KAISER PERMANENTE® Mid-Atlantic States	**Preimplantation Genetic Testing (PGT)** **Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- All coverage is subject to the terms and conditions of the member's benefit plan; coverage varies widely for diagnosis and treatment of infertility, and in exclusions and limitations of procedures.
- PGD is considered a procedure separate from infertility procedures; testing when criteria for coverage are met is covered under the laboratory services benefit.
- Medicare currently does not have a National Coverage Determination (NCD) for Preimplantation Genetic Testing.
- In addition, Local coverage determinations (LCD)/Local Coverage Articles (LCA) do not exist at this time.
- If, after searching the Medicare Coverage Database, no NCD/LCD/LCA is found, please use this KP-MAS Medical Coverage Policy for coverage guidelines for Medicare members.

I. Procedure: **Preimplantation Genetic Testing (PGT)**

II. Diagnosis: **Embryonic risk for genetic disorders**

III. Specialties: **Genetics and Reproductive Endocrinology**

IV. **Indications for Coverage**

A. Preimplantation Genetic Testing (PGT) for monogenic/single gene defects (PGT-M) or inherited structural chromosome rearrangements (PGT-SR) is covered for detection of a genetic disorder in an embryo as follows:
   1. For autosomal recessive conditions when both parents are known carriers, or one parent is a known carrier and the couple has previously produced offspring affected by that disorder **and** when the disorder is associated with possible severe disability or lethal history; **or**
   2. For autosomal dominant disorders, when at least one parent is diagnosed, and when the disorder is associated with possible severe disability or lethal history
   3. For X-linked disorders, when at least one parent is diagnosed, when the disorder is associated with possible severe disability or lethal history
   4. Balanced or unbalanced chromosomal translocations of one of the parents

B. PGT-M and PGT-SR treatment and coverage is not limited solely to women or couples diagnosed with infertility requiring advanced reproductive technologies. PGT-M is medically necessary to diagnose specific detectable genetic mutations (cystic fibrosis, fragile X) where there is a valid genetic test based

on peer-reviewed literature and/or MCG Care Guidelines.

C. PGT-M and PGT-SR treatment requires in vitro fertilization (IVF) as a secondary process. The IVF services, including oocyte/follicle retrieval and embryo transfer, are covered when the patient meets the definition of infertility and has the IVF benefit.

D. Assisted hatching is only covered when IVF is covered. Assisted hatching is not covered when only PGT-M and PGT-SR are covered.

E. ICSI (Intracytoplasmic Sperm Injection) is only covered for PGT-M for single gene disorders where PCR testing will be needed. In all other cases, ICSI is only covered when IVF is covered and medical necessity is met.

V. **Exclusions and Limitations**

A. KPMAS considers preimplantation genetic testing for aneuploidy (PGT-A) i.e., screening embryos for chromosomal abnormalities in the absence of specific inherited genetic conditions identified in either parent to be experimental or investigational, including the following:
   1. Preimplantation genetic screening and comprehensive chromosome screening of polar bodies and blastocysts to enhance delivery rates in advanced reproductive technologies;
   2. Aneuploidy screening (AS) in the setting PGT-A for purposes of optimizing IVF outcomes in women with advanced maternal age, history of failed IVF cycles, or recurrent miscarriages, in the absence of inherited genetic abnormalities.

B. Preimplantation genetic diagnosis for fetal chromosomal abnormalities is currently not as accurate as cytogenetic analysis performed on prenatal diagnostic specimens obtained by chorionic villus sampling and amniocentesis. Therefore, PGT-A is considered experimental and investigational for detecting fetal chromosomal abnormalities.

C. PGT for nonmedical gender selection and/or nonmedical traits

D. PGT for multifactorial inheritance disorders

E. PGT for hereditary mutations which manifest in adulthood (e.g., BRCA testing)

F. PGT for screening of conditions with incomplete penetrance or significant variability of expression (e.g., Alzheimer's disease, cancer predisposition)

G. Screening for polygenic risk (PGT-P)

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Approval History

Date approved by RUMC*	Date filed with the State of Maryland	Effective Date (Ten days after filing)
06/30/2015	07/02/2015	07/14/2015
08/27/2015	08/282015	09/08/2015

Approval History

Effective June 01, 2016, state filing no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
09/13/2016	09/13/2016
11/21/2017	11/21/2017
11/26/2018	11/26/2018

KAISER PERMANENTE® Mid-Atlantic States	**Preimplantation Genetic Testing (PGT)** **Medical Coverage Policy**

11/20/2019	11/20/2019
11/18/2020	11/18/2020
04/16/2021	04/16/2021
10/19/2021	10/19/2021
10/20/2022	10/20/2022
09/27/2023	09/27/2023
09/26/2024	09/26/2024

*The Regional Utilization Management Committee received delegated authority from the Regional Quality Improvement Committee to review and approve designated Utilization Management and Medical Coverage Policies in 2011.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Whenever possible, Medical Coverage Policies are evidence-based and may also include expert opinion. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.