Preimplantation Genetic Testing Medical Policy

Updated Revision Effective 7/1/2024

Policy Number	UM481POL-PGD	Approval Date:	5/21/2024
Line(s) of Business: ☒ Commercial ☐ Medicare Advantage ☐ Medicaid (BeHealthy)			

Description

Preimplantation Genetic Testing (PGT) is used in conjunction with In-Vitro Fertilization (IVF) with or without Intra-Cytoplasmic Sperm Injection (ICSI), even if the member is not infertile, to identify and select embryos free of chromosomal abnormalities and specific genetic disorders.

Line of Business

Commercial:
Refer to criteria under Policy section in this medical policy.

MassHealth:
This policy does not apply.

Medicare:
This Policy does not apply.

Policy

For members with infertility benefits, HNE covers up to 5 cycles of non-experimental/investigational PGT/ when such testing is medically necessary to impact clinical decision-making and/or clinical outcomes for members who have, or are carriers of, certain genetic disorders or chromosomal abnormalities.

*****Any state mandates for genetic testing take precedence over this policy. *****

I. Criteria for Approval

A. PGT-M may be **medically necessary** including IVF with/without ICSI including members that are not infertile when the following criteria are met:

1. Genetic counseling has been provided to the member/couple. AND
2. Member has a >5% chance of live birth per cycle with IVF with/without ICSI. AND
3. Purpose of test is to evaluate the embryo that has a risk of one of the following:
   a. Genetic disorder that is associated with severe disability or with a lethal natural history such as when:
      - One partner is a carrier of a single gene autosomal dominant disorder.
      - Both partners are a carrier of a single gene autosomal recessive disorder.
      - One partner is a carrier of a single gene autosomal recessive disorder and partners have one offspring that has been diagnosed with that recessive disorder.
      - One partner is a carrier of a single X-linked disorder.
      - Chromosomal structural abnormality with parent having a balanced or unbalanced chromosomal translocation

II. MEDICALLY NECESSARY diagnoses include but are not limited to the following:

Single Gene Autosomal Recessive Disorders	Single Gene Autosomal Dominant Disorders	Single Gene X–Linked Recessive Disorders
• B-Thalassemia Syndromes • Canavan Disease • Cystic Fibrosis • Epidermolysis Bullosa Simplex (autosomal recessive type) • Fanconi Anemia • Familial Dysautonomia • Gaucher Disease • Hurler Syndrome • Metabolic Disorders (e.g., methylmalonic acidemia or proprionic acidemia) • Sickle Cell Anemia • Spinal Muscular Atrophy Type I • Spinocerebellar Ataxia (autosomal recessive type) • Tay-Sachs Disease	• Epidermolysis Bullosa (autosomal dominant type) • Huntington's Disease • Marfan's Syndrome • Myotonic Dystrophy • Neurofibromatosis Type I & II • Retinoblastoma • Spinocerebellar Ataxia (autosomal dominant type) • Tuberous Sclerosis	• Adrenoleukodystrophy • Alport Syndrome • Becker Muscular Dystrophy • Choroideremia • Duchenne Muscular Dystrophy • Fabry's Disease • Fragile X Syndrome • Hemophilia A & B • Hunter Syndrome • Incontinentia pigmenti • Lesch-Nyhan Syndrome • Muscular Dystrophy • X-Linked Mental Retardation

III. What is Considered Investigational

A. PGT-M in conjunction with IVF is INVESTIGATIONAL in patients/couples who are undergoing IVF in all situations other than those specified above. PGT-M for all other indications, including a parent with a documented history of aneuploidy in a previous pregnancy, is INVESTIGATIONAL.

B. Preimplantation Genetic Screening (PGT-A) in conjunction with IVF is INVESTIGATIONAL in patients/couples who are undergoing IVF in all situations.

C. Aneuploidy screening, including in the setting of recurrent miscarriage, advanced maternal age, or repeated implantation failure during IVF

D. Screening for genetic or chromosomal abnormalities in the absence of a known genetic or chromosomal defect in the genetic parent.

E. Selecting against conditions or disorders (e.g., autism) in the absence of a known and identifiable genetic or chromosomal defect in the genetic parent

F. Gender selection, or selection of nonmedical traits

G. To determine an embryo's carrier status

H. Screening for autosomal recessive disorders when the embryos are created using donor egg or donor sperm

I. Detecting genetic or chromosomal abnormalities contributed by donor egg or donor sperm

J. Screening for adult-onset/late-onset disorders or predisposition to disease (e.g., Alzheimer's disease, cancer predisposition), except for the specific disorders listed above

K. Human leukocyte antigen (HLA) typing of an embryo to identify a future suitable stem cell, tissue or organ transplantation donor is considered experimental and investigational.

L. Infertility services when clinical documentation confirms an individual or couple is using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g., cigarettes, marijuana, opiates, cocaine, or alcohol)

M. PGT for monogenic/single gene diseases (PGT-M) in conjunction with IVF is INVESTIGATIONAL in individuals/couples who are undergoing IVF in all situations other than those specified above.

Policy Guidelines and Definitions

PGT-M should only be offered in centers where there is expertise in genetic counseling, molecular genetics, and embryology, because it is imperative that patients be aware of the potential diagnostic errors, risks of the IVF procedure, and the unknown (though presumed low) risks of the embryo biopsy procedure to the future fetus.

Required Documentation

Clinical information from an Infertility Specialist or Medical Geneticist documenting the presence of the above disorders or carrier gene in one or more parents

DEFINITIONS

Preimplantation Genetic Testing (PGT) - 3 different types of PGT:

A. PGT for monogenic/single gene defects (PGT-M)
B. PGT for chromosomal structural rearrangements (PGT-SR)
C. PGT for aneuploidies (PGT-A)

Preimplantation Genetic Testing (PGT):

Testing technique, which includes both preimplantation genetic diagnosis and preimplantation genetic screening, used to identify genetic defects in embryos soon after fertilization following in vitro fertilization (IVF) and prior to implantation leading to pregnancy

Preimplantation Genetic Testing for Aneuploidy (PGTA):

****NOT covered by HNE****

Preimplantation Genetic Testing for Monogenic/Single Gene Defects (PGT-M):

Formerly referred to as PGD: A genetic test that is designed to reduce risk of having a baby with a specific inherited genetic disorder. This test analyzes the DNA of each embryo (prior to being transferred) to determine healthy embryos, which helps the physician to determine which embryos to transfer.

Preimplantation Genetic Testing for Chromosomal Structural Rearrangements (PGT-SR):

A genetic test that is designed to detect inherited rearrangements and increase the chance of a successful pregnancy. Reduces risk of having a pregnancy or child with an unbalanced structural abnormality. This involves having extra or missing genetic material, which typically results in pregnancy loss.

Autosomal Recessive Disorder:

A genetic condition that appears only in individuals who have received 2 copies of an autosomal gene, one copy from each parent. This gene is on an autosome which is a non-sex chromosome. Autosomal recessive diseases include: Cystic fibrosis, Sickle cell disease (see table below).

Autosomal Dominant Disorder:

A pattern of inheritance where the affected individual has one copy of a normal gene and one copy of a mutant gene on a pair of autosomal chromosomes. An individual that has an autosomal dominant has a 50/50 chance of passing the mutant gene on. Autosomal dominant diseases include: Huntington disease, Neurofibromatosis, Polycystic (see table below).

Coding Guidance

CPT Codes:

Code	Description
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); less than or equal to 5 embryos.
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); greater than 5 embryos.
89398	Unlisted reproductive medicine laboratory procedure ** Experimental & Investigational **

Additional genetic testing may require authorization from eviCore healthcare.

References

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Policy Implementation

Approved by the Medical and Pharmacy Policy Committee
Kate McIntosh MD MBA
Chief Medical Officer

Saad Usmani MD MBA
Medical Director

Date	Update
2/2023	New Policy Template. No change to Policy Language
1/2024	Line of Business section added
5/2024	Reviewed with minor changes for clarity.

Medical Criteria Disclaimer

 The treating physician or primary care provider must submit to Health New England the clinical evidence that the patient meets the criteria for the treatment, testing or surgical procedure. Without this documentation and information, Health New England will not be able to properly review the request for prior authorization. The clinical review criteria reflect how Health New England determines whether certain services or supplies are medically necessary. Health New England established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). Health New England expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by Health New England, as some programs exclude coverage for services or supplies that Health New England considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. Health New England has adopted the herein policy in providing management, administrative and other services to its Health Plan.