Upper Extremity Prosthetic Devices (for Indiana Only)

Policy Number: CS360IN.03
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➲ Instructions for Use

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Related Policies
None

Application

This Medical Policy applies to Medicaid only plans in the state of Indiana.

Coverage Rationale

State-Specific Criteria

- For coverage criteria, refer to the Indiana Health Coverage Programs: Bulletin BT2025171.
- For coverage guidelines for prosthetic devices and medical necessity clinical coverage criteria for myoelectric upper extremity prosthetics, refer to the Indiana Health Coverage Programs, Provider Reference Module: Durable and Home Medical Equipment and Supplies.

Non–State-Specific Criteria

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 the 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 have been evaluated for the member by a physician, health care professional, or another licensed practitioner of the healing arts acting within the scope of practice authorized under State law, with appropriate prosthetic qualifications and training under the supervision of the ordering physician annually; 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] evaluation

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

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 services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

Definitions

Activities of Daily Living: Basic tasks people need to do to function and interact such as bathing, grooming, dressing, toileting, eating, and physically ambulating (Mlinac and Feng, 2016; Edemekong et al., 2022).

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

Myoelectric Prosthetic: A prosthetic device controlled by electromyographic (EMG) signals created in the residual musculature, which are picked up by electrodes housed within the prosthetic socket (Chadwell et al., 2016).

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

Prosthetist: A health care 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 (Johns 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
L6034	Partial hand, finger, and thumb prosthesis without prosthetic digit(s)/thumb, amputation at transmetacarpal level, including flexible or non-flexible interface, molded to patient model, for use without external power and/or passive prosthetic digit/thumb, not including inserts described by L6692

HCPCS Code	Description
Upper Limb Prosthetics	
L6035	Single prosthetic digit, mechanical, can include metacarpophalangeal (MCP), proximal interphalangeal (PIP), and/or distal interphalangeal (DIP) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement
L6036	Prosthetic thumb, mechanical, can include metacarpophalangeal (MCP), interphalangeal (IP) joint(s), with or without locking mechanism, can include flexion or extension assist, any material, attachment, initial issue or replacement
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
L6038	Addition to single prosthetic digit or thumb, mechanical, attachment, multiaxial and/or internal/external rotation/abduction/adduction mechanism, with or without locking feature, any material
L6039	Passive prosthetic digit or thumb prosthesis not including hand restoration partial hand, full or partial, custom made, any material, initial or replacement, per single passive prosthetic digit or thumb
*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
*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

HCPCS Code	Description
Upper Limb Prosthetics	
*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

Note: Codes labeled with an asterisk (*) are not managed for medical necessity review for the state of Indiana at the time this policy became effective. Refer to the most up to date prior authorization list for Indiana at Prior Authorization and Notification: UnitedHealthcare Community Plan of Indiana.

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 as the transradial

(below elbow) and the transhumeral (above elbow). 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, performing basic Activities of Daily Living, and returning to work whenever possible.

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

- Passive Prosthesis is the lightest of all Prostheses and often termed as cosmetic. It has no motors and contains limited mechanical features.
- Body-powered Prosthesis comes from the individual's movements and uses a body harness and strap, which connects to a cable system that operates the device. Advantages include that it is lightweight and durable and may be waterproof; disadvantages include a required harness, strength, and range-of-motion capability from the user.
- Externally powered Prosthesis is powered by batteries contained within the system; controlled by electromyographic signals, force-sensing resistors, and pull/push switches; and most often reserved for high-level amputees. Advantages include that little or no harnessing of the device is required, it generates more force, and it appears more cosmetic. Disadvantages include that it has a short battery life and requires daily charging, it is not waterproof, and it is more complex. Therefore, it is 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 Osseointegrated Prostheses for the Rehabilitation of Amputees (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 OPRA implants have been commonly used as TH osseointegration systems. The TH osseointegrated prostheses offered considerable improvements in functional outcomes, with individuals demonstrating enhanced range of motion and improved performance of activities compared with those 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 that osseointegrated prostheses hold the potential to significantly improve the quality of life in individuals with TH amputations. Continued research and clinical expansion are expected to lead to the realization of enhanced efficacy and safety of 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 Defense and Veterans Pain Rating Scale (DVPRS) among TH amputees. The authors prospectively administered the DASH, DVPRS, and PROMIS (including Upper Extremity, Pain Interference, and Pain

Behavior domains) testing to participants presenting for consideration of osseointegration after TH amputation with poor tolerance of conventional socket prostheses. Participants with concurrent peripheral vascular disease, diabetes, or infection of the residual limb were not eligible for consideration of osseointegration. Concurrent validity was assessed via Pearson correlation testing. The mean DASH score in 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 ($r = -0.85$; $p = 0.002$). A significant correlation between DVPRS and PROMIS Pain Interference scores ($r = 0.69$; $p = 0.03$) was also observed. The PROMIS Pain Behavior domain did not significantly correlate with either the 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 outcomes in this population of TH amputees. In terms of limitations, the entirety of participants selected were male and had their amputations in the setting of trauma, which was most often combat-related blast injury. Therefore, these results may not be generalizable to other TH amputees, such as those amputated in the setting of tumor resection, infection, or intractable complex regional pain syndrome. Further investigation is needed before the 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 participants after 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 participants 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 participant, natively innervated biceps and triceps muscles were used for prosthetic motor control. Four to 6 weeks after surgery, the participants 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 participant) and September 2018 (two participants), 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 participant 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 participants 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 participants used signals acquired by the implanted epimysial electrodes as the source of control for their prostheses in daily life. Because the participants 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 participants 2 and 3, was observed at the first follow-up and 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 participants. Participant 4 did not participate in follow-up but had documented use of his neuromusculoskeletal prosthesis in daily life for 2 years and 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 participants. The sensations were described as a “touch by the tip of a pen” and gradually acquired a more “electric” character at a higher intensity, with increased pulse frequency. Initially, participants could perceive a difference in the intensity of sensations when the frequency of stimulation was increased or reduced by 50%. After 1 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 the intensity of tactile sensation. The neuromusculoskeletal interface remained functional after 3 to 7 years of use in all three participants who could be followed up. Electrode impedance increased for approximately 5 months after implantation and then remained relatively stable. Participants 1 and 3 had complete relief of phantom limb pain. Participant 2 did not have phantom limb pain before the intervention. Participant 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 for participant 2 became a myoelectric hand rather than a gripper due to the superior control provided by the implanted electrodes. He has been

able to engage in rally-car racing and repair cars with his neuromusculoskeletal prosthesis. Participant 3 is able to orienteer, canoe, and ski while using his neuromusculoskeletal prosthesis. All participants 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; however, 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 participant populations, are needed to further describe safety and clinical outcomes.

Stenlund et al. (2019) conducted a retrospective analysis to investigate, in a population of 11 TH amputees with osseointegrated implants, the load levels reached during specific prosthetic movements at maximum voluntary effort and during daily activities. Eleven patients with unilateral 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 (SD, 10 years), and the mean time since the completion of Stage 2 of the osseointegration procedure was 9 years (SD, 5.5 years). The patients' mean stump length was 19 cm (SD, 6.7 cm), and their mean age was 49.4 years (SD, 16.3 years). The data showed a wide range of maximum load levels throughout the different activities. Furthermore, the data indicate that some patients felt apprehensive about loading the prosthesis, resulting in relatively low loads compared with those in the group as a whole. The authors concluded that loading the implant system was patient specific, which resulted in large patient-to-patient variability. Moreover, some patients had 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 TH amputees treated with bone-anchored prostheses in terms of loading in daily life. This study is subject to limitations; the first is the number of included patients, although both the number of treated TH amputees and those of them who met the inclusion criteria were limited. Moreover, four patients were unable to complete the fourth part of the study protocol due to limited time at their follow-up due to travel arrangements. The second limitation is the chosen activities, which were selected from a relevance perspective and restricted to the current selection to not wear the patient out, with the aim of minimizing the risk of the measurements affecting the true load levels. The third relates to unknown patient characteristics, specifically mass and prosthesis weight. The fourth is not being able to determine actual stress and strain levels in the tissues, as mentioned above, because of making load measurements but not performing any modeling. Further investigation is needed before the 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 TH amputees. This study reports on 2- and 5-year implant survival, adverse events, and radiological 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 them, 16 patients were available for follow-up at a minimum of 2 years (median, 8 years; range, 2-19 years). These include all TH amputees who had received osseointegrated prostheses and represented approximately 20% of all the TH amputees 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 adherent 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 radiological 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, making this 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 a 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) was 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 2- and 5-year survival rates of 83% and 80%, respectively, in TH amputees, which appear lower than the 2-year survival rate (92%) with 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 could not be evaluated thoroughly. The residual bone around the implant in TH amputees showed radiological changes similar to those in transfemoral amputees, although some differences were observed. 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 radiological 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 amputees. To the authors' knowledge, this is the first study on implant survival, adverse events, and radiological signs of bone remodeling in TH amputees treated with an osseointegrated percutaneous implant, which reports up to 19 years of 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 these complications were not serious and 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 that 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 greater shoulder range of motion than socket prostheses. Comparative studies are needed to support its potential superiority. Further investigation is needed before the clinical usefulness of this procedure is proven.

Jönsson et al. (2011) conducted a retrospective study of osseointegration prostheses involving patients with upper limb amputations enrolled in the osseointegration program for upper extremity amputation started in Sweden in 1990, during which 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 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 6 months later involved a skin-penetrating abutment to which the prosthesis was attached. Patients 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 prostheses: 10 thumbs and one partial hand as well as 10 transradial and 16 TH amputations. Of these patients, seven at the time of this study were not current prosthetic users. Patients 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.

Clinical Practice Guidelines

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

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

- Preprosthetic training recommendation:
  - The care team should ensure that patients undergo preprosthetic 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 education for 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
        - Nonamputated 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, 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 FDA review. For additional information, use product codes GXY, IQZ.

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

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id = DEN120016
- https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN120016.pdf

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Policy History/Revision Information

Date	Summary of Changes
06/01/2026	• New Medical Policy

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, 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.