October 17, 2020

CRAIG ARMSTRONG
PROTEOR USA
1236 W SOUTHERN AVE #101
TEMPE, AZ 85282

DCN Number:20244003000002

Manufacturer Name	Product Name	Model Number	Assigned HCPCS Code(s)
PROTEOR USA	ALLUX 2	NE-Z41	L5613+L5856+L5848+L5845
PROTEOR USA	ALLUX 2	NE-Z41SH	L5613+L5856+L5848+L5845

Dear CRAIG ARMSTRONG,

The Pricing, Data Analysis, and Coding (PDAC) Contractor has reviewed the product(s) listed above and has approved the listed Healthcare Common Procedure Coding System (HCPCS) code(s) for billing the four Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

The PDAC Contractor provides coding assistance to manufacturers to ensure proper coding of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). The PDAC publishes coding decisions based on the coding guidelines established by the Local Coverage Determinations (LCDs) and associated Policy Articles and any related Advisory Articles established by the DME MACs. All products submitted to the PDAC for a coding verification review are examined by coders and professionals following a formal, standardized process.

Based on this review and application of DME MAC policy, the HCPCS code(s) listed below should be used when billing the DME MACs:

If you disagree with this decision, you may request a reconsideration within 45 days of the letter's

date and provide evidence to substantiate a reconsideration of PDAC's original coding determination. To request a reconsideration, complete the Reconsideration Request form located on the PDAC website at www.dmepdac.com. If your request for a reconsideration is made after the 45-day time frame, it will require a new application and documentation to support the request.

It is the responsibility of manufacturers and distributors to notify the PDAC immediately of any changes involving their products, as listed on the Product Classification List (PCL) on the Durable Medical Equipment Coding System (DMECS). Further information for requesting updates to the PCL can be found on the PDAC website at www.dmepdac.com. It is also the responsibility of manufacturers and distributors to assure their websites and product marketing materials accurately reflect the product reviewed by the PDAC and the coding decision assigned.

An assignment of the HCPCS code(s) to product(s) is not an approval or endorsement of the product(s) by Medicare or Palmetto GBA; nor does it imply or guarantee claim reimbursement or coverage.

If you have questions, please contact the PDAC HCPCS Helpline at (877) 735-1326 during the hours of 9:30 a.m. to 5:00 p.m. ET, Monday through Friday. You may also visit our website to chat with one of our representatives or select the Contact Us button at the top of the page for email, FAX or postal mail information.

Sincerely,

Pricing, Data Analysis, and Coding Contract (PDAC)
Palmetto GBA, LLC
www.dmepdac.com

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard,
Baltimore, Maryland 21244-1850

Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations

First Biannual (B1), 2022 HCPCS Coding Cycle

This document presents final Medicare benefit category and payment determinations for non-drug and non-biological items assigned a new HCPCS Level II code effective January 1, 2020 to April 1, 2022 and final coding, benefit category and payment determinations for HCPCS Level II applications processed in CMS' B1 2022 coding cycle for non-drug and non-biological items and services. Preliminary coding, benefit category and/or payment determinations for the items presented in the application summaries below were discussed at the HCPCS public meeting on June 7-10, 2022.

In accordance with the procedures at 42 CFR §414.240 and §414.114, final Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) benefit category and payment determinations are listed below, if applicable. These procedures follow HCPCS determinations and payment determinations for new DME under Medicare Part B following public consultation held through public meetings in accordance with section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub L. 106-554). CMS started using these public meetings and procedures for HCPCS Level II code requests for items and services other than DME in 2005. The procedures for making Medicare benefit category and payment determinations for new DMEPOS items and services using the BIPA 531(b) public meeting process were promulgated through regulations. The final rule (86 FR 73902) is available at https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched.

Whether or not an item or service falls under a Medicare benefit category, such as the Medicare Part B benefit category for DME, is a necessary step in determining whether an item may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the items and services. If the item is excluded from coverage by the Social Security Act or does not fall within the scope of a defined benefit category, the item cannot be covered under Medicare Part B. When the item is not excluded from coverage by statute and is found to fall within a benefit category, CMS needs to determine what payment rules apply to the item if other statutory criteria for coverage of the item are met. DMEPOS payment categories with corresponding HCPCS pricing indicator codes are included in the Appendix.

All new coding actions will be effective October 1, 2022, unless otherwise indicated.

The HCPCS coding decisions below will also be included in the October 2022 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at https://www.cms.gov/Medicare/Coverage/DeterminationProcess and https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center

Agenda Item # 11

ALLUX™ – 20.156

Topic

Medicare Benefit Category and Payment Determination for ALLUX™.

Temporary HCPCS code: K1014 "Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control"

Applicant's Summary

According to information submitted by Proteor USA, the ALLUX™ microprocessor-controlled knee that utilizes a 4-bar geometry with hydraulic control of both stance and swing phases of gait. The ALLUX™ is intended for use by amputees that are missing their leg through knee joint or higher (KD through HD). An automatic stance-phase lock feature will lock knee flexion when the user maintains a load on a flexed, stationary knee. Upon knee extension, the lock is released, and the knee returns to normal function. The ALLUX™ has an internal lithium-ion battery that is regularly charged by the user. This internal battery will allow the user to walk approximately 30,000 steps on a single charge, or roughly four days of use before the ALLUX™ needs to be charged. The ALLUX™ is continually monitoring the battery level and will notify the user that the battery level is low (4-6 hours of remaining charge) through a series of vibrations. The user can also query the knee using the remote control for an immediate status of the battery. All accessories and software are included (remote, emergency back-up battery, charger, software download, and wireless USB dongle).

Final CMS HCPCS Coding Action

Established new HCPCS Level II code K1014 effective April 1, 2021, "Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control."

Requested Benefit Category

Prosthetic (Artificial Leg) – section 1861(s)(9) of the Social Security Act.

Preliminary Medicare Benefit Category Determination

Artificial Leg (prosthetic).

The application supports a preliminary benefit category determination that ALLUX™ replaces a missing leg through knee joint or higher (KD through HD) and would fall under the Medicare benefit for artificial legs (prosthetics).

Preliminary Medicare Payment Determination

In accordance with regulations at 42 CFR § 414.238(b), fee schedule amounts for new HCPCS codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee

schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components; mechanical components; electrical components; function and intended use; and additional attributes and features. The preliminary payment determination for code K1014 for this particular endoskeletal knee-shin system is that this item should be priced using the existing fee schedule amounts for comparable items described by:

- L5613, addition to lower extremity, endoskeletal system, above knee-knee disarticulation, 4 bar linkage, with hydraulic swing phase control;
- L5828, addition, endoskeletal knee-shin system, single axis, fluid swing and stance phase control;
- L5826, addition, endoskeletal knee-shin system, single axis, hydraulic swing phase control, with miniature high activity frame;
- L5930, addition, endoskeletal system, high activity knee control frame.

Pricing for K1014 can be represented by the following formula: L5613 + ((L5828 – L5826) + L5930). The average 2022 fee schedule amount for K1014 would be $6,463.27.

K1014	L5613	L5828	L5826	L5930
Physical Components				
4-Bar linkage	X			
High activity frame			X	X
Mechanical Components				
Swing phase	X	X	X	
Stance phase		X		
Fluid control	X	X	X	
Electrical Components				
Function and Intended Use				
Endoskeletal knee shin system	X	X	X	X
Lower extremity device/component	X	X	X	X
Additional Aspects and Features				

The use of L5613 accounts for the 4-bar mechanical feature as the base knee code. The addition of L5828 adds the fluid swing and stance phase control features. This duplicates the hydraulic swing phase feature. This hydraulic swing phase duplication is then subtracted out by removing L5826. However, this removes the high activity frame feature, but is added back by the addition of L5930. The need to add back in the high activity frame is to equalize the deduction of L5826 knee unit since it contains a feature, miniature high active frame, that should not be removed.

Payment would be on a lump sum purchase basis.

Pricing = 38

Summary of Public Feedback

Proteor USA, the manufacturer of the ALLUX™, agreed with the preliminary benefit category and payment determinations.

Final Medicare Benefit Category Determination

Prosthetic (Artificial Leg).

Final Medicare Payment Determination

The fee schedule amounts for HCPCS code K1014 will be established using the fee schedule amounts for comparable items (HCPCS codes) represented by the following formula: L5613 + ((L5828 – L5826) + L5930), resulting in an average 2022 fee schedule amount of approximately $6,463.27.

Payment will be made on a lump sum purchase basis for any covered claims.

Pricing = 38

Appendix: DMEPOS Payment Categories

The Social Security Act separates DMEPOS into different Medicare payment categories, each with its own unique payment rules. The pricing indicator codes in the HCPCS identify which major payment category a HCPCS code falls under. The pricing indicator codes applicable to DMEPOS.

Pricing = 00 Service Not Separately Priced

Items or services described by the HCPCS codes that are either not covered under Medicare Part B or for which payment is bundled into the payment some other Medicare service or procedure.

Pricing = 31 Frequently Serviced Items

Payment is generally made on a monthly rental fee schedule basis for items such as ventilators that require frequent and substantial servicing in order to avoid risk to the patient's health. Payment for E0935 is based on a daily rental fee schedule basis since coverage of this device is limited to 21 days.

Pricing = 32 Inexpensive and Other Routinely Purchased Items

Payment is made on a purchase or rental fee schedule basis. This category includes items that have a purchase price of $150 or less, were purchased 75 percent of the time or more from July 1986 through June 1987, or which are accessories used in conjunction with a nebulizer, aspirator, continuous airway pressure device, or respiratory assist device. The beneficiary has the option to acquire the item on a purchase or monthly rental basis. Total payments for the item cannot exceed the purchase fee schedule amount for the item.

Pricing = 33 Oxygen and Oxygen Equipment

Monthly fee schedule payments are made for furnishing oxygen and oxygen equipment. This monthly payment includes payment for all stationary oxygen equipment, supplies, and accessories and delivery of oxygen contents (stationary and portable). A monthly add-on to this payment is made for portable oxygen equipment only for those beneficiaries who require portable oxygen. The monthly payments for oxygen equipment cap after the 36th monthly payment is made, after which payment for the ongoing delivery of contents continues for gaseous or liquid systems.

Pricing = 34 Supplies Necessary for the Effective Use of DME

Payment is made on a purchase fee schedule basis for supplies necessary for the effective use of DME (e.g., lancets that draw blood for use in blood glucose monitor).

Pricing = 35 Surgical Dressings

Payment is made on a purchase fee schedule basis for surgical dressings.

Pricing = 36 Capped Rental Items

Payment is made on a monthly rental fee schedule basis. The beneficiary takes over ownership of the item after the 13th rental payment is made. The rental fee for capped rental items, other than power wheelchairs, for each of the first 3 months of rental is equal to 10 percent of the purchase fee for the item. The rental fee for months 4 through 13 is equal to 7.5 percent of the purchase fee for the item. The rental fee for power wheelchairs for each of the first 3 months of rental is equal to 15 percent of the purchase fee for the item. The rental fee for power wheelchairs for months 4 through 13 is equal to 6 percent of the purchase fee for the item. Complex rehabilitative power wheelchairs can also be purchased in the first month.

Pricing = 37 Ostomy, Tracheostomy and Urological Supplies
Payment is made on a purchase fee schedule basis for ostomy, tracheostomy and urological supplies.

Pricing = 38 Orthotics, Prosthetics, Prosthetic Devices, and Vision Services (Prosthetic Lenses)
Payment is made on a purchase fee schedule basis for orthotics, prosthetics, and prosthetic devices & lenses.

Pricing = 39 Parenteral and Enteral Nutrition (PEN)
Payment is made on a purchase fee schedule basis for parenteral and enteral nutrients and supplies. Payment is made on a purchase or rental fee schedule basis for parenteral and enteral equipment. The beneficiary has the option to acquire the item on a purchase or monthly rental basis.

Pricing = 45 Customized DME
Payment is made for lump-sum purchase of DME that meets the Medicare regulatory definition of customized DME at 42 CFR 414.224. The payment amount is based on the carrier's individual consideration of the item and judgment of a reasonable payment amount, which, at a minimum, includes a review of the costs of labor and material used in constructing the equipment.

Pricing = 46 Carrier Priced Item
The allowed payment amount for covered items is based on local carrier pricing (e.g., local fee schedule amounts or reasonable charges or other carrier pricing method.