Application of AMD Genetic Testing

Macula Risk/Vita Risk Genotype-Guided Follow-up and Nutritional Therapy by AMD Stage and AREDS Formula Recommendation

Category 1 - "No AMD"

or FHx AMD

Non-extensive (~5-15) small drusen < 63 µm or no drusen

(unilateral/bilateral)

Category 2 - Early AMD

Extensive small drusen, non-extensive intermediate drusen, or pigment abnormalities

(unilateral/bilateral)

Category 3 - Intermediate AMD

Large druse > 125 μm, extensive (~65) intermediate size (63-125 μm) drusen, or ~20 drusen with soft, indistinct drusen present, or non-central geographic atrophy (unilateral/bilateral)

Category 4 - Advanced AMD

Either Choroidal Neovascularization (CNV) [wet AMD] or Geographic Atrophy (GA)

(unilateral)

Vita Risk Standalone Genetic Test

OPTIMAL TREATMENT

Macula Risk Prognostic Genetic Test

Includes **Vita Risk** Pharmacogenetic Test Macula Risk Prognostic Genetic Test

Includes **Vita Risk** Pharmacogenetic Test Vita Risk Standalone Genetic Test

AREDS Not Recommended for Early AMD or FHx⁴

Patients intent on taking supplements may utilize macular carotenoids to maintain visual performance⁵

If GTG 4 -Antioxidants No Zinc² Increase Exam Frequency for Higher Risk Patients³

If GTG 1 -Antioxidants No Zinc

If GTG 2 -Antioxidants No Zinc If GTG 3 -Zinc or AREDS

Define Px AREDS Formula¹

If GTG 4 -AREDS Tx Ineffective

3 Brown et al., 2015 A Value-Based Medicine cost-utility analysis of genetic testing for neovascular macular degeneration

4 AAO Preferred Practice Pattern Guidelines for Age-Related Macular Degeneration



¹ Vavvas et al., 2018 CFH and ARMS2 genetic risk determines progression to neovascular age-related macular degeneration after antioxidant and zinc supplementation Seddon et al., 2016 Response to AREDS supplements according to genetic factors: survival analysis approach using the eye as the unit of analysis Awh et al., 2014 Treatment response to antioxidants and zinc based on CFH and ARMS2 genetic risk allele number in the Age-Related Eye Disease Study

² Awh et al., 2017 Progression from no AMD to Intermediate AMD as Influenced by Antioxidant Treatment and Genetic Risk: An analysis of data from the Age-Related Eye Disease Study Cataract Trial

⁵ Ma et al., 2012 Effect of lutein an zeaxanthin on macular pigment and visual function in patients with early age-related macular degeneration

CARMS Guide

Defining AMD Status Using the Clinical Age-Related Maculopathy Staging System (CARMS)



The predictive algorithm used in the Macula Risk test incorporates a patient's status of Age-related macular degeneration (AMD) based on AREDS category and the Clinical Age-Related Maculopathy Staging System (CARMS). The CARMS system, a 5-level clinical scale, is a valid and reliable staging system that can be used in both clinical practice and in clinical research protocols involving patients with all stages of Age-Related Maculopathy².

Please refer to the following classification guide when documenting a patient's AMD Status on the Macula Risk Test Requisition Form.

AMD STATUS	CLINICAL FEATURES	EXAMPLE IMAGES
No AMD	No drusen or bilateral nonextensive (~5-15) small drusen < 63 microns*, without pigment abnormalities	
*63 µm (microns) is approximately equivalent to one half of the diameter of an average normal retinal vein at the optic disc margin³. Drusen less than or equal to this diameter are considered small.		
Early AMD	Extensive small, or nonextensive (< 65) intermediate drusen (63-125 microns) with no soft, indistinct drusen present; or, pigment abnormalities in at least one eye	Early AMD

- ¹ Yu Y, Reynolds R, Rosner B, Daly M, Seddon J. Prospective Assessment of Genetic Effects on Progression to Different Stages of Age-Related Macular Degeneration Using Multistate Markov Models. IOVS. 2012;53(3):1548-1556.
- ² Seddon J, Sharma S, Adelman R. Evaluation of the Clinical Age-Related Maculopathy Grading System. Ophthalmology. 2006;113:260-266.
- ³ Age-Related Eye Disease Study Research Group. Risk factors associated with age-related macular degeneration: Age-Related Eye Disease Study Report No. 3. Ophthalmology 2000; 107(12):2224-2232.

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AMD STATUS	CLINICAL FEATURES	EXAMPLE IMAGES
normal retinal vein at the op	Extensive (~65) intermediate drusen or ~20 intermediate drusen with presence of soft, indistinct drusen; 1 large druse > 125 microns; or non-central GA < 350 microns juivalent to the diameter of an average tic disc margin ³ . Drusen greater than or	Intermediate AMD
equal to this diameter are co	nsidered large.	
Advanced AMD: GA	Geographic Atrophy (GA) with involvement of the macular center, or non-central geographic atrophy at least 350 µm in size	
		Advanced AMD: GA
Advanced AMD: CNV	Exudative AMD, including non-drusenoid Pigment	

non-drusenoid Pigment **Epithelial Detachment** (PED), serous or hemorrhagic retinal detachments, Choroidal Neovascularization (CNV) with sub-retinal or sub-**Retinal Pigment** Epithelium (RPE) hemorrhages or fibrosis, or

scars consistent with treatment of AMD

Advanced AMD: CNV

Photography courtesy of Peter L. Sonkin, M.D., Tennessee Retina, Nashville, TN, and Allan J. Laurens, Florida Eye Microsurgical Institute, Inc., Boynton Beach, FL.