

Last Review Date: 04/21

Preimplantation Genetic Testing for Health Plan Members Policy

PURPOSE

The purpose of this policy is to provide guidelines when a Preimplantation Genetic Diagnosis (PGD) is considered Medically Necessary for a Member.

POLICY

It is policy to appropriately review requests for Preimplantation Genetic Testing to determine medical necessity.

SCOPE

This policy applies to Sutter Health, and any legal entity for which Sutter Health or an affiliate is the sole member or directly or indirectly controls at least 51% of the voting power, if that entity performs delegated Utilization Management (UM) for specific benefit/service for Health Plan Members on behalf of Sutter Bay Medical Foundation or Sutter Valley Medical Foundation (herein after referred to as "Sutter").

Sutter is not responsible for reviewing and/or making a final determination on a request that has been identified as Health Plan responsibility to review.

DEFINITIONS

Aneuploidy is a condition where there are either fewer or more than the normal number of chromosomes present in cells of a person's body.

Autosomal Dominant is a gene mutation located on a non-sex chromosome that is expressed when present as part of a heterozygotic gene pair.

Autosomal Recessive is a gene mutation located on a non-sex chromosome that is only expressed when present in homozygous pairs.

Genetic Counseling is a process involving the guidance of a specially trained professional in the evaluation of family history, medical records, and genetic test results, in assessing the risk of genetic diseases.

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Health Plan means health care service plans, Health Maintenance Organizations (HMOs), and other purchasers of covered services that arrange for the provision of health care services for their Members.

Human Leukocyte Antigen (HLA) Typing is the name given to the system used to identify the unique cell markers (antigens) that the immune system recognizes.

In Vitro Fertilization (IVF) is a type of assisted reproductive procedure where an egg is fertilized outside a woman's body and then implanted into the womb.

Medically Necessary means health care services or supplies needed to diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.

Member is a person covered under a Health Plan, either the enrollee or eligible dependent.

Preimplantation Genetic Diagnosis (PGD) is the testing of an embryo for a specific genetic disorder, involving a biological couple in which one or both partners are carriers of the disorder.

Preimplantation Genetic Screening (PGS) is the testing of an embryo for a specific genetic disorder, involving a biological couple of no known risk (that is, neither partner is a known carrier of the disorder).

Preimplantation Genetic Testing describes a variety of techniques performed as part of an assisted reproductive procedure, in which either maternal or embryonic DNA is sampled and genetically analyzed, thus permitting deselection of embryos harboring a genetic defect prior to implantation of the embryo into the uterus.

Utilization Management (UM) means the evaluation of the medical necessity, appropriateness, and efficiency of the use of health care services, procedures, and facilities under the provisions of the applicable health benefits plan, sometimes called 'utilization review.'

X-Linked Disorder is a disease associated with a genetic mutation on the X sex chromosome; X linked genes are expressed in all males with the gene, but only in females when the same gene is on both X chromosomes.

PROCEDURE

- A. Preimplantation Genetic Testing is generally considered to be divided into two (2) categories:
 1. PGD is used to detect a specific inherited disorder and aims to prevent the birth of affected children in couples at high risk of transmitting a disorder. PGD requires all of the following:
 - a. A specific mutation, or set of mutations, has been identified that specifically identifies the genetic disorder with a high degree of reliability; and

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- b. The genetic disorder is associated with severe disability or has a lethal natural history; and
 - c. Testing is accompanied by Genetic Counseling.
 2. PGS is considered investigational and uses similar techniques to screen for potential chromosome abnormalities in conjunction with IVF for couples without a specific known inherited disorder (high risk of Aneuploidy).

Note: The use of IVF services are subject to separate benefit determination. Many Health Plans specifically exclude IVF and all related procedures.

- B. PGD, when used to de-select embryos with genetic mutations, is Medically Necessary when any one (1) of the following criteria is met:
1. Both partners are known carriers of the same Autosomal Recessive disorder; or
 2. One partner is a known carrier of an Autosomal Recessive disorder, and the couple have previously produced offspring affected by that disorder; or
 3. One partner is a known carrier of a single gene Autosomal Dominant disorder; or
 4. One partner is a known carrier of a single gene X-Linked Disorder; or
 5. When used to evaluate HLA status alone in families with a child with a bone marrow disorder requiring a hematopoietic cell transplant, and in whom there is no other source of a compatible donor other than an HLA matched sibling.
- C. When the specific criteria noted above are met, the polar body biopsy/cleavage stage embryo biopsy procedure to obtain the cell and the genetic test associated with PGD can be considered Medically Necessary.
- D. PGD is considered investigational and not Medically Necessary when the criteria above have not been met.
- E. Single gene disorders include the following:
1. Autosomal Recessive diseases (e.g., cystic fibrosis, beta thalassemia, Tay-Sachs).
 2. Autosomal Dominant diseases (e.g., Marfan's syndrome, myotonic dystrophy).
 3. X linked diseases (e.g., Duchenne and Becker's muscular dystrophy, hemophilia, fragile X syndrome).

REFERENCE

[Agency for Healthcare Research and Quality: Effectiveness of Assisted Reproductive Technology](#)

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[American Society for Reproductive Medicine](#)

ATTACHMENTS

None