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Notice of Independent Review Decision

DATE OF REVIEW: June 25, 2014

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:

BiOM Ankle System (L5301, L5620, L5629, L5637, L5645, L5647, L5685, L5781, L5901, L5940, L5973, L5969, L5988, L5999, L5681, L5678, L8400, L8420 and L8470).

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION

M.D., Board Certified in Physical Medicine and Rehabilitation and Pain Management.

REVIEW OUTCOME

Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be:

- Upheld (Agree)
- Overturned (Disagree)
- Partially Overturned (Agree in part/Disagree in part)

The requested BiOM Ankle System (L5301, L5620, L5629, L5637, L5645, L5647, L5685, L5781, L5901, L5940, L5973, L5969, L5988, L5999, L5681, L5678, L8400, L8420 and L8470) is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

PATIENT CLINICAL HISTORY [SUMMARY]:

The patient is a male who reported a work-related injury to his right foot on xx/xx/xx. The patient suffered a crush injury to the right foot resulting in a right transtibial amputation in xxxx xxxxx. His diagnoses include status post right transtibial amputation and status post ankle reconstruction, 3 times. The patient reports residual limb pain with activity limitation and a lack

of endurance. The patient has been unable to return to work and currently utilizes an endoskeletal transtibial total contact prosthesis with suction suspension and a carbon fiber. The documentation submitted for review indicates that with the patient's current prosthesis he has difficulties climbing and descending stairs, walking and standing for a minimum of 8 hours per day, navigating uneven terrain and navigating ramps. A request was submitted for BiOM Ankle System transtibial prosthesis for the right lower extremity.

The URA indicated that the patient did not meet Official Disability Guidelines (ODG) criteria for the requested services. Per the denial letter dated 4/23/14, the URA indicated that there is no indication that there has been a recent physician evaluation to render an opinion as it relates to the specific requested prosthesis.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.

The Official Disability Guidelines (ODG) states that a lower limb prosthetic may be considered medically necessary when the patient is motivated to ambulate, when the patient will reach or maintain a defined functional state within a reasonable period of time, and when the prosthesis is furnished to a physician's services or on a physician's order. A fluid or pneumatic knee may be considered medically necessary for patients demonstrating a functional level III or above the knee amputation, a single axis constant friction knee, and other basic knee systems are considered medically necessary for patients demonstrating a functional level I or above. A high activity knee control frame is considered medically necessary for patients whose functional level is at IV, and a microprocessor controlled leg prosthesis is considered medically necessary in otherwise healthy, active, community ambulating adults demonstrating a functional level III or above with a disarticulation amputation or transfemoral amputation. In this case, the patient currently utilizes a transtibial total contact prosthetic with suction suspension and a carbon fiber and per the documentation submitted for review the patient has not been able to return to work. Moreover, there is no documentation of any athletic needs that would warrant a custom prosthesis. Official Disability Guidelines further state there are over 100 different prosthetic knee designs currently available, and the choice of the most appropriate design depends on the patient's underlying activity level. As the medical necessity for the requested custom prosthesis has not been established, the current request for the BiOM Ankle System is not clinically indicated. In accordance with the above, I have determined that the requested BiOM Ankle System is not medically necessary for treatment of the patient's medical condition.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE

- AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- INTERQUAL CRITERIA**
- MEDICAL JUDGMENT, CLINICAL EXPERIENCE AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- MILLIMAN CARE GUIDELINES**
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- TEXAS TACADA GUIDELINES**
- TMF SCREENING CRITERIA MANUAL**
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**