Medical Coverage Policy

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Prosthetic Devices

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Overview

This Coverage Policy addresses prosthetic devices—fabricated items designed as replacements for missing body parts.

For information regarding other prosthetic devices not addressed in this policy, please reference the applicable Cigna Medical Coverage Policy in the Related Coverage Resources section above.

Coverage Policy

Coverage for prosthetic devices varies across plans. Please refer to the customer's benefit plan document to determine benefit availability and the terms and conditions of coverage.

Microprocessor-controlled/computer-controlled/myoelectric devices are considered a type of power enhancement/controlled device.

GENERAL CRITERIA FOR A PROSTHETIC DEVICE

Functional Levels

Medical necessity for a lower limb prosthetic appliance is based on an individual's functional ability when using the prosthetic device. Functional ability is based on the following classification levels:

- **Level 0:** Does not have the ability or potential to ambulate or transfer safely with or without assistance and prosthesis does not enhance his/her quality of life or mobility.
- **Level 1**: Has the ability or potential to use prosthesis for transfers or ambulating on level surfaces at fixed cadence; typical of the limited and unlimited household ambulator.
- **Level 2**: Has the ability or potential for ambulating with the ability to traverse environmental barriers such as curbs, stairs or uneven surfaces; typical of the limited community ambulator.
- **Level 3**: Has the ability or potential for ambulating with variable cadence; typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
- **Level 4:** Has the ability or potential for prosthetic ambulating that exceeds basic ambulating skills, exhibiting high impact, stress, or energy levels; typical of the prosthetic demands of the child, active adult, or athlete.

The following prosthetic devices are considered medically necessary when used to replace a missing or nonfunctional body part and when applicable medical necessity criteria listed below is met (Please note: prior authorization requirements may apply):

- External facial (e.g., nose, ear, midfacial, orbital, upper facial, hemifacial)
- Eye prosthesis (e.g., internal ocular, scleral shell)
- Lower extremity (e.g., foot, ankle, above/below knee)
- Upper extremity (e.g., finger, hand, wrist, above/below elbow, shoulder)
- Terminal devices, such as hands or hooks

Accessories to a prosthetic device are considered medically necessary when the accessory is required for the effective use of the prosthesis.

Not Medically Necessary

The following prosthetic devices are each considered not medically necessary:

- a lower limb prosthetic device for functional level 0
- additions/components that are not required for the effective use of the device
- prosthetic devices or additions/components not required for participation in normal activities of daily living, including those that are chiefly for convenience, for participation in recreational activities, or that otherwise exceed the medical needs of the individual (e.g., back-up/duplicate prosthetic devices, waterproof leg prosthesis [e.g., The Fin, used for swimming])

IRIS PROSTHESIS

An iris prosthesis (CPT® code 66683; HCPCS code C1839) is considered experimental, investigational or unproven for any indication, including but not limited to the treatment of full or partial aniridia.

EXTERNAL FACIAL PROSTHESIS

An external facial prosthesis is considered medically necessary when the prosthesis is prescribed to compensate for the loss or absence of facial tissue as a result of disease, injury, surgery, or congenital defect.

A duplicate external facial prosthesis is considered a convenience item and is considered not medically necessary.

UPPER LIMB: MYOELECTRIC PROSTHETIC DEVICE

If a benefit is available for an upper limb myoelectric device, the following medical necessity criteria apply.

An upper limb myoelectric prosthetic device is considered medically necessary for an individual with an amputation or congenital absence of a portion of an arm (e.g., hand, forearm, elbow) when ALL of the following criteria are met:

- The individual has sufficient cognitive ability to successfully utilize a myoelectric prosthetic device.
- The remaining musculature of the arm(s) contains the minimum microvolt threshold to allow operation of a myoelectric prosthetic device.

- A standard body-powered prosthetic device cannot be used or is insufficient to meet the functional needs of the individual in performing activities of daily living

An intent decoding module or pattern recognition add-on module for an upper limb myoelectric prosthetic device (e.g., Coapt Complete Control Gen2; Ottobock Myo Plus) (HCPCS code L6700) is considered experimental, investigational or unproven.

LOWER LIMB: MECHANICAL (NON-POWERED, NON-MICROPROCESSOR)

A single axis, fluid swing and stance phase control lower limb addition (HCPCS code L5828) is considered medically necessary when the individual is functional level 3 or greater.

LOWER LIMB: MICROPROCESSOR-CONTROLLED PROSTHETIC DEVICE

If a benefit is available for a microprocessor-controlled/computer-controlled lower limb prosthetic, the following medical necessity criteria apply.

Any of the following microprocessor-controlled prosthetics, including additions/components that are required for the effective use of the device (and consistent with the user's functional level), are considered medically necessary when the individual is functional level 3 or greater:

- a microprocessor-controlled ankle-foot prosthetic (HCPCS code L5973) for a transtibial amputee (i.e., below-the-knee)
- a microprocessor-controlled knee prosthetic (HCPCS codes L5856, L5857, L5858) for a knee disarticulation amputee or a transfemoral amputee (i.e., above-the-knee)
- a combination microprocessor-controlled prosthetic/system (e.g., Linx), when a microprocessor-controlled prosthetic knee alone is inadequate to meet the functional needs of the individual (e.g., continued knee/foot instability due to environmental/anatomical barriers)

A microprocessor-controlled prosthetic is considered not medically necessary for any other indication.

LOWER LIMB: POWERED MICROPROCESSOR-CONTROLLED PROSTHETIC DEVICE

If a benefit is available for a powered or power-enhanced lower limb prosthetic, the following medical necessity criteria apply.

An endoskeletal knee-shin system (addition to a lower limb device) with powered and programmable flexion/extension assist control, including any type of motor(s) (HCPCS code L5859) (e.g., Össur Power Knee™) is considered medically necessary when ALL of the following criteria have been met:

- The individual has a swing and stance phase-type microprocessor controlled (electronic) knee (HCPCS code L5856).
- The individual is functional level 3 (K3) only*.

- The individual has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K3 level function with the use of a microprocessor-controlled knee alone.

  <u>*Note:</u> Coverage of this device is limited to individuals who are Functional Level 3; the device is not intended for high impact activity, sports, excessive loading, or heavy duty use.

The following powered prosthetic devices are each considered not medically necessary:

- a microprocessor-controlled ankle foot prosthetic with power assist (e.g., Ottobock Empower [HCPCS codes L5973, L5969])
- a powered lower limb prosthetic for any other indication

<u>LOWER LIMB: VACUUM SUSPENSION SYSTEM</u>

A vacuum suspension system (e.g., vacuum-assisted socket system [VASS]) (HCPCS code L5781) is considered medically necessary to control residual limb volume when there is contraindication to or failure of other socket-suspension systems (e.g., mechanical, passive suction) to adequately secure the limb to the prosthesis.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

Prosthetic Devices
A prosthesis is an artificial device used to replace a missing body part and is intended to restore normal function. Prosthetic devices are secured or retained in place by harnesses or belts, by suction, or using anatomical structures; some devices such as facial prosthetics are held in place with the use of a skin adhesive. Additionally, devices may be held in place by implants, such as bone integrated titanium implants.

The following services and items are typically included in the allowance for a prosthetic device:

- the evaluation and fitting of the prosthesis
- the cost of base component parts and labor, as described in HCPCS base codes
- the repairs due to normal wear and tear during the 90-day period following the date of delivery
- adjustments of the prosthesis or the prosthetic component made when fitting the prosthesis or component and for 90 days from the date of delivery, when the adjustments are not necessitated by changes in the underlying tissue or the patient's functional ability

Iris Prostheses
An iris prosthesis is an implanted device proposed for treatment of partial or complete aniridia. Aniridia is absence of the iris and may be associated with visual conditions such as glare, photophobia, glaucoma, corneal opacification, and/or cataract formation. The degree of vision loss varies. Treatment generally consists of contact lenses with iris prints and tinted eyeglasses. Various surgical techniques may also be used to repair iris defects, depending on the nature, extent and size of the defect (Ferro Desideri, et al., 2024).

The prosthetic iris device is made out of foldable medical grade silicone which is then custom-sized and colored for each individual. The iris prosthetic is implanted surgically through a small incision, it is then unfolded, the edges are smoothed out and it is then held in place by anatomical structure of the eye or using sutures. It may be placed in the ciliary sulcus without sutures when there is a pre-existing intraocular lens, implanted into the capsular bag with a new intraocular lens, or can be sutured to the sclera, with or without an intraocular lens implant (IOL). The device purportedly reduces sensitivity to light while improving the appearance of the eye and visual acuity. Implant insertion can be done alone or in combination with cataract or lens fixation surgery.

U.S. Food and Drug Administration (FDA): The CustomFlex™ Artificial Iris (Clinical Research Consultants, Inc., Cinn., OH [HumanOptics]) received premarket approval (P170039) by the FDA in May 2018 as an artificial iris intended for use in children and adults for the treatment of full or partial aniridia resulting from congenital aniridia, acquired defects, or other conditions associated with full or partial aniridia. The device is available with or without embedded fiber mesh for implantation, and may or may not be sutured. The FDA is requiring a post approval study to evaluate long term safety outcomes up to three years postoperatively for adults and five years for pediatric subjects.

Other implants have been investigated in the medical literature, however these devices have not been cleared or approved by the FDA (e.g., BrightOcular implants, a newer generation of NewColorIris®, [Stellar Devices, New York, NY] and used for cosmetic purposes) and Ophtec Artificial Iris Model C1 [Reper – NN, Distributed by Ophtec BV, European Union]). Some of the cosmetic devices have been associated with a high incidence of serious complications such as corneal decompensation, glaucoma, native iris trauma, intraocular inflammation, and cataract development, which may result in permanent structural damage or visual impairment (Ghaffari, 2021).

Literature Review: While there is a growing body of evidence in the peer-reviewed scientific literature evaluating use of the artificial iris, in general, sample populations are small, studies are retrospective, study populations are heterogeneous, and surgical techniques vary precluding generalization of overall safety and efficacy. Several authors have reported high complications rates, both intra and post-operatively. As a result, strong evidence-based conclusions regarding safety and efficacy cannot be made. Additional clinical studies with longer follow-ups are needed to evaluate use of the device and impact on health outcomes. Professional society statements regarding use of the device as treatment for aniridia from the American Academy of Ophthalmology were not found.

Ayers et al. (2022) reported the results of a prospective, nonrandomized trial evaluating safety and efficacy of the CustomFlex Artificial Iris for treatment of partial or complete, congenital or acquired iris defects of various causes. Inclusion criteria were 22 years of age or greater, congenital or acquired iris defect and photophobia, glare sensitivity, or both, and pseudophakia, phakia, or cataract in the study eye. The initial cohort involved 180 subjects, afterwards eligible adults were enrolled in a continued access cohort until the device received premarket approval

from the FDA. Following at least four weeks post initial eye implantation fellow eye implantation was performed in 28 subjects. A compassionate use cohort (n=89) was also followed as part of the study protocol for individuals who did not meet one or more of the inclusion criteria. The authors reported subjects were reexamined one day following surgery and one week, one, three, six and 12 months after surgery. Three different techniques were used: (1) passive fixation within the capsular bag, (2) passive fixation within the ciliary sulcus, and (3) active suture fixation to residual iris tissue, the sclera, or an intraocular lens (IOL) that, in turn, was sutured to the sclera. Primary efficacy outcomes included a decrease in the severity of patient-reported photosensitivity (i.e., daytime and nighttime light sensitivity and daytime and nighttime glare), improvement in health-related quality of life, and improvement in postoperative cosmesis. Primary safety outcomes included cumulative IOL-related adverse events, cumulative surgery-related adverse events, and device-related adverse events. Secondary safety outcomes were tabulated and reported at the various study intervals and included changes in vision (CDVA, uncorrected distance visual acuity [UDVA], and manifest refraction), intraocular pressure (IOP), endothelial cell density (ECD), and slit-lamp observations. Endothelial cell density was measured at the screening visit and at six and 12 months after surgery if no corneal scarring, edema, or other pathologic features precluding measurement were present and was recorded as the average of three measurements obtained by noncontact specular or confocal microscopy. Results demonstrated a 59.7% reduction in marked to severe daytime light sensitivity ($p<0.0001$), a 41.5% reduction in marked to severe nighttime light sensitivity ($p<0.0001$), a 53.1% reduction in marked to severe daytime glare ($p<0.0001$), and a 48.5% reduction in severe nighttime glare ($p<0.0001$). A 15.4 point total score improvement was demonstrated in vision-related quality of life as measured by the 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) ($p<0.0001$), and 93.8% of participants rated an improvement in cosmesis on the Global Aesthetic Improvement Scale at the 12-month postoperative examination. There was no loss of CDVA of > two lines related to the device. Median ECD loss was 5.3% at six months after surgery and 7.2% at 12 months after surgery. The authors concluded that the artificial iris surpassed all key safety end points and met all key efficacy end points. Limitations of the trial include short term follow-up of 12 months.

Figueiredo and Snyder (2020) retrospectively evaluated the safety and effectiveness of the CustomFlex device used to treat photic symptoms in individuals with congenital aniridia (n=50 subjects, 96 eyes). Mean follow-up was 44 months (36 ± 36 months). Measured outcomes included pre and post-operative data regarding corrected distance visual acuity (CDVA), subjective photophobia and glare, keratopathy, glaucoma, intraocular pressure (IOP), glaucoma drops, and other comorbid pathologies. Additional data regarding postoperative complications, prosthesis decentration, and further surgeries was also collected. In all cases, additional procedures were performed at the time of implantation, including phacoemulsification, intraocular lens (IOL) implantation repositioning or replacement, limbal relaxing incision, keratectomy (superficial and lamellar) or vitrectomy. Intraoperative complications were reported in 14 eyes (14.6%). A total of 95.7% (89/93) reported a reduction in photophobia symptoms, 3.2% (3/93) reported no change in symptoms and 1.1% (1/93) reported worsening of symptoms. Similarly, subjective reporting of glare indicated a reduction of symptoms in 95.2% of subjects (79/83), 3.6% (3/83) reported no change in symptoms and 1.2% (1/83) reported worsening of symptoms. When individuals could not reliably report their symptoms, family member observations of behaviors were used to gauge functional improvement in photic symptoms. When preoperative visual acuity was compared to best achieved postoperative visual acuity, it was found that 72 eyes (75.0%) gained at least two lines and 24 eyes (25.0%) stayed within two lines, whereas no eye lost two or more lines. When compared with last measured visual acuity 58.3% (56) of the eyes improved two or more lines, 32.3% (31) of the eyes stayed within two lines of preoperative measurements, and 9.4% (9) of the eyes dropped two or more lines. The declines in the VA in the postoperative period were attributed to underlying comorbidities, which included worsening of the ocular surface, aniridia fibrosis syndrome, retinal detachment, and posterior capsule opacification. Aniridic keratopathy,

which was present in 84.4% (81) of the eyes preoperatively, was present in 85.4% (82) at last visit (28.4% [23] of the eyes with preoperative keratopathy had progression of the disease). Aniridic glaucoma was present in 33.3% (32) of the eyes preoperatively in comparison with 51.0% (49) of the eyes at last visit (53.1% [17] of the eyes with preoperative glaucoma had progression of the disease). Additional complications included aniridia fibrosis syndrome (AFS) (3.1%), prosthesis decentration (9.4%), choroidal folds/effusion secondary to ocular hypotony (2.1%), retinal detachment (1.0%), cystoid macular edema (1.0%) and vitreous hemorrhage (1.0%). Overall, 33.3% (32) eyes required additional surgical intervention. In the authors' opinion individuals with congenital aniridia syndrome present with highly complex eyes which require an individualized approach and long-term follow-up. Limitations noted by the authors included significant heterogeneity related to aniridic pathology within the group.

Mayer and colleagues (2019) reported the results of single center case series to evaluate the effect of an artificial iris implant on a remnant iris (n=42). Morphologic evaluation was carried out over 24 ± 14 months. Main outcome measures included remnant pupillary aperture, iris color, visual acuity (VA), intraocular pressure (IOP), and endothelial cell count (ECC). Retraction syndrome, manifested by progressive enlargement of the pupil and retraction of the residual iris, was detected in seven of 42 (16.7%) eyes following implantation of the artificial iris prosthesis. Residual iris aperture dilated from 36.6 ± 15.4 mm^2 pre-operatively to 61.1 ± 12.5 mm^2 one year post-operatively (66.9% increase). In five of seven affected eyes, the artificial iris had been implanted into the ciliary sulcus; in two eyes it had been sutured to the sclera. A total of four of the seven subjects presented with remarkable complications: two eyes needed glaucoma shunt surgeries owing to pigment dispersion; one suffered from recurrent bleeding; and in one case artificial iris explantation was performed owing to chronic inflammation and elevated intraocular pressure. Anterior chamber depth (ACD) and angle, ECC, and VA did not change in this cohort. Changes in color were not observed in the remnant iris. The authors concluded that the implantation of an artificial iris prosthesis could lead to a residual iris retraction syndrome as a late complication. It was likely that residual iris was trapped in the fissure between the artificial iris and the anterior chamber angle, preventing further pupil constriction. Another possibility noted by the authors could be the result of a constriction or atrophy of the residual iris. Due to the small sample population the authors were unable to determine statistical comparisons regarding different implantation methods. They concluded that with increased use of the artificial iris more cases of iris retraction syndrome may be detected in the future.

Yoeruek and Bartz-Schmidt (2019) reported the results of a small case series involving five subjects with traumatic aniridia, combined with aphakia and corneal scars or graft failure, who received an intraocular lens attached to a customized silicone iris prosthesis (Artificial Iris, HumanOptics). The mean age of the subjects was 46.2 years and the mean follow-up was 24.6 months. The mean BCVA improved from 1.36 logMAR before surgery to 0.78 logMAR after surgery during the follow-up. Data on glare and photophobia was available for three subjects; in three glare sensation was reduced. Postoperative complications included one graft failure during the first year after surgery. Three subjects had glaucoma prior to surgery; two were able to be controlled sufficiently postoperatively. There were no new cases of glaucoma postoperatively. At the last follow-up visit, the artificial iris-IOL complex was well-centered with good positioning in all cases. The authors concluded that management of post-traumatic aniridia combined with aphakia and corneal scars or graft failure by haptic fixation of a foldable IOL on an artificial iris combined with a simultaneous keratoplasty appeared to be a promising approach, which allowed to correct a complex lesion with a less traumatic and faster procedure. The study is limited by the small sample size, retrospective design and short term follow-up.

Mayer et al. (2018) retrospectively evaluated the learning curve of the implantation surgery for the iris prosthesis and potential complications. A total of 51 subjects were implanted with the Artificial Iris (HumanOptics), follow-up occurred at least three months post-procedure and

extended to a maximum of four years. Complications were grouped into categories of none, mild (with full recovery) or moderate (without full recovery) and severe (required surgical intervention). The overall complication rate was 25.5% (13/51 subjects). Mild complications included recurrent bleeding with rise in intraocular pressure (IOP) (n=1), slight but stable iris deviation (n=2), capsular fibrosis (n=2); moderate complications included suture cutting through the residual iris (n=1), new onset glaucoma (n=3), and corneal decompensation (n=5); severe complications included iris suture loosening (n=2), and dislocation (n=3), synechiae (n=2), glaucoma (n=2), and corneal decompensation (n=5) with need for surgery, cystoid macular edema (n=3) and retinal detachment (n=1). The complication rate decreased from 83.3% in the first year to 13.3% in the fourth year. The author group concluded implantation of the artificial iris implant requires significant surgical experience, should be limited to specialized centers, and requires careful postoperative management to detect unexpected adverse events.

Mostafa and associates (2018) evaluated the limitations and benefits of the BrightOcular prosthetic artificial iris (Stellar Devices) device in management of aniridia associated with aphakia or cataract. Designed as a retrospective study, the authors evaluated five eyes of four patients (ages 12, 13, 28 and 34 years) who underwent implantation of the BrightOcular iris prosthesis (Stellar Devices) for total or partial aniridia. Similar to the HumanOptics prosthesis, this device is silicone, yet not FDA approved. The study group included two eyes of one patient with congenital aniridia associated with congenital cataract, and three eyes with traumatic aniridia (one with subluxated cataractous lens and two with aphakia). The iris prosthesis was implanted after a 3-piece acrylic intraocular lens (IOL) was implanted in all cases. Measured outcomes included intraoperative and postoperative complications, and the cosmetic satisfaction and evaluation of the clinical course for at least six months. Uncorrected distance visual acuity (VA) and best-corrected distance visual acuity (BCVA) improved for all subjects. All patients had a transient corneal edema that resolved within the first postoperative week. Only the patient with congenital aniridia had a permanent increase in intraocular pressure (IOP) and developed a band keratopathy throughout a 2-year follow-up period. The prosthesis was well-centered in all eyes except for one case that needed scleral suture fixation after three months. One case required scleral suturing due to intraoperative displacement. In the authors opinion both cases were the result of improper sizing of the device. It was reported all subjects had a satisfactory cosmetic appearance, and improvement in glare and halos. The authors concluded that the BrightOcular iris prosthesis was a safe and useful tool to correct aniridia associated with pseudophakia or aphakia. In addition, more research is required to determine the best means of sizing the implant and to address the problem of postoperative IOP rise; further studies should also examine the safety of the prosthesis in clear phakic eyes. Limitations of the study include the small sample population and retrospective study design.

Mayer and colleagues (2016) reported results of a prospective case series investigating functional results and patient satisfaction after surgical iris reconstruction. Thirty-seven consecutive patients with traumatic iris defects who underwent pupillary reconstruction with a new artificial iris implant (Artificial Iris, HumanOptics), were included in the study. The main outcome measures included change of best-corrected visual acuity (BCVA), intraocular pressure (IOP), pupillary aperture, glare, contrast sensitivity, endothelial cell density, anterior chamber depth, anterior chamber angle, and patient satisfaction. Thirty-two eyes of 32 patients (mean age 52.9±16.0 years) were included. After implantation and during follow-up, BCVA and IOP did not change significantly (BCVA, 0.77±0.62 logarithm of the minimum angle of resolution [logMAR] preoperatively vs. 0.68±0.64 logMAR 1 month postoperatively [p=0.792]; (IOP, 14.94±3.55 mmHg preoperatively vs. 17.72±5.88 mmHg 1 month postoperatively [p=0.197]). The pupillary aperture was reduced significantly (42.11±20.1 mm^2) to 8.7±0.3 mm^2; p<0.001). Contrast sensitivity increased significantly (0.80±0.51 to 0.93±0.49; p=0.014). Endothelial cell count revealed a significant decrease postoperatively (1949±716 per 1 mm^2 to 1841±689 per 1 mm^2; p=0.003). Anterior chamber depth (4.03±1.06 mm preoperatively vs. 4.29±0.70 mm postoperatively; p=0.186) and

angle (43.2±13.5° preoperatively vs. 40.5±10.8° postoperatively; p=0.772) showed no significant differences. Subjective impairment through glare (9.12±1.62 preoperatively vs. 3.07±2.29 postoperatively; p<0.001) and cosmetic disturbance (6.33±3.21 preoperatively vs. 1.58±0.86 postoperatively; p<0.001) improved significantly. Overall patient satisfaction was 8.91±1.51 of 10 points on an analog scale. The authors concluded that the implantation of the artificial iris is an effective therapeutic option for the treatment of traumatic iris defects and results in an "individual, aesthetically appealing, and good functional outcome in addition to high patient satisfaction". Limitations of the study as noted by the authors include five subjects excluded from follow-up, and inclusion of subjects with varying iris defects.

Rickman et al. (2016) reported a retrospective interventional case series of 34 patients who received an artificial iris between 2004 and 2013 using the Artificial Iris (HumanOptics). Only eyes with a minimum follow-up period of two years were included; subjects ranged in age from 28-85 years. Indications for treatment were congenital, traumatic, or iatrogenic complete or partial aniridia. The artificial iris was implanted either with or without embedded fiber mesh for partial or full prostheses. Mean follow-up was 50.0 months (SD ±18.9 months). Repositioning of prostheses was not required in any of the 34 cases. In cases of keratopathy (17.6 %) visual function increased from baseline mean 1.6 logMAR (SD ±0.7) to 1.2 logMAR (SD ±0.7) after artificial iris implantation. The remaining iris tissue darkened during the follow-up in 23.5 % (83.3% with and 10.7% without mesh), 8.8% developed glaucoma (50% with and 0% without mesh) and 14.7% needed consecutive surgery after prostheses implantation (50% with and 7.1% without mesh). In three out of seven trauma cases (42.9%) silicone oil was spilled into the anterior chamber after 2.5 years, on average. When the VA at baseline was compared to the final examination, 16 eyes gained two or more VA lines, 15 eyes remained stable, and three eyes lost two or more VA lines. There was no significant difference in the mean IOP when baseline was compared to final examination. According to the authors, the artificial iris prosthesis revealed a good clinical outcome in terms of long-term stability, cosmetic appearance and visual function. Limitations noted by the authors included a wide range of aniridia causes and variation in disease and management. Therefore, direct correlation of the success rate and the surgical technique is not firmly established. Furthermore, the authors acknowledged long-term complications such as glaucoma, over-pigmentation of the remaining iris tissue, and need for a secondary surgery are significantly associated with implants with integrated fiber mesh, but not to implants without mesh.

Spitzer et al (2016) published the results of a retrospective case series involving 34 subjects who received a customized silicone iris prosthesis (Artificial Iris, HumanOptics) after severe globe injury with total or sub-total iris loss. The Artificial Iris is a customized, silicone prosthetic iris made from silicone material. The median follow-up was 24 months (range 12.0-48.8). Five patients (15%) had pre-existing glaucoma and eight patients (24%) had pre-existing hypotony. Mean visual acuity (VA) prior to artificial iris implantation was 1.1 logMAR (range 0.3-2.6). At 12 months after surgery, 14 subjects had VA improvement between 0.2 and 2.1 logMAR units (41%), 11 subjects had a VA change of less than 0.2 logMAR units (32%), and nine subjects had a reduction of VA between 0.2 and 1.4 logMAR units (27%). Visual acuity 12 months after surgery was 1.4 logMAR (range 0.2-2.6); median VA was unchanged. Complications included newly diagnosed glaucoma (9%) and hypotony (9%), persisting intraocular inflammation (8.8%), macular edema (11.8%), and corneal endothelial decompensation requiring corneal transplantation (18%). Patients' satisfaction increased by reducing photophobia and enhanced cosmetic appearance; 15 subjects had reduced subjective glare and while a majority of subjects were satisfied with functional and cosmetic results (80%), three continued to have persistent glaring or deteriorating vision and were not satisfied. Limitations of the study small sample population, short-term outcomes, lack of a statement regarding subjective discomfort due to glaring from 14 subjects (information was only available for 20 subjects at follow-up).

The National Institute for Health and Care Excellence (NICE) (United Kingdom) published interventional procedures guidance for artificial iris insertion as treatment for acquired aniridia (NICE, 2020a). NICE reviewed evidence consisting of one non-randomized comparative trial, seven case series, and one case report. The primary efficacy outcomes included reduction in symptoms of glare, improvement in visual acuity, quality of life and other patient-reported outcomes. Key safety outcomes included need for explantation, infection, worsening visual acuity, glaucoma, and implant displacement. Within this document NICE concluded the "evidence on the safety and efficacy of artificial iris implant insertion for acquired aniridia is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research." Similarly, for congenital aniridia NICE concluded "evidence on the safety and efficacy of artificial iris implant insertion for congenital aniridia is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research" (NICE, 2020b).

External Facial Prostheses
External facial prostheses are used to replace lost or absent facial tissue that is the result of disease, injury, surgery, or a congenital defect, or they may be considered an alternative to reconstructive surgery. An external device is usually made from silicone materials and requires frequent removal and cleaning while a surgically implanted prosthetic device is typically removed and cleaned less often. The function of the external prosthesis is to protect exposed tissues, cover exposed cavities, and restore physical appearance.

Common types of external facial prostheses include the following:

- Auricular (ear): Restores all or part of the ear, function includes directing sound into the auditory canal; supporting eyeglasses and acting as a hearing aide, if required.
- Nasal (nose): Restores all or part of the nose and may include the nasal septum; functions to direct airflow to the nasopharynx and may also provide support for eyeglasses.
- Midfacial (nose and adjacent tissues): Restores part or all of the nose and significant adjacent facial tissue/structures, does not include the orbit or any intraoral maxillary prosthesis; adjacent facial tissue/structures include one or more of the following: soft tissue of the cheek, upper lip, or forehead.
- Orbital (orbit/eyelids): Restores the eyelids and the hard and soft tissue of the orbit, may include the eyebrow; functions to house the artificial eye, does not include the ocular prosthesis.
- Upper facial (orbit and adjacent tissues): Restores the orbit, plus significant adjacent facial tissue/structures, does not include the nose, any intraoral maxillary prosthesis or ocular prosthesis; adjacent facial tissue/structures include soft tissue of the cheek(s) or forehead.
- Hemifacial (nose, orbit and adjacent tissues): Restores part or all of the nose, the orbit, and significant adjacent facial tissue/structures, does not include any intraoral maxillary prosthesis or ocular prosthesis.
- Partial facial prosthesis: Restores a portion of the face, does not specifically involve the nose, orbit or ear.
- Nasal septal prosthesis: Prosthesis that occludes a hole in the nasal septum, does not include superficial nasal tissue.

Prosthetic devices may be secured or retained in place by anatomical structures; however, in most cases the device is held in place with the use of a skin adhesive. Additionally, some devices may be held in place by implants, such as bone integrated titanium implants. The method chosen to secure the device and the type of device are usually dependent upon factors such as the degree of deformity, the person's ability to handle maintenance routines, the individual's occupation and lifestyle, and the availability of assistance when needed.

Upper Limb: Myoelectric Prosthetic Device
The conventional prosthetic appliance for replacement of an upper extremity, either below or above the elbow, is a body-powered prosthesis with a terminal hand or hook device. A myoelectric device functions by means of electrical impulses and operates on rechargeable batteries requiring external cables or harnesses. It is a prosthetic device used as an alternative to a passive or conventional body-powered device which enables an amputee to adjust the force of his/her grip and an ability to both open and close the hand voluntarily. Myoelectric devices may be recommended for amputees who are unable to use body-powered devices or who require improved grip function/motion for performance of daily activities. Adults or children with above- or below-the-elbow amputations may use the device effectively, although as a child grows the prosthesis may require multiple socket replacements for proper fit and function.

A hybrid prosthesis is a device that uses a combination of myoelectric and body-powered technology to enhance the amputee's overall functionality, depending on the level and location of amputation. A hybrid device is indicated for high level amputations, (i.e., at or above the elbow) and consists of a body-powered device to control shoulder and elbow movement and a myoelectric device to control hand and wrist motion, allowing control of two joints at one time.

The integration of intent decoding modules with prostheses is an evolving area of interest. Intent decoding modules (IDMs) are advanced components added to myoelectric upper limb prosthetic devices, which use machine learning (pattern recognition) algorithms to translate myoelectric/electromyographic (EMG) signals from residual muscles into corresponding movement commands to the prosthetic device. An accompanying app may also be used for configuration and feedback purposes. The purported benefits of machine learning pattern recognition control over conventional (direct) prosthesis control include more natural, fluid movements for improved function and precision. Examples of such devices include Coapt’s Complete Control Gen2 add-on controller kit, and Ottobock’s Myo Plus system.

Literature Review
Results of studies published in the peer-reviewed scientific literature evaluating the impact of these devices on clinical outcomes are mixed. Evidence is primarily in the form of case series and does not provide strong conclusions to support the use of these devices for improving quality of life, although some authors have reported greater function and range of motion among subjects using the device. In general, the reported outcomes are subjective and there is little data regarding outcomes such as functional status, studies with direct comparisons to body-powered devices or passive devices is limited. Moreover, patient selection criteria are not clearly defined. However, despite these and other confounding variables, the published literature supports clinical benefits from the use of a myoelectric prosthesis.

Evidence in the scientific peer-reviewed literature is insufficient to establish the efficacy and overall clinical utility of intent decoding or pattern recognition modules for upper limb prosthetic devices. Evidence is primarily in the form of case studies, case series, and randomized trials with small sample sizes, heterogenous patient populations, and mixed outcomes (Simon, et al., 2023b; Simon, et al., 2019; Woodward and Hargrove, 2019; Hargrove, et al., 2018; Resnick, et al., 2018; Hargrove, et al., 2017; Kuiken, et al., 2016).

Lower Limb
Prior to being fitted with a lower limb prosthetic device, the individual must demonstrate specific functional levels. A functional level is defined as a measurement of the capacity and potential of the individual to accomplish his/her expected post-rehabilitation daily function.

The Medicare Functional Classification Level (or “K level”) rating system consists of five classification levels and is used to gauge an individual's rehabilitation potential for using a lower

limb prosthesis. The characteristics of individuals classified as K0 through K4 include the following (Centers for Medicare & Medicaid Services [CMS], 2017):

- Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
- Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence, typical of the limited and unlimited household ambulator.
- Level 2: Has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs or uneven surfaces. This level is typical of the limited community ambulator.
- Level 3: Has the ability or potential for ambulation with variable cadence, typical of the community ambulator who has the ability to transverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
- Level 4: Has the ability or potential for prosthetic ambulation that exceeds the basic ambulation skills, exhibiting high impact, stress or energy levels typical of the prosthetic demands of the child, active adult, or athlete.

Lower limb prosthetic devices may be preparatory or permanent. A preparatory device is a prosthesis made soon after an amputation (approximately four weeks) as a temporary method of retraining a person to walk and balance while shrinking the residual limb. A permanent prosthesis is recommended when an individual has used a prosthetic device full time for a period of six months and when the limb volume has stabilized to a point where the socket fit remains relatively consistent for two to three weeks.

Components and/or additions to a prosthesis may be supported; the determination of medical necessity is based on the person's functional ability and expected functional potential as defined by the prosthetist and the ordering physician. Appropriate documentation supporting medical necessity must accompany requests submitted for prosthetic components and/or additions. Customizing prosthetic devices with enhanced features is generally not supported if activities of daily living can be met with standard devices.

Accessories that are necessary for the effective use of the prosthetic device may also be considered medically necessary devices. Accessories that are not necessary for the effective use of the device are considered not medically necessary. While some prosthetic manufacturers offer devices with waterproof features, including devices that are submergible (e.g., the Fin [Eschen Prosthetics and Orthotics Labs, New York, NY] [used for swimming]; Genium X3 and X4 [Ottobock], [waterproof microprocessor-controlled knee prosthetic devices]), when used for recreational purposes these prosthetic accessories/devices are considered a convenience item and not medically necessary.

Lower Limb Microprocessor-Controlled Device—Knee: Microprocessor-controlled knee prosthetics are sensor-equipped devices. The sensor detects when the knee is in full extension and adjusts the swing phases automatically, allowing a more natural pattern of walking at variable speeds (passive powered device). Multiple devices are available that use various degrees of computer technology to enhance the clinical function of the basic mechanical knee design; all microprocessor controlled systems do not have identical features and functions. Some devices have swing phase only, stance phase only, or swing and stance phase. Some of the devices currently available include but are not limited to the Ottobock C-Leg®, and the Orion3 SmartIP (Blatchford Limited, Miamisburg, OH). The Genium X3 and X4 microprocessor devices by Ottobock are waterproof and submersible. The Kenevo prosthetic knee (Ottobock) is a device that is recommended for users with low to moderate mobility (indoor ambulation, limited outdoor ambulation) and is purported to better support those who use a walker, cane, crutch or wheelchair

device. According to the manufacturer this device is not indicated for walking speeds greater than 3 km/hour and has a supported feature for stand-to-sit and sit-to-stand, wheelchair mode, and for putting on the prosthesis while seated. A number of other devices are currently under investigation.

The purported advantages of a microprocessor-controlled above-the-knee (AKA) prosthesis include:

- reduced energy expenditure of the amputee
- improved ability to walk on uneven ground
- improved ability to climb and descend stairs
- increased walking distance

Literature Review: In the published, peer-reviewed scientific literature, evidence supporting the use of microprocessor-controlled/computer-controlled prostheses comes primarily from small-group case studies with few randomized, case-controlled trials, and systematic reviews. Of the groups studied clinically, most individuals were in good health and without other medical complications. Evidence in the peer-reviewed, published scientific literature does support reduction in energy consumption, improved physical function, and a more symmetrical gait pattern when compared to a conventional device (Carse, et al., 2021; Lansade, et al., 2018; Aldridge Whitehead, et al., 2014), with some studies showing a decreased fall risk (McGrath, et al., 2022; Campbell, et al., 2020; Kaufman, et al., 2018). Some evidence supports both reduced hip moment and metabolic requirements particularly at faster speeds. Although the evidence continues to evolve, there is evidence that supports the effective use of these devices for limited populations. Evidence evaluating microprocessor prosthetic knee devices for users that are less active in the community, and/or limited to indoor use (i.e., < functional level 3) is insufficient to support clinical utility and improved health outcomes.

Lower Limb Microprocessor-Controlled Device—Ankle: In order to enhance the basic mechanical design and mimic the action of a biological ankle, researchers have applied microprocessor technology to prosthetic feet. Stair ambulation is limited in the transtibial amputee as a result of neutral and fixed ankle position. Newer prosthetic ankles which adjust for ankle angle during swing phase and identify sloping gradients and ascent or descent of stairs are under investigation. One such microprocessor-controlled ankle foot prosthesis is the Proprio Foot® (Ossur, Aliso Viejo, CA). The Proprio Foot is a quasi-passive ankle that is able to actively change the ankle angle in the unloaded swing phase as the result of microprocessor-control and sensor technology. The device is passive (without power) while in stance phase. According to the manufacturer, the proposed benefits of microprocessor–controlled ankle movements include the ability to identify slopes and stairs, when ascending or descending stairs the device automatically adapts ankle position to enable the next step; allows the user to place both feet behind their knees when rising from a chair; and automatically gives a toe-lift allowing sufficient ground clearance when walking. The device is designed to promote a more symmetrical and balanced gait and is intended for use by transtibial amputees engaging in low to moderate impact activities who are classified as level K3 (i.e., community ambulatory, with the ability or potential for ambulation with variable cadence). It is not suitable for sport and high impact activities.

Literature Review: Evidence in the published peer-reviewed scientific literature evaluating the use of microprocessor-controlled ankle foot devices is limited and consists mainly of pilot studies and case series involving small sample populations (Ernst, et al., 2022; Kim, et al., 2021; Struchkov and Buckley, 2016). Although limited, the evidence does demonstrate some clinical advantages for use compared to conventional ankle foot prosthesis for individuals who are functional level 3 or greater. These devices may improve slope and uneven terrain ambulation allowing larger range of motion of the ankle when compared with other conventional devices.

Combination Microprocessor-Controlled Knee-Ankle/Foot Prosthetic: Combination microprocessor prosthetics are available integrating both a microprocessor knee and the ankle/foot device (e.g., SYMBIONIC® LEG 3 [Ossur, Iceland] [no longer commercially available]; Linx Limb System [Endolite/Blatchford]). One device, the SYMBIONIC® LEG 3 is a prosthetic that combines a microprocessor knee with a powered microprocessor ankle with proactive ankle flexion. The device purportedly has a more powerful knee actuator and new kinematic sensors for improved stability, increased support with stance flexion, and more rapid, and consistent swing extension. For a transfemoral amputee, combining both types of prosthetic devices theoretically enables a more natural and symmetrical gait when ambulating, decreasing energy expenditure, and offering increased stability. The device is intended for use by individuals who are Functional Level 3 or 4. The Linx prosthetic system is intended for individuals who are Functional Level 3 or greater; according to the manufacturer this system is an integrated prosthetic utilizing a microprocessor-controlled system in addition to sensors and actuators which simultaneously controls the knee and foot.

Lower Limb Powered Microprocessor-Controlled Prosthetic Device
Powered Knee: Powered prosthetic devices that use signals from muscle activity in the remaining limb to bend and straighten the device remain under investigation. These devices utilize sensors and electronics to process data and control movement and power of the knee. Examples of this type of device include the Power Knee™, manufactured by Ossur. According to the manufacturer, the Power Knee is described as a motorized device which contains a rechargeable battery pack. It is designed to replace muscle activity of the quadriceps muscle and uses artificial proprioception with sensors in order to anticipate and respond with the appropriate movement required for stepping (active powered device). In comparison to a passive prosthetic knee, including a microprocessor device, the manufacturer suggests a power knee offers advantages such as powered extension with standing, controlled resistance with descending, and active flexion and extension during walking. The device controls the transition from a bent knee to an extended knee, at heel strike supports the individual's full body weight, and can help lift above-knee amputees out of a chair to a standing position. It is suggested the device helps to maintain walking speeds, assists with upward motion (required for stairs and inclines), and learns and responds to gait patterns. With the initial use of the device a practitioner must program and align the knee. Once programming and alignment are complete, the user needs only to press the power button to use the device. The device is compatible with a variety of dynamic flex-foot feet, must be re-charged daily and is not intended for high impact activity, sports, excessive loading or heavy duty use.

Powered Foot-Ankle: Similar to the powered knee device, powered foot-ankle prosthetic devices are currently being developed. Two such devices are the BiOM® Ankle (BionX Medical Technologies, [previously iWalk, Inc., Bedford, MA) and the Empower prosthetic foot (Ottobock). The BiOM device (previously referred to as Powerfoot One) uses a combination of processors, sensors, motors, and springs that allow the user a powered push-off with taking steps. Theoretically the device replaces the action of the foot, Achilles tendon and calf muscle to result in a near normalized gait for amputees and is intended for amputees that are functional level 3 or 4.

Literature Review: The available evidence in the published scientific literature consists mainly of studies evaluating device design and biomechanics with few comparative clinical trials available. While some authors have reported on performance such as kinematic measures, improved energy costs, and biomechanical analysis (Ingraham, et al., 2016; Simon, et al., 2016; Gates, et al., 2013; Aldridge, et al., 2012) with the use of a powered prosthetic device (ankle/foot or knee), these studies involve small sample populations and evaluate short-term outcomes. Wolfe et al. (2013) evaluated functional and clinical differences during sit-to-stand and step-up among power knee device users (n=5) compared to the microprocessor C-Leg (n=5). The authors noted few differences between users during sit-to-stand and step-up task and no difference with regards to

decreased impact on the intact limb. Currently there remains a paucity of published clinical trials evaluating ankle/foot powered devices (Esposito, et al., 2016; Rabago, et al., 2016; Takahashi, et al., 2013; Grabowski and D'Andrea, 2013; Herr and Grabowski, 2012). Until clinical trials are conducted to confirm the safety, efficacy and overall clinical utility of the powered ankle/foot device compared with other conventional or microprocessor prostheses, improvement in net health outcomes has yet to be determined.

Lower Limb Vacuum Suspension System: Suspension systems for lower limb prostheses keep the prosthesis in place, ensuring a good fit between the socket and residual limb. The intended function is to provide a connection that reduces rotational and shearing forces which can result in skin breakdown as well provide for balance and steady gait. Various types of suspension systems are available and include those that are primarily mechanical or suction-type systems. Mechanical systems involve the use of belts, straps, or sleeves, for example, to attach the device to the residual limb. Suction-type systems function by way of a negative pressure created between the socket and insert/liner. These devices can be passive (air escapes while donning via a one-way valve) or active (suction pump evacuates the air). Passive systems involve the use of a soft liner, a one-way valve and a donning sleeve. A liner is placed over the limb, the limb is placed in the socket and the force of one's body weight upon standing expels excess air through the valve creating a seal. With active suction devices the sleeve creates a seal around the edge of the socket and a pump and exhaust remove the excess air between the socket and the liner to ensure a secure fit.

Various vacuum suction-type devices (mechanical or electrical) are available and include the Vacuum-Assisted Socket System (VASS) (Ottobock Harmony Vacuum-Assisted Socket System), and the LimbLogic prosthetic vacuum suspension system (WillowWood). Each device is a vacuum suction-type suspension system that manufacturers claim helps control volume fluctuation in the residual limbs of lower-extremity amputees, reduces forces to the limbs, and improves both suspension and proprioception without restricting vascular flow. Although patient selection criteria have not been firmly established, the device has been proposed for individuals with non-healing skin ulcerations located on the stump and/or when other socket systems have failed to provide a secure fit.

The choice of a suspension system is determined by factors such as activity level, residual stump shape, age, and health status. There is some evidence to support vacuum systems decrease limb volume fluctuations, can improve socket fit, reduce inside movement for some individuals, as well as improve comfort and satisfaction (Gholizadeh, et al., 2016). For individuals where other types of suspension systems have failed to provide a secure fit or are contraindicated, a vacuum suction-type suspension system may be considered an effective alternative.

Appendix

Appendix 1 – Lower Limb Prosthetic "Device to Coding" Crosswalk

Please note, this list is for informational purposes only; it DOES NOT imply coverage or non-coverage of a device, or guarantee claim reimbursement. Coding may vary according to manufacturer.

Device Name	Brief Description	Manufacturer	HCPCS Code(s)
Allux™ 2	Microprocessor-controlled knee	Proteor/Nabtesco	L5856, L5848, L5845, L5615, L5925, L7367, L5930, L5999

Device Name	Brief Description	Manufacturer	HCPCS Code(s)
Bio Leg®	Microprocessor-controlled motor-powered knee	BionicM	L5859, L5856, L5827
C-Leg	Microprocessor-controlled knee	Ottobock	L5856, L5850, L5848, L5845, L5828, L5925
Elan	Microprocessor-controlled ankle foot	Blatchford	L5973
Empower	Microprocessor-controlled ankle foot (power)	Ottobock	L5969, L5973
Genium Genium X3 Genium X4	Microprocessor-controlled knee (X3 and X4 are waterproof)	Ottobock	L5999
INTUY® Knee	Microprocessor-controlled motor-powered knee	WillowWood Global	L5859, L5856, L5827
Kenevo	Microprocessor-controlled knee	Ottobock	L5856, L5850, L5848, L5845, L5828, L5925
Kinnex 2.0	Microprocessor-controlled ankle foot	Proteor	L5973
Linx	Combination microprocessor-controlled knee and foot	Blatchford	L5856, L5850, L5848, L5845, L5828, L5925, L5973
Meridium	Microprocessor-controlled ankle foot	Ottobock	L5973
Orion3	Microprocessor-controlled knee	Blatchford	L5856, L5850, L5848, L5845, L5828, L5925
Power Knee™	Microprocessor-controlled motor-powered knee	Össur	L5859, L5856, L5827
Plié 3®	Microprocessor-controlled knee (submersible)	Proteor	L5856, L5850, L5848, L5845, L5828
Pro-Flex® Pivot	Mechanical ankle foot	Össur	L5781, L5999
Proprio Foot®	Microprocessor-controlled ankle foot	Össur	L5973
Rheo Knee® Rheo Knee® XC	Microprocessor-controlled knee (Rheo Knee XC supports early rehabilitation to full recovery)	Össur	L5856, L5850, L5848, L5845, L5828, L5925
SmartIP	Microprocessor-controlled knee, with weight activated stance control	Blatchford	L5830, L5857 (+L5845 for Stanceflex models only)

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No Determination found	
LCD	CGS Administrators; Noridian Healthcare Solutions	Lower Limb Prostheses (L33787)	4/1/2025
LCD	CGS Administrators; Noridian Healthcare Solutions	Facial Prostheses (L33738)	1/1/2020
LCD	CGS Administrators; Noridian Healthcare Solutions	Eye Prostheses (L33737)	1/1/2020

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare and Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

IRIS PROSTHESIS
Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
66683	Implantation of iris prosthesis, including suture fixation and repair or removal of iris, when performed
0616T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens (Code deleted 12/31/2024)
0617T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens (Code deleted 12/31/2024)
0618T	Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange (Code deleted 12/31/2024)

HCPCS Codes	Description
C1839	Iris prosthesis

EXTERNAL FACIAL PROSTHESIS

Considered Medically Necessary when criteria in the applicable policy statements listed above are met and only when coverage is available under the plan for the specific device/component/item.

Facial Prosthesis

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
21088	Impression and custom preparation; facial prosthesis

UPPER LIMB ADDITIONS/COMPONENTS
Additional Components/Features of Non Myoelectric Prosthetic Device

Considered Medically Necessary when used to report a medically necessary component or addition to an upper limb prosthetic device in the absence of a specific code:

HCPCS Codes	Description
L6646	Upper extremity addition, shoulder joint, multipositional locking, flexion, adjustable abduction friction control, for use with body powered or external powered system
L6647	Upper extremity addition, shoulder lock mechanism, body powered actuator

UPPER LIMB: MYOELECTRIC PROSTHETIC DEVICE
Considered Medically Necessary when criteria in the applicable policy statements listed above are met and only when coverage is available under the plan for the specific device/component/item:

HCPCS Codes	Description
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)
L6611	Addition to upper extremity prosthesis, external powered, additional switch, any type
L6638	Upper extremity addition to prosthesis, electric locking feature, only for use with manually powered elbow
L6646	Upper extremity addition, shoulder joint, multipositional locking, flexion, adjustable abduction friction control, for use with body powered or external powered system
L6648	Upper extremity addition, shoulder lock mechanism, external powered actuator
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

HCPCS Codes	Description
L6920	Wrist disarticulation, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal, switch, cables, two batteries and one charger, switch control of terminal device
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
L6930	Below elbow, external power, self-suspended inner socket, removable forearm shell, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L6940	Elbow disarticulation, external power, molded inner socket, removable humeral shell, outside locking hinges, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L6950	Above elbow, external power, molded inner socket, removable humeral shell, internal locking elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L6960	Shoulder disarticulation, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch control of terminal device
L6965	Shoulder disarticulation, 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
L6970	Interscapular-thoracic, external power, molded inner socket, removable shoulder shell, shoulder bulkhead, humeral section, mechanical elbow, forearm, Otto Bock or equal switch, cables, two batteries and one charger, switch 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
L7040	Prehensile actuator, switch controlled
L7045	Electric hook, switch or myoelectric controlled, pediatric
L7170	Electronic elbow, Hosmer or equal, switch controlled
L7180	Electronic elbow, microprocessor sequential control of elbow and terminal device
L7181	Electronic elbow, microprocessor simultaneous control of elbow and terminal device
L7185	Electronic elbow, adolescent, Variety Village or equal, switch controlled

HCPCS Codes	Description
L7186	Electronic elbow, child, Variety Village or equal, switch controlled
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

Considered Experimental/Investigational/Unproven:

HCPCS Codes	Description
L6700	Upper extremity addition, external powered feature, myoelectronic control module, additional EMG inputs, pattern-recognition decoding intent movement

LOWER LIMB: MECHANICAL (NON-POWERED, NON MICROPROCESSOR)
Considered Medically Necessary when used to report a component or addition to a lower limb prosthetic device when criteria in the applicable policy statements listed above are met and when coverage is available under the plan for the specific device/component/item:

HCPCS Codes	Description
L5828†	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5999††	Lower extremity prosthesis, not otherwise specified

†**Note: Considered medically necessary for functional level 3 or above.**

††**Note: Considered medically necessary when used to report a medically necessary component or addition to a lower limb prosthetic device in the absence of a more specific code.**

LOWER LIMB MICROPROCESSOR-CONTROLLED PROSTHETIC DEVICES
Considered Medically Necessary when criteria in the applicable policy statements listed above are met and when benefits are available under the plan for a microprocessor-controlled prosthetic:

HCPCS Codes	Description
L5827	Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5857	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing phase only, includes electronic sensor(s), any type
L5858	Addition to lower extremity prosthesis, endoskeletal knee shin system, microprocessor control feature, stance phase only, includes electronic sensor(s), any type

HCPCS Codes	Description
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

Additional Components/Features of Microprocessor-Controlled Prosthetic Devices:

Considered Medically Necessary when criteria in the applicable policy statements listed above are met and when benefits are available under the plan for a microprocessor-controlled prosthetic:

HCPCS Codes	Description
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5999†	Lower extremity prosthesis, not otherwise specified

†**Note: Covered when used to report a medically necessary component/feature or addition to a lower limb prosthetic microprocessor-controlled device in the absence of a specific code.**

LOWER LIMB: POWERED MICROPROCESSOR-CONTROLLED PROSTHETIC DEVICES
Considered Medically Necessary and when benefits are available for a power-controlled or power- assisted lower limb knee device (e.g., Ossur Power Knee):

HCPCS Codes	Description
L5859†	Addition to lower extremity prosthesis, endoskeletal knee-shin system, powered and programmable flexion/extension assist control, includes any type motor(s)

†**Note: L5859 requires K-3 functional level; the device is not intended for high impact activity, sports, excessive loading or heavy duty use.**

Microprocessor-Controlled Ankle Foot Prosthetic with Power Assist (e.g., Ottobock Empower)

Considered Not Medically Necessary:

HCPCS Codes	Description
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)
L5973	Endoskeletal ankle foot system, microprocessor controlled feature, dorsiflexion and/or plantar flexion control, includes power source

Additional Components/Features of Powered Prosthetic Devices, Including Power Assist Features:

Considered Not Medically Necessary when reported in addition to a non-covered power-controlled (L5859, L5973) or power-assisted (L5969) prosthetic device:

HCPCS Codes	Description
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control
L5856	Addition to lower extremity prosthesis, endoskeletal knee-shin system, microprocessor control feature, swing and stance phase, includes electronic sensor(s), any type
L5969	Addition, endoskeletal ankle-foot or ankle system, power assist, includes any type motor(s)

LOWER LIMB: VACUUM SUSPENSION SYSTEM
Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
L5781	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system

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Revision Details

Type of Revision	Summary of Changes	Date
Focused Review	• Added noncoverage policy statement for intent decoding and pattern recognition add-on modules for upper limb prostheses.	6/15/2025
Annual Review	• Removed policy statements for consumable supplies; upper limb sensor and myoelectric controlled prosthetic device with simultaneous multiple degrees of freedom; upper limb prosthetic device using electromyography-based brain computer interface; osseointegrated/osseoanchored lower limb prosthetic device; and repair/replacement of a prosthetic device. • Revised policy statements for iris prostheses; external facial prostheses; and lower limb prostheses.	3/15/2025
Annual Review	• No clinical policy statement changes.	1/15/2024