



PARAMOUNT

ADVANTAGE | ELITE | HMO
INDIVIDUAL MARKETPLACE |
PROMEDICA MEDICARE
PLAN | PPO

Retinal Prosthesis

Policy Number: PG0418
Last Review: 10/25/2018

GUIDELINES

This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

SCOPE

- Professional
- Facility

DESCRIPTION

The Food and Drug Administration (FDA) has approved the Argus II Retinal Prosthesis System, 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 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

Retinal prosthesis (0100T, C1841, C1842) does not require prior authorization for Elite/ProMedica Medicare Plan.

Codes 0472T & 0473T are non-covered for Elite/ProMedica Medicare Plan.

Retinal prosthesis (0100T, 0472T, 0473T, C1841, C1842) is non-covered for HMO, PPO, Individual Marketplace, & Advantage.

COVERAGE CRITERIA

HMO, PPO, Individual Marketplace, Advantage

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

Current Procedural Terminology (CPT), the official CPT codebook with rules and guidelines from the American Medical Association's CPT editorial panel, includes a section of temporary codes created to identify emerging technology services, and procedures. Category III codes allow data collection for specific emerging technology services. All Category III codes end in a "T" for temporary. The inclusion of a service in the Category III section of CPT neither implies nor endorses clinical efficacy, safety or applicability to clinical practice and may not conform to

the usual requirements for CPT Category I codes.

Elite/ProMedica Medicare Plan

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 Elite/ProMedica Medicare Plan members.

The Argus II Retinal Prosthesis System is covered when ALL of 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.

The office outpatient AND hospital in-patient medical records must clearly reveal how all of 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 (eg, 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 (eg, retinal prosthesis), in person, including reprogramming and visual training, when performed, with review and report by a qualified health care professional
HCPCS CODES	
C1841	Retinal prosthesis, includes all internal and external components
C1842	Retinal prosthesis, includes all internal and external components; add-on to C1841
ICD-10-CM CODES	
H35.52	Pigmentary retinal dystrophy

REVISION HISTORY EXPLANATION

ORIGINAL EFFECTIVE DATE: 12/15/2017

12/15/17: 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).

10/25/18: 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

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Ohio Department of Medicaid

American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

Industry Standard Review

Hayes, Inc.