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RE: Joint DME MAC and PDAC Publication: Upper Limb Prostheses - Correct Coding

The American Academy of Orthotists and Prosthetists (Academy) is writing to express our concerns regarding the recent DME MAC/PDAC joint publication: Upper Limb Prostheses – Correct Coding. The Academy represents certified and licensed orthotic and prosthetic practitioners in the United States who provide direct care to patients who require orthotic or prosthetic intervention for physically disabling conditions. These providers are dedicated to the provision of high quality, evidence-based care for every patient entrusted to them. For this reason, we would like to share multiple concerns regarding the joint publication which, as currently written, will hinder the ability for Medicare upper limb amputee beneficiaries to receive appropriate levels of care. The guidance will additionally impact individuals with private health insurance plans that mirror Medicare policy.

As a starting point, we have serious concerns with respect to the process that the DME MACs and the PDAC used to publish the new interpretations set forth in the joint publication governing the coverage and payment of upper limb prostheses. In publishing the Upper Limb Prostheses - Correct Coding guidance, the DME MACs and the PDAC circumvented the required notice-and-comment rulemaking process by not presenting advanced notice and allowing for public comment. The joint publication's re-definitions and resulting restrictions constitute a substantive change to the provision of upper limb prostheses. The lack of public notice and a comment period effectively denied the opportunity for the proposed changes to be vetted prior to implementation. A comment period would have facilitated an important conversation which could have pointed out numerous unintended consequences that the 'correct coding' publication has created.

This newly revised interpretation of the upper limb prostheses code set has many errors and inconsistencies which need to be corrected and/or addressed. The issues noted are wide-ranging and appear throughout the document. Additionally, this updated coding guidance has introduced new barriers into what is already a somewhat challenging upper limb code set. As an example, the publication of this guidance supports as "correct coding" the utilization of existing codes for new products that are not vaguely 'same-or-similar' to those currently listed. Products that are more complex, higher in cost, or that require greater expertise and/or clinical time to provide, are apparently to be lumped under existing HCPCs codes that do not accurately reflect similar products or designs. The practice of bundling dissimilar devices under a singular code is clearly not consistent with the intent of the code set when it was created, nor is it appropriate to do so now.
It is additionally indicated that this new guidance will be applied retroactively. Given the inaccuracies and discrepancies that exist between these interpretations and well-established clinical care standards and current coding practices, this would hardly be appropriate. Until verifiably *correct* coding protocols are identified, there should be no implementation, nor enforcement, of current or past claims for upper limb prostheses based upon this guidance.

Some of the publication's "clarifications" are especially detrimental to the partial hand amputee population - a specific group of patients/beneficiaries who have the same need for functional rehabilitation as do higher level arm amputees. Yet, the new interpretation of the code set eliminates the continued use of some legitimate same-or-similar addition codes (without replacement alternatives) while bundling a wide range of different designs into base codes with singular reimbursement rates. Such restrictive interpretations make it functionally and fiscally impossible in a high percentage of cases to design prostheses that can effectively replace lost upper limb functions. Under this new guidance there is a high likelihood for a diminished level of care for Medicare beneficiaries with upper limb loss, as well as non-Medicare patients whose insurance companies may base their coverage determinations upon Medicare standards.

It is of equal concern that technical advancements made in recent years for upper limb amputations have neither been recognized nor assigned appropriate coding and pricing to make such technologies available to patients. Prosthetists simply cannot provide current and emerging technologies to any amputation level without an appropriate code set and the latitude to make clinical decisions based upon each patient's specific needs.

An unfortunate reality is that even the most advanced prostheses, of any type, can only imitate, but not replicate or restore, true natural function. With that being the case, it is vitally important that the code sets for prostheses do not restrict prosthetists' abilities to design and develop prostheses that can, to the extent possible, maximize patients' potentials to return to productive lives. This is reflected in the Medicare policy language stated in the June 2014 DMEPOS Qualification Standards Booklet ICN905709 which states in Appendix C, page 20, that the supplier shall: "Determine the appropriate orthoses/prostheses and

specifications based on beneficiary need for use of the orthoses/prostheses to ensure optimum therapeutic benefits and appropriate strength, durability, and function as required for the beneficiary." That language clearly indicates that it is Medicare's obligation to beneficiaries with orthotic and prosthetic needs to provide therapeutic benefits that will return them to the highest level of function possible. To achieve that, code sets must reflect a broad enough range of viable options to allow such outcomes. As it currently stands with the new guidelines for the upper limb prostheses codes, this is not possible. Our specific concerns regarding the DME MAC and PDAC publication and the code set in general, are more thoroughly detailed on a section-by-section basis in an attachment to this letter.

The Academy firmly believes that Medicare's objectives and those of the Orthotic and Prosthetic profession are one and the same. We share the obligation to provide our beneficiary/patient population with a level of care that will best enable them to live normal, productive lives. It is our desire to work cooperatively with you toward achieving that common goal. We would welcome a follow-up conversation with you via conference call to discuss how together we might better facilitate the provision of upper limb prosthetic care to Medicare beneficiaries.

Thank you for your interest and attention to this matter. We look forward to opportunities to assist in improving the coding system to the benefit of CMS, Medicare beneficiaries and the practitioners who provide their care.

Sincerely,

Sarah Thomas, CPO

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President

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Appendix A:

In this appendix, we have provided direct wording from the Correct Coding for Upper Limb Prostheses guidelines (listed in quotes and *italics*) as well as our response to the coding and suggested corrections based on real world clinical experience (listed in **bold**). Note that all wording has been copied directly into this document. However, we do not necessarily have commentary to provide on all sections. We would like this document to provide guidance on future discussions in order to come to a coding guidance and structure that more closely matches contemporary clinical practice and preserves access to competent clinical care for Medicare beneficiaries with upper limb loss or differences.

"Upper Extremity Prosthetic Limbs are generally categorized and described by the level of amputation and the type of power source utilized to operate the limb. There are three types of upper extremity prostheses that reference the power source:

1. Body power – Body power prostheses rely on a system of mechanisms such as cable(s)/linkage(s)/anchor point(s) and upon the coordination of contracting muscles create motion of the prosthetic limb's joints via the control mechanism.

2. External (i.e., electrical) power – External power prostheses are controlled by the use of electric signals from the body's muscles which are translated and amplified via battery power to eventual control of the prosthetic components.

3. Passive/restorative – Passive (restorative) prostheses do not have active motion within the prosthesis. Passive prostheses may allow motion of the next proximal joint; without controlling a motion within the prosthesis. Motion of the passive prosthesis is not described as external or body power.

Two of the three types of prosthetic limb systems are described by the primary mechanism or source of motive power which then causes a functional motion at a joint(s) within the prosthesis.

A prosthesis described as a hybrid- type typically combines body power and external power components into one prosthetic limb. A beneficiary may receive a hybrid limb which combines power sources such as body power and external power."

While these categories are technically true, they do not fully capture all the possibilities available to restore function to prosthetic users. According to the State of the Science Conference Proceedings on

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Upper Limb Control Strategies, it was found that the categories of prosthetic control options include passive, body powered, hybrid, externally powered, and activity specific designs[1] (Stevens, 2017). Each option was afforded equal importance (Figure 1) based on the needs of the person with limb loss as noted by the prosthetist and occupational therapist during the initial evaluations. The above CMS power source list is incomplete and does not recognize the breadth of important options currently available for upper limb prosthetic clinical care. It also, perhaps unintentionally, discriminates against patients with partial hand loss, who make up the largest sector of upper limb loss and arguably benefit the most from activity-specific adaptive devices.

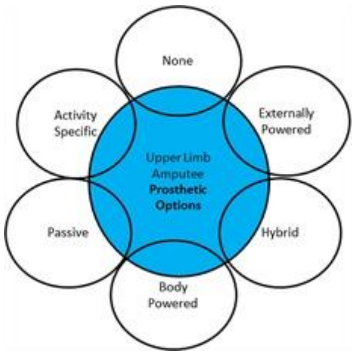

Figure 1: "Non-tiered view of upper limb prosthetic control options"[1]

The definition of external power is incomplete. An externally powered prosthesis may utilize switches, linear transducers, touch pads, or other alternative input devices. Function is not exclusively limited to control via surface EMG signals. Further, an external power prosthesis can include multiple input control methods. For example, a linear transducer could be used to activate the flexion and extension of an external powered elbow, while surface EMG electrode sensors could be used to operate the function of the terminal device and/or wrist rotator. An external power prosthesis may not even utilize surface EMG signals at all. For example, a shoulder disarticulation prosthesis may utilize touch pads within the socket, activated by touching the acromion process against them to perform different motions. Likewise, for an individual with an intercalary limb difference may utilize their residual digits to operate the desired motions of an external powered prosthesis.

The definition of passive/restorative prostheses is also incomplete. A passive prosthesis may also be a functional prosthesis and should be referred to as a passive functional prosthesis. This classification is not necessarily always cosmetically restorative. Passive functional prostheses do not necessarily need to take on an anatomical form. For example, an opposition post for a partial hand does not need to replicate the appearance of the missing portion of the hand. It does need to enhance function for the individual using it. For each person, the desired appearance may vary.

"Coding Guidelines

[1] Stevens, P. M., & Highsmith, M. J. (2017). Myoelectric and body power, design options for upper-limb prostheses: Introduction to the state of the science conference proceedings. *JPO Journal of Prosthetics and Orthotics*, *29*(4S).

Correct coding of an upper extremity prosthetic limb is based on the amputation level, using appropriate code(s) that are limited based on the level of amputation described in the code narrative. Upper extremity codes without a limb amputation level may be appropriate when it conforms to the coding guideline for that specific code."

We agree in theory with this method, as there are varying levels of time and materials required depending upon the level of amputation. However, the code set as it stands is insufficient to cover all scenarios for all levels of amputation. For example, partial hand "test socket" and "frame type socket" codes do not currently exist. However, to achieve the best fit and function from these devices, both are necessary. Previously, L6680 (test socket, below elbow) and L6687 (frame type socket, below elbow) have been used to account for this discrepancy as technically, the partial hand amputation is "below the elbow". This new guidance precludes use of these codes, thus eliminating reimbursements for necessary time and materials required to achieve successful outcomes. These two examples demonstrate the lack of coding 'band-width' that is necessary, but presently absent. Amputation levels of the upper extremity should have a set of HCPCS codes that describe the design and construction of the socket and interface, similar to what is provided for lower limb prostheses. There are also level-specific design characteristics that warrant separate coding.

"INTERSCAPULAR THORACIC

Codes L6350, L6360, L6370, L6570, L6970, and L6975 are base codes which describe a prosthetic limb used for an interscapular thoracic level amputation device. The base codes are further delineated by the type of power source. The use of the base code is determined by the level of amputation and the mechanism of function.

Codes L6350 and L6570 are described as a body-powered interscapular thoracic device.

Codes L6970 and L6975 are described as an external powered interscapular thoracic device.

Codes L6360 and L6370 are described as passive/restorative interscapular thoracic devices."

Code L6350 and L6570 do not clearly define a body-powered device and could define a passive functional prosthesis. There is no mention of cabling or control in the description.

"SHOULDER DISARTICULATION

Codes L6300, L6310, L6320, L6550, L6960, and L6965 are considered base codes which describe a prosthetic limb used for a shoulder disarticulation level amputation device. The base codes are further delineated by the type of power source. The use of the base code is determined by the level of amputation and the mechanism of function.

Codes L6300 and L6550 are described as a body-powered shoulder disarticulation device.

Codes L6960 and L6965 are described as an external powered shoulder disarticulation device.

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Codes L6310 and L6320 are described as passive/restorative shoulder disarticulation devices."

Code L6300 and L6550 do not clearly define a body-powered device and could define a passive functional prosthesis. There is no mention of cabling or control in the description.

"TRANS-HUMERAL (ABOVE ELBOW)

Codes L6200, L6205, L6250, L6450, L6500, L6940, L6945, L6950, and L6955 are base codes which describe a prosthetic limb used for a transhumeral (above elbow) or elbow disarticulation devices. The base codes are further delineated by the type of power source. The use of the base code is determined by the level of amputation and the mechanism of function.

Codes L6200, L6205, L6250, L6450, and L6500 are described as body-powered trans-humeral (above elbow) or elbow disarticulation level amputation devices.

Codes L6940, L6945, L6950, and L6955 are described as an external powered trans-humeral (above elbow) or elbow disarticulation level amputation devices."

Codes L6200, L6205, L6250, L6450 and L6500 do not clearly define a body powered device and could define a passive prosthesis. There is no mention of cabling or control.

"TRANS-RADIAL (BELOW ELBOW)

Codes L6100, L6110, L6120, L6130, L6400, L6930, and L6935 are base codes which describe a prosthetic limb used for a trans-radial (below elbow) device. The base codes are further delineated by the type of power source. The use of the base code is determined by the level of amputation and the mechanism of function.

Codes L6100, L6110, L6120, L6130, and L6400 are described as a body-powered trans-radial (below elbow) amputation device.

Codes L6930 and L6935 are described as an external powered trans-radial (below elbow) amputation device."

Codes L6110, L6120, L6130 and L6400 do not clearly define a body powered device and could define a passive prosthesis. There is no mention of cabling or control.

"WRIST DISARTICULTION

Codes L6050, L6055, L6920, and L6925 are base codes which describe a prosthetic limb used for a wrist disarticulation device. The base codes are further delineated by the type of power source. The use of the base code is determined by the level of amputation and the mechanism of function.

Codes L6050 and L6055 are described as a body-powered wrist disarticulation amputation device.

Codes L6920 and L6925 are described as an external powered wrist disarticulation amputation device."

Codes L6050, and L6055 do not clearly define a body powered device and could define a passive prosthesis. There is no mention of cabling or control.

"PARTIAL HAND

Codes L6000, L6010, L6020, and L6026 are base codes which describe a prosthetic limb used for a partial hand device. The base codes are further delineated by the type of power source. The use of the base code is determined by the level of amputation and the mechanism of function. Allowable addition codes are either amputation level-specific or have no amputation level specified.

Code L6000 (PARTIAL HAND, THUMB REMAINING) describes a base code for a cable/spring driven body-powered transcarpal /metacarpal partial hand prosthesis with the anatomical thumb still remaining. L6000 includes the standard friction wrist and control cable system. This code describes a complete terminal device, and thus the use of more than one terminal device code is considered incorrect coding.

Code L6010 (PARTIAL HAND, LITTLE AND/OR RING FINGER REMAINING) describes a base code for a cable/spring driven body-powered transcarpal /metacarpal partial hand prosthesis with the anatomical little and/or ring finger still remaining. L6010 includes the standard friction wrist and control cable system. This code fully describes a complete terminal device, and thus the use of more than one terminal device code is considered incorrect coding

Code L6020 (PARTIAL HAND, NO FINGER REMAINING) describes a base code for a cable/spring driven body-powered transcarpal /metacarpal partial hand prosthesis with no anatomical fingers remaining. L6020 includes the standard friction wrist and control cable system. This code fully describes a complete terminal device, and thus the use of more than one terminal device code is considered incorrect coding.

Code L6026 (TRANSCARPAL/METACARPAL OR PARTIAL HAND DISARTICULATION PROSTHESIS, EXTERNAL POWER, SELF-SUSPENDED, INNER SOCKET WITH REMOVABLE FOREARM SECTION, ELECTRODES AND CABLES, TWO BATTERIES, CHARGER, MYOELECTRIC CONTROL OF TERMINAL DEVICE, EXCLUDES TERMINAL DEVICE(S)) describes a base code for a transcarpal/metacarpal or a partial hand disarticulation, myoelectric-controlled prosthesis which includes all necessary components besides the terminal device.

Partial hand prostheses that utilize body powered individually articulating digits must be submitted to the DME MAC (Durable Medical Equipment Medicare Administrative Contractor)s with HCPCS (Healthcare Common Procedure Coding System) code L7499. Code L7499 should be used to describe the complete device, and thus the use of more than one code is considered incorrect coding not separately payable (unbundling)."

The guidelines set forth in this section will not support an appropriate level of clinical care, nor the financial costs incurred to provide patients with functional prostheses they are satisfied with and will not abandon. The time and material costs for building a partial hand prosthesis are similar to that of a wrist disarticulation or below elbow prosthesis. Often, they are even higher due to wide variation of amputation presentations requiring an advanced level of clinical skill, time, and ingenuity to accommodate remaining fingers, boney anatomy, or damaged tissues. Despite this, the base code for

a myoelectric partial hand prosthesis (L6026) reimburses at a maximum of $5253.74 while the code for a myoelectric wrist disarticulation prosthesis (L6925) is almost double that figure at $10796.62. Additionally, the guideline for L6026 apparently does not allow for the use of necessary codes for items such as test sockets, frame type sockets, acrylic resin, ultralight materials, suction suspension, removeable inserts, and others. All other levels of amputation are permitted to use these additional codes. For the external power hand prosthesis, the cost of a battery kit and myoelectrodes alone can account for almost $3000. The cost of the "inner socket" which is typically made from HTV silicone has to be custom made and takes multiple iterations to fabricate. It requires highly specialized equipment and tools to fabricate that most prosthetic clinics don't have access to. Therefore, they must contract that work out to a third party. Doing so typically costs in the range of $2,000. Considering just the cost of batteries, electrodes, and the inner socket alone, there is insufficient reimbursement left over to cover normal operating costs. Baseline expenses associated with clinical, technical and administrative overhead are not adequately provided for by codes and reimbursement rates that were set up in the 1990's. The current status of needed, but non-existent codes and outdated reimbursement rates makes the 'all-included' expectation of clinical training, follow-up, and maintenance over an anticipated 3-5 year period financially unsustainable. That should not be the case, as partial hand prostheses provided to non-Medicare recipients with appropriate coverage and reimbursement levels have historically resulted in optimal patient outcomes.

The description of L6000 is "Partial hand, thumb remaining." There is no indication from this description that this code represents a complete all-inclusive prosthesis. When this code was created, there was a partial hand prosthesis called the "Robin-Aids." However, this prosthesis has not been clinically available for more than 20 years. In the opening paragraph it states that "*Codes L6000, L6010, L6020, and L6026 are base codes."* **If these are in fact base codes, there should be other codes that could be used as addition codes to describe the rest of the prosthesis. The base codes therefore, should not be considered as all inclusive.**

Above it states that L6000, L6010, and L6020 "*describes a complete terminal device, and thus the use of more than one terminal device code is considered incorrect coding."* **Contemporary clinical practice allows for the use of a partial hand quick disconnect wrist unit from multiple manufacturers including Fillauer, TRS, and Texas Assistive Devices. Such partial hand quick disconnect wrist units allow for the changing of terminal devices used in the partial hand prosthesis. For someone with a partial hand amputation this can be a very functional and beneficial component. Specific terminal devices such as forks, knives, spoons, or a body-powered voluntary opening or voluntary closing terminal device can be interchanged to accomplish certain ADL tasks. This restrictive definition is unjustly prejudicial to the large population of partial hand amputees.**

In the past 10 years there have been significant improvements in the available functional options for individuals with partial hand amputations. This correct coding guideline prohibits Medicare beneficiaries from being able to access prosthetic components that can provide significant functional improvement. It further restricts them from accessing functional partial hand prostheses that have been commercially available since the 1990's.

With respect to this statement:

Partial hand prostheses that utilize body powered individually articulating digits must be submitted to the DME MAC (Durable Medical Equipment Medicare Administrative Contractor)s with HCPCS (Healthcare Common Procedure Coding System) code L7499. Code L7499 should be used to describe the complete device, and thus the use of more than one code is considered incorrect coding not separately payable (unbundling)."

Individually articulating digits describe only one part of a prosthesis. In this case, the terminal device for a partial hand prosthesis. Articulating digits can be connected to a prosthesis with a variety of designs and features that vary greatly depending on the number of digits involved and the functional requirements of the individual. There is no justification for these devices to be coded as all-inclusive. This again, points to the lack of available codes relating to partial hand prostheses. Individually articulating digits need to be custom fit to each individual. The fact they may be purchased from a single manufacturer who fabricates the prosthesis does not change that the prosthesis is custom made with different features based on the design requirements identified by the prosthetist. Different features and options have different costs associated with them and as such, cannot be considered 'all-inclusive' or 'off-the-shelf'.

"SOCKET FABRICATION

Codes L7400, L7401, L7402, L7403, L7404, and L7405 are used for ultra-light or acrylic materials and may only be used when materials such as carbon fiber, fiberglass, Kevlar®, or other advanced composite lamination materials are used in the fabrication of a socket for an upper limb prosthesis. They are not used for ultralight materials used in other components of a prosthesis - e.g., shoulders, elbows, wrists or terminal devices, etc. For codes L7400, L7401, 7402, L7403, L7404 and L7405, the unit of service (UOS) is per limb."

As previously stated, there is not an equivalent code listed for partial hand amputations. Given the advent of additive manufacturing capabilities, the ability to provide ultra-light materials is no longer restricted to laminations. For example, an additively manufactured upper limb prosthesis can be made lighter weight than a traditional wet lamination prosthesis due to the finite ability to control the dimensional thickness and integral structure of the prosthesis. As with carbon fiber or Kevlar, there is an increased cost in utilizing additive manufacturing to produce a lighter weight prosthesis. Therefore, these codes should not be restricted solely to the lamination process.

"TEST SOCKETS

Codes L6680, L6682, and L6684 describe plastic sockets to evaluate the socket fit. Test sockets are part of an intermediate fabrication process and are not a component of the final prosthesis delivered to the beneficiary. Each code describes the level of amputation for the respective test socket procedure."

Once again, there is not an equivalent code listed for partial hand amputations.

"SUSPENSION

Code L6686 (UPPER EXTREMITY ADDITION, SUCTION SOCKET) describes a modification to the socket using a suction valve component along with positive model rectifications specific to the suction socket design as compared to a non-suction socket design. Suction will provide a suspensory function for the prosthesis. When a suction valve is integral to another product such as L6698 the suction valve is considered not separately payable (unbundling)."

There are two essential issues with this line of thinking:

(1) A valve is not required for suction to be achieved. Due to the flexible nature of human tissue, air can pass across the limb surface as a prosthesis wearer is donning their device. This is often achieved with use of a lubricant to assist with donning. Once the limb is in the correct location, the tissue settles and prevents air from returning into the distal end of the socket. This can also be achieved with an adjustable socket that compresses the tissue, again preventing air from returning to the socket. When a person wishes to remove their prosthesis, they can re-shape the tissue to allow air to enter and release the suction. This approach is routinely utilized with fingertip prostheses that are held on with suction and no valve.

(2) When a suction valve is used in conjunction with another component (such as a locking component – L6698) there is a cost associated with that component as well as additional time required for exacting fabrication to ensure the suction is successful. A lock with an ancillary valve/suction component can greatly enhance suspension, but can be twice as expensive as a simple locking mechanism.

"Codes L6687, L6688, L6689, and L6690 describe amputation level-specific sockets fabricated with fenestrations (frame type socket) and when clinically appropriate, include inner sockets made of a more flexible material. The flexible inner socket is included with the "frame-type socket" and, billing of a flexible inner socket is considered not separately payable (unbundling)."

There are potentially three 'layers' to an upper limb prosthetic socket. The first is a flexible inner socket made from thermoplastic or silicone. The second is comprised of a gel liner or silicone insert to provide stability to the flexible inner socket and in some cases, to act as a protective barrier between the limb and electronic componentry. The third outermost layer encompasses all the components within a protective outer shell (wrist, batteries, etc.). Since 1996, these codes have been interpreted as representing the entire structural shell. Today's layered approach requires additional skill and time to match the contralateral limb AND to properly align the shoulder, elbow, or wrist for greatest function. There is not an equivalent code for the middle layer of socket intended for stabilizing the flexible inner or gel liner. Additionally, there is not an equivalent code listed for partial hand amputations.

"Socket inserts described by codes L6691, L6692, L6694, L6695, L6696, or L6697, should not be equated to the flexible inner socket included with codes L6687 or L6688 and L6689 or L6690. The socket inserts used in conjunction with a suspension locking mechanism are billed with codes L6694, L6696, and L6697

as appropriate. These codes include socket inserts with a distal umbrella adapter for attaching the locking mechanism. Code L6695 is a socket insert that does not include a locking mechanism.

Codes L6696 and L6697 are for use only with the initial issue of a custom fabricated socket insert. Additional inserts (either custom fabricated or prefabricated) provided at the time of initial issue or replacement socket inserts are coded L6694 and L6695, whichever is applicable."

We disagree with the flexible inner socket being included with the frame-type socket codes. Depending on the choice of materials for the flexible inner socket there may be a significant increase in labor and/or material costs. The outer frame and flexible inner socket represent singular components that can be replaced independent of each other. The gel liners noted by L6694, L6695, L6696, and L6697 can all be replaced after significant wear. Additionally, the flexible inner socket (whether made of plastic or silicone) should be noted by L6691 and L6692 as is customary. The flexible inner can be replaced as the limb shape changes without having to completely replace the frame component of the socket, thus saving time and money for the patient, provider, and payor. Since the flexible inner socket can be replaced independently, it makes sense to be able to assign L6691 or L6692 codes to this specific component instead of unnecessarily bundling it with the frame-type socket.

"Body powered harness systems are required additions for the suspension and function of the body powered prosthesis. Codes L6672, L6675, L6676, and L6677 describe the specific control design of the body-powered system and fully describe a complete harness, and thus the use of more than one code is considered incorrect coding."

The description of L6672 is "Upper extremity addition, harness, chest or shoulder, saddle type." This has nothing to do with the control mechanism for a body-powered prosthesis. This style of harness is utilized when heavier loads are carried, such as for a heavier external-powered prosthesis. It can also be utilized when an axilla loop is contraindicated for the user. L6675, L6676, and L6677 each describe a specific cable mechanism for operating a body-powered prosthesis. L6675 describes a single cable design, which is capable of operating one single degree of freedom or action of the prosthesis. L6676 describes a dual cable design, and L6677 describes a triple cable design. As a result, a prosthesis can easily be configured to use a shoulder saddle harness (L6672) in conjunction with either L6675, L6676, or L6677. There are additional components and fabrication time associated with providing L6672 which goes beyond the scope of L6676, L6676, and L6677. It would be uncommon to use L6675, L6676, and L6677 together in the same prosthesis. A transhumeral hybrid prosthesis will often use a shoulder saddle with a dual cable design to operate elbow flexion as well as the elbow locking mechanism.

"Code L7700 (GASKET OR SEAL, FOR USE WITH PROSTHETIC SOCKET INSERT, ANY TYPE, EACH) describes a stand-alone (i.e., not integrated into or a part of a prosthetic socket insert) sealing ring that is added to a socket insert to assist in providing or maintaining negative pressure for socket suspension. The ring creates a seal against the outer surface of the insert and against the inner wall of the socket. L7700 is not intended for use with mechanical socket suspensions such as a pin-lock system. It may be made of any suitable material. L7700 may be used with upper or lower extremity sockets. The UOS (Unit of Service) is 1 (one) item. This code is not to be used to bill for gaskets, seals, or other sealing materials

that are included as part of an insert. Integrated seals are included in the code for the insert. Separate billing of integrated gaskets or seals such as L7700, is considered not separately payable (unbundling)."

We are generally in agreement with this statement. Certain scenarios persist in which a seal would be used with a pin-lock system to increase the security of suspension, such as with individuals who lift large amounts of weight, whether for work or physical activity. If used to apply to a sealing sleeve for this purpose, two such items would be provided to the patient for this purpose.

"CABLE SYSTEMS

Cables and cable additions are appropriate with body-powered prostheses. Codes L6655 and L6660 fully describe a complete cable, and thus the use of more than one cable code is considered incorrect coding. Addition codes L6665, L6670, L6641, and L6642 are available if not described in the features or functions found in other L-codes of the prosthetic device."

No issues noted.

"SHOULDER UNITS

Body powered shoulder units are not included in the base codes identified as L6300, L6310, L6320, L6960, and L6965.

Codes L6640, L6645, L6646, L6647, L6648, and L6650 describe shoulder joints that are additions to the prosthesis for the function of the shoulder disarticulation prosthesis."

No issues noted.

"ELBOW UNITS AND ADDITIONS

Body powered elbow units are included in the base code identified as L6200, L6205, and L6250. Addition codes L6600, L6605, and L6610 describe elbow hinges for the body powered elbow disarticulation or above elbow prostheses are considered an upgrade to the prosthesis.

Additional features to the elbow unit, such as codes L6635, L6637, L6638, and L6693, are available if not described in the features or functions found in other L-codes of the prosthetic device.

Codes L7170, L7180, L7181, L7185, L7186, L7190, and L7191 describe electric powered elbow units that are additions to the base socket design. A single addition code can fully describe a complete elbow unit, and thus the use of more than one elbow unit code is considered incorrect coding."

L6600, L6605, and L6610 are never utilized for above elbow or elbow disarticulation amputations. These codes are always utilized for heavy-duty below elbow body-powered prostheses. Their inclusion in this portion of the document is completely inaccurate and illustrates the misinformation and confusion that this document has created and will continue to create, if not addressed.

The codes describing electric powered elbow units do not always fully describe a complete unit with a single code. Certain products have additional features that make them more useable and functional,

but also increase the cost of the device. For example, all elbow styles of the Ottobock elbow line include the option for an automatic forearm balance (L6693). However, this ruling indicates that we are allowed to use that addition code only for a body powered (hybrid) system, even if the fully electric elbow versions also include this feature (which is not standard among electric elbows). The forearm balance is an addition to the elbow that is not required for basic function, but serves as an additional aid to the user by reducing use exertion throughout the day. It can also be used to add the counterbalance feature to outside locking hinges for elbow disarticulation prostheses. This example demonstrates that electric elbow base codes may occasionally require addition codes and should not be deemed all-encompassing.

"WRIST UNITS AND ADDITIONS

Wrist unit codes L6615, L6616, L6620, L6623, L6624, L6625, L6628, L6629, and L6630 are not applicable for partial hand and distal amputations.

Codes L6616 and L6630 are additions to the wrist units that are available if not described in the features or functions found in other L-codes describing the prosthetic device.

Wrist unit codes L7259 and L6621 are not applicable for partial hand and distal amputations.

Code L6621 (UPPER EXTREMITY PROSTHESIS ADDITION, FLEXION/EXTENSION WRIST WITH OR WITHOUT FRICTION, FOR USE WITH EXTERNAL POWERED TERMINAL DEVICE) describes a complete product that allows the wrist to move in a wide range of motion and incorporates a locking feature in multiple flexion and extensions positions. L6621 is utilized with an external powered terminal device.

Code L7259 (ELECTRONIC WRIST ROTATOR, ANY TYPE) describes a complete product as an electronic wrist rotator, any type."

We disagree with this section of the guidelines with respect to three conditions:

(1) The wrist codes listed above have been determined not to apply to partial hand level amputations or amputations distal to the wrist. Earlier in this document, the base codes for partial hand prostheses indicated that the base code included "*the standard friction wrist and control cable system*". This coding is contradictory and ambiguous.

(2) There have been various components designed with the express purpose of providing extra "wrist-like" function to people with partial hand loss or difference. As many of these amputations result from traumatic events, remaining tissues are often damaged and painful, resulting in a severe reduction of range of motion. The goal of a prosthesis is to restore function, enhance activities of daily living and return the wearers to as normal a lifestyle as possible. Prostheses can only replace these lost motions through the use of componentry. As a representative example, when the ProCuff disconnect wrist unit (TRS division of Fillauer, Inc.) is combined with the N-Abler II flexion and extension wrist unit (L6624) from Texas Assistive Devices, the prosthesis then provides a connection for a variety of tools, thus reducing the need for grasp and mobility in damaged finger and wrist joints. This is especially important when the user has bilateral upper limb loss or difference. Such components have been used successfully in clinical practice for many years by prosthetists to create custom prostheses to meet the

individual functional needs of the end users. Unfortunately, the current code set for partial hand prostheses does not allow for such a contemporary clinical standard of care to be delivered to Medicare beneficiaries.

(3) The code L7259 does not cover a complete wrist rotator in all scenarios. There are two styles of wrists, one with microprocessor control and one without. The latter option is often used in conjunction with electric elbows and advanced control systems, while the former is used with standard two electrode input systems. Microprocessor control is necessary when there is not a device upstream to control the motor. However, the addition of the microprocessor also adds cost. In fact, the microprocessor version of one wrist is almost $4000, while the floor reimbursement for L7259 from CMS is only about $3300. In this situation, the singular code does not even cover the cost to purchase the wrist component.

"TERMINAL DEVICES AND ADDITIONS

Codes L6703, L6704, L6708, L6709, L6713, L6714, L6706, L6707, L6721, and L6722 describe body powered terminal devices (hand or hook type) that are additions to the base prosthetic limb design. A single addition code can fully describe a complete terminal device, and thus the use of more than one terminal device code is considered incorrect coding.

Codes L6805 and L6810 are additional features to a body powered terminal device and are available if not described in the features or functions found in other L-codes describing the prosthetic device."

No issues noted.

"*Codes L6880, L7007, L7008, L7009, and L7040 describe external powered terminal (hand or hook type) devices that are additions to the base prosthetic limb design. A single addition code can fully describe a complete terminal device, and thus the use of more than one terminal device code is considered incorrect coding."*

There exist electric hands and hooks that do not have microprocessor control nor an auto-grasp feature. Ottobock, Motion Control, Steeper and others, offer multiple versions of their terminal devices (L6880, L7007, L7008, and L7009) that come with or without microprocessor control and with or without auto-grasp. The selection of the features of the terminal device are predicated upon the functional needs of the user. When necessarily selecting a hand or hook with the additional features, there is a significant difference in cost to the clinic. The use of a terminal device that includes microprocessor control or auto-grasp, also requires additional clinical time for patient training, follow-up and device maintenance over the course of its expected life. Therefore, L6880, L7007, L7008 and L7009 codes should not be considered to be all-encompassing for all features. The L6881 and L6882 codes should be compatible to bill along with the terminal device base codes depending upon the features of the specific terminal device. By eliminating the ability to bill for L6881 and L6882 codes along with the base codes, it becomes cost-prohibitive to provide function-enhancing terminal devices to beneficiaries.

"Code L6880 (ELECTRIC HAND, SWITCH OR MYOLELECTRIC CONTROLLED, INDEPENDENTLY ARTICULATING DIGITS, ANY GRASP PATTERN OR COMBINATION OF GRASP PATTERNS, INCLUDES MOTOR(S)) has the following characteristics:

1. Includes all necessary components;

2. Is all-inclusive;

3. Is comprised of five (5) articulating digits and the necessary motors; and,

4. Includes all grasp patterns

The use of codes L6881 (AUTOMATIC GRASP FEATURE, ADDITION TO UPPER LIMB ELECTRIC PROSTHETIC TERMINAL DEVICE) and L6882 (MICROPROCESSOR CONTROL FEATURE, ADDITION TO UPPER LIMB PROSTHETIC TERMINAL DEVICE) are considered not separately payable (unbundling) with L6880. Billing of any additional features or functions used to describe a manufacturer's terminal device is considered not separately payable (unbundling).

Code L6715 (TERMINAL DEVICE, MULTIPLE ARTICULATING DIGIT, INCLUDES MOTOR(S), INITIAL ISSUE OR REPLACEMENT) describes multiple articulating digit(s) (fingers and/or thumb) which are used with initial use, when paired with a partial hand base, L6026. The articulating digit(s) can also be used as a "replacement" digit(s)" with the use of the RB modifier as part of a prosthetic repair.

Effective for claims with dates of service on or after January 1, 2022, the only products that may be billed using HCPCS (Healthcare Common Procedure Coding System) codes L6715 and/or L6880 are those that have received mandatory code verification review and are listed on the Product

Classification List (PCL) of the Pricing, Data Analysis, and Coding (PDAC) contractor website."

L6881 *"Automatic Grasp Feature,"* has nothing to do with the *"Grasp Patterns"* as noted in the description of L6880. Further down in this document it clearly defines how L6881 is different than "Grasp Patterns." Automatic grasp relies on additional sensors to prevent a terminal device from inadvertently opening and dropping an object. It is a safety feature added to a terminal device to prevent for example, accidently dropping a cup of hot coffee in your lap. "Grasp Patterns" as described in the L6880 descriptor refers to the ability of the terminal device to position each of the digits independently from each other in a custom posture. These grasp patterns can be preprogramed from the factory or customized by the user dependent on the desired functionality.

The initial prosthetic component for which this code was developed was the Touch Bionics iLimb. This terminal device featured independently articulating digits which offered the user the ability to grasp different sized and shaped objects they couldn't previously do with existing hand or hook terminal devices. Unfortunately however, the early-on designs could not stand up to the rigors of many activities of daily living and were only functional for light duty.

In subsequent years, enormous progress has been made with regard to durability and enhanced features that weren't even available for reimbursement-related consideration with the original code

application in 2012. Those advanced features and greater durability however, have come with increased costs to clinics and require additional time for training and maintenance. Therefore, only billing the L6880 code prevents users from accessing new technologies as the code does not cover the complete cost of all the features. Additionally, insurance ultimately pays more in repairs as the reimbursement rate only covers devices with a lower durability rating. If the goal is to simplify the coding by using one code per component, then the reimbursement level for L6880 needs to be increased appropriately. By disallowing the use of billing L6881 and L6882 with L6880, the reimbursement for a multi-articulated terminal device is being reduced by more than $7,500. Once again, this makes it unsustainable to provide such standard of care services to Medicare beneficiaries.

"EXTERNAL POWERED ADDITIONS

Codes L6638, L6881, L6882, L7180, and L7181 describe additional features to an externally powered terminal device and are available if not described in the features or functions found in other L-codes describing the prosthetic device. For codes L6638, L6881, L6882, L7180, and L7181, billing of any additional features or functions used to describe a manufacturer's terminal device is considered not separately payable (unbundling).

Code L6638 (UPPER EXTREMITY ADDITION TO PROSTHESIS, ELECTRIC LOCKING FEATURE, ONLY FOR USE WITH MANUALLY POWERED ELBOW) describes an addition for an electric locking mechanism that is used with a manually powered elbow unit. The UOS (Unit of Service) is per limb.

Code L6881 (AUTOMATIC GRASP FEATURE, ADDITION TO UPPER LIMB ELECTRIC PROSTHETIC TERMINAL DEVICE) describes slip detection through special sensors built into the thumb and fingers of the prosthetic hand (terminal device) that allows the device to detect changes in the position and weight of grasped objects in anticipation of when the object will slip. The slip detection causes the hand to automatically increase the gripping force applied to the object. The UOS (Unit of Service) is per limb.

Code L6882 (MICROPROCESSOR CONTROL FEATURE, ADDITION TO UPPER LIMB PROSTHETIC TERMINAL DEVICE) describes an on-board microprocessor that automates monitoring and compensatory control functions of an external powered terminal device. Terminal devices and wrist units are susceptible to performance degradation and this product provides a function to lessen the resulting dysfunction from the user's input and functional output. This additional electronic control is separate from the electronic control described in the base codes for external power such as L6925, L6935, L6950, L6955, L6965, or L6975. The UOS (Unit of Service) is per limb.

Code L7180 (ELECTRONIC ELBOW, MICROPROCESSOR SEQUENTIAL CONTROL OF ELBOW AND TERMINAL DEVICE) describes an on-board microprocessor providing input to an external powered device one device at a time, that follows a logical sequence for functional activities. The UOS (Unit of Service) is per limb.

Code L7181 (ELECTRONIC ELBOW, MICROPROCESSOR SIMULTANEOUS CONTROL OF ELBOW AND TERMINAL DEVICE) describes an on-board microprocessor that provides simultaneous control of an external powered elbow and external powered terminal device. This simultaneous control uses two separate microprocessors located in the elbow unit. One processor provides automated adjustment for

controlling the electrically powered elbow and other processor provides automated adjustment for controlling the electrically powered terminal device and electrically powered wrist unit. The UOS (Unit of Service) is per limb."

L7180 and L7181 are codes for electronic elbows, not terminal devices. L6638 applies to a locking mechanism for a body powered elbow, not a terminal device. Once again, a demonstration of the confusion that is integral to this document.

This statement *"For codes L6638, L6881, L6882, L7180, and L7181, billing of any additional features or functions used to describe a manufacturer's terminal device is considered not separately payable (unbundling)."* **essentially states that there can be no innovation beyond what the established code set defines. However, there are clearly examples of times when an L7499 code is necessary to describe a feature of terminal device that is not currently included in the defined codes such as waterproof features and waterproof protective sleeves. Additionally, some terminal devices have switches integrated into them that provide enhanced levels of function that need to be accounted for. All terminal devices are not the same, just as all prosthetic feet and knees are not the same. With the reality that upper limb prosthetic designs are often being far more complex and nuanced than lower limb designs, a broader, more descriptive set of upper limb codes is needed to reflect this.**

The unit of service for L6881 and L6882 as "per limb" does not allow for an individual to receive multiple terminal devices, such as an external powered hand and an external powered hook. A hook and a hand have very distinct functions and neither is independently capable for substituting for all the deficits associated with an upper limb loss. To provide both a hook and hand with autograsp and microprocessor control requires reimbursement for two units each of L6881 and L6882. This is a very common combination that represents appropriate care in restoring function to upper limb amputees.

As put forth, there is some ambiguity as to the implementation of this policy. An individual fitted with a multi-articulated hand and a powered wrist rotator requiring microprocessor control would require billing L6880 for the hand plus L7259 and L6882 codes. There is concern that such a claim would be denied because of automated processing seeing the L6880 and L6882 as duplicative same-or-similar items on the same claim. This of course would not be accurate as there would be a previously established medical necessity for the two functionally-distinctly terminal devices.

"PASSIVE-RESTORATIVE DEVICES

Codes L6900, L6905, L6910, and L6915 are complete products and afford shape, protection, and water resistance for normal daily usage of the prosthesis."

This guidance does not account for the process of making passive devices that will also restore a significant amount of function. However, for the devices to fit well-fitted and comfortable, test sockets must be fit before moving to the definitive stage. This ruling does not allow for that process. Indeed, the reimbursement rate provided by CMS for these codes barely pays for the materials to make the device.

"IMMEDIATE POST-SURGICAL/PREPARATORY

Immediate post-surgical prosthetic codes L6380, L6382, L6384, L6386, and L6388 are complete products and no additions are allowed.

Preparatory prosthetic codes L6580, L6582, L6584, L6586, L6588, and L6590 include the complete control mechanism and socket for the preparatory prosthesis. They do not include the body-powered terminal device necessary for the functional prosthesis."

Just because a prosthesis is preparatory does not preclude it from needing customization and the ability to select alternative components based on the functional needs of the individual. There is significant value in early prosthetic fitting. Clinical research has shown a significant increase in adoption and return to work for individuals fitted with a prosthesis within the first 30 days following amputation. Part of that entails being fit with prosthetic components that are appropriate for them. There is absence of coding options relating to partial hand prostheses.

"NOT OTHERWISE SPECIFIED

Code L7499 (UPPER EXTREMITY PROSTHESIS, NOT OTHERWISE SPECIFIED (NOS)), belongs to a group of codes which share the phrase "Not Otherwise Specified" (NOS) and are commonly referred to as NOC (Not Otherwise Classified) codes, is intended to describe a unique product which is not described by a specific Lcode(s). It is used to describe a complete product not included in the functions or features of another code. Therefore, the NOC (Not Otherwise Classified) code must not be used to bill for any features or functions already included in one or more L-codes. Examples (not all-inclusive) of items not to be billed with a NOC (Not Otherwise Classified) code are, equipment or supplier time used in the fabrication, modification, or delivery."

We agree generally with this sentiment. However, this guidance is often applied negatively to features that do not have an existing code. Examples of this include, waterproofing on any component, pattern recognition control, and ratcheting-style partial hand fingers. These types of features are often rejected as "unbundling" even though they do not have a specific code to describe them, and are not part of an already described component. The use of the term "complete product" or "complete device" has been applied in different ways throughout this document. In some places it is used as meaning a singular component such as an elbow or a wrist that is part of an overall prosthesis. In other areas in the document, it refers to the whole prosthesis, including all parts and sub-assemblies whether custom fabricated or purchase from a manufacturer. These inconsistencies and ambiguities create unnecessary confusion in coding.

"BATTERIES AND BATTERY CHARGERS

Refer to Billing of Powered L-Coded Items – Correct Coding – Revised for the correct coding of batteries and chargers related to upper extremity prostheses."

There are certain conditions under which a patient may need additional batteries and chargers over and above those included in the base code. For example, if a patient spends a lot of time in their car or

at their place of employment, they might require an additional charger to keep at each place, just as you might with a cell phone charger. The same thing applies to having additional batteries. A prosthesis is more than just a tool, as it adds real function to someone's life to allow them to engage in normal daily activities. If a patient legitimately needs additional batteries or a charger in order to maintain their function, this guidance should not preclude that possibility.

Similarly, more advanced systems require greater battery capacitance. Patients who use those devices need to be supplied with a sufficient amount, or appropriate type, of batteries to meet their daily functional needs. Higher capacitance batteries have a higher cost and obviously can't just be given away without proper reimbursement being provided.

"MODIFIERS

The right (RT) and left (LT) modifiers must be used with prosthesis codes. Effective for claims with dates of service on or after 3/1/2019, when the same code for prostheses, sockets, or other components for bilateral amputees are billed on the same date of service, bill each item on two separate claim lines using the RT (Respiratory Therapy) and LT modifiers and 1 unit of service (UOS) on each claim line. Do not bill the RTLT modifier as 2 UOS (Unit of Service) on the same claim line. Claim lines billed without the RT (Respiratory Therapy) and/or LT modifiers, or as 2 UOS (Unit of Service) with RTLT on the same claim line, will be rejected as incorrect coding.

Correct coding is an essential element for correct claim payment. The PDAC (Pricing, Data Analysis and Coding) contractor maintains a variety of resources to assist suppliers in determining the appropriate code for Medicare billing. For questions about correct coding, contact the PDAC (Pricing, Data Analysis and Coding) HCPCS (Healthcare Common Procedure Coding System) Helpline at (877) 735-1326 during the hours of 9:30 am to 5:00 pm ET, Monday through Friday. You may also visit the PDAC (Pricing, Data Analysis and Coding) website to chat with a representative or select the Contact Us button at the top of the PDAC (Pricing, Data Analysis and Coding) website for email, FAX, or postal mail information."

The (RT) modifier in the descriptive language above is incorrectly referencing "Respiratory Therapy"