GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Macular degeneration, the leading cause of severe vision loss in people older than age 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). AMD has an estimated prevalence of 1 in 2,000 people in the United States and affects individuals of European descent more frequently than African Americans in the United States.

AMD is a multifactorial or complex disease involving both genetic and nongenetic (e.g. age, smoking) influences. Testing for variants at certain genetic loci has been proposed to predict the risk of developing advanced AMD. AMD is divided into the dry form, associated with slowly progressive vision loss, and the wet form, which may be associated with rapidly progressive and severe vision loss.

Commercially available genetic testing for AMD is aimed at identifying those individuals who are at risk of developing advanced AMD. Commercially available tests include but are not limited to the following:

- Macula Risk® PGx (Arctic Medical Laboratories)
- Arctic Medical Laboratories offers Macula Risk® PGx which uses 15 associated biomarkers in an algorithm to determine an individual’s risk of progression to advanced AMD and aid in the selection of eye vitamin formulations for AMD based on his or her individual genetic risk profile. The Vita Risk® pharmacogenetic result can be provided as part of the Macula Risk® PGx laboratory report.

The evidence for genetic testing in individuals who are asymptomatic with a risk of developing AMD includes genetic association studies and risk prediction models. Relevant outcomes are test validity, change in disease status, and functional outcomes. The analytic validity of genetic testing for AMD is high, and the clinical validity of genetic testing appears to provide a small, incremental benefit to risk stratification based on nongenetic risk factors. The clinical utility of genetic testing for AMD is limited, in that there are currently no preventive measures that can be undertaken outside of modifying non-genetic risk factors such as not smoking and lowering cholesterol. No studies have shown improvement in health outcomes in patients who have been identified as being at high risk based on genetic testing. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY
Genetic testing for macular degeneration is non-covered, 81401, 81405, 81408. For all product lines.

HMO, PPO, Individual Marketplace, Elite, Advantage
Genetic testing for age-related macular degeneration (e.g., Macula Risk PGx) is considered experimental and investigational for the management/treatment of AMD because the effectiveness for this indication has not been established.

CODING/BILLING INFORMATION
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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| 81401 | Molecular pathology procedure, Level 2 (eg, 2-10 SNPs, 1 methylated variant, or 1 somatic variant [typically using nonsequencing target variant analysis], or detection of a dynamic mutation disorder/triplet repeat)  
- CFH/ARMS2 (complement factor H/age-related maculopathy susceptibility 2) (eg, macular degeneration), common variants (eg, Y402H [CFH], A69S [ARMS2]) |
<p>| 81405 | Molecular pathology procedure, Level 6 (eg, analysis of 6-10 exons by DNA sequence analysis, mutation scanning or duplication/deletion variants of 11-25 exons), regionally targeted cytogenomic array analysis |</p>
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>81408</td>
<td>Molecular pathology procedure, Level 9 (eg, analysis of &gt;50 exons in a single gene by DNA sequence analysis)</td>
</tr>
<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
</tr>
<tr>
<td>81599</td>
<td>Unlisted multianalyte assay with algorithmic analysis</td>
</tr>
</tbody>
</table>

**TAWG REVIEW DATES:** 09/22/2017, 07/26/2018

**REVISION HISTORY EXPLANATION**
09/22/17: Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
07/26/18: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
7/09/2019: Policy reviewed and updated to reflect most current clinical evidence. Added "age-related" to title to be more specific. Deleted section on RetnaGene as the test no longer exists. Further clarified description information. Added references. Still non-covered.

**REFERENCES/RESOURCES**
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.
American Macular Degeneration Foundation