PRECONCEPTION, PRENATAL, MATERNITY AND INFERTILITY TESTING

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.

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Description:

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

Genetic Testing and Counseling:
Genetic testing is the analysis of DNA, RNA, chromosomes, proteins and certain metabolites in order to detect alterations related to an inherited disorder. Genetic counseling 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.

Infertility:
Inability of a couple to conceive after one year of unprotected intercourse.
PRECONCEPTION, PRENATAL, MATERNITY AND INFERTILITY TESTING  (cont.)

**Description:** (cont.)

**Screening:**
Screening is the testing of an individual with no symptoms for the presence of disease or infection. 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. Genetic screening can be used to predict risk or potential risk for the individual or their offspring.

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

**Definitions:**

**Expanded Carrier Screening (ECS):**
ECS is a non-targeted approach to carrier screening genetic panels and has been investigated as a new technology to screen for mutations in many genes more efficiently than testing mutations in a single gene or a small number of population-specific mutations in several genes. There is no standardization in the makeup of these genetic panels.

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**Criteria:**

**MATERNITY COVERAGE IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER’S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.**

- If benefit coverage for maternity is available, the following standard screening tests of a pregnant woman are considered **medically necessary:**
  
  1. Alpha-fetoprotein (AFP)
  2. Glucose
  3. Group B Streptococcus culture
  4. Hemoglobin and hematocrit
  5. Hepatitis B
  6. Human Immunodeficiency Virus (HIV)
  7. Rh factor
  8. Rubella immunity
  9. Sexually transmitted diseases (e.g., chlamydia, gonorrhea, syphilis)
  10. Ultrasounds
  11. Urinary tract infections
PRECONCEPTION, PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Criteria: (cont.)

- **If benefit coverage for maternity is available**, amniocentesis or chorionic villous sampling is considered *medically necessary* with documentation of *ANY* of the following:
  1. Advanced maternal age (35 years or older)
  2. Congenital malformation(s) determined in utero
  3. Two consecutive spontaneous abortions or miscarriages of unknown etiology within the first 18 weeks of gestation

- **If benefit coverage for maternity is available**, chromosome analysis of products of conception following a spontaneous abortion is considered *medically necessary*. Chromosome analysis testing of parents is considered *not medically necessary*.

- **If benefit coverage for maternity is available**, genetic testing of the fetus during the current pregnancy is considered *medically necessary* with documentation of *ANY* of the following:
  1. Congenital malformation(s) determined in utero
  2. Intrauterine fetal growth retardation (estimated weight of fetus is below the 10th percentile for its gestational age)

- **If benefit coverage for maternity is available**, expanded carrier screening genetic panels are 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.

Tests include, *but are not limited to*:

- Counsyl™
- GoodStart Select™
- Inherigen™
- Inheritest™
- Natera One™ Disease Panel
PRECONCEPTION, PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Criteria: (cont.)

- Except as expressly described as covered in this guideline, preconception or prenatal and/or infertility genetic testing and/or counseling of an unaffected individual, regardless of risk factors is considered screening and not eligible for coverage.

Examples include, but are not limited to:

- A pregnant woman and/or her partner as part of a routine screening maternity assessment or infertility workup except as previously identified
- Bloom syndrome
- Canavan disease
- CFTR gene to determine the G551D mutation for cystic fibrosis in a fetus
- Cystic fibrosis screening of an infant
- Familial dysautonomia
- Fanconi anemia
- Gaucher disease
- Niemann-Pick
- Tay-Sachs disease screening, e.g. HEXA gene analysis

- Preconception or prenatal and/or infertility 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.
PRECONCEPTION, PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Resources:


PRECONCEPTION, PRENATAL, MATERNITY AND INFERTILITY TESTING (cont.)

Resources: (cont.)


