



## Kaiser Foundation Health Plan of Washington

### Clinical Review Criteria Preimplantation Genetic Diagnosis (PGD)

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#### **Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees (for in-network coverage)**

*Prevention and Invitae Corporation is the preferred lab for genetic testing\* when the test(s) is/are available at Prevention or Invitae and medical necessity criteria are met.*

*Invitae's test catalog can be found here: [Invitae Test Catalog](#)  
Prevention test catalog can be found here: [Prevention Test Catalog](#)*

*\*Note: This does not affect processing of tumor or other pathology specimens as they are not performed by Invitae/prevention.*

*PPO/POS members may use non-preferred labs at the out of network cost share.*

## Criteria

### For Non-Medicare Members

Preimplantation genetic diagnosis (PGD) is performed on single cells removed from an embryo. Standard prenatal diagnosis is customarily performed on multiple cells obtained by chorionic villous sampling (CVS) or amniocentesis. PGD on single, embryonic cells is considered medically necessary only when there is a need to diagnose a specific, detectable single gene mutation in an embryo at risk due to an identified deleterious genetic mutation in one or both genetic parents, as defined below:

- I. In order to meet medically necessary criteria for PGD, **both A and B must be met:**
  - A. There must be documentation confirming that PGD is medically necessary to detect a single gene disorder or chromosomal abnormality whose expression in the fetus or child would be expected to have a significant adverse medical impact and that detection in the pre-implantation period would directly affect reproductive decisions.
  - B. **One of the following** clinical circumstances must be documented:
    1. One genetic parent has a balanced, reciprocal translocation or Robertsonian translocation
    2. One genetic parent has a single gene autosomal dominant disorder
    3. Both genetic parents are known carriers of the same single gene autosomal recessive disorder
    4. The female genetic parent is a known carrier of a single gene X-linked recessive disorder

*The procedure to obtain a cell sample from an embryo for PGD is covered when the above criteria for PGD are met. However, the procedures and services (such as IVF) required to create the embryos to be tested and the transfer of embryos to the uterus after testing, are covered only for members with advanced reproductive technology (ART) benefits and who meet medical necessity criteria for IVF (in vitro fertilization).*

- II. The following are *not* covered for preimplantation screening:
  - A. Aneuploidy screening, including in the setting of recurrent miscarriage or repeated failure of IVF (e.g. screening for Down Syndrome, in women over the age of 35)

- B. Screening for chromosomal abnormalities in the absence of a known, clinically significant genetic or chromosomal defect in a genetic parent
- C. Selecting against conditions or disorders in the absence of a known and identifiable genetic or chromosomal defect in a genetic parent
- D. Gender selection of selection of nonmedical trait to determine an embryo's carrier status
- E. Screening for autosomal recessive disorders when the embryos are created using donor egg or sperm
- F. Detecting genetic or chromosomal abnormalities contributed by donor egg or sperm
- G. Screening for adult-onset disorders or for genetic predisposition to adult-onset disease
- H. HLA typing of an embryo to identify a future suitable stem cell, tissue or organ transplantation donor.

**If requesting this service, please send the following documentation to support medical necessity:**

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Historically, couples at high risk of transmission of a genetic disorder have had limited reproductive options, forced after prenatal diagnosis to choose between either termination of affected pregnancies or acceptance of the emotional and financial burden of having a child with severe disability and early mortality. Preimplantation genetic diagnosis (PGD) was introduced to enhance efficiency in assisted conception. It is a technique for reducing the burden of genetic disease performed on couples who are at risk of a specific inherited disorder and used to identify genetic defects present in embryos created through in vitro fertilization (IVF) before transferring them to the uterus.

PGD is performed in conjunction with IVF and is offered to both fertile and infertile couples. Introduced in 1990 as an experimental procedure, PGD has now become an established clinical option in reproductive medicine (Handyside, Kontogianni et al. 1990; Verlinsky, Ginsberg et al. 1990). Because only unaffected embryos are transferred to the uterus for implantation, PGD can provide an alternative to current post conception diagnostic procedures such as amniocentesis or chorionic villus sampling which are sometimes followed by pregnancy termination when results are unfavorable (Verlinsky, Cohen et al. 2004). PGD techniques are now also being utilized for preimplantation genetic screening (PGS) with the intent to identify potential genetic abnormalities in conjunction with IVF for couples without specific known inherited disorders.

With single gene disorders and inherited chromosomal abnormalities being the main indicators for PGD, the technique is available for most known genetic mutations. With that said, PGD can be considered a rapidly evolving technique. Put simply, PGD requires egg extraction, IVF, cell biopsy, genetic analysis and embryo transfer (Handyside, Kontogianni et al. 1990). At present, there are three different procedures utilized for cell biopsy, each with its own advantages and disadvantages, including polar body biopsy, cleavage-stage embryo biopsy and blastocyst biopsy. Depending on the whether the characteristic being tested for is associated with chromosomes or DNA, the sample can be analyzed in one of three ways including polymerase chain reaction (PCR), fluorescence in situ hybridization (FISH) and comparative genomic hybridization with new technologies emerging rapidly. Regardless of the methods, the results are used by parents and providers to select which embryos are transferred back to the uterus with the ultimate goal of establishing an unaffected pregnancy.

The accuracy and reliability of PGD are key issues and exploring these matters requires consideration of the technical challenges and risks inherent in the genetic test itself and in the IVF procedure that it entails. Any PGD strategy has to deal with the detection and avoidance of misdiagnosis from the onset with the risk and outcome relating directly to the type of genetic disorder for which testing is performed. Although PGD has been suggested as an alternative for current post conception diagnostic procedures, the amount of DNA available for testing is limited. Due to this risk, prenatal diagnosis by amniocentesis or chronic villus sampling testing is strongly recommended upon established pregnancy to confirm genetic health.

## Applicable Codes

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

CPT® Codes	Description
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); greater than 5 embryos

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
12/03/2013	12/03/2013 <sup>MPC</sup> , 10/07/2014 <sup>MPC</sup> , 08/04/2015 <sup>MPC</sup> , 06/07/2016 <sup>MPC</sup> , 04/04/2017 <sup>MPC</sup> , 02/06/2018 <sup>MPC</sup> , 01/08/2019 <sup>MPC</sup> , 01/07/2020 <sup>MPC</sup> , 01/05/2021 <sup>MPC</sup> , 03/01/2022 <sup>MPC</sup> , 01/10/2023 <sup>MPC</sup>	10/10/2022

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
06/02/2020	Added section: "Preferred Lab for Genetic Testing for Kaiser Permanente non-Medicare enrollees." Requires 60-day notice, effective date 10/01/2020.
10/10/2022	Noted Prevention lab as a preferred vendor for genetic testing.