Medical Coverage Policy

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Prosthetic Devices

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Intraocular Lens Implant
Male Sexual Dysfunction Treatment: Non-Pharmacogenic
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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

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

The policy statements below provide medical necessity criteria, including functional level requirements where applicable, and coding information for the following:

- General Criteria for any Prosthetic Device
- External Facial Prosthetic Device
- Upper Limb Prosthetic Device (Myoelectric)
- Lower Limb Prosthetic Device (Microprocessor-controlled, Powered-microprocessor controlled, Vacuum Suspension System)
- Repair and Replacement

For information regarding medical necessity criteria for any other prosthetic device please reference the applicable Cigna Medical Coverage Policy:

- Breast Reconstruction Following Mastectomy or Lumpectomy
- Intraocular Lens Implant
- Male Sexual Dysfunction Treatment: Non-Pharmacogenic
- Gender Dysphoria Treatment

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 w**hen 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
- consumable supplies for the care of prosthetic device (e.g., cosmetics, creams, cleansers, skin barrier wipes)
- 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., Water Leg, used for showering, swimming])

IRIS PROSTHESISs

An iris prosthesis (HCPCS code C1839) for the treatment of full or partial aniridia is considered experimental, investigational or unproven.

EXTERNAL FACIAL PROSTHESIS

An external facial prosthesis (HCPCS code L8040, L8041, L8042, L8043, L8044, L8045, L8046, L8047 and L8048) 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.

Each of the following supplies related to the care of, and/or application or removal of, an external facial prosthesis is a consumable item specifically excluded under most benefit plans and considered not medically necessary:

- cosmetics
- skin creams
- skin cleansers
- adhesives
- adhesive remover
- skin barrier wipes
- tape

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 upper limb sensor and myoelectric controlled prosthetic device with simultaneous multiple degrees of freedom (e.g., LUKE [Life Under Kinetic Evolution] Arm) is considered experimental, investigational or unproven.

An upper limb prosthetic device using electromyography-based brain computer interface (BCI) is considered experimental, investigational or unproven.

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

The following lower limb additions and/or components are considered medically necessary when the individual is functional level 3 or greater and medical necessity criteria has been met for the base device:

- A flex-walk system or equal, all lower extremity prosthesis (HCPCS code L5981)
- a single axis, fluid swing and stance phase control (HCPCS L5828)
- a fluid stance extension, dampening feature, with or without adjustability (HCPCS L5848)

An adjustable stance flexion feature (HCPCS L5845) is considered medically necessary when the individual is functional level 1 or greater and medical necessity criteria has been met for the base device.

A high activity knee control frame (HCPCS code L5930) is considered medically necessary for an individual who is functional level 4 and medical necessity criteria has been met for the base device.

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 (below-the-knee)
- a microprocessor-controlled knee prosthetic (HCPCS code L5856, L5857, L5858) for a knee disarticulation amputee or a transfemoral amputee (above-the-knee)
- a combination microprocessor-controlled prosthetic/system (e.g., SYMBIONIC® LEG 3, 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.

An osseointegrated/osseoanchored lower limb prosthetic device is considered experimental, investigational or unproven.

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:

- Individual has a swing and stance phase type microprocessor controlled (electronic) knee (HCPCS L5856)
- Is K3 functional level only*
- Has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone

  *Note: 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., BiOM® Ankle, emPOWER™ Ankle [HCPCS L5973, L5969])
- a powered lower limb prosthetic for any other indication

LOWER LIMB: VACUUM SUSPENSION SYSTEM

A vacuum suspension system (e.g., vacuum-assisted socket system [VASS™]) (HCPCS code L5781, L5782) 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.

REPAIR AND REPLACEMENT

Repair and/or replacement of a medically necessary prosthetic device is considered medically necessary for EITHER of the following indications:

- when anatomical change or reasonable wear and tear renders the item nonfunctional and the repair will make the equipment usable.
- when anatomical change or reasonable wear and tear renders the item nonfunctional and nonrepairable.

General Background

PROSTHETIC DEVICE

A prosthesis is an artificial device used to replace a missing body part and is intended to restore normal function.

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

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.

U.S. Food and Drug Administration (FDA)

Prosthetic devices are subject to regulation by the FDA as medical devices. Prosthetic accessories and limb components are classified by the FDA as Class I devices.

IRIS PROSTHESIS

An iris prosthesis is an implanted device recommended 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. 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 IOL. The device allegedly 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.

The CustomFlex™ Artificial Iris (Clinical Research Consultants, Inc., Cinn., OH [HumanOptics]) received premarket approval (P170039) by the U.S. Food and Drug Administration (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.

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. 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, Germany) 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 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).

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, presenting from 2011 through 2014 who underwent pupillary reconstruction with a new artificial iris implant (Artificial Iris, HumanOptics, Germany), 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, Germany). Only eyes with a minimum follow-up period of 2 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 followup 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 3 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, however not to implants without mesh.

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 5 eyes of 4 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 2 eyes of 1 patient with congenital aniridia associated with congenital cataract, and 3 eyes with traumatic aniridia (1 with subluxated cataractous lens and 2 with aphakia). The iris prosthesis was implanted after a 3-piece acrylic intra-ocular lens (IOL) was implanted in all cases. Measured outcomes included intra-operative and post-operative complications, and the cosmetic satisfaction and evaluation of the clinical course for at least six months. Uncorrected distance VA and best-corrected distance visual acuity (BCVA) improved for all subjects. All patients had a transient corneal edema that resolved within the 1st post-operative week. Only the patient with congenital aniridia had a permanent increase in IOP and developed a band keratopathy throughout a 2-year follow-up period. The prosthesis was well-centered in all eyes except for 1 case that needed scleral suture fixation after 3 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 post-operative 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, 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, Germany), 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 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.

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 was 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 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, VA, IOP, and endothelial cell count (ECC). Retraction syndrome, manifest 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 5 of 7 affected eyes, the artificial iris had been implanted into the ciliary sulcus; in 2 eyes it had been sutured to the sclera. A total of 4 of the 7 subjects presented with remarkable complications: 2 eyes needed glaucoma shunt surgeries owing to pigment dispersion; 1 suffered from recurrent bleeding; and in 1 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.

Figueiredo and Snyder (2020) retrospectively evaluated the safety and effectiveness of the CustomFlex device when 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, IOP, glaucoma drops, and other comorbid pathologies. Additional postoperative 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 was 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 2 lines and 24 eyes (25.0%) stayed within 2 lines, whereas no eye lost 2 or more lines. When compared with last measured visual acuity 58.3% (56) of the eyes improved 2 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 ariridic pathology within the group.

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 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), IOP, ECD, and slit-lamp observations. Endothelial cell density was measured at the screening visit and at 6 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 demonstrate 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 > 2 lines related to the device. Median ECD loss was 5.3% at 6 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 and is therefore safe and effective for the treatment of symptoms and an unacceptable cosmetic appearance created by iris defects. Limitations of the trial include short term followup of 12 months.

The National Institute for Health and Care Excellence (NICE) published interventional procedures guidance for artificial iris insertion as treatment for acquired aniridia (NICE, 2020). 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.

Other implants have been investigated in the medical literature, however FDA approvals were not found on the FDA site (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).

An ongoing clinical trial can be referenced at the National Library of Clinical Trials, it is a parallel non randomized study evaluating the safety and efficacy of the CustomFlex Artificial Iris for treatment of iris defects (NCT01860612). Although promising, evidence in the peer reviewed scientific literature evaluating use of the artificial iris prosthesis has not firmly established safety and efficacy of the device. Professional society statements regarding use of the device as treatment for anridia from the American Academy of Ophthalmology and American Association for Pediatric Ophthalmology were not found. Within the clinical studies 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 followup are needed to evaluate use of the device and impact on health outcomes.

EXTERNAL FACIAL PROSTHESIS

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.

Skin care products (e.g., cosmetics, creams, and cleansers) related to care of the prosthesis, and the application and/or removal of the device are considered personal care items.

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.

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 does lend some support in clinical benefits from the use of a myoelectric prosthesis.

Areas of development for powered upper limb prosthetic devices include devices that function using implantable sensors, reinnervation of muscle fibers to allow fine movement control as well as sensory feedback and multiple simultaneous degrees of freedom. The LUKE (Life Under Kinetic Evolution) Arm (Mobius Bionics, LLC) is an upper limb prosthesis that has been developed to restore function in individuals who have lost all or part of their upper limb and has multiple powered joints and grip patterns and is capable of multiple simultaneous degrees of freedom, controlled using EMG signals. In addition to the EMG electrodes, the LUKE Arm contains a combination of mechanisms, including switches, movement sensors, and force sensors. The primary control resides with inertial measurement sensors on top of the feet. The micro-electromechanical control system is operated through an inertial measurement unit (IMU), which is located in a sensor that is attached to or embedded in the individual’s shoe. The user commands motion of the prosthesis by moving the foot in various directions. The device is available for transradial, transhumeral or shoulder amputation. Nevertheless the evidence in the peer reviewed literature is insufficient to support safety and efficacy of these emerging-type of devices.

Upper limb devices (HCPCS L6880, L6935) using electromyography-based brain computer infterface are being investigated. These devices reportedly function by gathering brain activity or information in order to trigger movement. One device, the Esper Hand (Esper Bionics Inc., New York) has five moveable digits which can allow multiple grips and movements of rotation promoting the ability to perform everyday tasks in addition to a computer or smartphone platform that collects and stores information regarding the users movements. By doing so it can assume what the users next action would be allowing it to predict movements more rapidly. Evidence in the scientific peer reviewed literature evaluating brain based computer interface for upper limb prostheitc deivices is insufficient to support safety and efficacy at this time.

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.

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 2–3 weeks.

Components and/or additions to a prosthesis may be medically necessary; 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. Additional documentation supporting medical necessity must accompany claims submitted for prosthetic components and/or additions. Customizing prosthetic devices with enhanced features is not medically necessary 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., Water Leg, [Standard Cyborg, SF, CA] [used for showering, swimming], Genium X3 [Ottobock, US], [a waterproof microprocessor-controlled knee prosthetic device]), when used for recreational purposes these prosthetic accessories/devices are considered a convenience item and not medically necessary.

LOWER LIMB Osseointegrated Prosthesis

Additionally, more advanced technological systems using multiple sensors to send messages back to a microchip regarding changes in walking patterns and osseoanchored prosthetic devices for lower limbs are being investigated. These devices represent emerging technologies and are undergoing clinical trials evaluating performance, safety and durability. In contrast to the standard of care socket-suspended prosthesis, an osseoanchored prosthetic device consists of a fixture and abutment screw that is surgically implanted into bone. After healing and various stages of rehabilitation the fixture is then attached to a prosthesis. One such device, the OPRA™ Implant System (Integrum AB, Sweden), has received FDA approval as a humanitarian device for prosthetic use. According to the manufacturer the system consists of three parts; an anchoring element (the Fixture) and a skin penetrating connection (the Abutment), and a securing titanium screw (the Abutment Screw). FDA labeling indicates the intended use is for patients who have transfemoral amputation due to trauma or cancer and who have rehabilitation problems with, or cannot use, a conventional socket prosthesis. The OPRA device is intended for skeletally mature patients. A systematic review published in 2018 by Kunutsor and colleagues evaluating the safety and efficacy of osseintegrated prostheses included a total of 22 eligible articles; 13 of the studies were unique. The average sample size of the studies included ranged from 11 to 100 participants, none of the studies were RCTs. The reported outcomes of all studies supported improvement in functional outcomes (walking ability, prosthetic use and mobility), and satisfaction and quality of life following osseointegration, compared with their preoperative status or when using a conventional socket prosthesis. Infection rates varied from 1% to 77%, with the majority of infections described as low-grade soft tissue or superficial infections related to the skin–implant interface. Infections were treated effectively with antibiotics. According to the authors none of the studies reported additional amputation or death as a result of osseointegration and they concluded osseointegration following limb amputation improved prosthetic use, comfort when sitting, walking ability, mobility, gait and quality of life. However, use of such devices is associated with an increased risk of soft tissue infection.

In 2017 the Canadian Agency for Drugs and Technologies in Health (CADTH) published a systematic review to evaluate the evidence for osseointegrated prosthetic devices for lower limb amputation. After reviewing seven studies that met inclusion criteria, the authors concluded the quality of evidence is generally low, and while some evidence suggests there is improvement in quality of life, function and mobility after implantation there is concern regarding high rates of infection, and the design of and materials used affecting safety and efficacy. Overall, the authors

reported the available evidence suggests that careful attention should be given to patient selection, implant selection, and residual limb skin integration, as well as surgical and rehabilitation protocols, to optimize outcomes and reduce adverse event rates**.**

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 (L5666, L5670-L5672). 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™) (Otto Bock Harmony Vacuum-Assisted Socket System, Otto Bock HealthCare; Minneapolis, MN), the eVAC® (Smith, Global), and the LimbLogic ™ VS prosthetic vacuum suspension system (Mount Sterling, Ohio). 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.

Evidence in the published, peer-reviewed scientific literature evaluating suspension systems, in particular vacuum suction–type suspension systems is limited. Much of the published literature is in the form of feasibility trials, case reports, and uncontrolled case series involving small populations. Reported outcomes are mixed, are short term, lack high statistical power and cannot be generalized. The results of one published randomized trial (Traballesi, et al., 2012) demonstrated that following a 12 week rehabilitation program VASS users had better clinical mobility compared to subjects using a conventional prosthesis with a standard suction socket. The authors reported that VASS users used their prosthesis more than the control group and that despite increased use, pain while using the VASS device did not differ significantly compared to the control group at various points of follow-up. The sample size of the trial involved only 20 subjects, three of whom dropped out of the study, and therefore generalization of results to larger populations cannot be made.

The published evidence does not provide strong support of clinical utility for this technology compared to conventional socket-suspension systems for the general population and clinical effectiveness has not been firmly established in this subgroup. 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). While additional long term studies and higher quality data would be helpful for evaluating an active suction-type vacuum suspension system, 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.

LOWER LIMB: Microprocessor-controlled Device

Microprocessor-controlled 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 Otto Bock C-Leg® , Genium and X2 (Otto Bock HealthCare, Minneapolis, MN), and the Endolite Orion, Intelligent and SmartIP (Endolite North America, Chase A. Blatchford and Sons Ltd., Miamisburg, OH). Another microprocessor device, the X3 (Otto Bock HealthCare, Minneapolis, MN), is waterproof; the device is completely submersible according to the manufacturer. 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; Aldridge Whitehead, et al., 2014) with some studies showing a decreased fall risk (McGrath, et al., 2022; Campbell, et al., 2020**).** 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.

Microprocessor-controlled 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 (e.g., Proprio Foot, Ossur, élan Foot, Endolite). 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 microprocessor-controlled ankle foot prosthesis currently available which has received FDA approval 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, 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]; LiNX® [Endolite]). 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® [Endolite]) 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 (Foothill Ranch, CA). 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.

According to criteria outlined in the Centers for Medicare and Medicaid Services Local Coverage Determination, the following individuals may benefit from the use of a power knee-ankle device:

- the individual has a microprocessor (swing and stance phase type (L5856) controlled (electronic) knee
- is K3 functional level only
- has a documented comorbidity of the spine and/or sound limb affecting hip extension and/or quadriceps function that impairs K-3 level function with the use of a microprocessor-controlled knee alone
- is able to make use of a product that requires daily charging
- is able to understand and respond to error alerts and alarms indicating problems with the function of the unit.

Powered Foot-ankle: Similar to the powered knee device, powered foot-ankle prosthetic devices (HCPCS L5973 and L5969) are currently being developed. Two such devices are the BiOM® Ankle and emPOWER™ Ankle, (BionX Medical Technologies, [previously iWalk, Inc., Bedford, MA). 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. According to the manufacturer, the emPOWER™ Ankle is a more recent generation of the BiOM® Ankle.

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 (Simon, et al.,, 2016; Ingraham, 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 (Rabago, et al., 2016; Esposito, et al., 2016;Takahashi, et al., 2013; Grabowski, DeAndrea, 2013; Herr, 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.

Appendix

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

Please note, coding may vary according to manufacturer. This list is for informational purposes only, it DOES NOT indicate coverage/non-coverage of a device.

Device Name	Brief Description	Manufacturer	Code(s)
Allux	Microprocessor-controlled knee	Nabtesco	L5613, L5845, L5848, L5856, K1014
BiOM Foot	Microprocessor-controlled ankle foot (power)	BionX Medical Technologies	L5969, L5973
C-Leg	Microprocessor-controlled knee	Otto Bock	L5856, L5848, L5845, L5828

Device Name	Brief Description	Manufacturer	Code(s)
C-Leg Compact	Microprocessor-controlled knee	Otto Bock	L5858, L5828, L5848
Élan Foot	Microprocessor-controlled ankle foot	Blatchford	L5973
EmPOWER™	Microprocessor-controlled ankle foot (power)	BionX Medical Technologies	L5969, L5973
Genium	Microprocessor-controlled knee	Otto Bock	L5999, L5999, L5999,L5848, L5828, L5850, and L5930
Genium X2, Genium X3	Microprocessor-controlled knee (X3 is water proof)	Otto Bock	L5999
Kenevo	Microprocessor controlled knee joint	Otto Bock	L5828,L5845, L5848, L5856
Kinnex Foot	Microprocessor ankle/foot (waterproof)	Freedom Innovations	L5973
LiNX®	Combination microprocessor-controlled knee and foot; additionally has sensors and actuators	Blatchford	L5856, L5848, L5845, L5828, L5973
Meridium Foot	Microprocessor-controlled ankle foot	Otto Bock	L5999
Orion 3	Microprocessor-controlled knee	Blatchford	L5856, L5848, L5845, L5828
Össur Power Knee	Motor powered knee	Össur	L5859, L5856, L5828, L5848, L5845
Plié 3	Microprocessor-controlled knee (submersible)	Freedom Innovation (Freedom innovation component recently purchased by Otto Bock)	L5856, L5848, L5845, L5828
Proprio Foot®	Microprocessor-controlled ankle foot	Össur	L5973
Raize Foot	Microprocessor foot (does not have the power ankle)	Fillauer	L5973
Rheo	Microprocessor-controlled knee	Össur	L5856, L5848, L5845, L5828
Rheo XC	Microprocessor-controlled knee (supports rehabilitation to full recovery)	Össur	L5856, L5848, L5845, L5828
Smart IP	Microprocessor-controlled knee, with weight activated stance control	Blatchford	L5857, L5830, (L5845 for Stancflex models only)

Device Name	Brief Description	Manufacturer	Code(s)
SYMBIONIC® LEG 3	Combination microprocessor-controlled knee and ankle with proactive ankle flexion	Össur	L5856, L5848, L5845, L5828, L5973

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	No NCD	
LCD	CGS Administrators	Lower Limb Prosthesis (LCD L33787)	1/1/2020
LCD	Noridian Healthcare Solutions	Lower Limb Prosthesis (LCD L33787)	1/1/2020
LCD	CGS Administrators	Facial Prosthesis LCD L33738)	1/1/2020
LCD	Noridian Healthcare Solutions	Facial Prosthesis (LCD L33738)	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 AMA and 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

Experimental/ Investigational/ Unproven:

CPT®* Codes	Description
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
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
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

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.

Nasal Prosthesis

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

CPT®* Codes	Description
21087	Impression and custom preparation; nasal prosthesis

HCPCS Codes	Description
L8040	Nasal prosthesis, provided by a non-physician
L8047	Nasal septal prosthesis, provided by a non-physician

Orbit Prosthesis

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

CPT®* Codes	Description
21077	Impression and custom preparation; orbital prosthesis

HCPCS Codes	Description
L8042	Orbital prosthesis, provided by a non-physician

Ear Prosthesis

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

CPT®* Codes	Description
21086	Impression and custom preparation; auricular prosthesis

HCPCS Codes	Description
L8045	Auricular prosthesis, provided by a non-physician

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

HCPCS Codes	Description
L8041	Midfacial prosthesis, provided by a non-physician
L8043	Upper facial prosthesis, provided by a non-physician
L8044	Hemi-facial prosthesis, provided by a non-physician
L8046	Partial facial prosthesis, provided by a non-physician

Maxillofacial Prosthesis, External

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

HCPCS Codes	Description
L8048	Unspecified maxillofacial prosthesis, by report, provided by a non-physician

Considered not medically necessary when used to report non-covered consumable supplies outlined in the coverage policy:

HCPCS Codes	Description
A4364	Adhesive, liquid or equal, any type, per ounce
A4450	Tape, non-waterproof, per 18 square inches
A4452	Tape, waterproof, per 18 square inches
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per ounce
A4456	Adhesive remover, wipes, any type, each
L9900	Orthotic and prosthetic supply, accessory, and/or service component of another HCPCS "L" code

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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
L7499†	Upper extremity prosthesis, not otherwise specified

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

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
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

HCPCS Codes	Description
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
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
L7499†	Upper extremity prosthesis, not otherwise specified

†Note: Considered Medically Necessary when used to report components and/or additions to an upper limb prosthetic myoelectric device, if coverage for a myoelectric prosthetic device is available, and when medical necessity criteria are met.

Experimental/ Investigational/ Unproven when used to report an upper limb sensor and myoelectric controlled prosthetic device with simultaneous multiple degrees of freedom (e.g., LUKE [Life Under Kinetic Evolution] Arm) or for an upper limb prosthetic device using electromyography-based brain computer interface (BCI):

HCPCS Codes	Description
L7499	Upper extremity prosthesis, not otherwise specified

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
L5845††	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848†	Addition to endoskeletal, knee-shin system, fluid stance extension, dampening feature, with or without adjustability
L5930†††	Addition, endoskeletal system, high activity knee control frame
L5981†	All lower extremity prostheses, flex-walk system or equal
L5999††††	Lower extremity prosthesis, not otherwise specified

†Note: Considered medically necessary for functional level 3 or above when medical necessity criteria has been met for the base device.

††Note: Considered medically necessary for functional level 1 or above when medical necessity criteria has been met for the base device.

†††Note: Requires K-4 functional level and when medical necessity criteria has been met for the base device.

††††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 and when medical necessity criteria has been met for the base device.

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
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
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
K1014	Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control
L5828	Addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control

L5845	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848	Addition to endoskeletal, knee-shin system, fluid stance extension, dampening feature, with or without adjustability
L5920	Addition, endoskeletal system, above knee or hip disarticulation, alignable system
L5925	Addition, endoskeletal system, above knee, knee disarticulation or hip disarticulation, manual lock
L5930†	Addition, endoskeletal system, high activity knee control frame
L5950	Addition, endoskeletal system, above knee, ultra-light material (titanium, carbon fiber or equal)
L5999††	Lower extremity prosthesis, not otherwise specified

†Note: L5930 requires K-4 functional level.

††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., BiOM® Ankle, emPOWER™ Ankle)

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

LOWER LIMB OSSEOINTEGRATED DEVICE
Experimental/Investigational/Unproven:

HCPCS Codes	Description
L5991	Addition to lower extremity prostheses, osseointegrated external prosthetic connector

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

Experimental/Investigational/Unproven 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
L5845	Addition, endoskeletal knee-shin system, stance flexion feature, adjustable
L5848	Addition to endoskeletal knee-shin system, fluid stance extension, dampening feature, with or without adjustability
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
L5782	Addition to lower limb prosthesis, vacuum pump, residual limb volume management and moisture evacuation system, heavy duty

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

HCPCS Codes	Description
L7510	Repair of prosthetic device, repair or replace minor parts
L7520	Repair prosthetic device, labor component, per 15 minutes
L8049	Repair or modification of maxillofacial prosthesis, labor component, 15 minute increments, provided by a non-physician

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Revision Details

Type of Revision	Summary of Changes	Date
Annual	No changes.	1/15/2024