PREIMPLANTATION GENETIC DIAGNOSIS

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:

Preimplantation genetic diagnosis (PGD) describes a variety of adjuncts to assisted reproductive procedures in which either maternal or embryonic DNA is sampled and genetically analyzed. PGD permits deselection of embryos harboring a genetic defect prior to implantation of the embryo into the uterus. PGD is used to detect genetic evidence of a specific inherited disorder in the oocyte or embryo derived from the mother or couple, respectively, which has a high risk of transmission.

The ability to identify preimplantation embryos with genetic defects before the initiation of pregnancy provides an alternative to amniocentesis or chorionic villous sampling (CVS) with selective pregnancy termination of affected fetuses.

Three general categories of individuals have undergone PGD:

1. Embryos at risk for a specific inherited single genetic defect
2. Identification of aneuploid embryos (having a chromosome number that is not an exact multiple of the usual number)
3. Embryos at a higher risk of translocations
PREIMPLANTATION GENETIC DIAGNOSIS (cont.)

Criteria:

COVERAGE FOR THE TREATMENT OF INFERTILITY AND/OR ASSISTED REPRODUCTION IS DEPENDENT UPON BENEFIT PLAN LANGUAGE. REFER TO MEMBER’S SPECIFIC BENEFIT PLAN BOOKLET TO VERIFY BENEFITS.

Preimplantation genetic diagnosis will be reviewed by the medical director(s) and/or clinical advisor(s).

- **If benefit coverage for the treatment of infertility and/or assisted reproduction is not available**, preimplantation genetic diagnosis is considered a **benefit plan exclusion** and **not eligible for coverage**.

- **If benefit coverage for fertility/infertility services is available**, preimplantation genetic diagnosis as an adjunct to in vitro fertilization (IVF) for couples not known to be infertile is considered **medically necessary** for the evaluation of an embryo at an identified elevated risk of a potentially lethal chromosomal abnormality or genetic disorder (for which a reliable genetic test is established and for which there are limited treatment options) with documentation of **ANY** of the following genetic or chromosomal disorders:

  1. Both partners are known carriers of a single gene autosomal recessive disorder
  2. One partner is a known carrier of a single gene autosomal recessive disorder and the partners have one offspring that has been diagnosed with that recessive disorder
  3. One partner is a known carrier of a single gene autosomal dominant disorder
  4. One partner is a known carrier of a single X-linked disorder
  5. Parent with balanced or unbalanced chromosomal translocation

- Preimplantation genetic diagnosis as an adjunct to in vitro fertilization (IVF) for all other indications not previously listed or if above criteria not met is 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.

These indications include, but are not limited to:

- Gender selection
- Identification of possible predispositions to late-onset disorders (e.g., Alzheimer's disease, cancer)
PREIMPLANTATION GENETIC DIAGNOSIS (cont.)

Resources:

