Anthem

Medical Policy

Subject: Osseointegrated Limb Prostheses
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Description/Scope

This document addresses the use of osseointegrated (bone-anchored) prosthetic devices for improving the mobility and function of people who have had limb loss. A prosthetic device can play an important role in rehabilitation when an upper or lower extremity is lost. The standard type of device used after limb loss is a socket-type prosthesis. The use of a bone-anchored prosthetic device such as the Osseointegrated Prostheses for the Rehabilitation of Amputees system (OPRA™, Integrum, Mölndal, Sweden) has been proposed as an alternative.

Note: This document does not address other types of limb prostheses. Please see the following related documents for additional information on limb prostheses:

- CG-DME-13 Lower Limb Prosthesis
- CG-OR-PR-08 Microprocessor Controlled Lower Limb Prosthesis
- CG-OR-PR-05 Myoelectric Upper Extremity Prosthetic Devices

Position Statement

Medically Necessary:

Osseointegrated limb prostheses are considered **medically necessary** for individuals with transfemoral, transtibial, transhumeral, or forearm amputations when **all** of the criteria set forth in (A) and (B) below have been met:

A. Selection criteria:
   1. Individual is skeletally mature; **and**
   2. Has normal skeletal anatomy; **and**
   3. Is between 18 years old and 70 years old; **and**
   4. Does not have diabetes; **and**
   5. Does not have peripheral vascular disease; **and**
   6. Does not have metabolic bone disease (for example, osteoporosis with T score ≤ -2.5); **and**

B. Documentation and performance criteria:
   1. Cannot tolerate or use a conventional socket-type prosthesis (that is, there is documentation of problems that prohibit functional prosthetic use, including but not limited to: frequent or recurrent skin infections, ulcerations, severe pain, frequent physiological changes in residual limb, pistoning not corrected with adjustments of prosthetic sockets, inadequate limb length or musculature, excessive and uncontrolled perspiration); **and**
   2. Has a multidisciplinary treatment team comprised of, at minimum, a surgeon, a physiatrist, and a prosthetist who attest that the individual:
      a. Understands the use and risks of the osseointegrated prosthetic system; **and**
      b. Is likely to be able to comply with the system's requirements.

Not Medically Necessary:

Osseointegrated limb prostheses are considered **not medically necessary** when the criteria above are not met, and for all other indications.

Rationale

Most individuals with limb amputations are fitted with a prosthesis that uses a socket suspension system to keep the residual limb connected to the prosthesis. The prosthetic socket is the primary and critical interface between the amputee's residual limb and the rest of the prosthesis (Paternò, 2018). It is essential for the socket to be well designed and fitted to achieve a comfortable and functional prosthesis with proper load transmission, stability, and control. Socket-related problems such as poor fit, poor biomechanics, and reduced control are significant reasons why some individuals with amputations stop wearing their prostheses. In addition, many users of socket prostheses experience sweating, sores or skin irritation, pain in the residual limb, and other problems related to the fit of the socket that negatively affect their mobility and quality of life. Due to these issues, the socket prosthesis abandonment rate has been estimated at approximately 25-57%.

Osseointegration has been suggested as an alternative for individuals with limb amputations who cannot tolerate traditional socket prostheses. With osseointegration, a metal implant is anchored into the existing bone so that the prosthesis can be directly attached to the skeleton. Besides eliminating socket-related problems, osseointegration is proposed to improve functionality, range of motion and strength of the limb, as well as enhance proprioception.

The OPRA implant system received pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA) in 2020. The OPRA system consists of three main components: the fixture, the abutment, and the abutment screw. Installation of the system requires two operations 6 months apart, followed by rehabilitation. The first operation involves insertion of the fixture into the residual bone. The second operation involves insertion of the abutment which penetrates through the skin into the implant and is secured with the abutment screw.

A prospective, single-center, non-randomized cohort study of 51 individuals with transfemoral amputations provided the clinical data supporting the FDA approval (Brånemark, 2014; Brånemark, 2019; Hagberg, 2020). Key inclusion criteria were individuals aged 20-70 years with current or expected problems with a conventional prosthesis, or inability to use a prosthesis, full skeletal maturity, normal residual skeletal anatomy, suitability for surgery, and likeliness to comply with treatment and follow-up requirements. Key exclusion criteria were severe peripheral vascular disease, diabetes mellitus, skin disease involving the amputated limb, or other diseases that

could adversely affect the treatment. The main reasons for amputation were trauma and malignant tumor. On entry to the study, 42 of 51 individuals were using conventional socket prostheses. Of the 9 individuals who did not use a prosthesis, 8 had been unable to obtain a comfortable prosthesis and 1 had a very short amputation stump.

Functional outcome and health-related quality of life were assessed using two self-report questionnaires, the Questionnaire for Persons with a Transfemoral Amputation (Q-TFA) and the Short-Form (SF)-36 at 3, 6, 12, and 24 months after the final implantation procedure (Brånemark, 2014). At 2 years of follow-up, the Q-TFA showed improved prosthetic use, mobility, and fewer problems (all $p<0.001$). Physical function scores on the SF-36 were also improved ($p<0.001$). The most frequent complication was superficial infection, occurring 41 times in 28 individuals (rate of infection 54.9%). In 4 individuals, the implant was removed due to loosening (3 aseptic, 1 infection). At 5 years of follow-up (Brånemark, 2019), the cumulative fixture survival rate was 92%, and the revision-free survival rate was 45%. A total of 34 individuals had 70 superficial infections; 11 individuals had 14 deep infections. Mechanical complications were observed in 15 individuals. The authors concluded that although patient-reported outcome measures (PROMs) improved significantly, deep infections and mechanical complications were of concern.

Hagberg and colleagues (2020) reported results of a 15-year follow-up study of a cohort of 111 transfemoral amputees treated with the OPRA implant system. The survival rate of the fixture was 72% after 15 years. A total of 61 individuals (55%) had mechanical complications resulting in a change of the abutment or abutment screw, while 21 individuals (19%) had six or more events. The mean number of these mechanical complications per individual was 3.3 (SD 5.76). Mechanical complications were more common in individuals with a higher activity grade. Complications due to infection were not considered in this study. The Q-TFA scores at up to 10 years showed significantly more prosthetic use, better mobility, fewer problems, and an improved global situation, compared with baseline. At 15 years, the problem scores and global scores were significantly improved but there were no differences in other areas, possibly due to the reduced number of participants assessed. However, the authors concluded that the number of mechanical complications was a concern and that it will be necessary to “improve both the material properties of the implant, as well as to consider restrictions in the physical activity of this group of patients.”

In 2017, Tillander and colleagues reported the osteomyelitis risk in individuals with transfemoral amputations treated with osseointegration prostheses. In a group of 96 treated individuals, implant-associated osteomyelitis was diagnosed in 16 individuals, corresponding to a 10-year cumulative risk of 20% (95% confidence interval [CI], 0.12-0.33). Implants were extracted from 10 individuals with a 10-year cumulative risk of 9% (95% CI, 0.04-0.20). Prosthetic use was temporarily impaired in 4 of the 6 individuals with infection who did not undergo implant extraction. The overall risk of implant-related osteomyelitis increased with time since implantation. This was deemed to be a major problem as the osseointegration method is intended to be a lifetime solution for prosthetic support.

Several other types of osseointegration implant systems have been developed but are not yet approved by the FDA (Hoellwarth, 2020). These devices use either press-fit technology (Integral Leg Prosthesis [ILP], Osseointegrated Prosthetic Limb [OPL], Percutaneous Osseointegrated Prosthesis [POP], Intraosseous Transcutaneous Amputation Prosthesis [ITAP]) or cross-pins (Compress Device) to anchor the implant to the bone. In a systematic review of complications of bone-anchored prostheses, Atallah and colleagues (2018) reported that major complications (for example implant infection, implant loosening and intramedullary device breakage) seem to occur less frequently in individuals with press-fit implants compared to those with OPRA or Compress devices. However, peri-prosthetic bone fracture was only reported in individuals with press-fit implants or the Compress device, and not in those with screw type implants.

Hebert and colleagues (2017) conducted a systematic review of clinical outcomes of osseointegration for lower limb amputation. A total of 14 studies involving OPRA, ILP and OPL devices were included. A comprehensive summary of patient selection criteria was detailed including age >18 years and <70 years, ability to comply with the treatment program and follow-up, and qualifying problems with conventional socket prostheses. Notable contraindications, in addition to those described by Brånemark (2014) above, included mental illness or disabling psychiatric disorder, and osteoporosis. The most common complications of osseointegration were infection and soft tissue irritation at the stoma. It was concluded that, over time, changes in implant design, surgical technique, perioperative and postoperative care, and rehabilitation protocols have resulted in improvements in functional outcomes and health-related quality of life, and reduction in rates of complications.

In summary, despite some risks such as mechanical failure and infection, osseointegrated implants are a viable alternative to improve mobility and quality of life for appropriately selected individuals with limb amputations who cannot tolerate traditional socket prostheses.

Background/Overview

Approximately 185,000 individuals undergo a lower limb amputation in the United States each year according to the Amputee Coalition of America. The most common causes are diabetes, peripheral vascular disease, neuropathy and trauma. Currently there is an estimated population of 2 million American lower limb amputees but it is projected that this population will increase to 3.6 million by the year 2050. In contrast to lower limb loss, upper extremity amputation is much less frequent, affecting approximately 41,000 individuals, or about 2% of the US amputee population.

Definitions

Osseointegration: The direct structural and functional connection between living bone and the surface of a load bearing metal rod implanted into the residual bone of an amputated limb.

Osteomyelitis: An infection in a bone.

Prosthesis: An artificial body part, such as a limb.

Socket-type prosthesis: A device that uses a socket, typically custom-made of plastic or silicone according to the condition and shape of the residual limb, to join the residual limb to the prosthesis.

Transfemoral: Across the femur, or thigh.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

For the following procedure codes, or when the code describes an osseointegrated device or implantation procedure.

CPT	
24999	Unlisted procedure, humerus or elbow [when specified as surgery for implantation of fixture component or abutment attachment for upper limb]
27599	Unlisted procedure, femur or knee [when specified as surgery for implantation of fixture component or abutment attachment for lower limb]
HCPCS	
L5991	Addition to lower extremity prostheses, osseointegrated external prosthetic connector
L7499	Upper extremity prosthesis, not otherwise specified [when specified as an osseointegrated upper extremity external prosthetic connector]
L8699	Prosthetic implant, not otherwise specified [when specified as an implantable fixture component or abutment attachment for an osseointegrated upper or lower limb prosthesis]
ICD-10 Procedure	
	For the following codes **when specified as surgery for implantation of fixture component or abutment attachment**:
0PUF0JZ	Supplement right humeral shaft with synthetic substitute, open approach
0PUG0JZ	Supplement left humeral shaft with synthetic substitute, open approach
0QU80JZ	Supplement right femoral shaft with synthetic substitute, open approach
0QU90JZ	Supplement left femoral shaft with synthetic substitute, open approach
ICD-10 Diagnosis	
	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met.

References

Peer Reviewed Publications:

1. Atallah R, Leijendekkers RA, Hoogeboom TJ, Frölke JP. Complications of bone-anchored prostheses for individuals with an extremity amputation: a systematic review. PLoS ONE. 2018; 13(8):e0201821.
2. Brånemark R, Berlin O, Hagberg K, et al. A novel osseointegrated percutaneous prosthetic system for the treatment of patients with transfemoral amputation: a prospective study of 51 patients. Bone Joint J. 2014; 96-B(1):106-113.
3. Brånemark R, Hagberg K, Kulbacka-Ortiz K, et al. Osseointegrated percutaneous prosthetic system for the treatment of patients with transfemoral amputation: a prospective five-year follow-up of patient reported outcomes and complications. J Am Acad Orthop Surg. 2019; 27(16):e743-e751.
4. Hagberg K, Ghassemi Jahani S, Kulbacka-Ortiz K, et al. A 15-year follow-up of transfemoral amputees with bone-anchored transcutaneous prostheses. Bone Joint J. 2020; B(1):55-63.
5. Hebert JS, Rehani M, Stiegelmar R. Osseointegration for lower-limb amputation: a systematic review of clinical outcomes. JBJS Rev. 2017; 5(10):p e10.
6. Hoellwarth JS, Tetsworth K, Rozbruch SR, et al. Osseointegration for amputees: current implants, techniques, and future directions. JBJS Reviews. 2020; 8(3):e0043.
7. Paternò L, Ibrahimi M, Gruppioni E, et al. Sockets for limb prostheses: a review of existing technologies and open challenges. IEEE Transactions on Biomedical Engineering. 2018; 65(9):1996-2010.
8. Tillander J, Hagberg K, Berlin O, et al. Osteomyelitis risk in patients with transfemoral amputations treated with osseointegration prostheses. Clin Orthop Relat Res. 2017; 475(12):3100-3108.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Department of Veterans Affairs (VA)/Department of Defense (DoD) Clinical Practice Guideline for Rehabilitation of Individuals with Lower Limb Amputation. Version 2.0. 2017. Available at: https://www.healthquality.va.gov/guidelines/Rehab/amp/VADoDLLACPG092817.pdf. Accessed on January 2, 2024.
2. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness and labeling: Premarket Approval (PMA). Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. Accessed on January 2, 2024.
    - OPRA Implant System. Premarket approval application No. P190009. December 18, 2020.

Websites for Additional Information

1. The Amputee Coalition. Available at: https://www.amputee-coalition.org. Accessed on December 14, 2023.

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Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA™) Implant System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence

over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.