



RETINAL PROSTHESIS

Guideline Number: MPG267.06 Approval Date: August 12, 2020

Terms and Conditions (i)

Table of Contents	Page
POLICY SUMMARY	1
APPLICABLE CODES	1
PURPOSE	2
REFERENCES	2
GUIDELINE HISTORY/REVISION INFORMATION	2
TERMS AND CONDITIONS	2

Related Medicare Advantage Policy Guideline

• <u>Category III CPT Codes</u>

Related Medicare Advantage Coverage Summary

Vision Services, Therapy and Rehabilitation

POLICY SUMMARY

See Purpose (i)

Overview

An electronic retinal prosthesis is implanted to restore some lost vision and create visual perception by electronically stimulating the retina. These electronically conducting devices help patients detect light or distinguish between objects such as a cup or plate. The retinal prosthesis is a sliver, or tiny chip, of silicone and platinum attached to and sitting on top of the retina. The ArgusM II Retinal Prosthesis System has been approved by the FDA for marketing under the humanitarian device exemption (HDE) application.

Guidelines

This device is indicated for use in patients with severe to profound retinitis pigmentosa who are:

- Adults, age 25 years or older.
- Bare light or no light perception in both eyes. (If the patient has no residual light perception, then evidence of intact inner layer retina function must be confirmed.)
- Previous history of useful form vision.
- Aphakic or pseudophakic. (If the patient is phakic prior to implant, the natural lens will be removed during the implant procedure.)
- Patients who are willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

In addition, the Argus II implant is intended to be implanted in a single eye, typically the worse seeing eye. The office outpatient and hospital in-patient medical records must clearly reveal how all of the above indications were met. The ARGUSM II Retinal Prosthesis CPT Code is effective for dates of service on or after February 20, 2014. There is limited jurisdictional coverage outlined in the LCDs.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy
	CPT® is a registered trademark of the American Medical Association

ICD-10 Diagnosis Code	Description
H35.52	Pigmentary retinal dystrophy

PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the <u>References</u> section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A53044 (Billing and Coding: ArgusM II Retinal Prosthesis System)	Palmetto	AL, GA, NC, SC, TN, VA, WV	AL, GA, NC, SC, TN, VA, WV
N/A	A54327 (ArgusM II Retinal Prosthesis System)	CGS	KY, OH	KY, OH
L33392 (Category III CPT Codes) Retired 07/01/2020	A56195 (Billing and Coding: Category III CPT® Codes) Retired 07/01/2020	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
L35008 (Non-Covered Services) Retired 06/30/2020	A57642 (Billing and Coding: Non-Covered Services) Retired 06/30/2020	Noridian	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
L36219 (Non-Covered Services) Retired 06/30/2020	A57641 (Billing and Coding: Non-Covered Services) Retired 06/30/2020	Noridian	AS, CA, GU, HI, MP, NV	AS, CA, GU, HI, MP, NV
L35094 (Services That Are Not Reasonable and Necessary) Retired 07/01/2020	A56967 (Billing and Coding: Services That Are Not Reasonable and Necessary) Retired 07/01/2020	Novitas	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX

UnitedHealthcare Commercial Policy

Omnibus Codes

Others

FDA Humanitarian Device Exemption, FDA Website

Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Public Meeting Agenda for Orthotics & Prosthetics, Durable Medical Equipment (DME) and Accessories, CMS Website

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in guestion.

Date	Action/Description
08/12/2020	 Supporting Information Updated References section to reflect the most current information Archived previous policy version MPG267.05

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.