MEDICAL POLICY

POLICY TITLE	CARRIER SCREENING FOR GENETIC DISEASES
POLICY NUMBER	2.258

Original Issue Date (Created):	**8/1/2014**
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I. POLICY

Carrier screening for genetic diseases is considered **medically necessary** when one of the following criteria is met:

- One or both individuals have a first- or second-degree relative who is affected; or
- One individual is known to be a carrier; or
- One or both individuals are members of a population known to have a carrier rate that exceeds a threshold considered appropriate for testing for a particular condition (see Policy Guidelines 1 section).

First-degree relatives include a biological parent, brother, sister, or child; second-degree relatives include biologic grandparent, aunt, uncle, niece, nephew, grandchildren, and half-sibling.

AND all of the following criteria are met:

- The natural history of the disease is well understood and there is a reasonable likelihood that the disease is one with high morbidity in the homozygous or compound heterozygous state.
- Alternative biochemical or other clinical tests to definitively diagnose carrier status are not available, or, if available, provide an indeterminate result or are individually less efficacious than genetic testing.
- The genetic test has adequate clinical validity to guide clinical decision making and residual risk is understood (see Policy Guidelines 2 section).
- An association of the marker with the disorder has been established.

All targeted screening not meeting any of the above criteria is considered **not medically necessary**.

Expanded carrier screening panels are considered **investigational** (see Policy Guidelines 3 section). There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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Genetic counseling and testing associated with pregnancy management may be considered **medically necessary** for evaluation of previous unexplained stillbirth or repeated (two or more) miscarriages occurring prior to fetal viability (less than 24 weeks' gestation).

Policy Guidelines

Policy Guidelines 1
If there is no family history, risk-based predilection for a disease, carrier screening is not recommended when the carrier rate is less than 1% in the general population.

Policy Guidelines 2
The American College of Medical Genetics and Genomics (ACMG) has recommended s testing for specific variants, which will result in a carrier detection rate of 95% or higher for most disorders.

Policy Guidelines 3
ACMG has defined expanded panels as those that use next-generation sequencing to screen for variants in many genes, as opposed to gene-by-gene screening (e.g., ethnic-specific screening or pan-ethnic testing for cystic fibrosis). A 2013 ACMG position statement noted that, although commercial laboratories offer expanded carrier screening panels, there has been no professional guidance as to which disease genes and variants to include (Grody et al, 2013). The American College of Obstetricians and Gynecologists (ACOG) Committee Opinion 690 offered the following summary pertaining to expanded carrier screening: "Given the multitude of conditions that can be included in expanded carrier screening panels, the disorders selected for inclusion should meet several of the following consensus-determined criteria: have a carrier frequency of 1 in 100 or greater, have a well-defined phenotype, have a detrimental effect on quality of life, cause cognitive or physical impairment, require surgical or medical intervention, or have an onset early in life. Additionally, screened conditions should be able to be diagnosed prenatally and may afford opportunities for antenatal intervention to improve perinatal outcomes, changes to delivery management to optimize newborn and infant outcomes, and education of the parents about special care needs after birth. Carrier screening panels should not include conditions primarily associated with a disease of adult onset" (ACOG Committee Opinion No. 690, 2017).

Expanded panels may include the diseases that are present with increased frequency in specific populations, but typically include testing for a wide range of diseases for which the patient is not at risk of being a carrier.

Carrier screening should only be performed in adults.

Genetics Nomenclature Update
Human Genome Variation Society (HGVS) nomenclature is used to report information on variants found in DNA and serves as an international standard in DNA diagnostics. It is being implemented for genetic testing medical evidence review updates starting in 2017 (see Table

PG1). HGVS nomenclature is recommended by HGVS, the Human Variome Project, and the HUman Genome Organization (HUGO).

The American College of Medical Genetics and Genomics (ACMG) and Association for Molecular Pathology (AMP) standards and guidelines for interpretation of sequence variants represent expert opinion from ACMG, AMP, and the College of American Pathologists. These recommendations primarily apply to genetic tests used in clinical laboratories, including genotyping, single genes, panels, exomes, and genomes. Table PG2 shows the recommended standard terminology- "pathogenic," "likely pathogenic," "uncertain significance," "likely benign," and "benign"—to describe variants identified that cause Mendelian disorders.

Table PG1. Nomenclature to Report on Variants Found in DNA

Previous	Updated	Definition
Mutation	Disease-associated variant	Disease-associated change in the DNA sequence
	Variant	Change in the DNA sequence
	Familial variant	Disease-associated variant identified in a proband for use in subsequent targeted genetic testing in first-degree relatives

Table PG2. ACMG-AMP Standards and Guidelines for Variant Classification

Variant Classification	Definition
Pathogenic	Disease-causing change in the DNA sequence
Likely pathogenic	Likely disease-causing change in the DNA sequence
Variant of uncertain significance	Change in DNA sequence with uncertain effects on disease
Likely benign	Likely benign change in the DNA sequence
Benign	Benign change in the DNA sequence

ACMG: American College of Medical Genetics and Genomics; AMP: Association for Molecular Pathology.

Genetic Counseling

Genetic counseling is primarily aimed at patients who are at risk for inherited disorders, and experts recommend formal genetic counseling in most cases when genetic testing for an inherited condition is considered. The interpretation of the results of genetic tests and the understanding of risk factors can be very difficult and complex. Therefore, genetic counseling will assist individuals in understanding the possible benefits and harms of genetic testing, including the possible impact of the information on the individual family. Genetic counseling may alter the utilization of genetic testing substantially and may reduce inappropriate testing. Genetic counseling should be performed by an individual with experience and expertise in genetic medicine and genetic testing methods. Carrier screening with appropriate genetic counseling is performed in adults.

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Benefits are available for specialized diagnostic genetic testing when it is medically necessary to diagnose and/or manage a patient's medical condition. Genetic screening related to family history of cancer or other disease (except for BRCA testing/screening as described in the brochure) is not covered. The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

III. DESCRIPTION/BACKGROUND

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Carrier screening is performed to identify biological parents or prospective parents at risk of having offspring with inherited single-gene disorders. Carriers are usually not at risk of developing the disease, but can pass pathogenic variants to their offspring. Carrier testing may be performed in the prenatal or preconception periods.

Inherited Recessive Disorders

There are more than 1300 inherited recessive disorders (autosomal or X-linked) that affect 30 out of every 10,000 children.[1] Some diseases have limited impact on either length or quality of life, while others are uniformly fatal in childhood.

Targeted Carrier Screening

Carrier screening tests asymptomatic individuals in order to identify those who are heterozygous for serious or lethal single-gene disorders. The purpose of screening is to determine the risk of conceiving an affected child and "to optimize pregnancy outcomes based on … personal preferences and values."[2,] Risk-based carrier screening is performed in individuals having an increased risk based on population carrier prevalence, or personal or family history. Conditions selected for screening can be based on ethnicities at high risk or may be pan-ethnic. An example of effective ethnicity-based screening involves Tay-Sachs disease, with a 90% reduction in the disease following the introduction of carrier screening in the 1970s in the United States and Canada.[3,] An example of pan-ethnic screening involves cystic fibrosis, when the American College of Obstetricians and Gynecologists (ACOG) noted that ethnic intermarriage was increasing in the US[4,5,] and recommended pan-ethnic cystic fibrosis carrier screening in 2005.[6,]

Expanded Carrier Screening

Expanded carrier screening (ECS) involves screening individuals or couples for disorders in many genes (up to 100s) by next generation sequencing (NGS). ECS panels may screen for diseases that are present with increased frequency in specific populations, but also include a wide range of diseases for which the patient is not at increased risk of being a carrier. Chokoshvili et al (2018) identified 16 providers offering ECS as of January 2017; the number of conditions tested ranged from 41 to 1792 (see Table 1).[7,] There was high variability in the genes covered by the different ECS panels with only three conditions (cystic fibrosis, maple syrup urine disease

1b, and Niemann-Pick disease) included in all 16 panels. For ECS panels in which the same disease was screened, there were notable differences in the specific mutations assessed and in variant interpretation and reporting strategies.

Table 1. Available Expanded Carrier Screening Tests as of January 2017[7,]

ECS	Provider	Country	No. Conditions Screened
23andMe	23andMe	US	41
Baby Genes	Baby Genes Inc.	US	71
Baylor Miraca Genetics Laboratories	Baylor Genetics	US	158
Counsyl	Myriad Genetics	US	113
EGL Genetics	EGL Genetics LLC	US	147
GenPath Diagnostics	Gen Path	US	166
Good Start Genetics	Good Start Genetics	US	252
Igenomix	Igenomix	Spain	633
Integrated Genetics	LabCorp	US	135
Macrogen	Macrogen Inc.	South Korea	1792
Natera	Natera Inc.	US	272
NextStep Carrier Screening	Mount Sinai Hospital	US	256
Pathway Genomics	Pathway Genomics	US	73
Progenity	Progenity Inc.	US	230
Recombine	CooperGenomics	US	314
Academic Medical Center Amsterdam		Netherlands	50

Arguments for ECS include the potential to assess ethnicity, identify more potential conditions, efficiency, and cost. Uncertain are the possible downsides of screening individuals at low risk, including a potential for incorrect variant ascertainment and the consequences of screening for rare single-gene disorders in which the likely phenotype may be uncertain (e.g., due to variable expressivity and uncertain penetrance). The conditions included in ECS panels is not standardized and the panels may include many conditions not routinely evaluated and for which there are no existing professional guidelines.

This evidence review applies only if there is no separate evidence review that outlines specific criteria for carrier screening. If a separate evidence review exists, then criteria for medical necessity in that evidence review supersede the guidelines herein.

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Regulatory Status

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests (LDTs) must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Laboratories that offer LDTs must be licensed by CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration has chosen not to require any regulatory review of this test.

A number of commercially available genetic tests exist for carrier screening. They range from testing for individual diseases, to small panels designed to address testing based on ethnicity as recommended by practice guidelines (American College of Obstetricians and Gynecologists, American College of Medical Genetics and Genomics), to large expanded panels that test for numerous diseases.

IV. RATIONALE

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Summary of Evidence

For individuals who are asymptomatic but at risk for having offspring with an inherited recessive genetic disorder who receive targeted risk-based carrier screening, the evidence includes studies supporting clinical validity and clinical utility. Relevant outcomes are test validity and changes in reproductive decision making. Results of carrier testing can be used to inform reproductive decisions such as preimplantation genetic diagnosis, in vitro fertilization, not having a child, invasive prenatal testing, adoption, or pregnancy termination. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are either at increased risk or population risk for having offspring with an inherited recessive genetic disorder who receive expanded carrier screening (ECS), the evidence includes studies supporting clinical validity and clinical utility. Relevant outcomes are test validity and changes in reproductive decision making. Studies have found that ECS identifies more carriers and more potentially affected fetuses. However, evidence to support the clinical validity of ECS beyond risk-based recommendations is limited and accompanied by some concerns regarding interlaboratory inconsistency of variant pathogenicity assessment, the validity of disease severity classifications for rare disorders, and uncertainty that the offspring will be affected by a severe phenotype for all the disorders included in a panel. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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VI. BENEFIT VARIATIONS TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER TOP

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Expanded Carrier Screening panels are considered Investigational; therefore, not covered:

CPT Codes®								
81479								

Covered when Medically Necessary:

CPT Codes ®							
81161	81171	81172	81200	81205	81209	81220	81221
81222	81223	81224	81242	81243	81244	81251	81255
81257	81260	81290	81330	81412	81443	81479	

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ICD-10-CM Diagnosis Codes	Description
Z13.71	Encounter for nonprocreative screening for genetic disease carrier status
Z31.430	Encounter of female for testing for genetic disease carrier status for procreative management
Z31.440	Encounter of male for testing for genetic disease carrier status for procreative management
Z31.7	Encounter for procreative management and counseling for gestational carrier
Z33.3	Pregnant state, gestational carrier
Z36.0	Encounter for antenatal screening for chromosomal anomalies
Z84.81	Family history of carrier of genetic disease

IX. REFERENCES

TOP

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X. POLICY HISTORY

TOP

MP 2.258	**CAC 3/25/14** New policy adopting BCBSA. Information related to carrier testing for cystic fibrosis, prenatal testing of parents or prospective parents for other conditions, and statement related to genetic counseling and testing

	associated with pregnancy management was extracted from MP 2.232 Genetic Testing for Inheritable Disease and placed in this policy along with other additional guidelines for testing.
	CAC 3/24/15 Consensus. No change to policy statements. References and rationale updated.
	11/2/15 Administrative change. LCD number changed from L33640 to L35062 due to Novitas update to ICD-10.
	CAC 3/29/16 Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed.
	Admin update 1/1/17: Product variation section reformatted. New diagnosis codes added effective 10/1/16
	CAC 3/28/17 Consensus review. No changes to the policy statements. References reviewed. Appendix added. Coding reviewed.
	Admin update 10/1/17: New ICD 10 diagnosis codes added effective 10/1/17.
	CAC 7/28/17 Minor review with the following changes. • The policy statement criteria were revised for clarity. • The final policy statement was revised indicating expanded carrier screening panels are considered investigational. • A policy statement was added indicating targeted carrier screening not meeting the stated criteria/indications is not medically necessary. • The Genetic Counseling section was revised, stating carrier screening should only be performed in adults following counseling, in accordance with ACOG guidelines. • The policy title was changed replacing “testing” with “screening”. • Replaced the word "individual" in the policy statement section to "biological parent or biological parent(s)" • Added Medicare variation to reference IOM Section 280 – Preventative and Screening Services of the IOM 100-02, *Medicare Benefit Policy Manual*, Chapter 15. Background/Description, Rationale and References updated. Coding Reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	2/22/18 Consensus review. No changes to the policy statements. References reviewed**.**
	1/1/19 Admin Update: Added new codes 81172, 81173, 81443 effective 1/1/19.
	2/8/19 Consensus review. No change to policy statements. Background and references updated. Rationale condensed.
	02/27/20 Consensus review. No change to policy statement. References updated.

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