal knee-shin systems, socket insertions and suspensions, lower limb-hip prostheses, limb-ankle prostheses, etc. See also Microprocessor-controlled knee prostheses. Criteria for the use of prostheses: A lower limb prosthesis may be considered medically necessary when: 1. The patient will reach or maintain a defined functional state within a reasonable period of time; 2. The patient is motivated to ambulate; and 3. The prosthesis is furnished incident to a physician's services or on a physician's order. Prosthetic knees are considered for medical necessity based upon functional classification, as follows: (a) A fluid or pneumatic knee may be considered medically necessary for patients demonstrating a functional Level 3 (has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion), or above. (b) A single axis constant friction knee and other basic knee systems are considered medically necessary for patients demonstrating a functional Level 1 (has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, typical of the limited and unlimited household ambulator), or above. (c) A high-activity knee control frame is considered medically necessary for patients whose function level is 4. (has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels, typical of the prosthetic demands of the child, active adult, or athlete), or above. (d) Microprocessor-controlled leg prostheses (e.g., Otto Bock C-Leg, Intelligent Prosthesis, and Ossur Rheo Knee) are considered medically necessary in otherwise healthy, active community ambulating adults (18 years of age or older) demonstrating a 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. Recommended as indicated below. Microprocessor-controlled leg prostheses (e.g., Otto Bock C-Leg, Intelligent Prosthesis, and Ossur Rheo Knee) are considered medically necessary in otherwise healthy, active community ambulating adults (18 years of age or older) demonstrating a functional Level 3 (has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion), or above. In addition, the patient should have 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. There are over 100 different prosthetic knee designs currently available. The choice of the most appropriate design depends on the patient's underlying activity level. Microprocessor-controlled prosthetic knees are equipped with a sensor that detects when the knee is in full extension and adjusts the swing phase automatically, permitting a more natural walking pattern of varying speeds. This patient has use of a fully functional Microprocessor-controlled leg prosthesis C-leg model. It would appear that the only deference between the patient's current prosthesis and the requested X-3 model, is that the X-3 is marketed as a water proof model and is adapted to more rigorous outdoor activities. The Ottobock X-3 is apparently marketed as a newer and more advanced model, however, the medical records do not establish that this product is medically necessary for the patient to function. Typically, prosthetic limbs are not water-proof, and are removed prior to bathing/showering. The patient is able to perform all necessary ADLs and function within the community with his current prosthesis. The medical necessity of the request has not been established.