

Policy Name: Genetic Testing - Reproductive Testing: Fertility MP9574

Effective Date: July 01, 2025

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. <u>https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers</u>

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

OVERVIEW

This policy addresses the use of tests that analyze biopsied cells from an embryo as a part of an assisted reproductive procedure. These tests can detect monogenic disorders (<u>PGT-M</u>), structural rearrangements (<u>PGT-SR</u>), and chromosomal aneuploidy (<u>PGT-A</u>).

Genetic counseling is highly encouraged for patients considering and undergoing in vitro fertilization and should be performed by an individual with experience and expertise in genetic medicine and testing methods, such as a genetic counselor, medical geneticist, or advanced practice practitioner specializing in genetics.

For additional information see the Rationale section.

The tests, CPT codes, and ICD codes referenced in this policy are not comprehensive, and their inclusion does not represent a guarantee of coverage or non-coverage.

POLICY REFERENCE TABLE

COVERAGE CRITERIA	EXAMPLE TESTS	COMMON BILLING	<u>REF</u>	
SECTIONS	(LABS)	CODES		
Preimplantation Genetic Testing for Aneuploidy (PGT-A)				



COVERAGE CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	REF	
Preimplantation Genetic Testing for Aneuploidy (PGT-A)	Spectrum - 24- chromosome Preimplantation Genetic Testing for Aneuploidy (PGT-A) (Natera)	81229, 81479, 89290, 89291, 0254U, N97.0, N97.9, Z31	2, 3, 4	
	SMART PGT-A (Preimplantation Genetic Testing - Aneuploidy) - 0254U (Igenomix)			
Preimplantation Genetic Testing for Monogenic Disorders (PGT-M)				
Preimplantation Genetic Testing for Monogenic Disorders (PGT-M)	PGT-M (CooperSurgical - CooperGenomics)	81479, 89290, 89291, 0396U, N97.0, N97.9, Z14.8, Z31	1, 2	
	Spectrum PGT-M - 0396U (Natera)	214.0, 201		
Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR)				
Preimplantation Genetic Testing for Structural Rearrangements (PGT- SR)	Spectrum - Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR) (Natera)	81228, 81229, 81479, 89290, 89291, N97.0, N97.9, Z14.8, Z31	2	

RELATED POLICIES

This policy document provides coverage criteria for preimplantation genetic testing. Please refer to:

- **Reproductive Testing: Carrier Screening** for coverage criteria related to parental carrier screening for genetic disorders before or during pregnancy.
- **Reproductive Testing: Prenatal Diagnosis** for coverage related to fetal diagnostic genetic testing during pregnancy or for a pregnancy loss.
- **Reproductive Testing: Prenatal Screening** for coverage criteria related to fetal screening for genetic disorders during pregnancy.
- **Specialty Testing: Multisystem Genetic Conditions** for coverage criteria related to diagnostic tests for genetic disorders that affect multiple organ systems (e.g. whole exome and genome sequencing, chromosomal microarray, and multigene panels for broad phenotypes).



• **General Approach to Laboratory Testing** for coverage criteria related to preimplantation genetic testing, including known familial variant testing, that is not specifically discussed in this or another non-general policy.

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COVERAGE CRITERIA

PREIMPLANTATION GENETIC TESTING FOR ANEUPLOIDY (PGT-A)

Preimplantation Genetic Testing for Aneuploidy (PGT-A)

I. Preimplantation genetic testing for an uploidy (<u>PGT-A</u>) is considered **investigational** for all indications.

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PREIMPLANTATION GENETIC TESTING FOR MONOGENIC DISORDERS (PGT-M)

Preimplantation Genetic Testing for Monogenic Disorders (PGT-M)

- I. Preimplantation genetic testing for monogenic disorders (<u>PGT-M</u>) may be considered **medically necessary** when:
 - A. The embryo is at an elevated risk of a genetic disorder due to one of the following:
 - 1. Both biological parents are known carriers for the same autosomal recessive disorder, **OR**
 - 2. One biological parent is a known carrier of an autosomal dominant disorder, **OR**
 - 3. One biological parent is a known carrier of an X-linked recessive disorder.
- II. Preimplantation genetic testing for monogenic disorders (<u>PGT-M</u>) is considered **investigational** for all other indications.

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PREIMPLANTATION GENETIC TESTING FOR STRUCTURAL REARRANGEMENTS (PGT-SR)

Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR)

- I. Preimplantation genetic testing for structural rearrangements (<u>PGT-SR</u>) may be considered **medically necessary** when:
 - A. The embryo is at an elevated risk of a genetic disorder because one biological parent has a chromosomal rearrangement.
- II. Preimplantation genetic testing for structural rearrangements (<u>PGT-SR</u>) is considered **investigational** for all other indications.



PRIOR AUTHORIZATION

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

RATIONALE

Preimplantation Genetic Testing for Aneuploidy (PGT-A)

American Society of Reproductive Medicine

The American Society for Reproductive Medicine issued an opinion on the use of preimplantation genetic testing (PGS) for an euploidy (2018), which concluded, "Large, prospective, well-controlled studies evaluating the combination of multiple approaches (genomics, time-lapse imaging, transcriptomics, proteomics, metabolomics, etc.) for enhanced embryo selection applicable in a more inclusive IVF population are needed to determine not only the effectiveness, but also the safety and potential risks of these technologies. PGT-A will likely be part of a future multidimensional approach to embryo screening and selection. At present, however, there is insufficient evidence to recommend the routine use of blastocyst biopsy with an euploidy testing in all infertile patients" (p. 34).

This position was reaffirmed in a 2020 committee opinion regarding clinical management of mosaic results from preimplantation genetic testing for aneuploidy of blastocysts, stating, "It should be recognized that this document does not endorse nor does it suggest that PGT-A is appropriate for all cases of IVF" (p. 253).

American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists issued Committee Opinion No. 799 (2020, reaffirmed 2023) regarding Preimplantation Genetic Testing. The recommendations include the following:

"The clinical utility of preimplantation genetic testing-monogenic and preimplantation genetic testing-structural rearrangements is firmly established; however, the best use of preimplantation genetic testing-aneuploidy remains to be determined" (p. e133).

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Preimplantation Genetic Testing for Monogenic Disorders (PGT-M)

American Society for Reproductive Medicine

The American Society for Reproductive Medicine published an opinion on the use of preimplantation genetic diagnosis (PGD) for serious adult-onset conditions (2013). The statement includes the following:

- "Preimplantation genetic diagnosis (PGD) for adult-onset conditions is ethically justifiable when the conditions are serious and when there are no known interventions for the conditions or the available interventions are either inadequately effective or significantly burdensome."
- "For conditions that are less serious or of lower penetrance, PGD for adult-onset conditions is ethically acceptable as a matter of reproductive liberty. It should be discouraged, however, if the risks of PGD are found to be more than merely speculative."



The opinion also stated that physicians and patients should be aware that much remains unknown about the long-term effects of embryo biopsy on the developing fetus and that experienced genetic counselors should be involved in the decision process (p. 54).

American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists issued Committee Opinion No. 799 (2020, reaffirmed 2023) regarding Preimplantation Genetic Testing. The recommendations include the following:

"Preimplantation genetic testing comprises a group of genetic assays used to evaluate embryos before transfer to the uterus. Preimplantation genetic testing-monogenic (known as PGT-M) is targeted to single gene disorders. Preimplantation genetic testing-monogenic uses only a few cells from the early embryo, usually at the blastocyst stage, and misdiagnosis is possible but rare with modern techniques. Confirmation of preimplantation genetic testing-monogenic results with chorionic villus sampling (CVS) or amniocentesis should be offered" (p. 133).

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Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR)

American College of Obstetricians and Gynecologists (ACOG)

The American College of Obstetricians and Gynecologists issued Committee Opinion No. 799 (2020, reaffirmed 2023) regarding Preimplantation Genetic Testing. The recommendations include the following:

"To detect structural chromosomal abnormalities such as translocations, preimplantation genetic testing-structural rearrangements (known as PGT-SR) is used. Confirmation of preimplantation genetic testing-structural rearrangements results with CVS or amniocentesis should be offered" (p. 133).

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DEFINITIONS

- 1. **Preimplantation genetic testing for aneuploidy (PGT-A)** is used to screen for chromosomal aneuploidy in conjunction with in vitro fertilization (IVF) for couples.
- 2. **Preimplantation genetic testing for monogenic disorders (PGT-M)** is used to detect a specific single-gene inherited disorder or chromosome rearrangement in conjunction with in vitro fertilization (IVF).
- 3. **Preimplantation genetic testing for structural rearrangements (PGT-SR)** is used to detect a specific single-gene inherited disorder or chromosome rearrangement in conjunction with in vitro fertilization (IVF).

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REFERENCES

- Ethics Committee of American Society for Reproductive Medicine. Use of preimplantation genetic diagnosis for serious adult onset conditions: a committee opinion. Fertil Steril. 2013;100(1):54-57. doi:10.1016/j.fertnstert.2013.02.043
- 2. Preimplantation Genetic Testing: ACOG Committee Opinion, Number 799. Obstet Gynecol. 2020 (reaffirmed 2023);135(3):e133-e137. doi:10.1097/AOG.00000000003714
- 3. Practice Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. Electronic address: ASRM@asrm.org; Practice



Committees of the American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology. The use of preimplantation genetic testing for aneuploidy (PGT-A): a committee opinion. Fertil Steril. 2018;109(3):429-436. doi:10.1016/j.fertnstert.2018.01.002

 Practice Committee and Genetic Counseling Professional Group (GCPG) of the American Society for Reproductive Medicine. Electronic address: asrm@asrm.org. Clinical management of mosaic results from preimplantation genetic testing for aneuploidy (PGT-A) of blastocysts: a committee opinion. Fertil Steril. 2020;114(2):246-254. doi:10.1016/j.fertnstert.2020.05.014

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Note: The Health Plan uses the genetic testing clinical criteria developed by Concert Genetics, an industry-leader in genetic testing technology assessment and policy development.

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