Upper Extremity Prosthetic Devices

Policy Number: CS360.C
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➲ Instructions for Use

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Related Community Plan Policy

- Lower Extremity Prosthetics

Commercial Policy

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Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Idaho	Upper Extremity Prosthetic Devices (for Idaho Only)
Indiana	None
Kansas	Upper Extremity Prosthetic Devices (for Kansas Only)
Kentucky	Upper Extremity Prosthetic Devices (for Kentucky Only)
Louisiana	Upper Extremity Prosthetic Devices (for Louisiana Only)
New Jersey	Upper Extremity Prosthetic Devices (for New Jersey Only)
New Mexico	Upper Extremity Prosthetic Devices (for New Mexico Only)
North Carolina	Upper Extremity Prosthetic Devices (for North Carolina Only)
Ohio	Upper Extremity Prosthetic Devices (for Ohio Only)
Pennsylvania	Upper Extremity Prosthetic Devices (for Pennsylvania Only)
Tennessee	Upper Extremity Prosthetic Devices (for Tennessee Only)

Coverage Rationale

An upper extremity prosthetic for amputations is proven and medically necessary when all of the following criteria are met:

- Member has a traumatic or surgical amputation of upper extremity or a congenital absence or defect; and
- Prosthetic replaces all or part of a missing limb; and
- Prosthetic will help the member regain or maintain function; and
- Prosthetic device is ordered by or under the direction of a physician; and
- Prosthetic needs evaluated for member by a healthcare professional with appropriate prosthetic qualifications and training under the supervision of the ordering physician; and
- Member is willing and able to participate in the training for the use of the prosthetic; and
- Member with expected rehabilitation potential undergoes functional assessment [including Activities of Daily Living (ADLs) and Instrumental ADLs (IADLs)] evaluation

An upper extremity Myoelectric Prosthetic for amputations above the wrist is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Prosthetics, Myoelectric, Upper Extremity, Above the Wrist (Custom) - UHG.

Click here to view the InterQual® criteria.

An upper extremity Myoelectric Prosthetic hand, partial-hand, or artificial digit(s) for amputations below the wrist is medically necessary when all of the following criteria are met:

- Member has a traumatic or surgical amputation below the wrist or a congenital missing or dysfunctional hand or finger; and
- Prosthetic replaces all or part of a missing limb; and
- Prosthetic will help the member regain or maintain function; and
- Prosthetic needs evaluated for member by a healthcare professional with appropriate prosthetic qualifications and training under the supervision of the ordering physician; and
- Member is willing and able to participate in the training for the use of the prosthetic; and
- Member is able to operate the stimulator of the computerized prosthetic or microprocessor; and
- Member with expected rehabilitation potential undergoes functional assessment [including Activities of Daily Living (ADLs) and Instrumental ADLs (IADLs)] evaluation; and
- Remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a Myoelectric Prosthetic device (usually 3-5 muscle groups must be activated to use a computerized hand), no external switch; and
- Ordering physician authorizes the final prosthetic proposal

Myoelectric Prosthetic components for hand, partial-hand, and artificial digits below the wrist are considered not medically necessary in members who do not meet the criteria above.

A bone anchored percutaneous limb Prosthesis [e.g., Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA) Implant System] is unproven and not medically necessary due to insufficient evidence of efficacy.

Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Definitions

Check the federal, state, or contractual definitions that supersede the definitions below.

Activities of Daily Living (ADLs): Basic tasks people need to do to function and interact such as bathing, grooming, dressing, toilet use, eating, and physical ambulation (Mlinac and Feng, 2016, Edemekong et al., 2022).

Instrumental Activities of Daily Living (IADLs): A higher cognitive and complex activity related to independent living such as shopping, transportation, meal preparation, housecleaning, managing finances, and managing medications (Mlinac and Feng, 2016, Edemekong et al., 2022).

Myoelectric Prosthetic: A prosthetic device operated by battery-powered electric motors that are activated through electrodes by the myoelectric potentials provided by muscles (Medical Dictionary).

Prosthesis: A man-made substitute for a missing body part (American Cancer Society®).

Prosthetist: A healthcare professional who makes and fits artificial limbs (Prostheses) for people with disabilities. This includes artificial legs and arms for people who have had amputations due to conditions such as cancer, diabetes, or injury (John Hopkins Medicine).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
Upper Limb Prosthetics	
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)
L6028	Partial hand including fingers, flexible or non-flexible interface, endoskeletal system, molded to patient model, for use without external power, not including inserts described by L6692
L6029	Upper extremity addition, test socket/interface, partial hand including fingers
L6030	Upper extremity addition, external frame, partial hand including fingers
L6031	Replacement socket/interface, partial hand including fingers, molded to patient model, for use with or without external power
L6032	Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)
L6033	Addition to upper extremity prosthesis, partial hand including fingers, acrylic material
L6037	Immediate postsurgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, partial hand including fingers
L6611	Addition to upper extremity prosthesis, external powered, additional switch, any type
L6621	Upper extremity prosthesis addition, flexion/extension wrist with or without friction, for use with external powered terminal device
L6629	Upper extremity addition, quick disconnect lamination collar with coupling piece, Otto Bock or equal
L6632	Upper extremity addition, latex suspension sleeve, each
L6677	Upper extremity addition, harness, triple control, simultaneous operation of terminal device and elbow
L6680	Upper extremity addition, test socket, wrist disarticulation or below elbow
L6682	Upper extremity addition, test socket, elbow disarticulation or above elbow
L6686	Upper extremity addition, suction socket
L6687	Upper extremity addition, frame type socket, below elbow or wrist disarticulation
L6688	Upper extremity addition, frame type socket, above elbow or elbow disarticulation
L6694	Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, for use with locking mechanism
L6695	Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated from existing mold or prefabricated, socket insert, silicone gel, elastomeric or equal, not for use with locking mechanism
L6696	Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated socket insert for congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L6694 or L6695)
L6697	Addition to upper extremity prosthesis, below elbow/above elbow, custom fabricated socket insert for other than congenital or atypical traumatic amputee, silicone gel, elastomeric or equal, for use with or without locking mechanism, initial only (for other than initial, use code L6694 or L6695)
L6698	Addition to upper extremity prosthesis, lock mechanism, excludes socket insert
L6700	Upper extremity addition, external powered feature, myoelectronic control module, additional EMG inputs, pattern-recognition decoding intent movement
L6715	Terminal device, multiple articulating digit, includes motor(s), initial issue or replacement

HCPCS Code	Description
Upper Limb Prosthetics	
L6880	Electric hand, switch or myoelectric controlled, independently articulating digits, any grasp pattern or combination of grasp patterns, includes motor(s)
L6881	Automatic grasp feature, addition to upper limb electric prosthetic terminal device
L6882	Microprocessor control feature, addition to upper limb prosthetic terminal device
L6883	Replacement socket, below elbow/wrist disarticulation, molded to patient model, for use with or without external power
L6884	Replacement socket, above elbow/elbow disarticulation, molded to patient model, for use with or without external power
L6890	Addition to upper extremity prosthesis, glove for terminal device, any material, prefabricated, includes fitting and adjustment
L6925	Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, otto bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6935	Below elbow, external power, self-suspended inner socket, removable forearm shell, otto bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6945	Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, otto bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6955	Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, otto bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L6975	Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, otto bock or equal electrodes, cables, two batteries and one charger, myoelectronic control of terminal device
L7007	Electric hand, switch or myoelectric controlled, adult
L7008	Electric hand, switch or myoelectric, controlled, pediatric
L7009	Electric hook, switch or myoelectric controlled, adult
L7045	Electric hook, switch or myoelectric controlled, pediatric
L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device
L7190	Electronic elbow, adolescent, variety village or equal, myoelectronically controlled
L7191	Electronic elbow, child, variety village or equal, myoelectronically controlled
L7259	Electronic wrist rotator, any type
L7360	Six volt battery, each
L7364	Twelve volt battery, each
L7366	Battery charger, twelve volt, each
L7367	Lithium ion battery, rechargeable, replacement
L7368	Lithium ion battery charger, replacement only
L7400	Addition to upper extremity prosthesis, below elbow/wrist disarticulation, ultralight material (titanium, carbon fiber or equal)
L7401	Addition to upper extremity prosthesis, above elbow disarticulation, ultralight material (titanium, carbon fiber or equal)
L7403	Addition to upper extremity prosthesis, below elbow/wrist disarticulation, acrylic material
L7404	Addition to upper extremity prosthesis, above elbow disarticulation, acrylic material
L7406	Addition to upper extremity, user adjustable, mechanical, residual limb volume management system
L8465	Prosthetic shrinker, upper limb, each

Description of Services

A Prosthesis is an artificial device used to replace all or part of a missing body part and is intended to restore normal function. Meier and Melton (2014) identify the most common levels of amputations for the upper limb are the transradial (TR) (below elbow, BE) and the transhumeral (TH) (above elbow, AE). The Prosthesis is a tool that helps the single-limb amputee gain functional independence. Ideally, upper limb unilateral amputees should be able to accomplish things such as wearing the prosthetic during waking hours, perform basic ADLs, and return to work whenever possible.

Upper limb Prosthesis can be classified into four categories of Prostheses:

- Passive Prosthesis is the lightest of all the Prosthesis and often termed as cosmetic. It has no motors and contains limited mechanical features.
- Body-powered Prosthesis comes from the patient's movements and utilizes a body harness and strap which connects to a cable system that operates the device. Advantages include lightweight, durable, and may be waterproof; disadvantages include a required harness, strength, and range of motion capability from user.
- Externally powered Prosthesis is powered by batteries contained within the system and controlled by EMG signals, force-sensing resistors, and pull/push switches and most often reserved for high-level amputees. Advantages include little or no harnessing of the device, generate more force, and appear more cosmetic; disadvantages include battery life and daily charging, not waterproof, more complex, and therefore prone to breakage and repair.
- Hybrid Prosthesis combines body-powered components and myoelectric/externally powered components in one device. This type of Prosthesis is most commonly used by transhumeral and shoulder disarticulation amputees and reserved for high-level amputees.
  (National Academies of Sciences, Engineering, and Medicine; 2017)

Clinical Evidence

Bone Anchored Percutaneous Limb Prostheses

The available clinical evidence is insufficient to conclude that the OPRA Implant System is effective and safe due to the limited low-quality evidence and high rates of infection and mechanical complications reported in the studies.

Tereshenko et al. (2024) conducted a systematic review to assess functional outcomes, implant longevity and retention, activities of daily living (ADLs), and complications associated with osseointegrated prostheses in transhumeral (TH) amputees. The literature search yielded 794 articles, with eight of these articles (retrospective analyses and case series) meeting the inclusion criteria. Myoelectric systems equipped with Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA) implants have been commonly used as transhumeral osseointegration systems. The TH osseointegrated prostheses offered considerable improvements in functional outcomes, with participants demonstrating enhanced range of motion and improved performance of activities compared with traditional socket-based prostheses. One study demonstrated the advantage of an osseointegrated implant as a bidirectional gateway for signal transmission, enabling intuitive control of a bionic hand. The authors concluded osseointegrated prostheses hold the potential to significantly improve the quality of life for individuals with TH amputations. Continued research and clinical expansion are expected to lead to the realization of enhanced efficacy and safety in this technique, accompanied by cost reductions over time because of improved efficiencies and advancements in device design. This article presents several limitations that should be acknowledged. First, the inclusion of a small number of procedures in the study represents a significant limitation. This limited sample size may restrict the generalizability of the findings and introduce potential biases. Future studies should include larger sample sizes to strengthen the evidence base and draw more robust conclusions. Second, the use of various study designs among the included studies introduces heterogeneity, which can pose challenges in effectively comparing and synthesizing the results. The lack of standardized protocols across studies further emphasizes the need for more consistent approaches in future research to enhance the reliability of the findings. Furthermore, there is a clear predominance of myoelectric systems with OPRA implants, potentially introducing a bias toward a specific type of prosthetic system. Another limitation is the limited information regarding the overall incidence or severity of complications associated with osseointegrated prostheses. A more comprehensive assessment of complications and their management is crucial for a clearer understanding of the risks and challenges associated with this technique. Future studies should emphasize thoroughly investigating and reporting complications to facilitate informed decision-making. Additionally, future research should focus on patient-reported outcome measures to precisely evaluate the impact of osseointegrated prostheses on quality of life. Incorporating patient-reported outcome measures in studies would provide valuable insights into how the quality of life is improved with this particular type of prosthesis [authors Sabharwal et al. (2023), Stenlund et al. (2019), and Tsikandylakis et al. (2014) previously cited in this policy, are included in this systematic review].

Sabharwal et al. (2023) conducted a prospective study to assess whether select domains of the Patient-Reported Outcomes Measurement Information System (PROMIS) significantly correlate with the Disabilities of the Arm, Shoulder,

and Hand (DASH) score and the Defense and Veterans Pain Rating Scale (DVPRS) among transhumeral amputees. The authors prospectively administered DASH, DVPRS, and PROMIS (including Upper Extremity, Pain Interference, and Pain Behavior domains) testing to individuals presenting for consideration of osseointegration after transhumeral amputation with poor tolerance of conventional socket prostheses. Individuals with concurrent peripheral vascular disease, diabetes mellitus, or infection of residual limb were not eligible for consideration of osseointegration. Concurrent validity was assessed via Pearson correlation testing. The mean DASH score of the cohort was 32.8. The mean DVPRS score was 1.8. The mean PROMIS scores were 33.8, 50.5, and 50.6 for Upper Extremity, Pain Interference, and Pain Behavior domains, respectively. Pearson testing demonstrated a significant, inverse correlation between DASH and PROMIS Upper Extremity scores ($r = -0.85$, $p = .002$). There was also significant correlation between DVPRS and PROMIS Pain Interference scores ($r = 0.69$, $p = .03$). The PROMIS Pain Behavior domain did not significantly correlate with either DASH or DVPRS. The authors concluded that PROMIS Upper Extremity and Pain Interference scores demonstrated significant concurrent validity with traditional measures (DASH and DVPRS) of patient-reported outcome in this population of transhumeral amputees. In terms of limitations, the individuals selected were entirely male and had their amputations in the setting of trauma – most often combat-related blast injury. Therefore, these results may not be generalizable to other transhumeral amputees, such as those amputated in the setting of tumor resection, infection, or intractable complex regional pain syndrome. Further investigation is needed before clinical usefulness of this procedure is proven.

Ortiz-Catalan et al. (2022) conducted a follow-up study on the use of a bone-anchored, self-contained robotic arm with both sensory and motor components over 3 to 7 years in four individuals after transhumeral (TH) amputation. The implant allowed for bidirectional communication between a prosthetic hand and electrodes implanted in the nerves and muscles of the upper arm and was anchored to the humerus through osseointegration, the process in which bone cells attach to an artificial surface without formation of fibrous tissue. Use of the device did not require formal training and depended on the intuitive intent of the user to activate movement and sensory feedback from the prosthesis. In preparation for the neuromusculoskeletal interface, three patients underwent nerve transfers to extract neural signals related to the opening and closing of the hand through remnant muscles at the stump. The nerve transfers consisted of rerouting the ulnar nerve to the motor branch of the short head of the biceps muscle and rerouting the deep branch of the radial nerve to the motor branch of the lateral head of the triceps. Neuromas at the ulnar nerve and distal branch of the radial nerve were excised. The distal ends of these nerves were coapted to the ends of motor branches of the musculocutaneous and radial nerves. In the fourth patient, natively innervated biceps and triceps muscles were used for prosthetic motor control. Four to six weeks after surgery, the individuals were fitted with self-contained arm prostheses that required no external batteries, wires, or equipment in order to function and that were controlled by the epimysial electrodes. In January 2017 (one individual) and September 2018 (two individuals), electrical stimulation intended to elicit tactile perception was coupled to force sensors in the thumb of the prosthetic hand, providing graded sensory feedback during grasping of common objects. The fourth individual did not participate in follow-up after the initial fitting of the prosthesis and was therefore not provided with sensory feedback. Functional prosthetic control was assessed through evaluation of the precision with which individuals could operate their prosthesis in two tasks: the minimum increment of force that could be applied to an object by the prosthetic hand during closing (grasping force) and the minimum incremental activation of the hand during opening and closing movements (displacement). These evaluations were performed when the prosthetic hand was controlled through surface electrodes (before surgery) and again when controlled by epimysial electrodes (1 month after the prosthetic fitting). In addition, the signal-to-noise ratio of these two sources of control was measured at maximum voluntary contraction before and after incorporation of the epimysial electrodes. Sensory acuity was measured with the use of psychometric tests. All individuals used signals acquired by the implanted epimysial electrodes as the source of control for their prostheses in daily life. Because the individuals were familiar with the operation of a prosthetic hand with surface electrodes, they did not require training to use the neuromusculoskeletal interface. Myoelectric activity, recorded by the epimysial electrodes on the reinnervated muscles in Individuals 2 and 3, was observed at the first follow-up, 4 weeks after surgery, and increased in amplitude over time. Operation of the prosthetic hand was switched to these intuitive control signals between 10 and 40 weeks after surgery. Precision in prosthetic control improved in all individuals. Individual 4 did not participate in follow-up but had documented use of his neuromusculoskeletal prosthesis in daily life for 2 years 6 months. He had an episode of sepsis after minor surgery of the implant in 2018 and a local infection in 2020 that required removal of the electrodes. Sensations elicited through direct nerve stimulation were referred to the phantom hand in all individuals. The sensations were described as like a “touch by the tip of a pen” and gradually acquired a more “electric” character at higher intensity, with increased pulse frequency. Initially, Individuals could perceive a difference in the intensity of sensations when the frequency of stimulation was increased or reduced by 50%. After a month of daily use of sensory feedback, a change of approximately 30% in the frequency of stimulation could be perceived as an increase or decrease in intensity of tactile sensation. The neuromusculoskeletal interface remained functional after 3 to 7 years of use in all three patients who could be followed. Electrode impedance increased for approximately 5 months after implantation and then remained relatively stable. Individuals 1 and 3 had complete relief of phantom limb pain. Individual 2 had not had phantom limb pain before the intervention. Individual 1 has become employed full-time because of the improved functionality of the prosthesis, which has also allowed him to ski, go ice fishing, and ride a snowmobile. The preferred terminal device of Individual 2 became a myoelectric hand rather than a gripper owing to the superior control provided by

the implanted electrodes. He has been able to engage in rally-car racing and to repair cars with his neuromusculoskeletal prosthesis. Individual 3 has been able to orienteer, canoe, and ski while using his neuromusculoskeletal prosthesis. All patients reported having greater trust in their prosthesis since the intervention, referred to it as being part of themselves, and reported positive effects on their self-esteem, self-image, and social relations, although these statements were not assessed with any established measure. The authors concluded that the relevance of the work presented here is not in the number of perceived and measured sensations but in the achievement of an integrated and fully self-contained prosthesis with implanted electrodes that can be used reliably in daily life, enabling intuitive control and somatosensory feedback of the hand. The daily use resulted in increasing sensory acuity and effectiveness in work and other activities of daily life. Well designed, comparative studies with larger patient populations are needed to further describe safety and clinical outcomes.

Stenlund et al. (2019) conducted a retrospective analysis to investigate, in a population of eleven transhumeral amputees with osseointegrated implants, the load levels reached during specific prosthetic movements at maximum voluntary effort and during daily activities. Eleven test subjects with unilateral transhumeral (TH) amputations treated with Osseointegrated Limb Prostheses (OPRA Implant System, Integrum AB, Mölndal, Sweden) met the inclusion criteria and participated in the study. At inclusion, the mean time since amputation was 17.5 years (standard deviation − SD 10) and the mean time since the completion of S2 the osseointegration procedure was 9 years (SD 5.5). The subjects' mean stump length was 19 cm (SD 6.7), and their mean age was 49.4 years (SD 16.3). The data showed a wide range of maximum load levels throughout the different activities. Furthermore, the data indicate that some test subjects felt apprehensive about loading the prosthesis, resulting in relatively low loads compared with the group as a whole. The authors concluded that loading the implant system was subject specific, which resulted in large subject-to-subject variability. Moreover, some subjects exhibited uncertainty about the levels that could damage the fixation or the implant system. The study illustrates the diversity and uncertainty that exist in a population of transhumeral amputees treated with bone-anchored prostheses in terms of loading in daily life. This study was subject to limitations; the first was the number of included subjects, although both the number of treated transhumeral amputees and those of them that met the inclusion criteria were limited. Moreover, four test subjects were unable to complete the fourth part of the study protocol owing to limited time at their follow-up due to travel arrangements. The second limitation was the chosen activities which were selected from a relevance perspective and restricted to the current selection in order not to wear the subject out, to minimize the risk of the measurements affecting the true load levels. The third relates to unknown subject characteristics, specifically mass and prosthesis weight. The fourth was not being able to determine actual stress and strain levels in the tissues as mentioned above, as a result of making load measurements but not doing any modeling. Further investigation is needed before clinical usefulness of this procedure is proven.

Tsikandylakis et al. (2014) conducted a retrospective case series study to determine implant survival, adverse events, and bone remodeling of osseointegrated percutaneous implants for transhumeral (TH) amputees. This study reports on 2- and 5-year implant survival, adverse events, and radiologic signs of osseointegration and bone remodeling in TH amputees treated with osseointegrated prostheses. Between 1995 and 2010, the authors performed 18 primary osseointegrated percutaneous implants and two implant revisions in 18 TH amputees; of those, 16 individuals were available for follow-up at a minimum of 2 years (median, 8 years; range, 2-19 years). These include all TH amputees who have received osseointegrated prostheses and represented approximately 20% of all the TH amputees they evaluated for potential osseointegration during that time; general indications for this approach included TH amputation resulting from trauma or tumor, inability to wear or severe problems wearing a conventional socket prosthesis, e.g., very short residual limb, and compliant patients. Medical charts and plain radiographs were retrospectively evaluated. The 2- and 5-year implant survival rates were 83% and 80%, respectively. Two primary and one revised implant failed and were removed because of early loosening. A fourth implant was partially removed because of ipsilateral shoulder osteoarthritis and subsequent arthrodesis. The most common adverse event was superficial infection of the skin penetration site (15 infections in five patients) followed by skin reactions of the skin penetration site (eight), incomplete fracture at the first surgery (eight), defective bony canal at the second surgery (three), avascular skin flap necrosis (three), and one deep implant infection. The most common radiologic finding was proximal trabecular buttressing (10 of 20 implants) followed by endosteal bone resorption and cancellization (seven of 20), cortical thinning (five of 20), and distal bone resorption (three of 20). The authors concluded that the implant system presented a survivorship of 83% at 5 years and a 38% 5-year incidence of infectious complications related to the skin penetration site that were easily managed with nonoperative treatment, which make it a potentially attractive alternative to conventional socket arm prostheses. Osseointegrated arm prostheses have so far only been used in TH amputations resulting from either trauma or tumor. Their use has not been tested and is therefore not recommended in TH amputations resulting from vascular disease. This method could theoretically be superior to socket prostheses, especially in TH amputees with very short residual humerus in which the suspension of a conventional prosthesis is difficult. Comparative studies are needed to support its potential superiority. Moreover, the radiological findings in this study need to be followed over time because some of them are of uncertain long-term clinical relevance. This study has certain limitations. The number of patients (18) is low, and the study was retrospective. Moreover, no comparison was made between the osseointegration cohort and amputees with socket arm prostheses;

also, the study did not include any patient-reported outcomes for pain, function, and prosthetic use, which makes it difficult to make any conclusions about the superiority of one or the other method. In some instances, the patients missed their follow-up appointment resulting in potential adverse events being registered at the next follow-up. This implant system had a 2- and 5-year survival rate of 83% and 80%, respectively, in TH amputees, which appears lower than the 2-year survival rate (92%) of the same implant system in transfemoral amputees in the OPRA study. The authors believe that this difference can be explained by the higher experience of their center in transfemoral amputees and that the use of custom-designed components can increase the risk of not having optimal primary stability at implant insertion. In this retrospective study, details of attachment of the skin penetration site were not possible to evaluate thoroughly. The residual bone around the implant in TH amputees showed radiologic changes similar to those in transfemoral amputees although with some differences. Distal bone resorption in the humerus occurred to a much lesser extent than in the femur and did not result in exposure of the fixture. Proximal buttressing, which was the most common radiologic change in the humerus, also appeared differently and looked rather like uniform thickening of the bone at the proximal third and above the fixture than triangular areas as observed in the transfemoral amputees. This may be the result of the different forces that act on these areas, because the residual femur is exposed for mainly compressive forces and bending moments (walking), whereas the residual humerus is exposed for mainly tensile forces and bending moments (lifting). The latter put more loading on the distal bone and less on the proximal bone in TH amputees compared with transfemoral. To the authors' knowledge, this is the first study on implant survival, adverse events, and radiologic signs of bone remodeling in TH amputees treated with an osseointegrated percutaneous implant, reporting up to 19 years follow-up. The authors found an implant survivorship of 83% at 2 years and 80% at 5 years. The frequency of skin reactions and infectious complications related to the skin penetration site was relatively high (38% at 5 years), although most of them were not serious and were easily managed with nonoperative treatment. The authors also found a number of radiological changes that need to be followed over time because some of them have uncertain clinical relevance. Even so, they believe osseointegrated arm prostheses are a potentially attractive alternative to conventional socket prosthesis that should be considered, especially in very high TH amputations in which adequate suspension of a socket prosthesis is difficult. Osseointegrated arm prostheses have so far only been used in amputations resulting from either trauma or tumor. It is uncertain whether the implant has a similar survivorship in amputations resulting from vascular disease. The authors' approach could theoretically provide TH amputees with better comfort and a greater shoulder ROM than socket prostheses. Comparative studies are needed to support its potential superiority. Further investigation is needed before clinical usefulness of this procedure is proven.

Jönsson et al. (2011) conducted a retrospective study of osseointegration prostheses involving participants with upper limb amputations enrolled in the osseointegration program for upper extremity amputation started in Sweden in 1990, when a titanium fixture was first implanted into a thumb. The objectives of this study were to describe the osseointegration procedure for surgery, prosthetics, and rehabilitation. This method has since been used for transhumeral (TH) and below-elbow amputation. The treatment involved two surgical procedures. During the first, a titanium fixture was surgically attached to the skeleton, and a second procedure six months later involved a skin penetrating abutment to which the prosthesis was attached. Participants with short stumps and previous problems with prosthetic fitting were selected. From 1990 to April 2010, 37 upper limb cases were treated and fitted with prosthesis: 10 thumbs, 1 partial hand, 10 transradial (TR) and 16 TH amputations. Of these, 7 patients at the time of this study were not current prosthetic users. Participants indicated that function and quality of life had improved since osseointegration. The authors concluded that osseointegration is an important platform for present and future prosthetic technology. Osseointegration has the potential to change the rehabilitation strategy for selected upper limb amputees and is an important platform for introducing new prosthetic technology, due to the stable fixation. Further reports on complications and outcome data, including quality of life assessment, will enhance the clinical relevance of this new treatment concept.

Myoelectric Hand, Partial-Hand, or Artificial Digits

Olsen et al. (2024) conducted a small, sample comparison study of myoelectric prostheses with and without the wrist. This study was completed in effort to quantify task performance, compensatory movements, and cognitive load. Three transradial (TR) amputees performed a modified Clothespin Relocation Task using two myoelectric prostheses with and without the wrists. The two myoelectric prostheses included a commercial prosthesis with a built-in powered wrist, and a newly developed inexpensive prosthetic wrist for research purposes, called the "Utah wrist", that can be adapted to work with various sockets and prostheses. For these three participants, task failure rate decreased from 66% ±12% without the wrist to 39% ±9% with the Utah wrist. Compensatory forward leaning movements also decreased from 24.2° ±2.5 without the wrist to 12.6° ±1.0 with the Utah wrist, and from 23.6° ±7.6 to 15.3° ±7.2 with the commercial prosthesis with an integrated wrist. Compensatory leftward bending movements also decreased from 20.8° ±8.6 to 12.3° ±5.3, for the commercial with an integrated wrist. The authors concluded that simultaneous myoelectric control of either prosthetic wrist had no significant impact on cognitive load, as assessed by the NASA Task Load Index survey and a secondary detection response task. This work suggests that functional prosthetic wrists can improve dexterity and reduce compensation without significantly increasing cognitive effort. These results, and the introduction of a new inexpensive prosthetic wrist for research purposes, can aid future research and development and guide the prescription of upper-limb prostheses.

Limitations include a small sample size which makes it difficult to decide whether these conclusions can be generalized to a larger population. The findings of this study need to be validated by well-designed studies before clinical usefulness of this prosthesis is proven.

A 2024 ECRI clinical evidence assessment on MyoPro 2+ (Myomo, Inc.) orthosis intended to support and move a weak limb in patients aged 12 years or older with long-term muscle weakness or partial paralysis. MyoPro 2+ uses noninvasive electromyography (EMG) to sense signals from a patient's nerves and coverts the EMG signals into orthosis motion to help complete the desired movement. ECRI concludes there are no published studies available that specify MyoPro 2+ use. Evidence from four small case series, two observational cohort studies, and two case series that report primarily on the MyoPro Motion-G suggests that use of this version improves motor control and function in patients with long-term muscle weakness and paralysis; however, the evidence is too limited in quantity and quality to be conclusive or determine how it compares with other therapies intended to improve arm and hand impairment.

Findings from a 2023 Hayes evidence analysis research brief on the Utah Arm (Fillauer Motion Control) for nonfunctional or missing upper extremities states there is currently not enough published peer-reviewed literature to evaluate the evidence related to the Utah Arm for nonfunctional or missing upper extremities in a full assessment. Based on a review of full-text clinical practice guidelines and position statements, guidance appears to confer weak support for use of externally powered prostheses in patients with major unilateral upper limb amputation.

Findings from a 2023 Hayes evidence analysis research brief on myoelectric multigrip prosthetic hands for upper extremity amputation states based on a review of full-text clinical practice guidelines and position statements, guidance appears to confer no/unclear support for myoelectric multigrip prosthetic hands for use in upper extremity amputation.

Kerver et al. (2023) compared the multi-grip myoelectric hand prosthesis (MHP) to that of a standard myoelectric hand prostheses (SHP) in all categories of the International Classification of Functioning, Disability, and Health-model (ICF-model). Thirty-three participants met the inclusion criteria. The nineteen members of the SHP group utilized a Myohand Variplus Speed (Ottobock; Duderstadt, Germany) or Motion Control Hand (Fillauer, USA), which has a movable thumb, index finger, and middle finger that can open and close in only one grip. The fourteen participants in the MHP group were in possession of a myoelectric prosthesis and consisted of one of the following: i-Limb Quantum/Ultra (Touch Bionics; Livingston, United Kingdom), BeBionic (Ottobock; Duderstadt, Germany) or VINCENT (Vincent Systems, Karlsruhe, Germany). Comparisons in joint coordination, dexterity, and prosthetic hand function were analyzed; in addition, comparisons on user experience, satisfaction and quality of life were performed. This study had a cross-over design which consisted of two parts: between-group comparison using questionnaires and/or scales and within group comparison based on physical measurements. The authors found no clear benefit for MHP devices when compared to SHP; the SHP outperformed the MHP in several outcome measures. The authors concluded with the expense and cost of repairs, a prescription for MHP should be carefully assessed. Limitations included small sample sizes, lack of randomization, and assumptions with users and their experience for device controls.

Widehammar et al. (2022) published the results of a single case study evaluating the effect of multi-grip myoelectric prosthetic hands-on performance of daily activities, pain-related disability, and prosthesis use, in comparison with single-grip myoelectric prosthetic hands. Nine adults with upper-limb loss participated in the study and all had previous experience of single-grip myoelectric prostheses and were prescribed a prosthesis with multi-grip functions. Both a single-baseline (for ACMC and SHAP data) and a multiple baseline single-case AB design was used. At 6 months' follow-up self-perceived performance and satisfaction scores had increased, prosthesis wearing time had increased, and pain-related disability had reduced in participants with musculoskeletal pain at baseline. The authors concluded that the multi-grip myoelectric prosthetic hand has favorable effects on performance of, and satisfaction with, individually chosen activities, prostheses use and pain-related disability. A durable single-grip myoelectric prosthetic hand may still be needed for heavier physical activities. With structured training, a standard 2-site electrode control system can be used to operate a multi-grip myoelectric prosthetic hand. However, the authors summarized that there may be a mismatch between the patients' wish for better prosthetic devices and their actual use of the new devices. Current knowledge is inconclusive and further studies are needed to support rehabilitation clinicians in their prescription decisions.

A 2021 health technology assessment by Hayes (updated 2023) found a very low-quality body of evidence that suggests the LUKE arm (referred to as the DEKA arm in many studies) appears to be safe and may allow some patients to perform certain ADLs, but not all. Some ADLs were more manageable with the patient's existing prosthesis; however, the limited evidence suggests inconsistent improvement on functional measures when compared to their existing prosthesis. Future studies which include larger sample sizes and long-term follow-up are needed to further compare the safety and efficacy of this device.

Resnik et al (2020) conducted a telephonic survey for 755 veterans with a prosthetic for upper limb amputation; 306 patients had no prosthesis, 325 had a body-powered device, 62 had a myoelectric or hybrid single-DOF terminal device and 22 utilized cosmetic devices. Overall, 35.8% had below elbow amputation, 30.9% above elbow, 16.4% wrist disarticulation, 9.1% shoulder disarticulation, 4.9% elbow disarticulation, and 2.9% forequarter amputation. The survey included scores from the Disabilities of the Arm, Shoulder, and Hand (QuickDASH), the Physical Component Summary (PCS) and the Mental Component Summary (MCS) score of the Veterans RAND 12-item Health Survey (VR-12) measured HRQOL. The authors found those veterans without a prosthesis reported more difficulty in activities, greater disability and more likely to need help with ADLs than those with any type of prothesis. However, the author did not find any differences observed between body-powered and myoelectric devices when it came to needing assistance with ADLs, self-reported disability, or quality of life. Limitations included study design, lack of randomization, disproportionate groups, varying amount of training and experience with prosthetic use, and self-reported data.

Wanamaker et al. (2019) reported the results of a cross-sectional study evaluating upper limb function and kinematics in 10 males with partial-hand amputations fitted with a partial-hand prosthesis. Three-dimensional kinematics were compiled as they performed the Southampton Hand Assessment Procedure (SHAP) with and without a prosthesis. Without a prosthesis, larger joint movements were noted. There was significant improvement for the individuals with a five-digit limb loss using a prosthesis seen in the SHAP scores in comparison with those not using a prosthesis ($p < 0.05$ for 6 of 7 SHAP score categories). The authors concluded the prosthesis reduced functional deficits and decreased joint range of motion in individuals with partial hand loss which may reduce the overuse injury risk.

Validated performance-based outcome measures for upper limb (UL) prosthesis users are sparse and may not adequately address all necessary aspects of functional restoration. Wang et al. (2018) evaluated and compared the following characteristics of performance-based outcome measures for UL function: (1) location of task performance around the body, (2) possible grips employed, (3) bilateral versus unilateral task participation, and (4) details of the scoring mechanisms, including subjectivity, assessment of sensation, and assessment of quality of motion (QoM). A literature search was conducted using the EMBASE, Medline, and Cumulative Index to Nursing and Allied Health electronic databases from 1970 to June 2015 to identify relevant clinical studies that used UL performance-based outcome measures as functional endpoints; a final list of 7 articles was found. Inclusion criteria included one or more outcome measures that were developed for amputees or individuals with neurologic/musculoskeletal impairments or disabilities of the UL, were intended to measure the functional restoration/ improvements through a series of activities or tasks and were intended for use in the adult population. For each identified outcome measured, specific characteristics were obtained: areas around the body in which tasks are performed; the types of grips that a user could possibly employ; bilateral versus unilateral task participation; and the subjectivity and details of the scoring mechanisms, with a particular focus on the assessment of sensation and quality of motion (QoM) (QoM was defined as any consideration of how a movement was performed). The authors suggested utilization or modification of existing measures designed for other clinical populations as first steps to more aptly measure prosthesis use while more complete assessments for UL prosthesis users are developed.

Resnik et al. (2018) conducted a two-part study on the Gen 3 DEKA arm when compared to conventional prosthesis. Part A consisted of laboratory training and part B addressed home training; 23 participants completed part A and then a subset (15) went on to complete part B. Participants in part A were at least 18 years old and had an upper limb amputation at the transradial, transhumeral, shoulder disarticulation or scapulothoracic level; participants were eligible for part B of the study if they had at least fair functional use of the DEKA Arm. The device includes 3 available configurations: radial configuration (RC) for persons with radial amputation; humeral configuration (HC) for persons with humeral amputation; and shoulder configuration (SC) for persons with shoulder disarticulation, forequarter amputation or very short transhumeral amputation. Unique features of all configuration levels are the powered wrist which allows flexion and extension and six programmable hand grip patterns. Performance based measures included a dexterity measure, the Jebsen-Taylor Hand Function Test (JTHFT), and measures of activity performance [Activities Measure for Upper Limb Amputees (AM-ULA); University of New Brunswick Test of Prosthetic Function for Unilateral Amputees (UNB); Timed Measure of Activity Performance (T-MAP), and Brief Activity Measure for Upper Limb Amputees (BAM-ULA)]. Each of the performance measures assess performance of daily activities but differ significantly in the scoring criteria and item content. For example, the T-MAP assesses the time it takes to perform an activity, while the AM-ULA assesses body compensation during activity performance. A variety of self-reported measures were completed as well. Upon completion of the data analysis for both performance and self-reported measures, the authors found at the end of part A participants using the DEKA arm had less perceived disability and more engagement in everyday tasks, but their activity performance was slower. However following completion of part B, participants perceived disability was lower, prosthesis engagement higher, activity performance was improved, and activity speed was equivalent to using a conventional prosthesis. It was also noted that the authors found no differences between the DEKA Arm and conventional prostheses in evaluation of dexterity, prosthetic skill, spontaneity, community integration or quality of life. Limitations included small sample size and participant experience with previous generations of DEKA.

Earley et al. (2016) developed a training protocol and a classifier that switches between long and short EMG analysis window lengths. A study involving 17 non-amputee, and 2 partial-hand amputee subjects participated to determine the effects of including electromyogram (EMG) from different arm and hand locations during static and/or dynamic wrist motion. Several real-time classification techniques were evaluated to determine which control scheme yielded the highest performance in virtual real-time tasks using a three-way analysis of variance (ANOVA). The outcome identified significant interaction between analysis window length and the number of grasps available. Including static and dynamic wrist motion and intrinsic hand muscle EMG with extrinsic muscle EMG significantly reduced pattern recognition classification error by 35%. Classification delay or majority voting techniques significantly improved real-time task completion rates (17%), selection (23%), and completion (11%) times, and selection attempts (15%) for non-amputee subjects, and the dual window classifier significantly reduced the time (8%) and average number of attempts required to complete grasp selections (14%) made in various wrist positions. Amputee subjects demonstrated improved task timeout rates, and made fewer grasp selection attempts, with classification delay or majority voting techniques. The authors concluded that the proposed techniques show promise for improving control of partial-hand prostheses and more effectively restoring function to individuals using these devices.

Carey et al. (2015) conducted a systematic review to identify evidence statements regarding the differences between myoelectric (MYO) and body-powered (BP) prosthesis in persons with upper limb amputations. A search was conducted using PubMed, CINAHL, RECAL Legacy, Cochrane Database of Systematic Reviews, Cochrane Clinical Trials Registry, EMBASE, PMC-NIH Research Publication Database, Web of Science, and Google Scholar. A total of 31 articles were found which spanned from 1993 to 2013, with most of the publications occurring in 2012. The median subject size was 12 and average age of participants was 43.3 years. Twenty-four articles were experimental or observational along with expert opinions in six publications which were therefore given a low quality of evidence. Device assessments fell into three categories with surveys being the most common in 12 of the 24 relevant articles; other assessments included laboratory and clinical functional assessments and ability to use ADLs. Eleven empirical evidence statements (EES) were created based on the following areas of interest: functionality, control, and feedback, cosmesis and psychosocial issues, and rejection. The EES were then divided into the following five categories: activity/sport specific, body-powered, control, myoelectric, and rejection rates. The authors found conflicting information in terms of the relative functional performance of BP and MYO prostheses. BP prostheses have advantages in training time, durability, and frequency in adjustments, measurements, and feedback. MYO prostheses have been shown to provide a cosmetic advantage, are more accepted for light-intensity work, and may have a positive effect on the patient's phantom limb pain. Study limitations included low number of controlled experiments and high number of observational studies.

Due to few measures developed for or validated with adults, and limited research to guide, Resnik et al. (2013) found it is a challenge to collect or analyze data outcomes for persons with upper limb amputation. The authors identify a need for new function tests for adult amputees, as well as new measures for use with higher-level amputees, bilateral amputees, and body-powered users. 52 patients with upper limb amputation were evaluated. A set of activities from the Atkins activities of daily living checklist were identified and a simple grading scale was used. Therapists were oriented to the measures and asked each patient some basic instructions with their prosthetic limb and then their sound limb. Videotaping of sessions occurred and then adjustments for scoring were made. Final scoring criteria was comprised of the following: "(1) extent of completion of all activity subtasks; (2) speed of completion; (3) movement quality; (4) skillfulness of prosthetic use and control over voluntary grip functions; and (5) independence." The authors developed and refined a new performance-based activity identified as Activities Measure for Upper Limb Amputees (AM-ULA) and demonstrated that the measure has acceptable reliability, consistency and known group validity.

Egermann et al. (2009) conducted a retrospective study on forty-one children (< six years of age) to evaluate the acceptance of myoelectric prostheses in preschool children. All patients suffered from a unilateral congenital upper limb deficiency or traumatic upper limb amputation; patients with bilateral amputations were excluded. Most of the children in the study received a passive device at the age of approximately one year. For the patient to be fitted with a myoelectric prosthesis, the following inclusion criteria needed to be met: 1) communicates well and follows instructions from strangers, 2) bi-manual handling and proactive interest in an artificial limb, and 3) family support for the child in using the myoelectric device. The myoelectric prosthesis was identical for all patients. A socket was manufactured using the "Muenster" technique and a single electrode which controlled the opening of the hand while closing automatically was placed. The "Elektrohand 2000" from Germany was used and powered by a six-volt rechargeable battery. Specialized occupational therapists made the initial introduction of the device to the children; structured training at the hospital occurred over one to two weeks by an interdisciplinary team. Families were asked to complete a specific questionnaire which included items such as information about internal/external occupational training, skin irritations at the stump, and activities of daily life. Successful use of the device was defined by daily wearing it for more than two hours per day. Over an observation period of two years, 76% of the study group was successful with the device. The actual mean time of daily use was 5.8 ±4.1 hours/day. The authors found children between two and four years of age (n = 23) showed a higher average time of daily use when compared to the older subgroup of patients in the four to six years of age (n = 18); in addition, they also found

above elbow amputees wore the device more often than children with below elbow amputations. It was concluded under the right conditions the application of a myoelectric hand prosthesis in a young child can be very successful; family involvement was a major key factor in the child's success. Limitations of the study included the small number of participants, weight of the prosthesis and low battery life span.

Crandall and Tomhave (2002) retrospectively evaluated 34 pediatric patients for long-term follow-up on a variety of prosthetic options given for below-elbow amputees. The patients were provided with a variety of prosthetic options, including a "passive" cosmetic upper extremity device. Most of the patients were fitted with conventional prostheses using a body-powered voluntary closing terminal device (97%) as well as myoelectric prostheses (82%). The average follow-up was 14 years, with many of the patients being followed up throughout their entire childhood. All patients were sent questionnaires, and patient interviews and chart review were completed. Final analysis indicated that 15 patients (44%) selected a simple cosmetic "passive hand" as their prosthesis of choice. In long-term follow-up 14 patients (41%) continued as multiple prosthetic users. Fourteen patients (41%) selected the conventional prosthesis using a voluntary closing terminal device as the prosthesis of choice. Only five patients (15%) selected the myoelectric device as their primary prosthesis. The authors concluded that successful unilateral pediatric amputees choose multiple prostheses based on function and that often the most functional prosthesis selected in the long-term was the simplest one in design. The authors felt strongly that unilateral pediatric amputees be offered a variety of prosthetic options to help with normal ADLs. Limitations included small sample size and focus on pediatric population.

Clinical Practice Guidelines

Department of Veterans Affairs (VA)/Department of Defense (DoD)

In a VA/DoD 2022 Clinical Practice Guideline for rehabilitation of individuals with lower limb amputation, the following is recommended:

- Pre-Prosthetic Training Recommendation:
  - The care team should ensure that patients undergo pre-prosthetic training to help determine the most appropriate type of device to achieve functional goals (Expert Opinion).
  - A comprehensive assessment should be conducted by the care team to determine the most appropriate types of prostheses to prescribe along with educating the patient and/or caregiver(s) on the various types of available prostheses.
  - Components of a comprehensive assessment include:
    - Present health status
    - Level of function
    - Modifiable/controllable health risk factors
    - Pain assessment
    - Cognition and behavioral health
    - Personal, family, social, and cultural context
    - Learning assessment
    - Residual limb assessment
    - Non-amputated limb and trunk assessment
    - Prosthetic assessment (if applicable)
    - Vocational assessment
- Prosthesis Prescription:
  - Once the appropriate type of prosthesis is identified, the care team should write a prescription for the device, including all necessary components (Expert Opinion).
    - Prescriptions for upper extremity prostheses should be based on a collaborative decision between the patient and the care team. Input should be received from all members of the care team and individualized for the patient based on the patient's specific needs and goals related to prosthesis use. Components for an upper extremity prosthesis should include:
      - Design (e.g., preparatory vs. definitive)
      - Control strategy (e.g., passive, externally powered, body powered, task specific)
      - The anatomical side and amputation level of the prosthesis
      - Type of socket interface (e.g., soft insert, elastomer liner, flexible thermoplastic)
      - Type of socket frame (e.g., thermoplastic or laminated)
      - Suspension mechanism (e.g., harness, suction, anatomical)
      - Terminal device
      - Wrist unit (if applicable)
      - Elbow unit (if applicable)
      - Shoulder unit (if applicable)

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Prostheses are class I devices exempt from U.S. Food and Drug Administration (FDA) review. For additional information, use product codes: GXY, IQZ.

In 2014, the DEKA Arm System was cleared for marketing by FDA through the de novo 513(f)(2) classification process which is a low- to moderate-risk medical device. Refer to the following website for additional information:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN120016 (Accessed November 6, 2024)
- https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN120016.pdf (Accessed November 6, 2024)

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Policy History/Revision Information

Date	Summary of Changes

06/01/2025	**Application**
	Idaho and ***Kansas***
	• Added language to indicate this Medical Policy does not apply to the states of Idaho and Kansas; refer to the state-specific policy versions
	Coverage Rationale
	• Added language to indicate a bone anchored percutaneous limb Prosthesis [e.g., Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA) Implant System] is unproven and not medically necessary due to insufficient evidence of efficacy
	Medical Records Documentation Used for Reviews
	• Added language to indicate:
	  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
	  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews
	Definitions
	• Removed definition of "Medically Necessary"
	Applicable Codes
	• Updated list of applicable HCPCS codes to reflect quarterly edits:
	  ○ Added L6028, L6029, L6030, L6031, L6032, L6033, L6037, L6700, and L7406
	  ○ Revised description for L6698
	Supporting Information
	• Updated *Clinical Evidence* and *References* sections to reflect the most current information
	• Archived previous policy version CS360.B

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.