



Medicare Part C Medical Coverage Policy

ForeSee Home AMD Monitoring

Origination: December 21, 2016

Review Date: July 21, 2021

Next Review: July, 2023

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

ForeSeeHome system is an interactive software driven device that provides a series of linear images to the macular and peri-macular region of the eye. The changes in macular and near macular function can be quantified by the device, thus enabling the reader to detect early changes in macular degeneration and associated diseases so as to allow earlier intervention.

Definitions

Age-related Macular Degeneration (AMD): is the leading cause of legal blindness in Americans over the age of 65. The cause of AMD it is thought to be related to multiple factors, and there is no cure for the disease. There are two basic types of AMD: dry and wet. Dry AMD is the most common type, accounting for 90% of all cases. Wet AMD accounts for 10% of cases and poses a higher risk of severe vision loss.

Drusen: appears as pale yellow spots beneath the Retinal Pigment Epithelium (RPE) and represent the earliest clinically detectable feature of age-related macular degeneration.

POLICY STATEMENT

Coverage will be provided for ForeSeeHome AMD monitoring when it is determined to be medically necessary when the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations, if the criteria are met.

Coverage decisions will be made in accordance with:

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- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCD);
- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

INDICATIONS FOR COVERAGE

1. Preauthorization by the Plan is required;

AND;

2. A best-corrected visual acuity of 20/60 or better

AND;

3. The presence of intermediate dry AMD. Intermediate AMD consists of many medium-sized drusen or one or more large drusen.

WHEN COVERAGE WILL NOT BE APPROVED

When all the criteria above are not met.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes: 0378T, and 0379T

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES

Retinal specialists seeking approval for the program should be required to provide documentation showing that the above criteria are met.

References: (Arial 10)

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1. U.S. Food and Drug Administration. K091579. Device Name, **FORESEE HOME**. Applicant, NOTAL VISION LTD. 733 Bolsana Drive. Laguna Beach, CA 9265: FDA; Issued October 31, 2016. Retrieved December 21, 2016 from http://www.accessdata.fda.gov/cdrh_docs/pdf9/K091579.pdf.
2. Foresee Home AMD Clinical Studies: <http://www.foreseehome.com/research.html>. Accessed 12/21/16.
3. Medicare Local Coverage Determination Fluorescein Angiography- (L33997); Effective Date 10/1/15; viewed via www.cms.gov on 6/3/19 (used for definition of Drusen only).
4. CMS MEDCAC Meeting Notes 11-29-05-Definition of Age-related Macular Degeneration. Viewed on <https://www.cms.gov/medicare-coverage-database/details/medcac-meeting-details.aspx?MEDCACId=32&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&Keyword=Drusen&KeywordLookUp=Doc&KeywordSearchType=Exact&kq=true&bc=IAAAACAAAA&> on 6/3/19. (used for definition only).

Policy Implementation/Update Information:

Revision Date: March 15, 2017- Added Code 0379T to coding section and removed unlisted code 66999. No other changes to policy.

Revision Date: May 17, 2017 – Added Code 0378T to coding section. No other changes to policy.

Revision Date: June 19, 2019 – Indications for Coverage modified with respect to disease criteria (intermediate AMD). Added Definition Section to include AMD and Drusen.

Revision Date: July 21, 2021-External Physician Review, no recommended updates. Minor revisions only.

Approval Dates:

Medical Coverage Policy Committee: July 21, 2021

Policy Owner: Carolyn Wisecarver, RN, BSN
Medical Policy Coordinator