Medical Necessity Guidelines:
Preimplantation Genetic Diagnosis (PGD)

Effective: September 16, 2020

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☒ No ☐**

Applies to:
COMMERCIAL Products
☒Tufts Health Plan Commercial products; Fax: 617.972.9409
☒Tufts Health Freedom Plan products; Fax: 617.972.9409
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products
☒Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055
☐Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055
☐Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404
☒Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) **–** Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

OVERVIEW

Preimplantation genetic diagnosis (PGD) 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. PGD makes it possible for couples or individuals who have or who carry serious inherited disorders to decrease the risk of passing the disorder on to their child. PGD is performed in centers where expertise in genetic counseling, molecular genetics, and embryology coexist. The decision to perform PGD should only be made in conjunction with genetic counseling because it is imperative that patients be aware of potential diagnostic errors. PGD is a continually evolving science with the number of tests for genetic disorders growing every year.

CLINICAL COVERAGE CRITERIA

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

Tufts Health Plan may cover PGD including IVF with or without ICSI and freeze-all cycle, when **ALL** the following criteria are met:

- The Member has a >5% chance of live birth per cycle of IVF and Member has infertility benefit per evidence of coverage. For Members with no history of intrauterine pregnancy, clinical documentation must be provided to support a greater than 5% chance of a live birth through IVF. This includes **both** the results of a uterine cavity evaluation performed within the previous two years and results of ovarian reserve testing (Follicle Stimulating Hormone (FSH) and Estradiol (E2) test on cycle day 3) performed within the previous year.

  AND

- Assisted Reproductive Technology (ART) procedures must be performed by one of Tufts Health 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 Tufts Health Plan contracting ART provider for coverage at the Authorized/In-network level of benefits.

AND

- Prior to approval of preimplantation genetic diagnosis (PGD), Tufts Health Plan requires evidence of genetic counseling, including documentation of a discussion of alternatives to this procedure, including prenatal diagnosis by ultrasound, chorionic villus sampling or amniocentesis, and documentation of a discussion regarding gamete donation, remaining childless, accepting genetic risk without testing and adoption. (The name of the geneticist/genetic specialist and the date of visit must be listed on the PGD Request Form.)

AND

- Fetus would be at risk for an inherited genetic disorder, as defined below, associated with severe disability and/or premature death.

AND

- The results of the genetic test will impact clinical decision-making and clinical outcome

AND **ONE** of the following, as documented by the genetic counselor:

- 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
  - Duschene/Becker muscular dystrophy
  - Fragile X syndrome
  - Anderson-Fabrey disease
  - Incontinentia pigmenti
  - Choroideremia
  - Alport Syndrome
  - Hunter Syndrome
- Biological mother and/or biological father is a known carrier of a single gene autosomal dominant disorder, including but not limited to:
  - Marfan's 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
- Biological mother and biological father are both known carriers of **same** single gene autosomal recessive disorder including but not limited to:
  - Spinocerebellar Ataxia (autosomal dominant type)
  - Epidermolysis Bullosa Simplex (autosomal recessive type)
  - Cystic Fibrosis
  - Tay-Sachs Disease
  - Spinal Muscular Atrophy
  - Sickle Cell And Fanconi's Anemias
  - B-Thalessemia Syndromes
  - Canavan
  - Familial Dysautonomia
  - Gaucher Disease
  - Hurler Syndrome
  - Metabolic disorders (e.g., methylmalonic acidemia or proprionic acidemia)

- 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.
- To test for an unbalanced chromosome rearrangement when biological mother or biological father is a known carrier of a chromosomal abnormality such as reciprocal or Robertsonian translocation.

LIMITATIONS

Tufts Health Plan will not cover the following:

- PGD for the purpose of human leukocyte antigen (HLA) tissue typing as it is not considered to be medically necessary at this time.
- PGD for aneuploidy in the setting of multiple spontaneous abortions of uncertain etiology as it has not proven to improve In Vitro Fertilization (IVF) outcomes.
- PGD for fetal chromosomal abnormalities, (This includes Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., bacterial artificial chromosome [BAC] or oligo-based comparative genomic hybridization [CGH] microarray analysis testing).
- PGD for Preimplantation genetic *screening* (PGS) of embryo.
- PGD for nonmedical gender selection and/or nonmedical traits.
- PGD for multifactorial inheritance disorders.
- PGD for hereditary mutations which manifest in adulthood (e.g. BRCA testing) is not covered
- PGD for variants of unknown significance.
- PGD for screening of conditions with incomplete penetrance or significant variability of expression (e.g., Alzheimer's disease, cancer predisposition).
- Any assisted reproductive technology (ART) procedure or related treatments that Tufts Health Plan deems experimental or investigative based on the scientific body of evidence with input from the American Society of Reproductive Medicine, the American College of Obstetrics and Gynecology, or another infertility expert recognized by the Massachusetts Division of Insurance.[6]
- ART services for Members who have undergone non-reversed voluntary sterilization.
- ART services when the Member is not the recipient of said services (e.g., donor egg in conjunction with gestational carrier) and drugs that are directly related to a stimulated ART cycle for anonymous or designated donors unless the ART service is prior authorized and the Member is the sole recipient of the donor's eggs.
- ART/Infertility services when clinical documentation indicates a Member or Member's partner is using or abusing substances that are known to negatively affect fertility potential, ART outcome, or fetal development (e.g. marijuana, opiates, cocaine, alcohol, tobacco). Results of serum or urine drug screening may be requested before infertility services are authorized.
- The cost of donor sperm, ART, and related services, if the male partner has a history of prior vasectomy with no subsequent vasectomy reversal procedure.
- Services or drugs directly related to non-covered services. (Specifically, there is no coverage of ART procedures or drugs when related to, or in conjunction with a non-covered benefit, or when the procedure is outside the scope of the Clinical Coverage Guidelines.)
- ART services for women who are not Rubella immune.
- ART services for women who are actively smoking cigarettes and/or are using nicotine containing products such as gum, patches or electronic cigarettes.
- Long-term sperm, oocyte or embryo storage, defined as greater than 90 days, unless the couple is actively receiving fertility treatment.

CODES

The following CPT code(s) require prior authorization:

Code	Description
89290	Biopsy, oocyte polar body or embryo blastomere, microtechnique (for pre-implantation genetic diagnosis); less than or equal to 5 embryos
89291	Greater than 5 embryos

REFERENCES

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2. American Society of Reproductive Medicine Practice Committee. Preimplantation genetic diagnosis. Fertility & Sterility. November 2006; 86(Supplement 4).
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5. Grace, J., El Toukhy, T. and Peter Braude. Preimplantation genetic testing. British Journal of Obstetrics and Gynaecology. November 2004; Vol. 111, pp. 1165–1173.
6. Horne, A.W., Alexander, C.I. Recurrent miscarriage. [Review] [94 refs] Journal of Family Planning & Reproductive Health Care. April 2005; 31(2):103-7.
7. Mastenbroek, S., Scriven, P., Twisk, M. et al. What next for preimplantation genetic screening? More randomized controlled trials needed? Human Reproduction. 2008; 23(12):2662-2628.
8. Yakini, K. and Bulent Urman. What next for preimplantation genetic screening? A clinician's perspective. Human Reproduction. 2008; 23(12):1686-1690.
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11. Wayne, G.W., MD, PhD, Thompson, B.H., MD, MS, et.al. American College of Medical Genetics Position Statement on Prenatal/Preconception Expanded Carrier Screening. Genetics in Medicine**.** June 2013; Volume 15 (6), pp. 482-483.
12. The American College of Obstetricians and Gynecologists. Identification and Referral of Maternal Genetic Conditions in Pregnancy. Committee Opinion 643. October 2015, reaffirmed 2017.
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15. Use of Reproductive Technology for Sex Selection for Nonmedical Reasons: A Committee Opinion. Fertility Sterility_ 2015; Vol. 103 (6) pp.1418-1422 by American Society for Reproductive Medicine.
16. Cooper, D.N., Crawczak, M. et. al. Where genotype is not predictive of phenotype: towards an understanding of the molecular basis of reduced penetrance in human inherited disease. Hum Genet (2013) 132:1077–1130.
17. Schattman, G.L., MD. Preimplantation genetic diagnosis. Up to Date®. Available at uptodate.com. Accessed December 20, 2017.

APPROVAL HISTORY

October 24, 2007: Reviewed by the Clinical Coverage Criteria Committee for a January 1, 2008 effective date.

Subsequent endorsement date(s) and changes made:

- March 11, 2008: Preimplantation Genetic Determination Form added.
- February 11, 2009: Reviewed and updated without changes.
- May 4, 2009 for the effective date of August 1, 2009: Testing for aneuploidy in the setting of multiple spontaneous abortions of uncertain etiology is no longer a covered indication. HLA testing was added to Limitations as not covered, not medically necessary.
- November 19, 2009: Administrative process updated
- February 1, 2010: Reviewed by Medical Specialty Policy Advisory Committee (MSPAC). No changes.
- March 2011: Reviewed at Medical Specialty Policy Advisory Committee (MSPAC). No changes.
- March 7, 2012: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), renewed with no changes.
- April 10, 2013: Reviewed by IMPAC, renewed without changes.
- June 12, 2013: Reviewed by IMPAC, coverage limitation added: CPT code 81228: Cytogenomic constitutional (genome-wide) microarray analysis; interrogation of genomic regions for copy number variants (e.g., Bacterial Artificial Chromosome [BAC] or oligo based comparative genomic hybridization [CGH] microarray analysis).
- November 14, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans.
- November 19, 2014: Reviewed by IMPAC, renewed without changes

- July 23, 2015: Reviewed by IMPAC; limitation added for uterine embryo lavage using Previvo catheter device, effective January 1, 2016.
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- November 16, 2015: Reviewed by IMPAC, renewed without changes
- July 20, 2016: Reviewed by IMPAC, renewed without changes
- August 10, 2016: Reviewed by IMPAC, title of guideline updated (formerly "Preimplantation Genetic Determination").
- December 14, 2016: Reviewed by IMPAC, renewed without changes
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- September 13, 2017: Reviewed by IMPAC, renewed without changes
- December 13, 2017: Reviewed by IMPAC, renewed without changes
- March 14, 2018: Reviewed at IMPAC. Coverage expanded to include IVF per added criteria and applicable limitations. PGD criteria clarified to identify specific genetic reason for PGD request.
- September 12, 2018: Reviewed by IMPAC. For effective date January 1, 2019, PGD testing for hereditary mutations which manifest in adulthood added to limitations section and update to limitation regarding medications or substances against medical advice and known to negatively affect ART outcome.
- October 2018: Template and disclaimer updated
- June 19, 2019: Reviewed by IMPAC, renewed without changes
- September 18, 2019: Reviewed by IMPAC, renewed without changes
- May 20, 2020: Reviewed by IMPAC, renewed without changes
- June 3, 2020: Fax number for Unify updated
- September 16, 2020: Reviewed by IMPAC, renewed without changes

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.

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.