Concert Genetic Testing: Preimplantation Genetic Testing

Reference Number: LA.CP.CG.18
Date of Last Revision ~~06/24~~01/25
Revision Log

Coding implications

See Important Reminder at the end of this policy for important regulatory and legal information.

OVERVIEW

Preimplantation genetic testing involves analysis of biopsied cells from an embryo as a part of an assisted reproductive procedure. Preimplantation genetic testing for monogenic disorders (PGT-M) and preimplantation genetic testing for structural rearrangements (PGT-SR) are used to detect a specific inherited disorder in conjunction with in vitro fertilization (IVF) and aims to prevent the birth of affected children to couples at an increased risk of transmitting either a gene mutation(s) or an unbalanced structural chromosomal rearrangement that can be typically targeted in this context. Preimplantation genetic testing for aneuploidy (PGT-A) is used to screen for potential chromosomal or subchromosomal abnormalities (e.g., chromosomal aneuploidy) in conjunction with IVF for couples; in this case testing is untargeted.

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

All patients who undergo PGT-M or PGT-SR should be offered diagnostic testing via chorionic villus sampling (CVS) or amniocentesis for confirmation of results.

All patients who undergo PGT-A should be offered traditional diagnostic testing or screening for aneuploidy in accordance with recommendations for all pregnant patients.

POLICY REFERENCE TABLE

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources

of professional coding guidance prior to the submission of claims for reimbursement of covered services.

The tests ~~and,~~ associated laboratories ~~and,~~ CPT codes, and ICD codes contained within this document serve only as examples to help users navigate claims and corresponding criteria; as such, they are not comprehensive and are not a guarantee of coverage or non-coverage. ~~Please see the Concert Genetics Platform~~Please see the Concert Platform for a comprehensive list of registered tests.

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis. The non-covered codes will only be denoted in the table below and not throughout the policy. Please only reference the policy reference table for covered and non-covered codes.

Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Preimplantation Genetic Testing for Aneuploidy (PGT-A)	Spectrum - 24-chromosome Preimplantation Genetic Testing for Aneuploidy (PGT-A) (Natera)	81229, 81479, 89290*, 89291*	N97.0, N97.9, Z31	2, 3, 4
	SMART PGT-A (Preimplantation Genetic Testing - Aneuploidy) (Igenomix)	0254U*		
Preimplantation Genetic Testing for Monogenic Disorders (PGT-M)	Spectrum PGT-M (Natera)	0396U*	N97.0, N97.9, Z14.8, Z31	1, 2
	PGT-M (~~Cooper Genomics~~CooperSurgical - CooperGenomics)	89290*, 89291*, 81479		
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

OTHER RELATED POLICIES

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

- ***Genetic Testing: Prenatal and Preconception Carrier Screening*** for criteria related to carrier screening.
- ***Genetic Testing: Prenatal Diagnosis (via amniocentesis, CVS, or PUBS) and Pregnancy Loss*** for ~~coverage~~criteria related to diagnostic genetic testing during pregnancy or for a pregnancy loss.
- ***Genetic Testing: Noninvasive Prenatal Screening (NIPS)*** for criteria related to prenatal cell-free DNA screening tests.
- ***Genetic Testing: Multisystem Inherited Disorders, Intellectual Disability, and Developmental Delay*** for criteria related to diagnostic genetic testing in the postnatal period.
- ***Genetic Testing: General Approach to Genetic and Molecular Testing*** for criteria related to preimplantation genetic testing that is not specifically discussed in this or another non-general policy, including known familial variant testing.

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CRITERIA

It is the policy of Louisiana Healthcare Connections that the specific genetic testing noted below is **medically necessary** when meeting the related criteria:

PREIMPLANTATION GENETIC TESTING FOR ANEUPLOIDY (PGT-A)

I. Preimplantation genetic testing for aneuploidy (PGT-A) (81229, 81479, 89290, 89291, 0254U) is considered **investigational**.

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PREIMPLANTATION GENETIC TESTING FOR MONOGENIC DISORDERS (PGT-M)

I. Preimplantation genetic testing for monogenic disorders (PGT-M) (0396U, 89290, 89291, 81479) 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 (PGT-M) (0396U, 89290, 89291, 81479) is considered **investigational** for all other indications.

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PREIMPLANTATION GENETIC TESTING FOR STRUCTURAL REARRANGEMENTS (PGT-SR)

I. Preimplantation genetic testing for structural rearrangements (PGT-SR) (81228, 81479, 81229, 89290, 89291) 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 (PGT-SR) (81228, 81229, 81479, 89290, 89291) is considered **investigational** for all other indications.

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DEFINITIONS

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

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BACKGROUND AND 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 aneuploidy (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 aneuploidy 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)

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)

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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Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
Converted corporate to local policy.	09/23	11/27/23	
Semi-annual review. Updated title to reflect V1.2024 version. Overview, coding, reference-table, background and references updated. Throughout policy: replaced "coverage criteria" with "criteria. For Preimplantation Genetic Testing for Monogenic Disorders (PGT-M) Panel: under II. removed "81403".	12/23	2/27/24	

Semi-annual review. Updated title to reflect V2.2024 version. In Overview and Clinical Considerations, Policy overview updated to include information from the Clinical Considerations section, which has been consolidated into the Overview section. Minor rewording for clarity throughout. Coding, reference-table, background and references updated.	06/24	9/4/24	10/4/24
Semi-annual review. Updated title to reflect V1.2025. Preimplantation Genetic Testing for Monogenic Disorders (PGT-M): Updated example test in Policy Reference Table, fixed PLA code in criteria.	1/25		

~~References~~

REFERENCES

1. 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.0000000000003714
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
4. 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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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing

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