



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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## Subject Prophylactic Mastectomy

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### Hyperlink to Related Coverage Policies

- Breast Reconstruction Following Mastectomy or Lumpectomy
- External Breast Prostheses and Mastectomy Bras Following Mastectomy or Lumpectomy
- Genetic Counseling
- Genetic Testing for Susceptibility to Breast and Ovarian Cancer (e.g., BRCA1 & BRCA2)
- Genetic Testing of Heritable Disorders
- Magnetic Resonance Imaging (MRI) of the Breast
- Mammography
- Prophylactic Oophorectomy or Salpingo-oophorectomy With or Without Hysterectomy

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of CIGNA. Copyright ©2011 CIGNA

## Coverage Policy

CIGNA covers prophylactic mastectomy as medically necessary for the treatment of individuals at high risk of developing breast cancer when any ONE of the following criteria is met:

### Individuals with a personal history of cancer as noted below:

- individuals with a personal history of breast cancer when any ONE of the following criteria is met:
  - diagnosed at age 45 or younger, regardless of family history
  - diagnosed at age 50 or younger and EITHER of the following:
    - at least one close blood relative\* with breast cancer at age 50 or younger
    - at least one close blood relative\* with epithelial ovarian, fallopian tube, or primary peritoneal cancer

- diagnosed with two breast primaries (includes bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors) when the first breast cancer diagnosis occurred prior to age 50
- diagnosed at age 60 or younger with a triple negative breast cancer
- diagnosed at age 50 or younger with a limited family history (e.g., fewer than two first- or second-degree female relatives or female relatives surviving beyond 45 years in either lineage)
- diagnosed at any age and there are at least two close blood relatives\* with breast cancer or epithelial ovarian, fallopian tube, or primary peritoneal cancer diagnosed at any age
- personal history of epithelial ovarian, fallopian tube, or primary peritoneal cancer
- close male blood relative\* with breast cancer
- an individual of ethnicity associated with higher mutation frequency (e.g., founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian, or Dutch)
- development of invasive lobular or ductal carcinoma in the contralateral breast after electing surveillance for lobular carcinoma in situ of the ipsilateral breast
- lobular carcinoma in situ confirmed on biopsy
- lobular carcinoma in situ in the contralateral breast
- diffuse indeterminate microcalcifications or dense tissue in the contralateral breast that is difficult to evaluate mammographically and clinically
- a large and/or ptotic, dense, disproportionately-sized contralateral breast that is difficult to reasonably match the ipsilateral cancerous breast treated with mastectomy and reconstruction
- personal history of epithelial ovarian, fallopian tube, or primary peritoneal cancer
- personal history of breast, ovarian or pancreatic cancer at any age with two or more close blood relatives\* with breast, ovarian, or pancreatic cancer at any age
- personal history of male breast cancer

**Individuals with no personal history of breast or epithelial ovarian cancer when any ONE of the following is met:**

- known breast risk cancer antigen (BRCA1 or BRCA2), p53 or PTEN mutation confirmed by genetic testing
- close blood relative\* with a known BRCA1, BRCA2, p53 or PTEN mutation
- first- or second-degree blood relative\* meeting any of the above criteria for individuals with a personal history of cancer
- third-degree blood relative with two or more close blood relatives\* with breast and/or ovarian cancer (with at least one close blood relative with breast cancer prior to age 50)
- history of treatment with thoracic radiation
- atypical ductal or lobular hyperplasia, especially if combined with a family history of breast cancer
- dense, fibronodular breasts that are mammographically or clinically difficult to evaluate, several prior breast biopsies for clinical and/or mammographic abnormalities, and strong concern about breast cancer risk

**\*Note:** A close blood relative/close family member includes first-, second-, or third-degree relatives. A first-degree relative is defined as a blood relative with whom an individual shares approximately 50% of his/her genes, including the individual's parents, full siblings, and children. A second-degree relative is defined as a blood relative with whom an individual shares approximately 25% of his/her genes, including the individual's grandparents, grandchildren, aunts, uncles, nephews, nieces and half-siblings. A third-degree relative is defined as a blood relative with whom an individual shares approximately 12.5% of his/her genes, including the individual's great-grandparents and first-cousins.

## General Background

Breast cancer accounts for one-third of all cancers in women. Known risk factors for breast cancer include age, early menarche, nulliparity, age at first live birth, radiation exposure, atypical hyperplasia, and family history. Approximately 5–10% of breast tumors are hereditary; the remaining cases are caused by genetic changes that occur during a woman's life and are commonly called sporadic. Women who test positive for breast risk cancer

antigen (BRCA1/BRCA2) mutations, which are located on chromosome 17q21 and 13q12–q13, respectively, carry a 60–85% lifetime risk of breast cancer and a 15–65% cumulative lifetime risk of invasive epithelial ovarian cancer. Male breast cancer is rare, accounting for less than 1% of all breast cancer cases. Nonetheless, inheritance of a breast cancer susceptibility gene, especially the BRCA2, is associated with these rare breast cancers as well (National Cancer Institute [NCI], 2010c). Males with a BRCA2 mutation have a 6% risk of developing breast cancer by the age of 70 (Agrawal, et al., 2006).

In addition, there are some histopathologic features that have been noted to occur more frequently in breast cancers that associated with BRCA1 or BRCA2 mutation. Several studies have demonstrated that BRCA1 breast cancer is more likely to be characterized as estrogen receptor (ER) negative, progesterone receptor (PR) negative, and human epidermal growth factor receptor 2 (HER2) negative, also referred to as triple negative breast cancer. Studies have reported BRCA1 mutations in 11% to 28% of patients with triple-negative breast cancer. It has also been noted that in patients with triple-negative disease, the BRCA mutation carriers were diagnosed at a younger age compared to non-carriers (NCCN, 2011a).

Breast cancer is also a component of Li-Fraumeni syndrome, in which germline mutations in the p53 gene on the short arm of chromosome 17 have been documented. The tumor suppressor gene p53 mutation is observed in 77% of Li-Fraumeni syndrome families. Inheritance of the syndrome is autosomal-dominant. The condition is characterized by multiple tumors in the same individuals and clustering of tumors within the same family. The Li-Fraumeni gene is thought to account for less than 1% of all breast cancers. Germline mutations in the protein tyrosine phosphatase with homology to tensin (PTEN) gene located on chromosome 10q23 are responsible for Cowden syndrome. This syndrome is also rare with an autosomal-dominant pattern of inheritance. Cowden syndrome is characterized by conditions that include an excess of breast cancer, gastrointestinal malignancies, and both benign and malignant thyroid disease. Lifetime estimates for breast cancer among women with Cowden syndrome range from 25%–50%. Like other forms of breast cancer, Cowden syndrome occurs at a young age and may be bilateral (National Comprehensive Cancer Network [NCCN], 2010a).

With the identification of high-risk individuals, prophylactic measures (e.g., surgery, tamoxifen chemoprevention, or increased surveillance) can be taken to decrease the risk of cancer occurrence or recurrence. Prophylactic mastectomy is the surgical removal of one or both breasts before cancer develops. Either the whole breast (i.e., total or simple mastectomy) or the underlying breast tissue excluding the nipple (i.e., subcutaneous mastectomy) is removed. The "gold standard" and most widely used form of prophylaxis is a total or simple mastectomy, since it removes more breast tissue. Reconstruction may occur immediately or be delayed. Because the surgery is not removing cancer, the lymph nodes are left intact. Some of the reasons for considering prophylactic mastectomy may include (American Cancer Society [ACS], 2010):

- mutated BRCA genes found by genetic testing
- previous cancer in one breast
- strong family history (breast cancer in several close relatives)
- biopsy specimens showing lobular carcinoma in situ (LCIS)

"Women  $\geq$  35 years of age without BRCA1/2, p53, or PTEN mutation, a strong family history of breast cancer, a history of thoracic radiation, or history of LCIS should have their risk for breast cancer estimated according to the Gail model" (NCCN, 2010b). This computerized risk-assessment program assesses risks using such factors as age, age at menarche, age of first live birth, ethnicity, first-degree relatives with breast cancer, BRCA 1–2 status and prior personal history of breast cancer or precancer.

### **Literature Review**

A Cochrane review by Lostumbo et al. (2010) concluded that BPM should only be considered by those at very high risk for breast cancer. It was found that while published observational studies (n=39; 7384 subjects) showed that BPM was effective in reducing both the incidence of and mortality from breast cancer more rigorous prospective studies are needed. For CPM, studies consistently reported reductions in contralateral incidence of breast cancer but were inconsistent about improvements in disease-specific survival.

A systematic review by Bermejo-Pérez and colleagues (2007) included systematic reviews (n=2), cohort studies (n=10), and case-control studies (n=6). The review assessed the effectiveness of preventive intervention strategies (i.e., prophylactic surgery, intensive cancer screening, and chemoprevention) implemented in women

carrying mutations in BRCA1 or BRCA2 genes, in terms of reducing breast and gynecological cancer incidence and/or mortality. Selection bias was the primary methodological flaw identified in these studies. BPM compared to surveillance was found to reduce the incidence of breast cancer in women carrying BRCA gene mutations with no previous history of cancer. Results from a single study (n=148) with three-year follow-up indicated that CPM versus surveillance reduced the incidence of contralateral breast cancer in women with unilateral breast cancer carrying BRCA gene mutations (Bermejo-Pérez, et al., 2007).

A number of prospective and retrospective studies have evaluated the effectiveness of prophylactic mastectomy for breast cancer reduction in women with known BRCA1 and BRCA2 mutations and with known family histories of breast and/or ovarian cancer (Rebbeck, et al., 2004; Meijers-Heijboer, et al., 2001; McDonnell, et al., 2001; Peralta, et al., 2000; Hartman, et al., 1999). In general, the results of these studies indicate that prophylactic mastectomy results in risk reduction of breast cancer occurrence by at least 90% for women in moderate- and high-risk groups.

### **Professional Societies/Organizations**

The NCCN published clinical practice guidelines for genetic/familial high-risk assessment of breast and ovarian cancer. According to NCCN guidelines, it is generally accepted that carriers of mutation in BRCA1 or BRCA2 have an excessive risk for both breast and ovarian cancer that warrants consideration of more intensive preventive and screening strategies. In addition, characteristics of hereditary breast and/or ovarian cancer (HBOC) syndrome in individuals with a personal history of breast cancer included onset of the disease at an early age, Ashkenazi Jewish ancestry, any male breast cancer and a family history of breast and/or ovarian cancer. Individuals who have only a family history of breast and/or ovarian cancer may also be at risk. The guidelines for HBOC contain criteria for referral to risk assessment, counseling, and consideration of genetic testing and risk reduction. These guidelines include the following (NCCN, 2011a):

- individual from a family with a known BRCA1/BRCA2 mutation
- personal history of breast cancer<sup>1</sup> plus one or more of the following:
  - diagnosed at age ≤45 years
  - diagnosed at age ≤50 years, with one or more close blood relative with breast cancer at ≤50 years and/or one or more close blood relative with epithelial ovarian/fallopian tube/primary peritoneal cancer
  - two breast primaries<sup>2</sup> when first breast cancer diagnosis occurred prior to age 50
  - diagnosed at age 60 or younger with a triple negative breast cancer
  - diagnosed at age 50 or younger with a limited family history (e.g., fewer than two first- or second degree female relatives or female relatives surviving beyond 45 years in either lineage)
  - diagnosed at any age, with two or more close blood relatives with breast and/or epithelial ovarian/ fallopian tube/primary peritoneal cancer at any age
  - close male blood relative with breast cancer
  - personal history of epithelial ovarian<sup>3</sup> /fallopian tube/primary peritoneal cancers
  - for an individual of ethnicity associated with higher mutation frequency (e.g., founder populations of Ashkenazi Jewish, Icelandic, Swedish, Hungarian or Dutch), no additional family history may be required<sup>4</sup>
- personal history of epithelial ovarian/fallopian tube/primary peritoneal cancers
- personal history of male breast cancer
- personal history of breast or ovarian cancer at any age with two or more close blood relatives\* with breast, ovarian, or pancreatic cancer at any age
- personal history of pancreatic cancer at any age with two or more close blood relatives\* with breast, ovarian or pancreatic cancer at any age
- family history only with one of the following:
  - First- or second-degree blood relative meeting any of the above criteria
  - Third-degree blood relative with ≥2 close relatives with breast and/or ovarian cancer (at least one close blood relative with breast cancer ≤50 years)

<sup>1</sup>for purposes of the guidelines, invasive and ductal carcinoma in situ breast cancers should be included.

<sup>2</sup>two breast primaries including bilateral disease or cases where there are two or more clearly separate ipsilateral primary tumors

<sup>3</sup>ovarian cancer is a component tumor of hereditary non-polyposis colorectal cancer (HNPCC)/Lynch syndrome, be attentive for clinical evidence of this syndrome.

<sup>4</sup>testing for founder-specific mutation(s), if available, should be performed first. Full sequencing may be considered if other hereditary breast and/or ovarian cancer criteria met.

The NCCN supports the use of risk-reducing or prophylactic mastectomy as an option for carefully selected women at high risk for breast cancer (e.g., BRCA1/BRCA2 mutation, p53 or PTEN mutation, possibly history of LCIS). Women with a history of LCIS are at substantially increased risk for invasive cancer in both the affected and contralateral breast. Women with a strong family history of breast cancer or a history of thoracic irradiation, particularly at a young age, may also be candidates for risk-reduction strategies (NCCN, 2011b).

According to the American Society of Plastic Surgeons' (ASPS) coverage criteria for prophylactic mastectomy, groups at a high risk for developing breast cancer include women with a family history of breast cancer in first- and second-degree relatives or those who carry the BRCA1 or BRCA2 gene. These women have a lifetime risk of breast cancer estimated from 60–90%. Patients who have had breast cancer at an early age (<40 years) have an increased lifetime risk of developing breast cancer in the contralateral breast. These patients may seek a prophylactic mastectomy, which carries a risk reduction of greater than 90% in high-risk women with or without the BRCA1 or BRCA2 gene. Other groups of women at high risk include those with atypical hyperplasia and fibrocystic breast disease and pathologic findings showing diffuse microcalcifications, lobular carcinoma in situ (LCIS) or invasive lobular cancer. Males who have had breast cancer, especially those with a family history of the disease, may want to consider prophylactic treatment. Family patterns that would be considered positive for breast cancer include (ASPS, 2008):

- Two or more first-degree relatives
- One first-degree and two second or third-degree relatives
- One first-degree relative with cancer prior to age 45 and one other relative
- One first-degree relative and one first-degree relative with ovarian cancer
- Two second or third-degree relatives and one relative with ovarian cancer
- Three or more second or third-degree relatives
- One first-degree relative with bilateral cancer
- Positive BRCA1 or BRCA2

The Society of Surgical Oncology (SSO) updated their position on prophylactic mastectomy in 2007. The position states that BPM in a patient without a diagnosis of breast cancer or evidence of a suspicious breast lesion is one form of risk reduction for the development of breast cancer. Indications for consideration of BPM are best evaluated by a multidisciplinary team which may include a surgeon, medical oncologist, pathologist, as well as a genetic counselor. According to the SSO, clinical presentations that suggest an additional risk of the development of breast cancer and that justify performing a BPM include any of the following:

1. A known mutation of BRCA 1 or BRCA2 or other strongly predisposing breast cancer susceptibility genes
2. A family history of breast cancer in multiple first-degree relatives and/or multiple successive generations of family members with breast and/or ovarian cancer (family cancer syndrome). Additionally, a family history of multiple family members with bilateral and/or premenopausal and/or male breast cancer may be associated with a familial breast cancer syndrome. Genetic counseling should be strongly considered, although prophylactic surgery is appropriate in women with a family history consistent with genetic predisposition and no demonstrable genetic mutation.
3. High-risk histology: Atypical ductal or lobular hyperplasia, or lobular carcinoma in situ confirmed on biopsy. These changes are especially significant if present in a patient with a strong family history of breast cancer.

The SSO further states that, rarely, BPM may be indicated for a patient without family history or high-risk histology. "Such a patient would exhibit the following characteristics: extremely dense fibronodular tissue that is difficult to evaluate with standard breast imaging, several prior breast biopsies for clinical and/or mammographic abnormalities, and strong concern about breast cancer risk" (SSO, 2007).

The SSO position statement notes that unilateral prophylactic mastectomy, also referred to as contralateral prophylactic mastectomy (CPM), “may be appropriate in a patient in whom therapeutic mastectomy has previously been performed or is being contemplated for breast cancer.” These patients are at a higher than normal risk for developing contralateral breast cancer. Mastectomy of the contralateral breast may be considered in the following situations (SSO, 2007):

- For risk reduction in patients at high risk for contralateral breast cancer. (See indications as listed above for bilateral prophylactic mastectomy.)
- For patients in whom subsequent surveillance of the contralateral breast would be difficult. This includes patients with clinically and mammographically dense breast tissue or diffuses, indeterminate microcalcifications in the contralateral breast. Stereotactic core biopsy should be performed of any suspicious cluster in this situation to rule out carcinoma. However, diffuse and/or indeterminate calcifications in some situations may make subsequent surveillance difficult. A clinically and mammographically dense breast may also make surveillance difficult.
- For improved symmetry in patients undergoing mastectomy with reconstruction for the index cancer who have a large and/or ptotic contralateral breast, or disproportionately sized contralateral breast. It is difficult to reasonably match these patients’ breasts with reconstructive techniques, and a contralateral mastectomy with reconstruction may be indicated to maintain symmetry. Mastopexy and reduction mammoplasty are alternatives to contralateral mastectomy. In rare situations, a patient having had, or who will undergo, mastectomy without reconstruction may also request a contralateral mastectomy to maintain balance and/or decrease the risk of contralateral breast cancer.

The National Hereditary Cancer Task Force developed Canadian consensus recommendations to address the clinical management of patients at high risk of HBOC and related cancers. The recommendations are based on current practice in high-risk cancer clinics that provide care for individuals with known BRCA1 or BRCA2 mutations and pertain to surveillance options, risk-reduction strategies (e.g., BPSO, prophylactic mastectomy), and the use of exogenous hormones. The guidelines state that consistent evidence from observational studies suggests that prophylactic mastectomy reduces the risk of breast cancer in women with known BRCA1 or BRCA2. The recommendations pertaining to prophylactic mastectomy include the following (Horsman, et al., 2007):

1. The potential benefits of prophylactic mastectomy as a risk-reduction strategy should be raised with all women with known BRCA1 or BRCA2 mutations.
2. Women considering prophylactic mastectomy should be managed by a multidisciplinary team that includes at least a geneticist/genetic counselor, a breast surgeon, and a plastic surgeon.
3. The surgical technique should aim for maximum removal of breast tissue, including removal of nipple and areola, and possibly also the axillary and subclavian extensions.
4. The possibility that histologically evident breast cancer may be diagnosed as a result of the surgical procedure should be discussed with the patient in advance.
5. Breast reconstruction options should be discussed with the patient in advance.

The National Institute for Health and Clinical Excellence (NICE) guideline on the classification and care of women at risk of familial breast cancer states that bilateral risk-reducing mastectomy is appropriate only for a small proportion of women who are from high-risk families and should be managed by a multidisciplinary team. Women considering this procedure should have genetic counselling before a decision is made (NICE, 2006).

The U.S. Preventive Services Task Force (USPSTF) found fair evidence in the published scientific literature that women with certain specific family history patterns have an increased risk for developing breast or ovarian cancer associated with BRCA1 or BRCA2 mutations. Fair evidence was also found to support prophylactic surgery for these women, as it significantly decreases breast and ovarian cancer incidence. The USPSTF recommendation is that women with the following family history patterns be referred for genetic counseling that will allow for informed decision-making about testing and further prophylactic treatment:

- two first-degree relatives with breast cancer, one of whom was diagnosed at age 50 or younger
- a combination of three or more first- or second-degree relatives with breast cancer, regardless of age at diagnosis
- a combination of both breast and ovarian cancer among first- and second-degree relatives

- a first-degree relative with bilateral breast cancer
- combination of two or more first- or second-degree relatives with ovarian cancer, regardless of age at diagnosis
- first- or second-degree relative with both breast and ovarian cancer, at any age
- history of breast cancer in a male relative

For women of Ashkenazi Jewish heritage, an increased risk family history includes any first-degree relative (or two second-degree relatives on the same side of the family) with breast or ovarian cancer (USPSTF, 2005).

### Summary

The overall body of evidence in the peer-reviewed medical literature indicates that prophylactic mastectomy is effective in reducing the occurrence of breast cancer for individuals in high-risk categories. It is important that affected individuals receive counseling regarding all available options, in addition to the risks and benefits of the procedure. If the procedure is under consideration as a treatment option, it is imperative that the patient understand that the surgery will not eliminate the risk of developing cancer. Nonetheless, for patients who carry BRCA, p53 or PTEN mutations, prophylactic mastectomy can minimize the additional risk conferred by genetics.

## Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered when medically necessary:**

CPT®* Codes	Description
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous

ICD-9-CM Diagnosis Codes	Description
157.0 – 157.9	Malignant neoplasm of pancreas
158.8	Malignant neoplasm of specific parts of peritoneum
158.9	Malignant neoplasm of peritoneum, unspecified
174.0 – 174.9	Malignant neoplasm of female breast
175.0 – 175.9	Malignant neoplasm of male breast
183.0	Malignant neoplasm of ovary
198.6	Secondary malignant neoplasm of ovary
198.81	Secondary malignant neoplasm of breast
233.0	Carcinoma in situ of breast
238.3	Neoplasm of uncertain behavior of breast
239.3	Neoplasm of unspecified nature of breast
610.1	Diffuse cystic mastopathy
610.2	Fibroadenosis of breast
610.3	Fibrosclerosis of breast
611.1	Hypertrophy of breast
V10.09	Personal history of malignant neoplasm of gastrointestinal tract; other
V10.3	Personal history of malignant neoplasm of breast
V10.43	Personal history of malignant neoplasm of ovary
V10.44	Personal history of malignant neoplasm of other female genital organs
V15.3	Other personal history presenting hazard to health; irradiation
V16.0	Family history of malignant neoplasm of gastrointestinal tract
V16.3	Family history of malignant neoplasm, breast
V16.41	Family history of malignant neoplasm, genital organs, ovary
V50.41	Prophylactic organ removal, breast

V84.01	Genetic susceptibility to malignant neoplasm of breast
V84.02	Genetic susceptibility to malignant neoplasm of ovary

**\*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.**

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## Policy History

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<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	8/15/2008	0029	Prophylactic Mastectomy
Great-West Healthcare	11/20/2006	95.232.07	Breast Surgery, Prophylactic Mastectomy

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