I. Description

Preimplantation genetic diagnosis (PGD), also referred to as preimplantation genetic testing (PGT), describes a variety of adjuncts to an assisted reproductive procedure (e.g., in vitro fertilization IVF), in which either maternal or embryonic DNA is sampled and genetically analyzed, thus permitting deselection of embryos harboring a genetic defect prior to implantation of the embryo into the uterus.

Two different sources of genetic material may be sampled in PGT; the first or second polar body of the oocyte may be sampled or the preimplantation embryo may be biopsied. The samples can be analyzed in a variety of ways. Polymerase chain reaction (PCR) or other amplification techniques can be used to amplify the harvested DNA with subsequent analysis for single genetic defects. This technique is most commonly used when the embryo is at risk for a specific genetic disorder such as Tay Sachs disease or cystic fibrosis. Fluorescent in situ hybridization (FISH) is a technique that allows direct visualization of specific (but not all) chromosomes to determine the number or absence of chromosomes. This technique is most commonly used to screen for aneuploidy, gender determination or to identify chromosomal translocations. FISH cannot be used to diagnose single genetic defect disorders. However, molecular techniques can be applied with FISH (such as microdeletions and duplications) and thus, single-gene defects can be recognized with this technique.

Another approach that is becoming more common is array comparative genome hybridization (CGH) testing at either the 8-cell or more often, the blastocyst stage. Unlike FISH analysis, this allows for 24 chromosome aneuploidy screening, as well as more detailed screening for unbalanced translocations and inversions and other types of abnormal gains and losses of chromosomal material.
II. Criteria/Guidelines

A. PGD is covered (subject to Limitations/Exclusions and Administrative Guidelines) as an adjunct to IVF, in couples meeting one of the following criteria:

1. Couples who are known carriers of a genetic mutation which causes a potentially lethal or severely disabling condition with limited treatment options meeting one of the following criteria:
   a. Both partners are known carriers of the same single autosomal recessive disorder
   b. One partner is a known carrier of an autosomal recessive disorder and the couple have previously produced offspring affected by that disorder
   c. One partner is a known carrier of a single gene autosomal dominant disorder
   d. One partner is a known carrier of a single X-linked disorder

2. Couples with an elevated risk of a chromosomal abnormality which causes a potentially lethal or severely disabling condition with limited treatment options meeting one of the following criteria:
   a. Parent with balanced or unbalanced chromosomal translocation
   b. Prior parental history of offspring with aneuploidy

B. Laboratories performing clinical tests must be certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988.

III. Limitations/Exclusions

A. PGD has not been shown to improve health outcomes in the following situations:

1. When performed in couples undergoing IVF who have failed prior IVF cycles, solely to increase the chances of live birth rates
2. For aneuploidy screening in IVF performed solely because of advanced maternal age
3. When used to determine gender selection or "family balancing"
4. To determine the human leukocyte antigen (HLA) or other marker status of an embryo as a potential future stem cell donor
5. For testing of late onset disease or disease disposition

B. PGD services are not related to or dependent upon the member's IVF benefit. (See IVF policy for clarification)

IV. Administrative Guidelines

A. Precertification is required. Please complete the PGD Precertification Form, attach the necessary documentation and mail or fax the request as indicated.

B. Applicable CPT codes

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<th>CPT</th>
<th>Description</th>
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<tr>
<td>89290-89291</td>
<td>Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis), less than or equal to, or greater</td>
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than 5 embryo(s), respectively

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References