Revision log
Coding Implications

CONCERT GENETIC TESTING: PREIMPLANTATION GENETIC TESTING

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

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 (PGT-M), structural rearrangements (PGT-SR), and chromosomal aneuploidy (PGT-A).

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.

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 2024, 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. 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, 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. Please see the Concert Platform for additional registered tests.

CRITERIA SECTIONS	EXAMPLE TESTS (LABS)	COMMON BILLING CODES	REF
Preimplantation Genetic Testing for Aneuploidy (PGT-A)			
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)		
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 criteria for preimplantation genetic testing. Please refer to:

- ***Reproductive Testing: Carrier Screening*** for criteria related to parental carrier screening for genetic disorders before or during pregnancy.

- ***Reproductive Testing: Prenatal Diagnosis*** for related to fetal diagnostic genetic testing during pregnancy or for a pregnancy loss.
- ***Reproductive Testing: Prenatal Screening*** for criteria related to fetal screening for genetic disorders during pregnancy.
- ***Specialty Testing: Multisystem Genetic Conditions*** for 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 criteria related to preimplantation genetic testing, including known familial variant testing, that is not specifically discussed in this or another non-general policy.

back to top

CRITERIA

It is the policy of health plans affiliated with Centene Corporation® that the specific genetic testing noted below is **medically necessary** when meeting the related criteria:

PREIMPLANTATION GENETIC TESTING FOR ANEUPLOIDY (PGT-A)

Preimplantation Genetic Testing for Aneuploidy (PGT-A)

I. Current evidence does not support preimplantation genetic testing for aneuploidy (PGT-A) for all indications.

view rationale

back to top

PREIMPLANTATION GENETIC TESTING FOR MONOGENIC DISORDERS (PGT-M)

Preimplantation Genetic Testing for Monogenic Disorders (PGT-M)

I. Preimplantation genetic testing for monogenic disorders (PGT-M) 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. Current evidence does not support preimplantation genetic testing for monogenic disorders (PGT-M) for all other indications.

view rationale

back to top

PREIMPLANTATION GENETIC TESTING FOR STRUCTURAL REARRANGEMENTS (PGT-SR)

Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR)

I. Preimplantation genetic testing for structural rearrangements (PGT-SR) 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. Current evidence does not support preimplantation genetic testing for structural rearrangements (PGT-SR) for all other indications.

view rationale

back to top

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).

back to top

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).

back to top

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).

back to top

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).

back to top

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	03/23	03/23
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".	10/23	10/23
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.	04/24	04/24
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.	11/24	11/24
Annual review. Minor rewording without clinical significance. Replaced "investigational" policy statements with "Current evidence does not support….." throughout policy. Policy reference table, rationale, background and coding table updated.	11/25	12/25

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

back to top

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of

coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid member/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare member/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.