APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then “Tools” and “Clinical Guidelines”.

BACKGROUND

According to the American College of Obstetricians and Gynecologists (ACOG), carrier screening is a term used to describe genetic testing that is performed on an individual who does not have any overt phenotype for a genetic disorder but may have one variant allele within a gene(s) associated with a diagnosis. Ideally carrier screening should be performed before pregnancy, however, if it has not been done preconception, counseling about genetic carrier screening should be provided to every pregnant woman. After counseling, a patient may decline any or all screening if they wish. Carrier screening for a particular condition generally should be performed only once in a person’s lifetime. If an individual is found to be a carrier for a specific condition, their reproductive partner should be offered testing as well in order to receive informed genetic counseling about potential reproductive outcomes. Screening of both partners is recommended if there is limited time in which to make decisions regarding the outcome of the evaluation. Prenatal carrier screening does not replace newborn screening, nor does newborn screening replace the potential value of prenatal carrier screening. It is important to obtain family history of the patient and, if possible, her partner as a screening tool for inherited risk. The family history should include the ethnic background of family members as well as any known union between two individuals who are second cousins or closer in family relationship. Individuals with a positive family history of a genetic condition should be offered carrier screening for the specific condition and may benefit from genetic counseling. Couples who express that they would not change the course of their pregnancy based on carrier screening, knowledge of positive carrier status can still benefit from carrier screenings. Benefits include management of a

Clinical Coverage Guideline
high-risk pregnancy, preparation for possible birth complications, and early intervention in the newborn period.\textsuperscript{1,2}

**POSITION STATEMENT**

**Applicable To:**
- Medicaid – Kentucky

**Exclusions**

Carrier screenings for genetic conditions are **not considered medically necessary** and **not a covered benefit** when any of the following apply:

1. Carrier screening for a particular condition generally should be performed only once in a person’s lifetime, and the results should be documented in the patient’s health record. Because of the rapid evolution of genetic testing, additional mutations may be included in newer screening panels. The decision to rescreen a patient should be undertaken only with the guidance of a genetics professional who can best assess the incremental benefit of repeat testing for additional mutations. Requests for repeated screenings must be sent for mandatory secondary review.\textsuperscript{1}

**Coverage**

**Spinal Muscular Atrophy Screening**

Carrier screening for Spinal Muscular Atrophy screening is **considered medically necessary** and **a covered benefit** when the member meets the following criteria:

1. Screening for spinal muscular atrophy should be offered to all women who are considering pregnancy or are currently pregnant and have never had a carrier screening for spinal muscular.

**Cystic Fibrosis**

Carrier screening for Cystic Fibrosis is **considered medically necessary** and **a covered benefit** when the member meets the following criteria:

1. Cystic fibrosis carrier screening should be offered to all women who are considering pregnancy or are currently pregnant and have never had a carrier screening cystic fibrosis.

**Hemoglobinopathies**

Carrier screening for hemoglobinopathies is **considered medically necessary** and **a covered benefit** when the member meets either of the following criteria:

1. A complete blood count with red blood cell indices demonstrates an increased risk of a hemoglobinopathy (low mean corpuscular hemoglobin or mean corpuscular volume). Ideally, this testing also should be offered to women before pregnancy; OR,
2. A hemoglobin electrophoresis should be performed in addition to a complete blood count if there is suspicion of hemoglobinopathy based on ethnicity (African, Mediterranean, Middle Eastern, Southeast Asian, or West Indian descent). If red blood cell indices indicate a low mean corpuscular hemoglobin or mean corpuscular volume, hemoglobin electrophoresis also should be performed.
Fragile X Syndrome

Carrier screening for Fragile X Syndrome is considered medically necessary and a covered benefit when the member meets the following criteria:

1. Member has never had a carrier screening for Fragile X Syndrome; AND,
2. One of the following applies to the member:
   A. Fragile X pre-mutation carrier screening is recommended for women with a family history of fragile X-related disorders or intellectual disability suggestive of fragile X syndrome and who are considering pregnancy or are currently pregnant; OR,
   B. If a woman has unexplained ovarian insufficiency or failure or an elevated follicle-stimulating hormone level before age 40 years, fragile X carrier screening is recommended to determine whether she has an FMR1 pre-mutation.

Genetic Conditions in Individuals of Eastern and Central European Jewish Descent

Carrier screening for genetic conditions in individuals of Eastern and Central European Jewish descent is considered medically necessary and a covered benefit when the member meets the following criteria:

1. When only one partner is of Ashkenazi Jewish descent, that individual should be offered screening first. If it is determined that this individual is a carrier, the other partner should be offered screening. However, the couple should be informed that the carrier frequency and the detection rate in non-Jewish individuals are unknown for most of these disorders, except for Tay–Sachs disease and cystic fibrosis. Therefore, it is difficult to accurately predict the couple’s risk of having a child with the disorder.

Tay–Sachs Disease

Carrier screening for Tay-Sachs Disease is considered medically necessary and a covered benefit when the member meets the following criteria:

1. Member has never had a carrier screening for Tay-Sachs Disease; AND,
2. One of the following applies to the member:
   A. Screening for Tay–Sachs disease should be offered when considering pregnancy or during pregnancy if either member of a couple is of Ashkenazi Jewish, French–Canadian, or Cajun descent; OR,
   B. Those with a family history consistent with Tay–Sachs disease should be offered screening; OR,
   C. When one member of a couple is at high risk (ie, of Ashkenazi Jewish, French–Canadian, or Cajun descent or has a family history consistent with Tay–Sachs disease) but the other partner is not, the high-risk partner should be offered screening. If the high-risk partner is found to be a carrier, the other partner also should be offered screening.

CODING

Covered CPT Codes

81220  CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; common variants (eg, ACMG/ACOG guidelines)
81329  SMN1 (survival of motor neuron 1, telomeric) (eg, spinal muscular atrophy) gene analysis; dosage/deletion analysis (eg, carrier testing), includes SMN2 (survival of motor neuron 2, centromeric) analysis, if performed
81412  Ashkenazi Jewish associated disorders (eg, Bloom syndrome, Canavan disease, cystic fibrosis, familial dysautonomia, Fanconi anemia group C, Gaucher disease, Tay–Sachs disease), genomic sequence analysis panel, must include sequencing of at least 9 genes, including ASPA, BLM, CFTR, FANCC, GBA, HEXA, IKBKAP, MCOLN1, and SMPD1

Clinical Coverage Guideline  page 3

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Genetic testing for severe inherited conditions (e.g., cystic fibrosis, Ashkenazi Jewish-associated disorders [e.g., Bloom syndrome, Canavan disease, Fanconi anemia type C, mucolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes (e.g., ACADM, ARSA, ASPA, ATP7B, BCKDHA, BCKDHB, BLM, CFTR, DHCR7, FANCC, G6PC, GAA, GALT, GBA, GBE1, HBB, HEXA, IKBKAP, MCOLN1, PAH).

Unlisted molecular pathology procedure

Covered HCPCS Codes – N/A

Covered ICD-10 Codes – All applicable codes.

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal/state laws.

REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

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