Medical Necessity Guidelines:
Preimplantation Genetic Diagnosis (PGD)

Effective: September 13, 2017

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Applies to:

☑ Tufts Health Plan Commercial Plans products; Fax: 617.972.9409
☑ Tufts Health Public Plans products
   ☑ Tufts Health Direct — Health Connector; Fax: 888.415.9055
   ☑ Tufts Health Together — A MassHealth Plan; Fax: 888.415.9055
   ☐ Tufts Health Unify — OneCare Plan; Fax: 781.393.2607
☑ Tufts Health RITogether — A Rhode Island Medicaid Plan; Fax: 857.304.6404
☑ Tufts Health Freedom Plan products; Fax: 617.972.9409

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW
Preimplantation genetic diagnosis (PGD) is a technique used in conjunction with in vitro fertilization (IVF) to test embryos for specific genetic disorders prior to their transfer to the uterus. PGD makes it possible for couples or individuals who have or who carry serious inherited disorders to decrease the risk of passing the disorder on to their child. This technique is controversial and raises issues of sex selection and genetic engineering. At present, PGD is offered only in a few centers, and may be offered under the supervision of an institutional ethics review board, but its use is increasing (American Society of Reproductive Medicine, 2005).

PGD is currently limited to certain genetic diseases and to centers where expertise in genetic counseling, molecular genetics, and embryology coexist. It is imperative that patients be aware of potential diagnostic errors and the possibility of currently unknown long-term consequences on the fetus of the embryo biopsy procedure. At present, PGD requires specialized equipment, methodology, and experience. PGD should be regarded as an established technique with specific and expanding applications for standard clinical practice (ASRM, 2006).

COVERAGE GUIDELINES
The completion of the Preimplantation Genetic Diagnosis Request Form is required.

- Tufts Health Plan’s coverage of preimplantation genetic diagnosis (PGD) is made independently of the decision for the coverage of other infertility services. Coverage of PGD does not include coverage of in vitro fertilization or other assistive reproductive technologies.

- Prior to approval of preimplantation genetic diagnosis (PGD), Tufts Health Plan requires evidence of genetic counseling, including documentation of a discussion of alternatives to this procedure, including prenatal diagnosis by ultrasound, chorionic villus sampling or amniocentesis, and documentation of a discussion regarding gamete donation, remaining childless, accepting genetic risk without testing and adoption. (The name of the geneticist/genetic specialist and the date of visit must be listed on the PGD Request Form.)

- Tufts Health Plan may cover PGD in any one the following circumstances. Please indicate under what circumstance the request is being made and provide supporting evidence:
  - To identify the gender of the embryo, when the member is a known carrier of an X-linked disease, (Polymerase Chain Reaction (PCR) technique preferred)\(^1\), such as:
    - Hemophilia A & B
    - Muscular dystrophy

\(^1\) PCR is preferred except when the woman is a documented carrier for an X-linked disorder for which the exact mutation has not been identified in her family.
Preimplantation Genetic Diagnosis (PGD)

- X-linked mental retardation
- Lesch-Nyhan Syndrome
- Adrenoleukodystrophy
- Duschen/Becker muscular dystrophy
- Fragile X syndrome
- Anderson-Fabrey disease
- Incontinentia pigmenti
- Choroideremia
- Alport Syndrome
- Hunter Syndrome

To identify if the embryo is affected when the member has any known single gene disorder² (Polymerase Chain Reaction (PCR) technique preferred), such as:
- Cystic Fibrosis
- Tay-Sachs Disease
- Marfan’s Syndrome
- Spinal Muscular Atrophy
- Muscular Dystrophy
- Sickle Cell And Fanconi’s Anemias
- B-Thalessemia Syndromes
- Neurofibromatosis Type I & II
- Myotonic Dystrophy
- Spinocerebellar Ataxia
- Retinoblastoma
- Epidermolysis Bullosa

In the setting of male infertility:
- To test for CF in the embryo when the female is a known CF carrier (PCR technique preferred).
- To test for unbalanced chromosome rearrangements when the male partner has a known balanced chromosome abnormality or sex chromosome abnormality (FISH technique is preferred).

To test for unbalance chromosome rearrangement in a couple where one of the partners is a known carrier of a chromosomal inversion or other rearrangement (Fluorescent In Situ Hybridization (FISH) technique preferred).

LIMITATIONS
- Tufts Health Plan will not cover PGD for the purpose of human leukocyte antigen (HLA) tissue typing as it is not considered to be medically necessary at this time.
- Tufts Health Plan will not cover PGD to test for aneuploidy in the setting of multiple spontaneous abortions of uncertain etiology as it has not proven to improve In Vitro Fertilization (IVF) outcomes.
- Tufts Health Plan will not cover the costs related to in-vitro fertilization for members who are not eligible for such services as determined by the Infertility Services Medical Necessity Guidelines for Massachusetts or the Infertility Services Medical Necessity Guidelines for Rhode Island.
- Tufts Health plan will not cover the following test for preimplantation genetic diagnosis: Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., bacterial artificial chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis)

CODES
The following CPT code(s) require prior authorization:

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<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>89290</td>
<td>Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos</td>
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<tr>
<td>89291</td>
<td>Greater than 5 embryos</td>
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² This includes autosomal recessive, autosomal dominant, X-linked recessive and X-linked dominant disorders.
The following CPT code is not covered for preimplantation genetic diagnosis:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>81228</td>
<td>Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., Bacterial Artificial Chromosome [BAC] or oligo based comparative genomic hybridization [CGH] microarray analysis)</td>
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**REFERENCES**


**APPROVAL HISTORY**

October 24, 2007: Reviewed by the Clinical Coverage Criteria Committee for a January 1, 2008 effective date.

Subsequent endorsement date(s) and changes made:

- March 11, 2008: Preimplantation Genetic Determination Form added.
- February 11, 2009: Reviewed and updated without changes.
- May 4, 2009 for the effective date of August 1, 2009: Testing for aneuploidy in the setting of multiple spontaneous abortions of uncertain etiology is no longer a covered indication. HLA testing was added to Limitations as not covered, not medically necessary.
- November 19, 2009: Administrative process updated
- February 1, 2010: Reviewed by Medical Specialty Policy Advisory Committee (MSPAC). No changes.
- March 2011: Reviewed at Medical Specialty Policy Advisory Committee (MSPAC). No changes.
- April 10, 2013: Reviewed by IMPAC, renewed without changes.
- June 12, 2013: Reviewed by IMPAC, coverage limitation added: CPT code 81228: Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., Bacterial Artificial Chromosome [BAC] or oligo based comparative genomic hybridization [CGH] microarray analysis).
- November 19, 2014: Reviewed by IMPAC, renewed without changes
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- November 16, 2015: Reviewed by IMPAC, renewed without changes
- July 20, 2016: Reviewed by IMPAC, renewed without changes
- August 10, 2016: Reviewed by IMPAC, title of guideline updated (formerly "Preimplantation Genetic Determination").
- December 14, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Medical Necessity Guidelines apply to the fully insured Commercial and Medicaid products when Tufts Health Plan conducts utilization review unless otherwise noted in this guideline or in the Member’s benefit document, and may apply to Tufts Health Unify to the same extent as Tufts Health Together. This guideline does not apply to Tufts Medicare Preferred HMO, Tufts Health Plan Senior Care Options or to certain delegated service arrangements. For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates or other requirements will take precedence. For CareLink℠ Members, Cigna conducts utilization review so Cigna’s medical necessity guidelines, rather than these guidelines, will apply.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.