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Clinical Appropriateness Guidelines

# Additional Outpatient Utilization Management

# Appropriate Use Criteria: Preimplantation Embryo Biopsy

**Proprietary**

# Table of Contents

# Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon. Use of the Guidelines by any external AI entity without the express written permission of Carelon is prohibited.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Use of an FDA-approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

# General Clinical Guideline

## Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Genetic tests not specifically mentioned in the guidelines are considered not medically necessary.

## Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

## Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues

- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

## Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for ongoing services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

# Preimplantation Embryo Biopsy

## Description and Scope

This guideline addresses preimplantation embryo biopsy. The procedure is performed to allow for preimplantation genetic testing (PGT), which includes various methods for analyzing embryonic DNA. By evaluating genetic variants such as aneuploidies, monogenic/single gene defects, or chromosomal structural rearrangements, PGT aims to increase pregnancy rate per embryo transfer. These procedures may be performed as part of assisted reproductive technology (ART).

***Note:*** *This guideline addresses preimplantation embryo biopsy only. This guideline does not address genetic testing, including for aneuploidies (PGT-A), monogenic disorders (PGT-M), or structural rearrangements (PGT-SR). For criteria related to genetic testing, please refer to the applicable Carelon Genetic Testing guidelines.*

***Note:*** *The use of in vitro fertilization (IVF) services is subject to separate benefit determination. Not all benefit contracts or certificates include benefits for IVF services, including preimplantation embryo biopsy. Preimplantation embryo biopsy is only covered when IVF services are covered benefits. Benefit language supersedes this guideline.*

## Clinical Indications

Preimplantation embryo biopsy is considered **medically necessary** when supporting preimplantation genetic testing is also considered **medically necessary** to evaluate increased risk of a recognized inherited condition of the embryo based on **ALL** of the following criteria (1-3):

1. The medical inherited condition and gene variants being evaluated would result in significant morbidity and/or mortality
2. The condition is known to result from a single gene (PGT-M) abnormality **OR** from structural changes of a gamete provider, preimplantation genetic testing for structural rearrangements (PGT-SR)
3. Gamete providers meet **ANY** of the following criteria:
    - Both gamete providers are known carriers of the same autosomal recessive condition
    - One partner is a known carrier of an autosomal recessive disorder **AND** the couple have previously produced offspring affected by that condition
    - At least one gamete provider is a known carrier of an autosomal dominant or sex-linked condition
    - One gamete provider is at greater than or equal to 25% risk to be a carrier of an autosomal dominant single gene condition **OR** an X-linked condition based on family history **AND** is requesting non-disclosure testing (e.g., Huntington's disease, X-linked adrenoleukodystrophy)
    - At least one gamete provider is a carrier of a balanced structural chromosome abnormality
    - At least one gamete provider is an anonymous reproductive donor with unknown/unavailable carrier status when the other gamete provider is a known carrier

Preimplantation embryo biopsy is considered **medically necessary** when done for preimplantation genetic testing for aneuploidy (PGT-A) in the presence of a clear heritable indication which includes:

- X-linked recessive conditions (e.g., Duchenne muscular dystrophy, adrenoleukodystrophy, Fabry disease)
- Sex-limited condition

Preimplantation embryo biopsy is considered **not medically necessary** when done to support PGT for conditions not meeting above criteria, including all indications below:

- PGT-A for indications that do **NOT** include a heritable risk including:

    - Advanced maternal age
    - Previous pregnancy with a trisomy
    - Recurrent pregnancy loss
    - Recurrent implantation failure
- Testing solely to determine if an embryo is a carrier of an autosomal recessive condition
- Somatic genetic changes
- Multifactorial conditions
- PGT for polygenic disorders (PGT-P) (uses polygenic risk scores)
- Variants of unknown significance
- Gender selection in the absence of sex-linked or sex-limited risk
- Nonmedical traits such as physical characteristics like height and eye color, etc.

## Rationale

Preimplantation embryo biopsy is performed to allow for genetic testing of the embryo as part of fertility services. Embryonic DNA is sampled and genetically analyzed. The testing is used to help guide selection of embryos to identify for deselection of embryos containing a genetic abnormality prior to implantation of the embryo in the uterus. The procedure is done in coordination with assisted reproductive technology (ART).

While there are no evidence-based guidelines specifically addressing the net benefit of the embryo biopsy procedure, there are consensus recommendations addressing the use of biopsy-based preimplantation testing. Further, there are multiple scenarios in which preimplantation genetic testing is well established. Though noninvasive techniques for evaluating embryonic DNA have been studied, the reliability of these techniques has not been established. Therefore, embryo biopsy is necessary to perform preimplantation genetic testing when such testing is clinically appropriate.

## References

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2. Brouillet S, Martinez G, Coutton C, et al. Is cell-free DNA in spent embryo culture medium an alternative to embryo biopsy for preimplantation genetic testing? A systematic review. Reprod Biomed Online. 2020;40(6):779-96.
3. Dahdouh EM, Balayla J, Garcia-Velasco JA. Impact of blastocyst biopsy and comprehensive chromosome screening technology on preimplantation genetic screening: a systematic review of randomized controlled trials. Reprod Biomed Online. 2015;30(3):281-9.
4. Kokkali G, Coticchio G, Bronet F, et al. ESHRE PGT Consortium and SIG Embryology good practice recommendations for polar body and embryo biopsy for PGT. Hum. 2020;2020(3):hoaa020.
5. Li Piani L, Petrone P, Brutto M, et al. A systematic review and meta-analysis of double trophectoderm biopsy and/or cryopreservation in PGT: balancing the need for a diagnosis against the risk of harm. Hum Reprod Update. 2025;31(2):102-15.
6. Orvieto R. The use of preimplantation genetic testing for aneuploidy: a committee opinion. Fertil Steril. 2024;122(3):555.
7. Shi WH, Jiang ZR, Zhou ZY, et al. Different Strategies of Preimplantation Genetic Testing for Aneuploidies in Women of Advanced Maternal Age: A Systematic Review and Meta-Analysis. J. 2021;10(17):30.

## Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

### CPT/HCPCS



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| 89290 | Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); less than or equal to 5 embryos |
| 89291 | Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); greater than 5 embryos |

### ICD-10 Diagnosis

All diagnoses

# History

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