Department:	Medical Management	**Original Approval:**	04/19/2018
Policy #:	MM165	**Last Approval:**	04/05/2019
Title:	Genetic Testing Medical Policy for Non Pregnancy Related Scenarios		
Approved By:	UM Medical Sub-committee		

Required Documentation:

History, physical exam, family history and pedigree analysis, imaging studies, laboratory studies, and the results of any genetic testing already performed.
Clear explanation of how the test results will impact the care plan for the patient in a clinically meaningful way.

BACKGROUND

This policy is created to address scenarios where genetic testing has been ordered and there are questions remaining about the appropriate use of the genetic test, or when the indications for the test are not clearly indicated by the requesting provider. The general criteria referenced below reflect standard of care for the provision of genetic test pre and post-test counseling. This policy is intended to supplement any applicable coverage criteria for the specific genetic test ordered as determined by MCG 22nd edition.

DEFINITIONS

None.

INDICATIONS/CRITERIA

General Criteria for a Genetic test to be considered Medically Necessary include all of the following:

1. The test is ordered by a licensed practitioner acting within the scope of their practice, **and**
2. Pre and Post test counseling is provided by a medical geneticist, certified genetic counselor, or the ordering practitioner, **and**
3. There are key risk factors that are documented as the reasons to suggest a genetic disorder (one or more of the following apply)
    - The clinical features of the condition or disease indicate an “in-born error” rather than an acquired illness.
    - There appears to be a high risk of inheriting the condition or disease based on the personal history, family history, or documented genetic mutations and/or ethnic background associations.
    - Following a complete history and physical exam, pedigree analysis, and completion of conventional ancillary tests, a definitive diagnosis remains uncertain with a strong suspicion of a hereditary disease or condition.

4. **Documentation is provided that supports the clinical utility of test results which will be used to significantly alter the management or treatment of the disease or condition.** (Supporting scientific literature on the above criteria will be accepted in lieu of case specific findings when applicable to addressing key risk factors and clinical utility of tests to address condition management or treatment strategies).
5. Carrier or predictive testing (of an individual that does not phenotypically express the genetic condition) requires documentation (rather than the appearance of a high risk of having inherited the condition) confirming the causative genetic change has been identified in an affected family member

Exclusion criteria for coverage of Genetic testing

1. Testing individuals on the basis of criteria other than as outlined above
2. Testing for purposes or conditions where the result would not directly influence the management or treatment of the disease or condition
3. Testing for informational purposes only, or for managing a tested insured member's family member.
4. Predictive or carrier testing in a person under age 18
5. Members under age 18 who are tested for adult onset conditions for which there are no preventative or therapeutic options.
6. Population screening in individuals with no personal or family history of a given illness or condition (exception for state mandated population screening)
7. More than one lifetime test for each disease of condition presence
8. Whole exome or genome sequencing to identify genetic variants in patients not diagnosed with conventional and genetic test methods due to insufficient evidence to assess the whole exome or genome sequencing for clinical purposes.

SPECIAL CONSIDERATIONS

None.

LIMITATIONS/EXCLUSIONS

Please refer to a product line's certificate of coverage for benefit limitations and exclusions for these services:

PRODUCT LINE	LINK TO CERTIFICATE OF COVERAGE
MEDICARE ADVANTAGE	http://healthfirst.chpw.org/for-members/resource-library/handbooks-and-guides
WASHINGTON APPLE HEALTH	http://chpw.org/our-plans/apple-health/
INTEGRATED MANAGED CARE	http://chpw.org/our-plans/apple-health/

Citations & References

CFR		
WAC		
RCW		
Contract Citation	☒ WAH	17.1.9.19 Genetic testing for all Enrollees.
	☒ IMC	
	☒ MA	
Other Requirements	A New Definition of Genetic Counseling: National Society of Genetic Counselors' Task Force Report, Resta et al, Journal of Genetic Counseling, April 2006, Volume 15, Issue 2, pp 77–83. https://link.springer.com/article/10.1007%2Fs10897-005-9014-3 Psychological responses to genetic testing, Marteau et al, BMJ. 1998 Feb 28; 316(7132): 693–696. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1112686/ Clinical whole-exome sequencing for the diagnosis of mendelian disorders, Yang et al, N Engl J Med. 2013 Oct 17;369(16):1502-11. doi: 10.1056/NEJMoa1306555. Epub 2013 Oct 2. https://www.ncbi.nlm.nih.gov/pubmed?term=24088041	
NCQA Elements		

Revision History

Revision Date	Revision Description	Revision Made By
04/09/2018	New policy	LuAnn Chen
04/19/2018	Approval	UM Committee

06/01/2018	Changes in order of criteria, further definition of carrier or predictive testing	Tom Paulson, MD
06/04/2018	Approval	UM Committee
04/04/2019	Corrected erroneous statement that prenatal testing is a carve out service. Added Required documentation.	LuAnn Chen, MD
04/05/2019	Approval	UM Medical Sub-committee