Mass General Brigham
Health Plan

Medical Policy
Preimplantation Genetic Testing

Policy Number: 044

	Commercial* and Connector/ Qualified Health Plans	MassHealth	Medicare Advantage
Authorization required	X		X
No notification or authorization			
Not covered		X	

* Not all commercial plans cover this service, please check plan's benefit package to verify coverage.

Overview
The purpose of this document is to describe the guidelines Mass General Brigham Health Plan utilizes to determine medical necessity for preimplantation genetic testing (PGT) which includes preimplantation genetic diagnosis for single gene defects (PGT-M) and translocations (PGT-SR), and preimplantation genetic screening for aneuploidy (PGT-A).

Coverage Guidelines
Mass General Brigham Health Plan covers medically necessary preimplantation genetic diagnosis (PGT-M) (and associated assisted reproductive services; e.g. IVF, ICSI) for a debilitating, genetically-defined and genetically predictable disease with early onset mortality or morbidity when there is no known treatment for the condition or the available interventions are either inadequately effective or significantly burdensome. Mass General Brigham Health Plan does not cover PGT-A.

This process requires two authorizations; the first from Mass General Brigham Health Plan utilization management (UM). If approval is obtained, a second authorization must be obtained by eviCore.

The specialist and/or the primary care provider are responsible for providing all necessary clinical information including medical history of patient and partner or child, where appropriate. It is expected that the member/couple are counselled regarding the testing alternatives to PGT-M (e.g. amniocentesis, chorionic villous sampling), potential risks of PGT-M (embryo arrest, diagnostic uncertainly and unknown long-term effects of PGT-M), and that traditional prenatal diagnostic testing may still be recommended after successful PGT-M and pregnancy.

Authorization of PGT-M is limited to the following criteria:

Preimplantation Genetic Testing (PGT)

1. Mass General Brigham Health Plan covers medically necessary PGT-SR to test for unbalanced chromosome rearrangements when one of the genetic parents is known to have a balanced reciprocal or Robertsonian translocation, or to have a microdeletion /duplication or other structural chromosomal abnormality associated with the birth of an affected child. Mass General Brigham Health Plan may require laboratory documentation of the genetic tests.

2. Mass General Brigham Health Plan covers medically necessary PGT-M to detect evidence of any of the following genetic disorders in an embryo when:
    a. Both genetic parents are known carriers of a single gene autosomal recessive disorder, or one of the genetic parents is a known carrier and they have a child who has been diagnosed with the disorder such as, but **not limited to** the following:

i. Canavan disease
ii. Cystic Fibrosis
iii. Epidermolysis Bullosa Simplex (autosomal recessive type)
iv. Familial dysautonomia
v. Fanconi's Anemia
vi. Gaucher Disease
vii. Hurler Syndrome
viii. Methylmalonic acidemia
ix. Propionic academia
x. Sickle Cell Anemia
xi. Spinal Muscular Atrophy Type I
xii. Spinocerebellar Ataxia (autosomal recessive type)
xiii. Tay-Sachs Disease
xiv. Thalassemia Syndromes

b. One genetic parent is a known carrier of a single gene autosomal dominant disorder such as, but **not limited to**, the following:
   i. Epidermolysis Bullosa (autosomal dominant type)
   ii. Huntington's Disease
   iii. Myotonic Dystrophy
   iv. Neurofibromatosis Type I AND II
   v. Spinocerebellar Ataxia (autosomal dominant type)
   vi. Tuberous sclerosis

c. The genetic female parent is a known carrier of a single gene X-linked recessive disorder such as, but **not limited to** the following:
   i. Adrenoleukodystrophy
   ii. Alport Syndrome
   iii. Becker muscular dystrophy
   iv. Fabry disease
   v. Choroideremia
   vi. Duchenne muscular dystrophy
   vii. Fragile X syndrome
   viii. Hemophilia A & B
   ix. Hunter Syndrome
   x. Incontinentia pigmenti
   xi. Lesch-Nyhan Syndrome
   xii. X-linked intellectual disability

Exclusions

1. PGT as an adjunct to infertility services for members who are not eligible for such services as determined by the *Preimplantation Genetic Testing* clinical coverage criteria.
2. PGT for:
   a. Screening for aneuploidy (PGT-A) including in the setting of: recurrent miscarriage, repeated failed implantation during IVF, or advanced maternal age.
   b. Carrier testing to determine embryo's carrier status.
   c. Human Leukocyte antigen (HLA) typing of an embryo to identify a future suitable stem cell, tissue or organ transplantation donor.
   d. Translocations which will always produce an abnormal gamete such as 45XX (21;21) & 45XY(21;21)

e. Gender selection in the absence of a documented X-linked disorder.
f. Selecting non-medical traits.
g. Selecting against predisposition to disease when there is no single known genetic or chromosomal defect that definitively causes the disease.
h. Late onset/adult onset disorders that are not listed in criteria above.
i. Genetic conditions contributed to by donor egg and sperm.

Medicare Variations

Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When there is no guidance from CMS for the requested service, Mass General Brigham Health Plan's medical policies are used for coverage determinations.

Definitions

Autosomal Dominant: Autosomal dominant is one of several ways that a trait or disorder can be passed down through families. If a disease is autosomal dominant, it means you only need to get the abnormal gene from one parent in order for you to inherit the disease. One of the parents may often have the disease.

Autosomal Recessive: A disorder characterized by two mutated copies of the gene must be present in each cell in order for the disease or trait to develop. Affected persons usually have two unaffected parents who each carry a single copy of the mutated gene and they are known as carriers.

Preimplantation Genetic Testing: A test involving an embryo that has been created using assisted reproductive technology such as in-vitro fertilization. After the eggs are removed the eggs are fertilized. Those eggs which are successfully fertilized are developed into blastocyst. Five to ten cells are removed from the growing blastocyst in order to test for the specific genetic condition in question.

X-linked Dominant Disorders: Caused by mutations in the gene on the X chromosome. Females are more frequently affected than males and the chances of passing on an X linked dominant disorder differ between men and women.

X-Linked Recessive: Are caused by mutations in the genes on the X chromosome. Males are more frequently affected than females and the chances of passing on the disorder differ between men and women. Families with an X linked recessive disorder often have affected males but rarely affected females in each generation. A characteristic of X linked inheritance is that fathers cannot pass X-linked traits to their sons.

Codes

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

This list of codes applies to commercial plans only.

Authorized CPT/HCPCS Codes	Code Description
89290	Biopsy, oocyte polar body or embryo blastomere, micro technique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	Biopsy, oocyte polar body or embryo blastomere, micro technique (for pre-implantation genetic diagnosis); greater than 5 embryos

Related Policies

- Assisted Reproductive Services/Infertility Services

Effective
March 2024: Annual update.
March 2023: Annual update. Medicare Advantage added to table. Subheading title changed to Preimplantation Genetic Testing (PGT). Exclusions updated. Medicare Advantage language added. Definitions updated.
March 2022: Annual update. References updated.
March 2021: Annual update. References updated.
June 2020: Annual update. Under coverage guidelines added clarification statement regarding authorization requirements. Updated references.
March 2019: Annual update. Updated references.
August 2018: Added language under item 1 subheading Preimplantation Genetic Diagnosis to include *(and associated assisted reproductive services; e.g. IVF, ICSI)*.
April 2018: Annual update.
July 2017: Annual update. Added the exclusion "PGD Services if the member or member's spouse are using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g., marijuana, opiates, cocaine, or alcohol)"
July 2016: Annual update
July 2015: Updated references
August 2014: Added language to Coverage Guidelines, "a debilitating genetic disease with early onset mortality or morbidity and when there is no known treatment for the condition or the available interventions are either inadequately effective or significantly burdensome." Added exclusions: 3f selecting for non-medical traits and 3j Genetic conditions contributed to by donor egg and sperm.
June 2013: Annual update, added specific genetic disorders.
June 2012: Effective date.

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