Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening)

Policy Number: OCA 3.726
Version Number: 9
Version Effective Date: 09/01/17

Product Applicability

- All Plan* Products

Well Sense Health Plan
- New Hampshire Medicaid
- NH Health Protection Program

Boston Medical Center HealthNet Plan
- MassHealth
- Qualified Health Plans/ConnectorCare/Employer Choice Direct
- Senior Care Options

* Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan considers preimplantation genetic diagnosis to be medically necessary when Plan criteria are met (as specified in the Medical Policy Statement and Limitations sections of this Plan policy). Prior authorization is required for all preimplantation genetic testing, including preimplantation genetic diagnosis and preimplantation genetic screening. The Plan considers preimplantation genetic screening to be experimental and investigational.

It will be determined during the Plan’s prior authorization process if the service is considered medically necessary for the requested indication. See the Plan policy, Medically Necessary (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. The Plan complies with coverage guidelines for all applicable state-mandated benefits and federally-mandated benefits that are medically necessary for the member’s condition. Review the following Plan medical policies for clinical review criteria, applicable definitions, and prior authorization requirements for BMC HealthNet Plan members (available at www.bmchp.org): Experimental and Investigational Treatment (policy Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening))

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number OCA 3.12), Infertility Services (policy number OCA 3.725), and Genetic Testing Guidelines and Pharmacogenetics (policy number OCA 3.726).

Description of Item or Service

**Preimplantation Genetic Testing (PGT):** Testing technique, which includes both preimplantation genetic diagnosis and preimplantation genetic screening, used to identify genetic defects in embryos soon after fertilization following in vitro fertilization (IVF) and prior to implantation leading to pregnancy.

**Preimplantation Genetic Diagnosis (PGD):** Testing performed on a preimplantation stage embryo (via single-cell biopsy) to determine if the embryo carries the specific pathogenic mutation(s) present in one or both genetic parents whose genetic abnormality or carrier state is known from prior testing. (See the Medical Policy Statement section of this Plan policy for medical criteria.)

**Preimplantation Genetic Screening (PGS):** Screening techniques where embryos from presumed chromosomally normal genetic parents are screened for aneuploidy. (See the Limitations section of this Plan policy.)

Medical Policy Statement

The Plan considers preimplantation genetic diagnosis (PGD) to be medically necessary when ALL applicable Plan criteria are met and documented in the member’s medical record, as specified below in item 1 (Member Criteria), item 2 (Medical Record Documentation Criteria), and item 3 (Testing Frequency Criteria):

1. **Member Criteria:**

   ALL of the following member criteria are met, as specified below in items a through e:

   a. Member meets the Plan’s definition of infertility, general eligibility and evaluation requirements, and service-specific criteria for coverage of infertility services, as specified in Plan’s Infertility Services medical policy, policy number OCA 3.725; AND

   b. Member is undergoing in vitro fertilization (IVF) for the evaluation of embryos that have been identified at an increased risk of a genetic disorder, and infertility services, including IVF, are covered for the BMC HealthNet Plan member (as specified in the member’s evidence of coverage or applicable benefit document available at [www.bmchp.org](http://www.bmchp.org)); AND

   c. The member has a > 5% chance of live birth per cycle of IVF with or without intracytoplasmic sperm injection (ICSI); AND

   d. The results of PGD will impact clinical decision making and/or the clinical outcome; AND
e. The member has coverage for PGD (as specified in the member’s evidence of coverage or applicable benefit document available at www.bmchp.org for a BMC HealthNet Plan member); AND

2. **Medical Record Documentation Criteria:**

Documentation in the member’s medical record includes ALL of the following, as specified below in items a through d:

a. The member has received genetic counseling that includes a discussion of alternatives to the procedure such as prenatal diagnosis by ultrasound, chorionic villus sampling, or amniocentesis; AND

b. The member discussed with the provider other reproductive options, including gamete donation, remaining childless, accepting genetic risk without testing, and/or adoption; AND

c. The services are provided in a center where appropriate expertise (i.e., genetic counseling, molecular genetics, maternal-fetal medicine, embryology) is available; AND

d. Documentation of at least ONE (1) of the following conditions, as specified below in items (1) through (6):

   (1) Both partners are known carriers of a single gene autosomal recessive disorder (defined in the Definitions section of this policy); OR

   (2) One (1) partner is a known carrier of a single gene autosomal recessive disorder (defined in the Definitions section of this policy) and the partners has one (1) offspring that has been diagnosed with that recessive disorder; OR

   (3) One (1) partner is a known carrier of a single gene autosomal dominant disorder (defined in the Definitions section of this policy); OR

   (4) One (1) partner is at risk (50%) of carrying a mutation of a single-gene dominant disorder (by virtue of having an affected biological parent or biological sibling) but does not wish to know his/her carrier status (which would be revealed if standard prenatal diagnosis were performed and the fetus revealed to be affected); IVF/PGD allows for unaffected embryos to be selected and implanted without revealing to the parents whether or not any affected embryos were also detected; OR

   (5) One (1) partner is a known carrier of a single X-linked disorder (defined in the Definitions section of this policy); OR

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(6) Evaluation is for an embryo identified to be at an elevated risk of chromosomal abnormality based on one (1) partner having EITHER of the following conditions, as specified below in item (a) or item (b):

(a) A balanced (reciprocal or non-Robertsonian) chromosomal translocation (defined in the Definitions section of this policy); OR

(b) An unbalanced (Robertsonian) chromosomal translocation (defined in the Definitions section of this policy); AND

3. Testing Frequency Criteria:

BOTH of the following PGD testing frequency criteria must be met, as specified below in item a and item b:

a. The Plan considers up to two (2) PGD procedures medically necessary in conjunction with IVF for members who meet the above criteria (as specified in the Member Criteria and Documentation Criteria sections); AND

b. The member is eligible for up to two (2) additional PGD procedures with IVF (beyond testing frequency specified in item 3a of this section) when ALL of the following criteria are met, as specified below in item (1), item (2), and item (3):

(1) The member had previously undergone two (2) cycles of PGD with IVF; AND

(2) The member continues to meet the PGD criteria specified above in this Medical Policy Statement section; AND

(3) There has been an intervening birth.

Limitations

1. The Plan considers preimplantation genetic diagnosis (PGD) testing for non-medical gender selection and/or testing for non-medical traits to NOT be medically necessary.

2. The Plan considers PGD testing to NOT be medically necessary unless applicable criteria in the Medical Policy Statement section are met.

3. The Plan considers ONE (1) or more of the following services to be experimental, investigational, or unproven, as specified below in items a through i:

   a. Carrier testing to determine the embryo’s carrier status; OR

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b. Human leukocyte antigen (HLA) typing of an embryo to identify a future suitable stem cell, tissue, or organ transplantation donor; OR

c. Preimplantation genetic screening (PGS) (i.e., screening embryos for chromosomal abnormalities in the absence of specific inherited genetic conditions identified in either biological parent); OR

d. Screening for autosomal recessive disorders when the embryos are created using donor egg or donor sperm; OR

e. Detecting genetic or chromosomal abnormalities contributed by donor egg or donor sperm; OR

f. Screening for adult-onset/late-onset disorders or predisposition to disease (e.g., Alzheimer's disease, cancer predisposition) unless Plan criteria are met in the Medical Policy Statement section of this policy; OR

g. An individual or couple who are using illicit substances or abusing substances known to negatively interfere with fertility or fetal development (e.g., marijuana, opiates, cocaine, or alcohol); OR

h. Aneuploidy screening (AS) in the setting of PGS (also called PGD-AS) for purposes of optimizing IVF outcomes in women with advanced maternal age, history of failed IVF cycles, or recurrent miscarriages, in the absence of inherited genetic abnormalities; OR

i. PGD for chromosomal microarray or whole-genome sequencing.

Definitions

**Autosomal Dominant Disorder:** One mutated gene in each cell is sufficient for an individual to be affected by an autosomal dominant disorder, either inheriting the mutation from an affected, biological parent or it is a new mutation in the gene. An autosomal dominant disorder is a chromosomal abnormality in which an affected individual has ONE (1) copy of a mutant gene and one (1) normal gene on a pair of autosomal chromosomes (unlike an autosomal recessive diseases that requires two [2] copies of a mutated gene). Individuals with autosomal dominant diseases have a 50 percent chance of passing the mutant gene and associated disorder on to each of their children. Examples of single gene autosomal dominant disorders include but are not limited to the following: epidermolysis bullosa (autosomal dominant type), Huntington disease, Marfan’s syndrome, myotonic dystrophy, neurofibromatosis type I (NF1) and type 2 (NF2), retinoblastoma, spinocerebellar ataxia (autosomal dominant type), and tuberous sclerosis.
**Autosomal Recessive Disorder:** A chromosome abnormality where BOTH copies of a mutated gene, one (1) from each biological parent, must be present in order for the disease or trait to develop (unlike an autosomal dominant disorder that requires one copy of a mutant gene). The biological parents (of the individual with an autosomal recessive condition) often do not show signs and symptoms of this disorder. The autosomal recessive disorder is not typically demonstrated in every generation of the affected families. **Examples of single gene autosomal recessive disorders include** but are not limited to the following: autosomal recessive spinocerebellar ataxia, beta thalassemia syndromes, Canavan disease, cystic fibrosis, epidermolysis bullosa simplex (autosomal recessive type), familial dysautonomia, Fanconi anemia, Gaucher disease, Hurler syndrome, sickle cell anemia, spinal muscular atrophy type I (also known as Werdnig-Hoffman disease), Tay-Sachs disease, and some types of metabolic disorders (e.g., methylmalonic acidemia or propionic acidemia).

**Chromosomal Translocation:** A chromosome abnormality caused by rearrangement of parts between non-homologous chromosomes. A gene fusion may be created when the translocation joins two (2) otherwise separated genes. There are two (2) main types:

1. **Balanced (Reciprocal or Non-Robertsonian):** An even exchange of material with no genetic information extra or missing.

2. **Unbalanced (Robertsonian):** An unequal exchange of chromosome material resulting in extra or missing genes.

**Human leukocyte antigen (HLA) Typing:** System used to identify the unique cell markers (antigens) that the immune system recognizes. Using preimplantation genetic diagnosis (PGD) through in vitro fertilization (IVF) rather than prenatal diagnosis allows diagnosis before a pregnancy is established. PGD may be performed to select an HLA compatible embryo that would serve as a donor for a sibling requiring a stem cell transplant.

**Intracytoplasmic Sperm Injection (ICSI):** An in vitro fertilization procedure in which a single sperm is injected directly into an egg using a small tube called a micropipette.

**In Vitro Fertilization (IVF):** The process of fertilization by manually combining an egg and sperm in a laboratory container.

**X-linked Dominant Disorder:** A chromosomal abnormality caused by mutations in genes on the X chromosome in one (1) of the two (2) sex chromosomes in each cell. In **phenotypical females**/individuals with two (2) X chromosomes, a **mutation in only one (1) of the two (2) copies of the gene in each cell is sufficient to cause the disorder.** In **phenotypical males**/individuals with only one (1) X chromosome, a **mutation in the only copy** of the gene in each cell causes the disorder. In most cases, phenotypical males/individuals with only one (1) X chromosome experience more severe symptoms of the disorder than phenotypical females/individuals with two (2) X chromosomes. A characteristic of X-linked inheritance is that a biological parent who is phenotypical male/biological parent with only one (1) X chromosome cannot pass X-linked traits to this parent’s biological offspring.
when the offspring has typical male karyotype with only one (1) X chromosome; i.e., no phenotypical male-to-phenotypical male transmission. (Source: Genetic Home Reference from the U. S. Department of Health & Human Services.)

**X-linked Recessive Disorder:** A chromosomal abnormality caused by mutations in genes on the X chromosome. In **phenotypical males**/individuals with only one (1) X chromosome, **one (1) altered copy of the gene** in each cell is sufficient to cause the condition. In **phenotypical females**/individuals with two (2) X chromosomes, a **mutation would have to occur in both copies** of the gene to cause the disorder. Because it is unlikely that phenotypical females/individuals with two (2) X chromosomes will have two (2) altered copies of this gene, phenotypical males/individuals with only one (1) X chromosome are affected by X-linked recessive disorders much more frequently than phenotypical females/individuals with two (2) X chromosomes. A characteristic of X-linked inheritance is that a biological parent who is phenotypical male/biological parent with only one (1) X chromosome cannot pass X-linked traits to this parent’s biological offspring when the offspring has typical male karyotype with only one (1) X chromosome; i.e., no phenotypical male-to-phenotypical male transmission. Examples of **single gene X-linked recessive disorders** include but are not limited to the following: adrenoleukodystrophy, Alport syndrome, choroideremia, Fabry disease, fragile X syndrome (with some clinical sources categorizing fragile X syndrome as an X-linked dominant disorder), hemophilia A, hemophilia B, Hunter syndrome, incontinentia pigmeni, Lesch-Nyhan syndrome, muscular dystrophy, and X-linked mental retardation. (Source: Genetic Home Reference from the U. S. Department of Health & Human Services.)

**Y-linked Disorder:** A chromosomal abnormality caused by a mutation on the Y chromosome, one of the two (2) sex chromosomes in each cell of a phenotypical male/individual with typical male karyotype with only one (1) X chromosome. These types of genetic mutations are transferred only from a biological parent who is a phenotypical male/individual with only one (1) X chromosome to this parent’s offspring when the offspring has typical male karyotype with one (1) X chromosome (e.g., Y chromosome infertility and some cases of Swyer syndrome).

**Applicable Coding**

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for

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Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member’s benefit plan. Please refer to the member’s benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines. Review the following Plan medical policies for further prior authorization requirements: Genetic Testing Guidelines and Pharmacogenetics (policy number OCA 3.726) and Infertility Services (policy number OCA 3.725). See the Plan’s reimbursement policy, Reimbursement Guidelines – Infertility Services (policy number 4.34) available at www.bmchp.org.

### CPT Codes

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<th>Description: Codes Covered When Medically Necessary</th>
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<td>89290</td>
<td>Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); less than or equal to 5 embryos</td>
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<tr>
<td>89291</td>
<td>Biopsy, oocyte polar body or embryo blastomere, microtechnique (for preimplantation genetic diagnosis); greater than 5 embryos</td>
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**Clinical Background Information**

During preimplantation genetic diagnosis (PGD), one (1) or two (2) cells are removed by biopsy from the embryos created by in vitro fertilization (IVF) and tested. This cell biopsy is typically performed at the polar body (for maternal chromosomal abnormalities) or on the embryo at cleavage (8 cell) stage which occurs three (3) days after fertilization. Once the cell has been extracted, its genetic material can be amplified to analyze for single gene defect via polymerase chain reaction (PCR), most commonly used to identify Tay-Sachs disease or cystic fibrosis. PGD may also be used to evaluate human leukocyte antigen (HLA) status alone in families with a child with a bone marrow disorder requiring a stem cell transplant, and in whom there is no other source of a compatible bone marrow donor other than an HLA matched sibling.

An alternative method involves fluorescent in situ hybridization (FISH), a method which allows direct visualization of specific (but not all) chromosomes to determine the number or absence of chromosomes. This technique is utilized most commonly to screen for aneuploidy, gender determination, or to identify chromosomal translocations. Although FISH cannot be used to diagnose single genetic defect disorders, molecular techniques can be applied along with FISH to identify single gene defects such as microdeletions and duplications.

A third technique, called array comparative genome hybridization (aCGH), involves testing at either the 8 cell or more often, the blastocyst stage. This test may be used for 24 chromosome aneuploidy

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Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening)

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screening, as well as screening for unbalanced translocations and inversions and other types of abnormal losses and gains of chromosomal material.

PGD is used to screen out embryos carrying a genetic disease with the intended goal of a healthy pregnancy and offspring free of genetic abnormalities. Based on the results of genetic tests, parents and maternal-fetal medicine specialists are able to select or deselect which embryos to implant. Given that only unaffected embryos are transferred to the uterus for implantation, preimplantation genetic testing provides an attractive alternative to current in utero diagnostic procedures (i.e., amniocentesis or chorionic villus sampling), which are frequently followed by the difficult decision of selective pregnancy termination for affected fetuses. The American Society for Reproductive Medicine and the Society for Assisted Reproductive Technology recommend the following guidelines for preimplantation genetic testing:

1. Before PGD is performed, genetic counseling must be provided.

2. PGD can reduce the risk for conceiving a child with a genetic abnormality carried by one (1) or both parents if that abnormality can be identified with tests performed on a single cell.

3. Prenatal diagnostic testing by traditional methods (amniocentesis or CVS) to confirm the results of PGD is encouraged strongly because PGD has technical limitations that include the possibility of false negatives (due to “allele drop-out” or other technical problems).

PGD should only be offered in centers where there is expertise in genetic counseling, molecular genetics, and embryology because it is imperative that patients be aware of the potential diagnostic errors, risks of the IVF procedure, and the unknown (though presumed low) risks of the embryo biopsy procedure to the future fetus.

References


Preimplantation Genetic Testing (Preimplantation Genetic Diagnosis and Preimplantation Genetic Screening)


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Reproductive Health Technologies Project. Pre-implantation Genetic Diagnosis (PGD).


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<td>01/01/12 Version 1</td>
<td>Medical Policy Manager as Chair of MPCTAC</td>
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<td>06/01/12</td>
<td>Review for effective date 08/01/12. Referenced Plan policy, Genetic Testing Guidelines, policy number (OCA: 3.726). Revised the introductory paragraph in Applicable Coding section and updated references.</td>
<td>08/01/12 Version 2</td>
<td>06/20/12: MPCTAC 07/25/12: QIC</td>
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<td>Review for effective date 08/01/13. Revised title. Referenced applicable Plan policies. Revised Summary section. Reformatted Medical Policy Statement section and Limitations without changing criteria. Removed redundant text from Clinical Background Information section and added relevant documentation.</td>
<td>08/01/13 Version 3</td>
<td>06/19/13: MPCTAC 07/18/13: QIC</td>
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<td>Review for effective date 08/01/14. Revised Policy Summary, Description of Item or Service, Definitions, and Clinical Background Information sections. Moved criteria from the Summary section to the Medical Policy Statement section without changing Plan criteria. Revised introductory paragraph in the Applicable Coding section</td>
<td>08/01/14 Version 4</td>
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**Policy Revisions History**

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<td>10/01/15 Version 5</td>
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<td>Medical Policy - Experimental and Investigational Treatment, policy number OCA 3.12</td>
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<td>11/25/15</td>
<td>Review for effective date 01/01/16. Updated template with list of applicable products. Revised language in the Applicable Coding section.</td>
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<td>Review for effective date 10/01/16. Revised criteria in the Limitations section. Updated Definitions, Clinical Background Information, References, and References to Applicable Laws and Regulations sections.</td>
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<td>Review for effective date 11/01/16. Administrative changes made to clarify language related to gender.</td>
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<td>09/01/17 Version 9</td>
<td>MPCTAC</td>
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**Last Review Date**

06/01/17

**Next Review Date**

06/01/18

**Authorizing Entity**

MPCTAC

**Other Applicable Policies**

- Medical Policy - *Experimental and Investigational Treatment*, policy number OCA 3.12
- Medical Policy - *Infertility Services*, policy number OCA 3.725
- Medical Policy - *Medically Necessary*, policy number OCA 3.14
- Reimbursement Policy - *Infertility Services*, policy number 4.34

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Reference to Applicable Laws and Regulations


Code of Massachusetts Regulations. 211 CMR 52.03. Definitions. Medical Necessity or Medically Necessary.

Code of Massachusetts Regulations. 958 CMR 128.020. External Review.


Disclaimer Information: *

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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