Preimplantation Genetic Testing

Policy Number:	**M20210312010**
Effective Date:	**5/1/2021**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☐ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☐Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's medical necessity criteria for **preimplantation genetic testing**.

Policy:

Commercial, Self-Funded and Medicare Advantage:
Preimplantation genetic diagnostic testing may be considered medically necessary and a covered benefit when any of the following criteria are met:

- The couple is known to be at-risk to have child with a genetic condition because of ANY of the following:
  - Both parents are known carriers of a recessive genetic condition, and the specific gene mutation has been identified in each parent; OR

- One parent is affected by or known to be a carrier of a dominant condition, and the specific gene mutation has been identified; OR
- The female contributing the egg is known to be a carrier of an X-linked condition and the specific gene mutation has been identified; OR
- One or both parents are carriers of a structural chromosome rearrangement (e.g., translocation or inversion); OR
- One or both parents have a known chromosome microdeletion (e.g., 22q11 deletion – DiGeorge syndrome, 7q11.23 deletion – Williams syndrome);

AND

- The genetic condition is associated with potentially severe disability or has a lethal natural history.

Preimplantation genetic diagnostic testing as an adjunct to **in vitro fertilization (IVF)** is considered investigational in patients or couples who are undergoing IVF in all situations other than those specified above.

Preimplantation genetic screening as an adjunct to IVF is considered investigational in patients or couples who are undergoing IVF in all situations.

MediSource, MediSource Connect, Essential Plan:
Preimplantation genetic diagnosis associated with in vitro fertilization services is not covered by New York Medicaid.

Background:
Preimplantation genetic diagnosis (PGD) testing can detect specific genetic diseases (usually autosomal recessive conditions) by using molecular analysis techniques on single cells removed from the embryo. It is a diagnostic procedure that provides an alternative to traditional prenatal genetic diagnosis. The procedure is recommended when embryos may be affected by certain genetic conditions, due to one or both parents as known carriers of a genetic condition. One or two cells are removed from the embryos by biopsy during IVF procedures and examined for genetic analysis. Embryos with normal biopsy results are available for transfer into the uterus while additional normal embryos may be frozen. Only normal, healthy embryos are transferred into the uterus, reducing the risk of adverse pregnancy outcomes such as birth defects and miscarriages and possible pregnancy termination after prenatal diagnosis.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No ☐

Pre-authorization is required for this service.

1. The ordering /rendering laboratory is responsible for securing Prior Authorization for Medically Necessary molecular diagnostic testing. Independent Health's Prior Authorization form is available at: https://ihprovider.healthtrioconnect.com/app/docMgr/single/downloadDocument?xsesschk=bab717256b644f69a209563709ab55af&documentId=f546db5e761b43d98bae9c070ed523f4

and Independent Health's Utilization Management Department can be reached by calling (716) 631-3282.

2. The ordering / referring physician is responsible for submitting all relevant member-level clinical information to the rendering laboratory to support the Prior Authorization request.

3. Claims received for molecular diagnostic testing lacking Prior Authorization will deny to the responsibility of the rendering laboratory, and Independent Health members shall not be billed. Therefore, it is imperative for rendering laboratories, with clinical information supplied by ordering / referring physicians, to secure and verify Prior Authorization in accordance with the process above and clinical requirements above.

Definitions

In vitro fertilization (IVF) is a procedure to treat infertility and produce a pregnancy. The ovaries are stimulated by a combination of fertility medications and then one or more oocyte(s) are aspirated from ovarian follicles. The oocytes are fertilized in the laboratory, after which, one or more embryo(s) are transferred into the uterine cavity.

Preimplantation genetic testing refers to testing performed on an embryo for either diagnostic or screening purposes.

Preimplantation diagnostic testing is performed on cells from the developing embryo prior to implantation, allowing at risk couples to avoid a pregnancy affected with a genetic condition. when one or both parents have a known genetic abnormality.

Preimplantation screening testing refers to screening an embryo for aneuploidy when both parents are chromosomally normal.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references
American College of Obstetrics and Gynecology (ACOG) [web site]. Preimplantation Genetic Testing. Committee Opinion Number 799. March 2020. Reaffirmed 2023. Available at: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/03/preimplantation-genetic-testing Accessed August 6, 2024.

American Society for Reproductive Medicine and Society for Assisted Reproductive Technology. Preimplantation genetic testing: a practice committee opinion. Fert Steril. 2008;90(5 Suppl):S136-143.

American Society for Reproductive Medicine and Society for Assisted Reproductive Technology. The use of preimplantation genetic testing for aneuploidy (PGT-A): a committee opinion. Fert Steril. 2018;109(3):429-436.

Brezina PR, Kutteh WH. Clinical applications of preimplantation genetic testing. BMJ. 2015 Feb 19;350:g7611.

Gleicher N, Kushnir VA, Barad DH. Preimplantation genetic screening (PGS) still in search of a clinical application: a systematic review. Reprod Biol Endocrinol. 2014 Mar 15;12:22.

Schattman GL, Xu K. Preimplantation genetic testing. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed on August 6, 2024.

Regulatory References

New York State Department of Health Medicaid Update [web site]. NYS Medicaid Coverage of Genetic Testing. July 2015. Volume 31; No.8. p.14. Available at: https://www.health.ny.gov/health_care/medicaid/program/update/2015/jul15_mu.pdf Accessed August 6, 2024.

New York State Department of Health Medicaid Update [web site]. NYS Medicaid Coverage of Genetic Testing. December 2010. Volume 26, Number 14. Pp. 4-5. Available at https://health.ny.gov/health_care/medicaid/program/update/2010/2010-12.htm Accessed August 6, 2024.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
10/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
10/1/2023	Health Care Services	Reviewed
10/1/2022	Health Care Services	Revised
5/1/2022	Health Care Services	Reviewed