

Effective: June 1, 2024

<b>Prior Authorization Required</b> If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request to the FAX numbers below	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<b>Notification Required</b> IF <u>REQUIRED</u> , concurrent review may apply	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

#### Applies to:

##### Commercial Products

- ☐ Harvard Pilgrim Health Care Commercial products; 800-232-0816
- ☒ Tufts Health Plan Commercial products; 617-972-9409  
 CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

##### Public Plans Products

- ☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
- ☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
- ☐ Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
- ☐ Tufts Health One Care—A dual-eligible product; 857-304-6304

##### Senior Products

- ☐ Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
- ☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
- ☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
- ☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

**Note:** While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

## Overview

Preimplantation genetic testing (PGT) is a technique used in conjunction with in vitro fertilization (IVF) to test embryos for specific genetic disorders prior to their transfer to the uterus. PGT makes it possible for couples or individuals who have or who carry a serious inherited disorder to decrease the risk of passing the disorder on to their child. PGT is performed in centers where expertise in genetic counseling, molecular genetics, and embryology coexist. The decision to perform PGT should be made in conjunction with genetic counseling to discuss the benefits and limitations of PGT, including potential diagnostic errors.

PGT can be performed to detect aneuploidy (PGT-A), monogenic (single-gene) disorders (PGT-M), or structural rearrangements (PGT-S).

## Clinical Guideline Coverage Criteria

The completion of the Preimplantation Genetic Testing Request Form is required.

The Plan may cover PGT, including IVF with or without ICSI and freeze-all cycle, when ALL the following criteria are met:

- Coverage for assisted reproductive technology/infertility treatment is based on the member's individual medical history and should demonstrate > 5% chance of live birth: **and**

2. Assisted Reproductive Technology (ART) procedures must be performed by one of the Plan's contracting ART providers in order for ART procedures to be covered for HMO and EPO Members. POS and PPO Members must also go to a Plan contracting ART provider for coverage at the Authorized/In-network level of benefits **and**;
3. Fetus would be at risk for an inherited genetic disorder, as defined below, associated with severe disability and/or premature death; and
4. The results of the genetic test will impact clinical decision-making and clinical outcome; and
5. **ONE** of the following criteria is met:
  - a. **Preimplantation Genetic Testing for Monogenic Disease (PGT-M):**
    - a. Biological mother and/or biological father is a known carrier of a single X-linked disorder, including but not limited to:
      - Hemophilia A & B
      - Muscular dystrophy
      - X-linked mental retardation
      - Lesch-Nyhan Syndrome
      - Adrenoleukodystrophy
      - Duchenne/Becker muscular dystrophy
      - Fragile X syndrome
      - Anderson-Fabry disease
      - Incontinentia pigmenti
      - Choroideremia
      - Alport Syndrome
      - Hunter Syndrome
    - b. Biological mother and/or biological father is a known carrier of a single gene autosomal dominant disorder, including but not limited to:
      - Marfan Syndrome
      - Muscular Dystrophy
      - Neurofibromatosis Type I & II
      - Myotonic Dystrophy
      - Spinocerebellar Ataxia (autosomal dominant type)
      - Retinoblastoma
      - Epidermolysis bullosa (autosomal dominant type)
      - Huntington's Disease
      - Tuberous sclerosis
    - c. Biological mother and biological father are both known carriers of same single gene autosomal recessive disorder including but not limited to:
      - Spinocerebellar Ataxia (autosomal recessive type)
      - Epidermolysis Bullosa Simplex (autosomal recessive type)
      - Cystic Fibrosis
      - Tay-Sachs Disease
      - Spinal Muscular Atrophy
      - Sickle Cell Anemia
      - Fanconi Anemias
      - B-Thalassemia Syndromes
      - Canavan Disease
      - Familial Dysautonomia
      - Gaucher Disease
      - Hurler Syndrome
      - Metabolic disorders (e.g., methylmalonic acidemia or propionic acidemia)
    - d. One biological parent is a known carrier of a single gene autosomal recessive disorder, and the biological parents have together had one offspring that has been diagnosed with this recessive disorder: OR
    - e. There is one biological parent that is a known carrier and the other is an anonymous donor with an unknown or unavailable status

#### **Preimplantation Genetic Testing for Structural Rearrangements (PGT-SR)**

1. To test for an unbalanced chromosome rearrangement when biological mother or biological father is known carrier of a balanced structural chromosome rearrangement (e.g., translocations, inversions, deletions, and insertions)
2. There is one biological parent that is a known carrier and the other is an anonymous donor with an unknown or unavailable status

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## Limitations

1. PGT for the purpose of human leukocyte antigen (HLA) tissue typing as it is not considered to be medically necessary at this time.
2. PGT-aneuploidy (PGT-A)•
3. PGT for nonmedical gender selection and/or nonmedical traits.
4. PGT for multifactorial inheritance disorders.
5. PGT for hereditary mutations which manifest in adulthood (e.g. BRCA testing) is not covered
6. PGT for variants of unknown significance.
7. PGT for screening of conditions with incomplete penetrance or significant variability of expression (e.g., Alzheimer's disease, cancer predisposition) Screening for polygenic risk (PGT-P)
8. Refer to Medical Necessity Guidelines: Assisted Reproductive Technology Services – Massachusetts Products for any applicable limitations

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## Codes

The following code(s) require prior authorization:

**Table 1: CPT/HCPCS Codes**

Code	Description
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

## References:

1. American Society for Reproductive Medicine. Preimplantation Genetic Testing, Patient Fact Sheet. Revised 2014. Available at asrm.org. Accessed December 20, 2017.
2. Committee Opinion No. 643: Identification and Referral of Maternal Genetic Conditions in Pregnancy. Obstet Gynecol. 2015;126(4):e49-e51. doi:10.1097/AOG.0000000000001107
3. Committee on Ethics, American College of Obstetricians and Gynecologists; Committee on Genetics, American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 410: Ethical issues in genetic testing. Obstet Gynecol. 2008;111(6):1495-1502. doi:10.1097/AOG.0b013e31817d252fCommittee Opinion No. 693: Counseling About Genetic Testing and Communication of Genetic Test Results. Obstet Gynecol. 2017;129(4):e96-e101. doi:10.1097/AOG.0000000000002020
4. Schattman, G.L., MD Xu, K, PhD, HCLD. Preimplantation genetic testing. Up to Date®. Available at uptodate.com. Accessed December 7, 2022.
5. Ho j, MG. In vitro fertilization: Overview of clinical issues and questions. Up to Date®. Available at uptodate.com. Accessed December 7, 2022.
6. Preimplantation Genetic Testing: ACOG Committee Opinion, Number 799. Obstet Gynecol. 2020;135(3):e133-e137. doi:10.1097/AOG.0000000000003714

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## Approval And Revision History

December 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC) for February 1, 2023 effective date  
Subsequent endorsement date(s) and changes made:

- May 17, 2023: Reviewed by MPAC, renewed without changes, effective June 5, 2023
- October 18, 2023: Reviewed by MPAC, renewed without changes
- December 2023: Rebranded Unify to One Care effective January 1, 2024
- April 17, 2024: Criteria updated to cover PGT when “there is one biological parent that is a known carrier and the other is an anonymous donor with an unknown or unavailable status”, effective June 1, 2024

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## Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better

understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment, or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.