GENETIC TESTING FOR MACULAR DEGENERATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental” and “investigational” are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans.

Description:

Macular degeneration, the leading cause of severe vision loss in individuals older than 60 years, occurs when the central portion of the retina, the macula deteriorates. Because the disease develops as a person ages, it is often referred to as age-related macular degeneration (AMD).

There are two major types of AMD, known as the dry form and the wet form. The dry form is more common, and is characterized by the buildup of yellow deposits called drusen in the retina and slowly progressive vision loss. The condition typically affects vision in both eyes. AMD is generally thought to progress along a continuum from dry AMD to neovascular wet AMD.

The wet form of AMD is characterized by the growth of abnormal blood vessels from the choroid underneath the macula, and is associated with severe vision loss. The abnormal vessels leak blood and fluid into the retina, which damages the macula, leading to permanent loss of central vision.

Genetic testing for mutations at certain genetic loci has been proposed to predict the risk of developing advanced AMD.
Definitions:

Genetic Testing:
Analysis of DNA, RNA, chromosomes, proteins and certain metabolites in order to detect alterations related to an inherited disorder.

Gene:
A hereditary unit consisting of segments of DNA that occupies a specific location on chromosomes. Genes undergo mutation when their DNA sequence changes.

Genetic Counseling:
Instruction that provides interpretation of genetic tests and information about courses of action that are available for the care of an individual with a genetic disorder or for future family planning.

Affected Individual:
An individual displaying signs or symptoms characteristic of a suspected or specific inherited disorder.

Unaffected Individual:
An individual who displays no signs or symptoms characteristic of a suspected or specific inherited disorder.

Screening:
Genetic screening is the testing of an individual with no symptoms for a specific inherited disorder to determine if the individual carries an abnormal gene. Screening can be used to predict risk or potential risk for the individual or their offspring.
GENETIC TESTING FOR MACULAR DEGENERATION (cont.)

Criteria:

- Genetic testing and/or counseling of an unaffected individual, regardless of risk factors is considered screening and not eligible for coverage.

- Genetic testing and/or counseling of an affected individual to confirm a disease when confirmation of the diagnosis would not impact the care and/or management is considered not medically necessary and not eligible for coverage.

- Genetic testing and/or counseling for macular degeneration is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

These tests include, but are not limited to:

- Macula Risk® Test
- RetnaGene™ AMD
GENETIC TESTING FOR MACULAR DEGENERATION (cont.)

Resources:

Resources prior to 01/21/14 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


Macula Risk is a registered trademark of Arctic Medical Laboratories, Inc., an independent corporation that is not affiliated with BCBSAZ.
RETNAGENE AMD is a trademark of Sequenom, Inc., an independent corporation that is not affiliated with BCBSAZ.