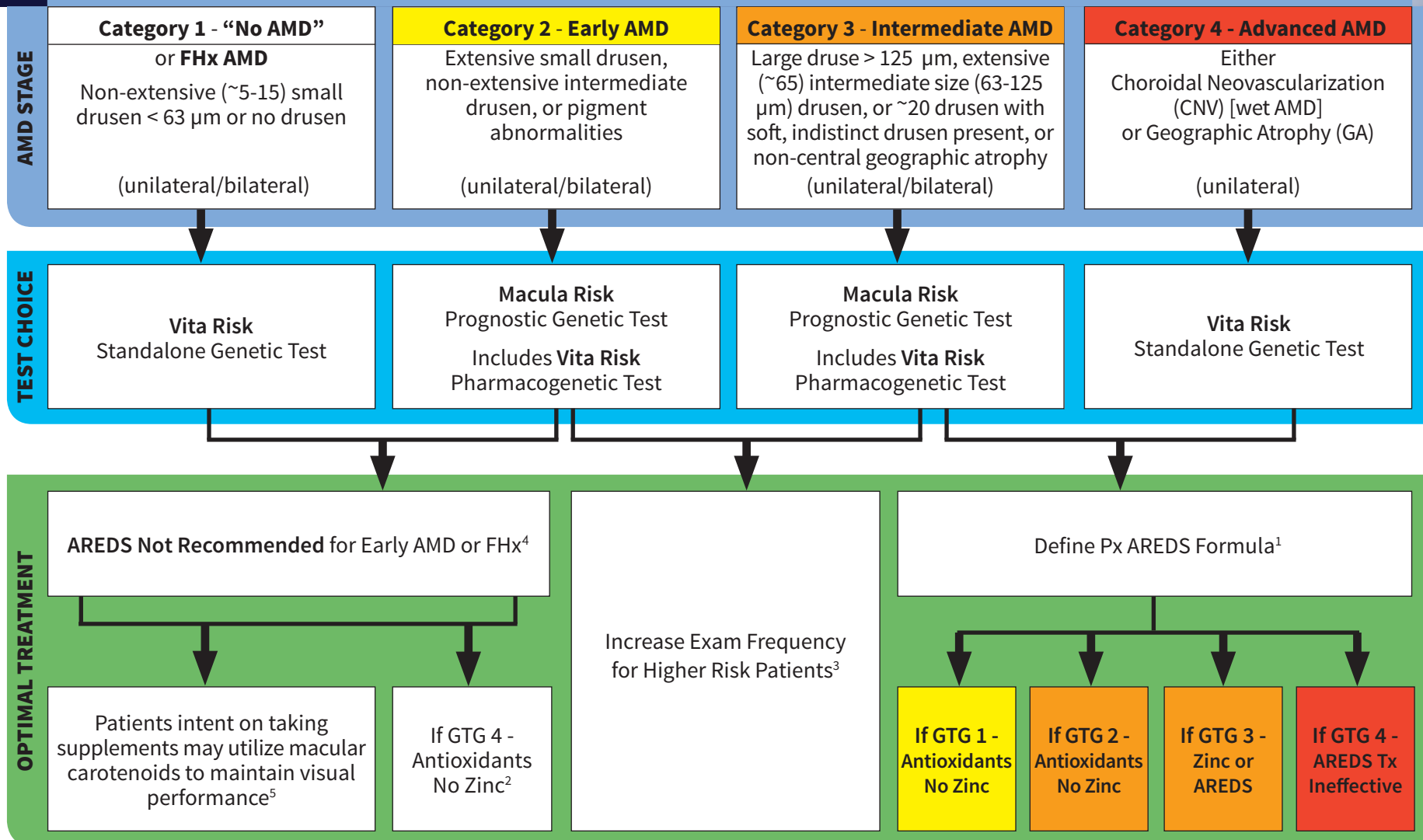


Application of AMD Genetic Testing

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



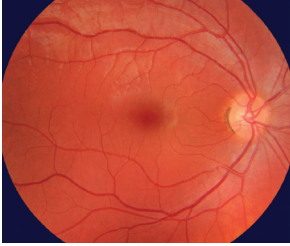
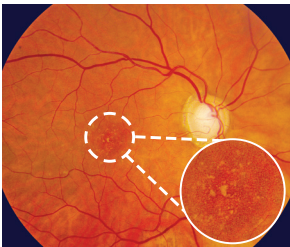
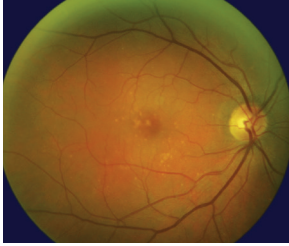
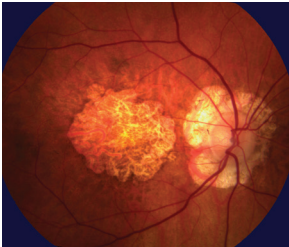
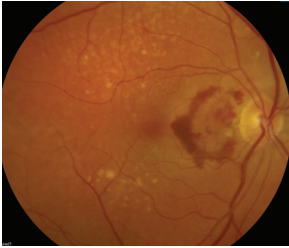
- Vavvas et al., 2018 CFH and ARMS2 genetic risk determines progression to neovascular age-related macular degeneration after antioxidant and zinc supplementation
- Seddon et al., 2016 Response to AREDS supplements according to genetic factors: survival analysis approach using the eye as the unit of 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
- 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
- Brown et al., 2015 A Value-Based Medicine cost-utility analysis of genetic testing for neovascular macular degeneration
- AAO Preferred Practice Pattern Guidelines for Age-Related Macular Degeneration
- Ma et al., 2012 Effect of lutein and 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 algorithm¹ 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 margin ³ . Drusen less than or equal to this diameter are considered small.	No AMD
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
Intermediate AMD	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	
	* 125 µm is approximately equivalent to the diameter of an average normal retinal vein at the optic disc margin ³ . Drusen greater than or equal to this diameter are considered large.	Intermediate AMD
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 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

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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