

Local Coverage Article: Billing and Coding: ArgusM II Retinal Prosthesis System (A53044)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

Article Information

General Information

Article ID A53044	Original Effective Date 10/01/2015
Article Title Billing and Coding: ArgusM II Retinal Prosthesis System	Revision Effective Date 10/03/2019
Article Type Billing and Coding	Revision Ending Date N/A
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CMS National Coverage Policy

N/A

Article Guidance

Article Text:

The ArgusM II Retinal Prosthesis System (CPT Code 0100T) has been approved by the FDA for marketing under the humanitarian device exemption (HDE) application.

As indicated in the Department of Health and Human Services (DHHS) FDA approval letter dated February 13, 2013 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.

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

Coding Information

CPT/HCPCS Codes	
Group 1 Paragraph:	
N/A	
Group 1 Codes:	
CODE	DESCRIPTION
0100T	PLACEMENT OF A SUBCONJUNCTIVAL RETINAL PROSTHESIS RECEIVER AND PULSE GENERATOR, AND IMPLANTATION OF INTRAOCULAR RETINAL ELECTRODE ARRAY, WITH VITRECTOMY

CPT/HCPCS Modifiers	
N/A	

ICD-10 Codes that Support Medical Necessity	
Group 1 Paragraph:	
N/A	
Group 1 Codes:	
ICD-10 CODE	DESCRIPTION
H35.52	Pigmentary retinal dystrophy

ICD-10 Codes that DO NOT Support Medical Necessity	
N/A	

Additional ICD-10 Information	
N/A	

Bill Type Codes:	
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally	

to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

Other Coding Information

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
10/03/2019	R6	This article is being revised in order to adhere to CMS requirements per chapter 13, section 13.5.1 of the Program Integrity Manual, to remove all coding from LCDs and incorporate into related Billing and Coding Articles.
02/26/2018	R5	The Jurisdiction "J" Part B Contracts for Alabama (10112), Georgia (10212) and Tennessee (10312) are now being serviced by Palmetto GBA. Effective 02/26/18, these three contract numbers are being added to this article. No coverage, coding or other substantive changes (beyond the addition of the 3 Part B contract numbers) have been completed in this revision.
01/01/2018	R4	<p>Under CPT/HCPCS Codes Group 1 the description was revised for CPT code 0100T. This revision is due to the Annual CPT/HCPCS Code Update.</p> <p><i>At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
03/10/2016	R3	Under Article Text the following verbiage was added to the second sentence, "As indicated in the Department of Health and Human Services (DHHS) FDA approval letter dated February 13, 2013..." Under Other URL(s) added the URL for the FDA approval letter.
10/01/2015	R2	Under Associated Documents, subtitle Statutory Requirements, added Title XVIII of the Social Security Act 1833 (e).
10/01/2015	R1	Added ICD-10 code to Covered ICD-10 codes. Added URL and name of Statutory Requirement.

Associated Documents

Related Local Coverage Document(s)

N/A

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

Title XVIII of the Social Security Act, §1862(a)(1)(A)

Title XVIII of the Social Security Act, §1833(e)

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

DHHS FDA Approval Letter dated February 13, 2013

Public Version(s)

Updated on 09/26/2019 with effective dates 10/03/2019 - N/A

Updated on 01/31/2018 with effective dates 02/26/2018 - N/A

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Keywords

N/A