Geisinger Health Plan Policies and Procedure Manual

Policy: MP380

Section: Medical Policy

Subject: Prenatal and Preimplantation Genetic Testing

Applicable line of business:

Commercial		**Medicaid**	
Medicare		**ACA**	
CHIP			

I. Policy: Prenatal and Preimplantation Genetic Testing

II. Purpose/Objective: To provide a policy of coverage regarding Prenatal and Preimplantation Genetic Testing

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

Commercial

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP

Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicaid

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Infertility, as defined by the American Society for Reproductive Medicine, is characterized by the inability to achieve a successful pregnancy based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors.

Early miscarriage is experienced by 1 in 4 pregnant women. Two or more miscarriages may warrant evaluation of genetic abnormality in both partners involved in conception.

Patients experiencing primary infertility are having regular, unprotected intercourse and without any known etiology for either partner suggestive of impaired reproductive ability. Evaluation for potential causes is offered at 12 months when the female partner is under 35 years of age and at 6 months when the female partner is 35 years of age or older.

Secondary Infertility is classified when a patient has conceived at least once, but is now unable to conceive again after 6 months at 35 years of age or older, or 12 months younger than 35 years of age. In cases where a patient has two or more living children, there is less concern for a genetic etiology.

Advances in preimplantation genetic testing (PGT) have led to significant practice changes in assisted reproductive technologies (ART), enabling fertility centers to transfer single embryos while maintaining excellent ongoing pregnancy rates, reducing miscarriage rates, and reducing ART-associated multiple pregnancies.

Preimplantation genetic tests (PGTs) are performed on embryos following in vitro fertilization (IVF). PGT covers a group of genetic or molecular tests used to evaluate embryos before transfer to the uterus. Patients and health care providers should be aware that a "normal" or negative preimplantation genetic test result is not a guarantee of a newborn without genetic abnormalities.

There are two main types of PGT called PGT-Aneuploidy (PGT-A) and PGT-Monogenic (PGT-M). A third type of PGT for assessment of structural rearrangements is called PGT-SR.

PGT-A refers to testing an embryo for aneuploidies, by screening an embryo for whole chromosome abnormalities. Although some randomized trials have shown a higher frequency of ongoing pregnancy with PGT-A than with conventional IVF, (https://www.nejm.org/doi/10.1056/NEJMoa2103613) two recent trials showed that PGT-A did not improve the frequency of ongoing pregnancy or live birth among women under 35 years of age (Yan J, et al., 2021). Despite multiple large-scale studies, it remains uncertain whether PGT-A improves the cumulative live-birth rate as compared with conventional in vitro fertilization (IVF) without aneuploidy screening. Numerous studies highlight the challenges faced in technical analysis, showing that mosaicism may be present in up to 50% of blastocysts. Unfortunately, outcome data following the transfer of blastocysts diagnosed as mosaic remain limited. The exclusion of mosaic blastocysts results in fewer embryos available for transfer, which may inevitably compromise treatment outcomes.

Traditional diagnostic testing or screening for aneuploidy are still be offered to all patients who have had preimplantation genetic testing-aneuploidy, in accordance with recommendations for all pregnant patients.

PGT-M refers to testing an embryo for targeted, single gene disorders. This testing is used to test for a specific genetic variant related to a known diagnosis, or known predisposition, in a family. PGT-M does not test for all single gene disorders at once and will not detect de novo pathogenic variants.

PGT-SR (Structural Rearrangement) refers to testing an embryo for to evaluate chromosome structure. This study can find where segments may have been deleted, duplicated or inverted. It can be used for people with a known chromosomal rearrangement (eg: a translocation), to improve the chance of a healthy pregnancy.

NOTE: Fertility benefits and assisted reproductive technologies, including IVF, IUI, and ICSI, are not reviewed in this policy.

CRITERIA FOR COVERAGE:

Genetic Testing for Infertility and/or Multiple Miscarriages:

Karyotype testing, also called "chromosome analysis," to evaluate for a chromosomal rearrangement, is covered for a male or female member in the following scenarios:

- When a member has had two or more miscarriages, consecutive or non-consecutive, occurring at any gestational age; OR
- A diagnosis of primary infertility, without an otherwise apparent cause, such as a structural uterine anomaly, thyroid dysfunction, or an autoimmune disorder.

PGT-A is covered for members in the following scenarios:

- If the member or egg donor is 39 years of age or older at the time of embryo implantation, OR
- There is a family history of a genetic condition that is associated with a sex-dependent disorder (eg: Fragile X syndrome)

PGT-SR is covered for a member when:

- One parent is a known carrier of a balanced (e.g. Robertsonian translocation, inversion) or unbalanced chromosomal rearrangement (e.g. insertion, deletion) or translocation**.**

PGT-M for evaluation of an embryo is covered for members in the following scenarios:

- To diagnose an autosomal dominant or X-linked condition for which a parent or sperm/egg donor has a confirmed molecular diagnosis, (eg: Fragile X syndrome); OR
- To diagnose an autosomal recessive condition for which both parents are known to be carriers, (eg: Cystic Fibrosis); OR
- One biological parent is a known carrier of an early-onset, autosomal recessive disorder and together, the biological parents have produced previous offspring affected with the disorder AND both variants are known or confirmed in the affected child,

AND

- The genetic condition is associated with clinically significant symptoms or disability; AND
- The PGT-M procedure will eliminate the need for invasive testing during the pregnancy (eg: chorionic villus sampling or amniocentesis); AND
- The member/couple has undergone genetic counseling

EXCLUSIONS:

GT-A is considered to be **Unproven** and **NOT COVERED** for cases to aid in sex selection for non-medical purposes.

PGT-A is considered to be **Unproven** and **NOT COVERED** for aneuploidy screening in egg donors <39y due to insufficient evidence for improved outcomes.

PGT-M is considered to be **Unproven** and **NOT COVERED** for cases where a disorder is not life-threating, life-limiting, or does not require urgent medical intervention or attention. (eg: biotinidase deficiency, hemochromatosis)

PGT-M is considered to be **Unproven** and **NOT COVERED** in cases where human leukocyte antigen (HLA) status alone in families with a child with a bone marrow disorder requiring a stem cell transplant, and in whom there is no other source of a compatible bone marrow donor other than an HLA matched sibling.

Multi-gene test panels completed at the time of PGT-M are considered to be **Unproven** and **NOT COVERED.**

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

CODING ASSOCIATED WITH:

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov ***or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.***

81228 Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number variants, comparative genomic hybridization [CGH] microarray analysis
81229 Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and single nucleotide polymorphism (SNP) variants, comparative genomic hybridization (CGH) microarray analysis
81349 Cytogenomic (genome-wide) analysis for constitutional chromosomal abnormalities; interrogation of genomic regions for copy number and loss-of-heterozygosity variants, low-pass sequencing analysis
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
0254U Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using embryonic DNA genomic sequence analysis for aneuploidy, and a mitochondrial DNA score in euploid embryos, results reported as normal (euploidy), monosomy, trisomy, or partial deletion/duplication, mosaicism, and segmental aneuploidy, per embryo tested *{SMART PGT-A}*
0396U Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions *{Spectrum PGT-M (Natera)}*

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 4/25

Revised:

Reviewed:

CMS UM Oversight Committee Approval: 6/25

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies