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Notice of Independent Review Decision

Sent to the Following

IRO REVIEWER REPORT

Date: X

IRO CASE #: X

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE: X

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

REVIEW OUTCOME:

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

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

Provide a description of the review outcome that clearly states whether medical necessity exists for each of the health care services in dispute

INFORMATION PROVIDED TO THE IRO FOR REVIEW: • X

PATIENT CLINICAL HISTORY [SUMMARY]: X who was injured on X. The mechanism of injury was not available in the provided medical records. The diagnosis was complete traumatic amputation at level between right shoulder and elbow.

Please note, no office visit notes, imaging, or treatment to date was available in the provided medical records.

A physician order, prescription, and statement of medical necessity signed by X, MD, on X, was documented. The prescription was for X. X had been a consistent user of X body-powered prosthesis for function in most daily living and work tasks. X reported experiencing overuse and fatigue in X affected right shoulder due to using the harness in activities requiring a greater functional envelope. The prescribed X is medically necessary to address functional goals and reduce the incidence of further overuse issues. The X provided proportionally controlled grip force within the largest available range of motion. The X devices accommodated a range of grasp patterns utilized in daily activities. Anatomically contoured sockets were necessary to maintain skin integrity, secure suspension and electrode contact throughout the range of motion. Anatomically contoured sockets were necessary to maintain skin integrity, secure suspension and electrode contact throughout the range of motion. X delivered by therapists with specialized training and expertise in X. Repairs would be as needed to maintain the function of the prescribed X.

Per a utilization review adverse determination letter dated X, the requests 1. X were denied by X, MD. Rationale: "ODG supports a X. The claimant had sufficient neurological function to operate the X. Their current body-powered device is causing pain in increased use in activities of daily living. However, there are limited indications that their X. Clinical guidelines and/or published medical literature do not support this request for claimants with similar presentations and histories. Exceptional indications are not evident within the records provided for review. Therefore, this request would not be considered medically reasonable and necessary at this time. Recommend noncertification for X. ODG supports a X. The claimant had sufficient neurological function to operate the X. Their current body-

powered device is causing pain in increased use in activities of daily living. However, there are limited indications that their X. Clinical guidelines and/or published medical literature do not support this request for claimants with similar presentations and histories. Exceptional indications are not evident within the records provided for review. Therefore, this request would not be considered medically reasonable and necessary at this time. Recommend noncertification for X. This is based upon this reviewer's clinical experience, the entire clinical picture, standards of care and evidence-based medicine, as well as the cited guidelines and/or literature.”

An appeal letter dated X by X, CP, Clinical Manager, X was written in response to X denial of X care for X. X presented with a X. A rehabilitation plan to include a X. The X had been denied not meeting medical necessity requirements. Per the denial, "there are limited indications that their X is unable to perform current functional needs and activities of daily living. Clinical guidelines and/or published medical literature do not support this request for claimants with similar presentations and histories. Exceptional indications are not evident within the records provided for review. Therefore, this request would not be considered medically reasonable and necessary at this time." Overall, X had been very successful with X. With a lot of hard work, practice, patience, and commitment, X had been able to wear X. X utilized this device for many hours a day in order to be able to provide for X family. While X had been able to utilize X. A body-powered device utilizes a restrictive harness to capture large movements of the back and shoulders (excursion) and pull a cable that opens/closes a hook or other terminal device. The wearer must use compensatory movements to position the shoulders and upper torso properly and with sufficient clearance to produce the considerable excursion needed for control. The X limits function particularly around the head, down by the feet and at an extension away from the body. Overcompensation with the sound hand is required. X was experiencing challenges in daily tasks using X ongoing body-powered prosthesis including dressing (manipulating buttons and tying X shoes), meal preparation (holding and grasping handles of pots and pans), caring for X children, and home and yard maintenance; particularly when mowing the grass due to awkward positioning of the hook and when using the weed eater. X worked full time as a X. X also performed X as needed, and helped X. Provision of the X would provide X with improved function in daily tasks that X struggled to perform with X. It would

minimize X reliance on X sound side hand and further overuse stress issues in X affected shoulder. The X that they were requesting was not a luxury item. X would like to continue utilizing and being successful with a X at home and in the community even after a full/hard day's work in dirty and dusty conditions. The continued repetitive shoulder motion required to help X operate X. The X did require some shoulder motion for elbow positioning, but not the continued, repetitious motion required to open and close X terminal device. The use of the electric powered components in the X would allow X to use relatively small muscle contractions in X residual limb to provide great grip strength / control with reduced effort and discomfort. The X would enable X to operate the X efficiently by simultaneously moving the elbow into position as X operated the X. The advantages of this system for X. As stated in their original authorization request letter, dated, X, "provision of different types of X." For example, wearing the X all day was similar to wearing X heavy, dusty / dirty work boots all day then being expected to wear them to perform household tasks such as cooking, eating, being around X family, and going to a restaurant, and community outings; they not only caused discomfort, but were not always acceptable or offered the same type of function and / or dexterity needed for use in areas that required cleanliness.

Per a utilization review adverse determination letter dated X, the requests X were denied by X, MD. Rationale: "Regarding X. X have been shown to have advantages of durability, training time, adjustment frequency, maintenance, and feedback; while they could still benefit from control improvements. X have been shown to improve cosmesis and phantomlimb pain, as well as being more accepted for light-intensity work. The request is not supported. In this case, the claimant is a X and is noted to have been very successful with the X. There is limited documentation to establish that the current X was insufficient to meet functional needs as the claimant had successfully been using it. Further, the X being requested with the X. Hence, the claimant does not meet the guideline criteria for use. The submitted records do not justify the need for the requested X over the current one with limited documentation to override the guideline recommendations. Therefore, the request for X is non-certified. Regarding X, the Official Disability Guidelines criteria for the use of X included sufficient neurological, myocutaneous, and cognitive function to operate the X effectively; free of comorbidities that could interfere with maintaining the function of the X;

retains sufficient microvolt threshold in the residual limb to allow proper function of the X; standard X devices cannot be used or are insufficient to meet functional needs in performing ADLs; and not functioning in an environment that would inhibit prosthesis function (ie, wet environment, the situation involving electrical discharges. The request is not supported. In this case, the claimant is a X. There is limited documentation to establish that the current X was insufficient to meet functional needs as the claimant had successfully been using it. Further, the X being requested with the X is more accepted for light-intensity work, cosmesis, or phantom limb pain as per the guidelines. Hence, the claimant does not meet the guideline criteria for use. The submitted records do not justify the need for the requested X. Therefore, the request for X is non-certified.”

In a letter dated X, X, CP, Clinical Manager, X, wrote in response to X denials of X for X. X presented with a X. X was fit with a X, and overall, X had been very successful with X. With a lot of hard work, practice, patience, and commitment, X was able to wear X. X was now experiencing pain to X anterior distal humerus due to having to continually flex X shoulder to operate the terminal device with the X. A rehabilitation plan to include a X. The X had been denied as not meeting medical necessity requirements. Per the denial, "There is limited documentation to establish that the current X was insufficient to meet functional needs as the claimant had successfully been using it. Further, the X being requested with the X is more accepted for light-intensity work, cosmesis, or phantom limb pain as per the guidelines. Hence, the claimant does not meet the guideline criteria for use. The submitted records do not justify the need for the requested X over the current one with limited documentation to override the guideline." As stated in previous letters, X relied on X for function in X work tasks, so no one was stating it was insufficient or X had not been successfully using the X; however, X did experience challenges in other daily tasks at home and in the community while using X current X including dressing (manipulating buttons and tying X shoes), meal preparation (holding and grasping handles of pots and pans), grocery shopping, caring for X children, and home and yard maintenance; particularly when mowing the grass due to awkward positioning of the hook and when using the weed eater. It was noted that X utilized a restrictive harness to capture large movements of the back and shoulders (excursion) and pull a cable that opened / closed a hook or other terminal device. The wearer must use compensatory movements to position

the shoulders and their upper torso properly and with sufficient clearance to produce the considerable excursion needed for control. The X limited function particularly around the head, down by the feet, and at an extension away from the body. Overcompensation with the sound hand was required. Provision of the prescribed X would provide X with improved function in daily tasks that X was struggling to perform at the time with X. The X would minimize X reliance on X sound side hand and further overuse stress issues in X affected shoulder. X would like to continue utilizing and being successful with a X when performing lighter-intensity tasks at home and in the community, after a full / hard day's work in heavy-duty, dirty, and dusty conditions. The continued repetitive shoulder motion required to help X operate X was too much, and did not let X recuperate for the following day's work. The X did require some shoulder motion for elbow positioning, but not the continued, repetitious motion required to open and close X terminal device. The use of the X components in the X would allow X to use relatively small muscle contractions in X residual limb to provide great grip strength / control with reduced effort and discomfort. The X would enable X to operate the X efficiently by simultaneously moving the elbow into position as X operated the electric terminal devices. The advantages of this system for an amputation above the elbow was that there was a greater functional envelope from the basic X; it offered reduced weight from the X; it offered the greater grip force like the X. X further wrote that X met all required ODG criteria: 1. X had sufficient neurological, myocutaneous, and cognitive function to effectively operate the prescribed X. 2. X was free of comorbidities that could interfere with maintaining function of the X. 3. X retained sufficient microvolt threshold in the residual limb to allow proper function of the X. Action: Open / Supinate Triceps gain was X and signal X. Close / pronate biceps gain was X and signal X. The standard X device was the correct option for use in X heavy-duty work environments, but it was the incorrect option for X home tasks because X was experiencing pain to X anterior distal humerus due to having to continually flex X shoulder to operate the terminal device with the harness. A X was not sufficient to meet X functional needs for performing activities of daily living in X home environment. X required a X with a larger work envelope that would allow X residual limb and shoulder to have some rest from the harness so X could accomplish all activities and tasks required to support and care for X family. 5. The X would not be utilized in an environment that would inhibit its function. As they stated in their original authorization request letter, dated, X, "provision of

different types of X for the some patient is one of the basic axioms of upper limb prosthetic care." For example, wearing the X all day was similar to wearing X heavy, dusty / dirty work boots all day then being expected to wear them to perform household tasks such as cooking, eating, being around X family, and going to a restaurant, and community outings; they not only caused discomfort, but were not always acceptable or offered the same type of function and / or dexterity needed for use in areas that required cleanliness.

Per a reconsideration review adverse determination letter dated X, the requests for 1. X were denied by X, MD. Rationale: "Regarding the X upper extremity X, the referenced guidelines recommend its use when there are adequate neurological, myocutaneous, and cognitive abilities to effectively operate the X. Additionally, there should be no comorbidities that could interfere with the device's performance. It is also essential that the residual limb maintains a sufficient microvolt threshold to ensure proper functionality. Furthermore, standard X must be insufficient for the individual's daily activities, and the user must not be in an environment that could impede the prosthesis's operation. The request for X was non-certified by X, MD in review X on X due to the submitted documentation do not justify the need for the requested X over the current one with limited documentation to override the guideline recommendations. Upon review of the submitted records, it appears that the prior non-certification was appropriate. The claimant, a successful X, has not provided sufficient documentation to prove that their current prosthesis does not meet their functional needs, despite reports of ongoing pain. The guidelines recommend X primarily for light work, cosmetic reasons, or phantom limb pain, which the claimant does not meet. Therefore, due to a lack of adequate justification the appeal request for X is non-certified. The request for 1 X was non-certified by X, MD in review X on X due to the submitted documentation do not justify the need for the requested X over the current one with limited documentation to override the guideline recommendations. Upon review of the submitted records, it appears that the prior non-certification was appropriate. The claimant, a X, has made significant progress with their current X despite some pain. The requested X which incorporates a myoelectric component designed for light work and managing phantom limb pain, does not meet the necessary criteria for approval. Additionally, there is insufficient justification to replace the existing prosthesis based on the provided documentation. Therefore,

the appeal request for 1 X is noncertified.”

Thoroughly reviewed provided records including provider notes and peer reviews.

While peer reviews cite functioning X, the multiple appeals as well as initial documentation from X support request for X given multiple issues with current X that have been described at length. Thus, request is warranted. X is medically necessary and certified

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

While peer reviews cite functioning X, the multiple appeals as well as initial documentation from X support request for X given multiple issues with current X that have been described at length. Thus, request is warranted. X is medically necessary and certified

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
- ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
- AHRQ- 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
- PRESLEY REED, THE MEDICAL DISABILITY ADVISOR
- TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS
- TMF SCREENING CRITERIA MANUAL
- PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)
- OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)