Minuteman Health

Clinical Review Criteria Related to Preimplantation Genetic Testing (PGT)/Preimplantation Genetic Diagnosis (PGD)

I.Criteria for Approval

Procedure: Preimplantation Genetic Testing (PGT)/Preimplantation Genetic Diagnosis (PGD) 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.

For members with infertility benefits, Minuteman Health Insurance (MHI) covers up to 2 cycles of non-experimental/investigational PGT/PGD 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.

A. PGT/PGD may be **MEDICALLY NECESSARY**, including IVF with or without ICSI, even if the member is not infertile, when **ALL** of the following criteria are met:

1. The member has undergone genetic counseling, **AND**

2. PGT is for evaluation of an embryo at an identified elevated risk for one of the following:

   a. A genetic disorder that is associated with severe disability or has a lethal natural history, such as when:
      - One parent has the diagnosis or is a known carrier of a single gene autosomal dominant disorder, or
      - Both parents are known carriers of a single gene autosomal recessive disorder.
      - One parent is a known carrier of a single gene autosomal recessive disorder and the parents have one offspring that has been diagnosed with that recessive disorder.
      - One parent is a known carrier of a single X-linked disorder.

   b. A structural chromosomal abnormality such as for a parent with balanced or unbalanced chromosomal translocation.

B. 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

II. Required Documentation

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

III.What is Not Covered

A. PGD in conjunction with IVF is INVESTIGATIONAL in patients/couples who are undergoing IVF in all situations other than those specified above.

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

C. PGT for all other indications, including a parent with a documented history of aneuploidy in a previous pregnancy, is INVESTIGATIONAL.

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

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

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

G. Gender selection, or selection of nonmedical traits.

H. To determine an embryo's carrier status.

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

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

K. 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.

L. Human leukocyte antigen (HLA) typing of an embryo to identify a future suitable stem cell, tissue or organ transplantation donor, or otherwise not considered to be medically necessary at this time.

M. An individual or couple using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g., marijuana, opiates, cocaine, or alcohol).

IV.CPT/ ICD-10/ HCPCS Codes

Applicable Coding: Codes may not be all inclusive as the American Medical Association (AMA) code updates may occur more frequently or at different intervals than policy updates. These codes are not intended to be used for coverage determinations.

CPT Codes:

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.

V.References

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

Preimplantation Genetic Diagnosis, An Overview, Indications, and Conditions: Molina B. Dayal, MD, MPH. Updated 11/04/13.
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Preimplantation Genetic Diagnosis--An Overview, Ogilvie, Braud, Scriven. Journal of Histochemistry and Cytochemistry, March 2005, vol. 53, no.3, 255-260.
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Preimplantation Genetic Testing: A Practice Committee opinion. Practice Committee of the Society for Assisted Reproductive Technology; Practice Committee of the American Society for Reproductive Medicine. Fertil Steril 2007; 88:1497-504.
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Pregnancy outcome after preimplantation genetic screening or natural conception in couples with unexplained recurrent miscarriage: a systemic review of the best available evidence. Fert Ster. 2011; 95: 2153-7.
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(Last Accessed 12/23/16)

Centers for Disease Control. Assisted Reproductive Technology: Success Rates: National Summary and Fertility Clinic Reports. 2009; http://www.cdc.gov/art/ARTReports.htm.
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VI.Summary of Changes

04/13/2017

- Under Policy Statement, sentence added:
  Benefit plans that specifically exclude In-Vitro Fertilization (IVF) and related procedures will not be covered for IVF services associated with Preimplantation Genetic Diagnosis (PGD).

VII.Review Dates

HNE Review Dates: 9/9/2014, 9/8/2015, 4/12/2016, 04/04/2017
MHI Review Dates: 01/01/2014, 10/23/2014, 10/07/2015, 04/13/2017