Medical Policy

Retinal Prosthesis

Policy Number: PG0418
Last Reviewed Date: 03/01/2025
Last Revised: 03/01/2025

PARAMOUNT

HMO AND PPO
ELITE (MEDICARE ADVANTAGE)
MARKETPLACE

GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE:

X Professional
X Facility

DESCRIPTION:

A retinal prosthesis replaces lost photoreceptor function by transmitting external images to an array of electrodes or via light sensors placed in the epiretinal or subretinal space. The artificial retina could restore sight to patients with blindness secondary to retinal diseases, such as retinitis pigmentosa, hereditary retinal degeneration, and some forms of age-related macular degeneration.

Several models of retinal prostheses are in development in the United States, Europe, and Asia. Only the Argus II system has been cleared for use by the U.S. Food and Drug Administration (FDA). The Argus II Retinal Prosthesis System is the first implanted device to treat adult patients with advanced retinitis pigmentosa (RP). RP is a rare genetic eye condition that damages the light-sensitive cells that line the retina, resulting in gradual loss of side vision and night vision, and later of central vision. The condition can lead to blindness.

The device, which includes a small video camera, transmitter mounted on a pair of eyeglasses, video processing unit (VPU) and an implanted retinal prosthesis (artificial retina), replaces the function of degenerated cells in the retina and may improve a patient's ability to perceive images and movement. The VPU transforms images from the video camera into electronic data that is wirelessly transmitted to the retinal prosthesis. While the Argus II Retinal Prosthesis System will not restore vision to patients, it may allow them to detect light and dark in the environment, aiding them in identifying the location or movement of objects or people.

The Argus II system is intended for use in adults 25 years of age or older, with severe to profound RP who have bare light (can perceive light, but not the direction from which it is coming) or no light perception in both eyes, evidence of intact inner layer retina function, and a previous history of the ability to see forms. The patients must also be willing and able to receive the recommended post-implant clinical follow-up, device fitting, and visual rehabilitation.

POLICY:

Elite (Medicare Advantage) Plans

- **Retinal prosthesis (0100T, 0472T, 0473T) does not require prior authorization for Medicare Advantage Plans.**
  Effective July 1, 2022
  - **Medicare has determined that the Argus II device, which is the device that is implanted for the retinal prosthesis implant procedure, is no longer available in the marketplace**
  - **Medicare also understands that both outpatient hospital providers and ASCs (ambulatory surgical centers) are no longer performing the Argus II implantation procedure**

Paramount Commercial Insurance Plans

- **Retinal prosthesis (0100T, 0472T, 0473T) is non-covered**

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans

Paramount has determined that retinal prosthesis is **experimental/investigational** and therefore non-covered because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of this procedure.

Elite (Medicare Advantage) Plans

Only the Argus II system has been cleared for use by the U.S. Food and Drug Administration (FDA).
While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of retinal prosthesis, The Center for Medicare & Medicaid Services requires this procedure be covered for Medicare Advantage Plan members.

The Argus II Retinal Prosthesis System is covered when ALL the criteria below are met:

- Diagnosed with severe to profound retinitis pigmentosa
- 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.

Additional devices are in development, none of which are presently approved or cleared by the U.S. Food and Drug Administration (FDA), include the following; Alpha IMS, Boston Retinal Implant Project, EPIRET3, Intelligent Retinal Implant System, Learning Retinal Implant, MICROELECTRODE-STS.

The office outpatient AND hospital in-patient medical records must clearly reveal how all the above indications were met.

When submitting a claim for code 0100T the ICD-10 code H35.52 should be submitted on the claim.

CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
0100T	Placement of a subconjunctival retinal prosthesis receiver and pulse generator, and implantation of intra-ocular retinal electrode array, with vitrectomy
0472T	Device evaluation, interrogation, and initial programming of intra-ocular retinal electrode array (e.g., retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional
0473T	Device evaluation and interrogation of intra-ocular retinal electrode array (e.g., retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional
ICD-10-CM CODES	
H35.52	Pigmentary retinal dystrophy

REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 12/15/2017

Date	Explanation & Changes
12/15/2017	• Retinal prosthesis (0100T, C1841, C1842) is covered without prior authorization for Elite • Codes 0472T & 0473T are non-covered for Elite • Retinal prosthesis (0100T, 0472T, 0473T, C1841, C1842) is non-covered for HMO, PPO, Individual Marketplace, & Advantage • Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
10/25/2018	• Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)
12/28/2020	• Medical policy placed on the new Paramount Medical policy format
03/03/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023 • Removed deleted HCPCS Codes C1841 and C1842
04/01/2024	• Medical Policy reviewed and updated to reflect the most current clinical evidence • Retinal prosthesis (0100T, 0472T, 0473T) does not require prior authorization for Medicare Advantage Plans. • Effective July 1, 2022, Medicare has determined that the Argus II device, which is the device that is implanted for the retinal prosthesis implant procedure, is no longer available in the marketplace. Medicare also understands that both outpatient hospital providers and ASCs (ambulatory surgical centers) are no longer performing the Argus II implantation procedure.
03/01/2025	• Medical Policy reviewed and updated to reflect the most current clinical evidence

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to
https://www.paramounthealthcare.com/providers/medical-policies/policy-library

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs

Jul. 2022 CMS Transmittals:

- 11472 [Update of the Ambulatory Surgical Center (ASC) Payment System]
- 11457 [Update of the Hospital Outpatient Prospective Payment System (OPPS)]

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services https://www.ama-assn.org/amaone/cpt-current-procedural-terminology

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting https://www.cms.gov/medicare/coding/icd10

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee Schedule administration and coding Requirements https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for Medicare Services https://www.cms.gov/medicare-medicaid-coordination/national-correct-coding-initiative-ncci/ncci-medicare

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs) https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits
U.S. Preventive Services Task Force, https://www.uspreventiveservicestaskforce.org/uspstf/

Hayes, Inc., https://www.hayesinc.com/

Industry Standard Review