Policy Key: Prosthetics

TriWest Clinical Operations – TRICARE West Region

SCOPE

This Policy Key provides criteria to use during medical necessity review for prosthetic devices, services, and supplies. Prosthetic Hearing Devices are covered in a separate Policy Key.

NOT COVERED

- Duplicate or similar items are not covered; therefore, only one permanent prosthesis at a time is covered, unless a beneficiary requires bilateral prosthesis. [1]
- Prosthetic devices categorized by the U.S. Food and Drug Administration (FDA) as experimental/investigational (FDA Category A) Investigational Device Exemption (IDE). [1]
- Prosthetic devices intended for sports-related purposes, exercise equipment, physiotherapy, personal comfort, or convenience. [1]
- Cranial prosthesis for alopecia for conditions other than treatment of malignant disease. [5]
- Maintenance supplies or replacement of cranial prosthesis (limit of one per lifetime). [5]
- Hair transplants or any other surgical procedure involving the attachment of hair or a cranial prosthesis to the scalp. [5]
- Penile implant and related services for psychological impotence, sex gender change surgery, or other conditions such as gender dysphoria. [3]
- Testicular implant and related services for sex gender change surgery, or other conditions such as gender dysphoria. [3]
- Communication aids that do not generate speech are not covered. Communication aids that are not ACDs/SGDs are not considered prosthetics for speech. Examples of noncovered communication aids include the following: picture books; flashcards; Braille typewriters; Teletypewriter (TTY) devices; devices that allow the patient to communicate messages to others with writing (e.g., a display screen or printout) rather than with synthesized speech; and devices that allow the user to communicate with a computer rather than with another person. Although these devices may be useful, they do not meet the definition of an ACD/SGD, prosthetic, or DE. [4]
- Computer or PDA based devices unless modified to only run augmented communication device or speech generating device software. [4]
- Altered auditory feedback devices are communication aids. [4]

COVERAGE CRITERIA

Investigational Device Exemption (IDE) [1]

- **Medical Director** may approve, if meets the following conditions:
  - Prosthetic devices with an FDA-approved IDE categorized by the FDA as nonexperimental/investigational (FDA Category B) will be considered for coverage.
  - Coverage is dependent on the device meeting all other requirements of the law and rules governing TRICARE and upon the beneficiary involved meeting FDA-approved IDE study protocols.

General Criteria

- **Initial Level of Review** may approve for **ANY** of the following reasons: [1]
  - Prosthetics, prosthetic devices, and supplies consistent with the beneficiary's symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs
  - Any accessory or item of supply that is used in conjunction with the device for the purpose of achieving therapeutic benefit and proper functioning
  - Device repair for normal wear and tear or damage
  - Services necessary to train the use of the device
  - Prosthetic customization is covered when provided by an otherwise authorized provider.
  - Surgical implants that are approved for use in humans by FDA are covered as an essential and integral part of an otherwise covered surgical procedure.
  - Myoelectric prosthetic devices, e.g., a myoelectrical prosthesis with a hand is an acceptable alternative to conventional prosthesis with a hook.
  - Ear, nose, or finger prosthesis due to significant conditions resulting from trauma, congenital anomaly or disease
  - Replacement of a prosthetic is covered when [1]
    - required due to growth or a change in the patient's condition,
    - the device is lost or irreparably damaged, or
    - the repair cost would exceed 60% of the replacement cost.

Breast Prosthesis [2]

- **Initial Level of Review** may approve the following conditions:
  - Initial breast prosthesis per breast
  - External surgical garments/mastectomy bras (those specifically designed as an integral part of an external prosthesis), instead of reconstructive breast surgery or when reconstruction surgery has failed
    Note: Limit 2 per year.

Testicular Prosthesis [3]

- **Initial Level of Review** may approve an FDA-approved testicular prosthesis for **ANY** of the following conditions:
    - Following testicular disease, trauma, injury, radical surgery
    - Correction of ambiguous genitalia which has been documented to be present at birth
    - Removal and reinsertion of prosthesis for a covered indication to treat complications **Note:** If the initial testicular prosthesis surgery was for an indication not covered or coverable by TRICARE, implant removal may be covered only if it is necessary treatment of a complication that represents a separate medical condition. See PK for Unfortunate Sequalae.

Penile Implant, (insertion, removal and reinsertion) [3]

- **Initial Level of Review** may approve an FDA approved penile implant device for ANY of the following conditions:
    - Organic impotence which has resulted from a disease process, trauma, radical surgery
    - Correction of a congenital anomaly
    - Correction of ambiguous genitalia which has been documented to be present at birth

Augmentative Communication Devices (ACDs) AKA Speech Generating Devices (SGDs) [4]

Including devices with digitized speech output, prerecorded messages, or synthesized speech output with multiple methods of message formulation, or a computer, laptop, or PDA modified to only run ACD/SGD software

- **Initial Level of Review** may approve if meets **ALL** of the following conditions:
    - Severe speech impairment is a result of trauma, congenital anomaly, or disease.
    - Recommended after evaluation by speech-language pathologist
    - Provides the ability to meet functional speaking needs to an individual with severe speech impairment
    - Used solely by the individual with severe speech impairment as a dedicated speech device

Wigs or Hairpiece (cranial prosthesis) [5]

- **Initial Level of Review** may approve the following reasons:
    - Attending physician certifies the alopecia as a result of treatment of a malignant condition **AND** beneficiary certifies that a cranial prosthesis has not previously been obtained through the US government or VA

  Note: limited to one cranial protheses per lifetime with price limited to DMEPOS PEN rates for current calendar year. (Any cost over these limits is the responsibility of the beneficiary).

DEFINITIONS

Prosthetic – A prosthetic or prosthetic device (prosthesis) determined to be necessary because of significant conditions resulting from trauma, congenital anomalies, or diseases [1]

Prosthetic supplies – Supplies that are necessary for the effective use of a prosthetic or prosthetic device [1]

CODES

NA

REFERENCES

[1] TRICARE Policy Manual 6010.63-M, April 2021, Change 17, (September 20, 2024), Chapter 8, Section 4.1, Prosthetic Devices and Supplies, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C8S4_1.html

[2] TRICARE Policy Manual 6010.63-M, April 2021, Change 17, (September 20, 2024), Chapter 4, Section 5.2, Post-Mastectomy Reconstructive Breast Surgery and Breast Prostheses, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C4S5_2.html

[3] TRICARE Policy Manual 6010.63-M, April 2021, Change 17, (September 20, 2024), Chapter 4, Section 15.1, Male Genital System, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C4S5_2.html

[4] TRICARE Policy Manual 6010.63-M, April 2021, Change 17, (September 20, 2024), Chapter 7, Section 23.1, Augmentative Communication Devices (ACDs), https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C7S23_1.html

[5] TRICARE Policy Manual 6010.63-M, April 2021, Change 17, (September 20, 2024), Chapter 8, Section 12.1, Wigs or Hairpiece, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-09-20/AsOf/TPT5/C8S12_1.html