


BENEFIT COVERAGE GUIDELINE – 7.01.533

Reconstructive Breast Surgery/Management of Breast Implants

Effective Date:	June 1, 2018	RELATED MEDICAL POLICIES:
Last Revised:	Sept. 7, 2018	7.01.503 Reduction Mammoplasty for Breast-related Symptoms
Replaces:	N/A	10.01.514 Cosmetic and Reconstructive Services
		11.01.524 Site of Service: Select Surgical Procedures

Select a hyperlink below to be directed to that section.

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Introduction

Breast reconstruction is surgery done after a woman has had all or part of a breast removed. A breast can be removed for a number of reasons, including cancer, accident, or injury. The goal of breast reconstruction is to recreate a breast that matches the shape and size of the nonaffected breast. The most common reason for breast reconstruction is following the removal of a breast (mastectomy) as cancer treatment. This policy describes when breast reconstruction is covered to address a medical situation. Breast reconstruction to change the shape or size of breasts only for appearance is cosmetic surgery. The plan does not cover cosmetic surgery.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Site of service is defined as the location where the surgical procedure is performed, such as an off campus-outpatient hospital or medical center, an on campus-outpatient hospital or medical center, an ambulatory surgical center, or an inpatient hospital or medical center.

Surgical procedures subject to review for site of service addressed in this policy are limited to:

- Reduction mammoplasty

Site of Service for Elective Surgical Procedures	Medical Necessity
<p>Medically necessary sites of service:</p> <ul style="list-style-type: none"> • Off campus-outpatient hospital/medical center • On campus-outpatient hospital/medical center • Ambulatory Surgical Center 	<p>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost effective site. These are the preferred medically necessary sites of service for certain elective surgical procedures.</p>
<p>Inpatient hospital/medical center</p>	<p>Certain elective surgical procedures will be covered in the most appropriate, safe, and cost-effective site. This site is considered medically necessary only when the patient has a clinical condition which puts him or her at increased risk for complications including any of the following (this list may not be all inclusive):</p> <ul style="list-style-type: none"> • Anesthesia Risk <ul style="list-style-type: none"> ○ ASA classification III or higher (see definition) ○ Personal history of complication of anesthesia ○ Documentation of alcohol dependence or history of cocaine use ○ Prolonged surgery (>3 hours) • Cardiovascular Risk <ul style="list-style-type: none"> ○ Uncompensated chronic heart failure (NYHA class III or IV) ○ Recent history of myocardial infarction (MI) (<3 months) ○ Poorly controlled, resistant hypertension* ○ Recent history of cerebrovascular accident (< 3 months) ○ Increased risk for cardiac ischemia (drug eluting stent placed < 1 year or angioplasty <90 days)



Site of Service for Elective Surgical Procedures	Medical Necessity
	<ul style="list-style-type: none"> ○ Symptomatic cardiac arrhythmia despite medication ○ Significant valvular heart disease ● Liver Risk <ul style="list-style-type: none"> ○ Advance liver disease (MELD Score > 8)** ● Pulmonary Risk <ul style="list-style-type: none"> ○ Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) ○ Poorly controlled asthma (FEV1 <80% despite treatment) ○ Moderate to severe obstructive sleep apnea (OSA)*** ● Renal Risk <ul style="list-style-type: none"> ○ End stage renal disease (on dialysis) ● Other <ul style="list-style-type: none"> ○ Morbid obesity (BMI ≥ 50) ○ Pregnancy ○ Bleeding disorder (requiring replacement factor, blood products, or special infusion product [DDAVP**** does not meet this criteria]) ○ Anticipated need for transfusion(s) <p>* 3 or more drugs to control blood pressure</p> <p>** https://reference.medscape.com/calculator/meld-score-end-stage-liver-disease</p> <p>*** Moderate-AHI ≥15 and ≤ 30, Severe-AHI ≥30</p> <p>****DDAVP-Deamino-Delta-D-Arginine Vasopressin (Desmopressin)</p>
Inpatient hospital/medical center	This site of service is considered NOT medically necessary for certain elective surgical procedures when the site of service criteria listed above are not met.

Procedure	Medical Necessity
Reconstructive breast surgery	<p>Reconstructive breast surgery may be considered medically necessary in the following circumstances:</p> <ul style="list-style-type: none"> ● A prior mastectomy or partial mastectomy was done to: <ul style="list-style-type: none"> ○ Treat disease <ul style="list-style-type: none"> ▪ Cancer



Procedure	Medical Necessity
	<ul style="list-style-type: none"> ▪ Severe fibrocystic breast disease unresponsive to medical therapy ○ Treat injury or trauma ○ Reduce risk of breast cancer occurrence (prophylactic mastectomy) <p>AND</p> <ul style="list-style-type: none"> ○ Reconstruction is to restore symmetry between the unaffected breast and the affected breast. <p>Reconstructive breast surgery may include but is not limited to:</p> <ul style="list-style-type: none"> • Autologous reconstruction using autologous tissue (eg, latissimus dorsi flap, transverse rectus abdominis myocutaneous flap, or free flap) <p>OR</p> <ul style="list-style-type: none"> • Autologous fat grafting obtained by liposuction <p>OR</p> <ul style="list-style-type: none"> • Immediate or delayed insertion of breast prosthesis with or without associated tissue expansion <p>OR</p> <ul style="list-style-type: none"> • Mastopexy or reduction mammoplasty or augmentation on the contralateral breast to achieve symmetry <p>OR</p> <ul style="list-style-type: none"> • Nipple/areola reconstruction and nipple tattooing when the breast reconstruction is considered eligible for coverage <p>OR</p> <ul style="list-style-type: none"> • Revision of a reconstructed breast, including reconstruction after the medically necessary removal of a breast implant that had been placed for medical reasons
<p>Explantation (removal) of breast implants</p>	<p>Explantation or removal of a silicone gel or saline-filled breast implant may be covered in the following situations if the original implant had been placed for a medically necessary reason and not for cosmetic reasons:</p> <ul style="list-style-type: none"> • One or more of the following are present: <ul style="list-style-type: none"> ○ Baker Class III or IV contracture (see Description section) ○ Documented implant rupture placed after a medically necessary mastectomy or partial mastectomy due to illness,



Procedure	Medical Necessity
	<p data-bbox="667 247 886 281">injury, or disease</p> <ul style="list-style-type: none"> <li data-bbox="621 296 789 323">○ Extrusion <li data-bbox="621 338 781 365">○ Infection <li data-bbox="621 380 1409 457">○ Surgical treatment of breast cancer or other malignancies involving the breast <p data-bbox="573 516 1414 594">The following conditions are not medically necessary reasons for implant removal:</p> <ul style="list-style-type: none"> <li data-bbox="573 606 1167 634">● Pain not related to contractures or rupture <li data-bbox="573 648 810 676">● Patient anxiety <li data-bbox="573 690 1398 768">● Systemic symptoms attributed to connective tissue diseases, autoimmune diseases, etc. <p data-bbox="573 827 1385 861">In the case that implants were placed for cosmetic reasons:</p> <ul style="list-style-type: none"> <li data-bbox="573 873 1382 993">● Explantation is covered only if there has been interval development of breast cancer or other cancer that requires breast surgery <li data-bbox="573 1008 1385 1169">● In the absence of a cancer, then the subsequent removal of breast implants placed for cosmetic reasons is considered a complication of a non-covered service, and is contractually excluded in most cases <p data-bbox="573 1228 1357 1291">Note: Please refer to the member contract for coverage associated with complications of non-covered procedures.</p>

Documentation Requirements
<p data-bbox="167 1451 1406 1528">For reconstructive breast surgery, submit clinical documentation supporting the following conditions:</p> <ul style="list-style-type: none"> <li data-bbox="167 1541 932 1568">● A prior mastectomy or partial mastectomy was done to: <ul style="list-style-type: none"> <li data-bbox="215 1583 431 1610">○ Treat disease <ul style="list-style-type: none"> <li data-bbox="269 1625 410 1652">▪ Cancer <li data-bbox="269 1667 1162 1703">▪ Severe fibrocystic breast disease unresponsive to medical therapy <li data-bbox="215 1717 545 1745">○ Treat injury or trauma <li data-bbox="215 1759 1122 1787">○ Reduce risk of breast cancer occurrence (prophylactic mastectomy) <p data-bbox="215 1801 285 1829">AND</p> <ul style="list-style-type: none"> <li data-bbox="215 1843 1370 1871">○ Reconstruction is to restore symmetry between the unaffected breast and the affected



Documentation Requirements

breast.

For explantation (removal) of breast implants, submit clinical documentation supporting that the original implant had been placed for a medically necessary reason and not for cosmetic reasons, and one or more of the following conditions is present:

- Baker Class III or IV contracture
- Documented implant rupture of implants placed after a medically necessary mastectomy or partial mastectomy due to illness, injury, or disease
- Extrusion
- Infection

Coding

Code	Description
CPT	
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq. cm or less
11921	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.1 to 20.0 sq cm
11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; each additional 20.0 sq cm, or part thereof (List separately in addition to code for primary procedure)
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion
11970	Replacement of tissue expander with permanent prosthesis
11971	Removal of tissue expander(s) without insertion of prosthesis
19303	Mastectomy, simple, complete
19304	Mastectomy, subcutaneous
19316	Mastopexy
19318	Reduction mammoplasty
19324	Mammoplasty, augmentation; without prosthetic implant
19325	Mammoplasty, augmentation; with prosthetic implant



Code	Description
19328	Removal of intact mammary implant
19330	Removal of mammary implant material
19340	Immediate insertion of breast prosthesis following mastopexy, mastectomy, or in reconstruction
19342	Delayed insertion of breast prosthesis following mastopexy, mastectomy, or in reconstruction
19350	Nipple/areola reconstruction
19357	Breast reconstruction, immediate or delayed, with tissue expander, including subsequent expansion
19366	Breast reconstruction with other technique
19370	Open periprosthetic capsulotomy, breast
19371	Periprosthetic capsulectomy, breast
19380	Revision of reconstructed breast
HCPCS	
L8600	Implantable breast prosthesis, silicone or equal
S2067	Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
S2068	Breast reconstruction with deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

When specific definitions are not present in a member's plan, the following definition of terms will be applied:



American Society of Anesthesiologists (ASA) Score:

ASA 1 A normal healthy patient.

ASA 2 A patient with mild systemic disease.

ASA 3 A patient with severe systemic disease.

ASA 4 A patient with severe systemic disease that is a constant threat to life.

ASA 5 A moribund patient who is not expected to survive

Cosmetic: Cosmetic services are those which are primarily intended to preserve or improve appearance. Cosmetic surgery is performed to reshape structures of the body in order to improve the patient's appearance or self-esteem.

New York Heart Association (NYHA) Classification:

Class I No symptoms and no limitation in ordinary physical activity, eg, shortness of breath when walking, climbing stairs etc.

Class II Mild symptoms (mild shortness of breath and/or angina) and slight limitation during ordinary activity.

Class III Marked limitation in activity due to symptoms, even during less-than-ordinary activity, eg, walking short distances (20–100 m). Comfortable only at rest.

Class IV Severe limitations. Experiences symptoms even while at rest. Mostly bedbound patients

Physical functional impairment: A limitation from normal (or baseline level) of physical functioning that may include, but is not limited to, problems with ambulation, mobilization, communication, respiration, eating, swallowing, vision, facial expression, skin integrity, distortion of nearby body parts or obstruction of an orifice. The physical functional impairment can be due to structure, congenital deformity, pain, or other causes. Physical functional impairment excludes social, emotional and psychological impairments or potential impairments.

Reconstructive surgery: Refers to surgeries performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function

State Laws on Breast Reconstruction Surgery after Mastectomy

- State of Alaska mandate for coverage for reconstructive surgery following mastectomy



- Source URL: http://www.legis.state.ak.us/basis/folioproxy.asp?url=http://wwwjnu01.legis.state.ak.us/cgi-bin/folioisa.dll/stattx05/query=*/doc/{t9629} Accessed May 2018.
- State of Washington mandate for coverage for reconstructive surgery following mastectomy
 - Source URL: <http://apps.leg.wa.gov/RCW/default.aspx?cite=48.46.280> Accessed May 2018.

Description

This policy describes different types of reconstructive breast surgery and establishes criteria for the explantation (removal) of breast implants based on whether the original implant was cosmetic or reconstructive in nature. Implants may be either silicone gel-filled or saline-filled.

Reconstructive breast surgery is defined as those surgical procedures designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. The most common indication for reconstructive breast surgery is a prior mastectomy. Benefits for reconstructive breast surgery in these patients are mandated by federal law, and also in many states. In contrast, cosmetic breast surgery is defined as surgery designed to alter or enhance the appearance of a breast that has not undergone surgery, accidental injury, or trauma

Local complications of breast implants are frequent and may require removal of the implant. Contracture is the most common local complication of breast implants.

Contractures have been graded according to the Baker Classification as follows:

- Grade I: Augmented breast feels as soft as a normal breast
- Grade II: Breast is less soft and the implant can be palpated but is not visible
- Grade III: Breast is firm, palpable, and the implant (or its distortion) is visible
- Grade IV: Breast is hard, painful, cold, tender, and distorted

Other types of reconstruction include nipple/areola reconstruction, nipple tattooing, and/or the use of autologous tissue, such as a transverse rectus abdominis myocutaneous flap (TRAM procedure) or a latissimus dorsi flap. In addition, augmentation, mastopexy, or reduction mammoplasty on the contralateral breast may be performed to achieve symmetry with the reconstructed breast.



Additional Information

Reconstructive breast surgery is considered medically necessary after a medically necessary mastectomy or after accidental trauma or injury. The most common type of reconstruction is insertion of a breast implant, either a silicone gel-filled or saline-filled prosthesis. The breast may also be reconstructed using autologous tissues, such as a free flap, a latissimus dorsi flap, or more commonly using a transverse rectus abdominis flap (TRAM procedure). Nipple areola reconstruction or nipple tattooing may also be considered reconstructive breast surgery. Since the purpose of reconstructive breast surgery is to restore the normal appearance of the breast, on some occasions, procedures are performed on the contralateral, normal breast in order to achieve symmetry, such as mastopexy and reduction mammoplasty or augmentation. These procedures fall into the category of reconstructive breast surgery only when performed in conjunction with a contralateral mastectomy or partial mastectomy for disease, injury, or trauma. Except for medically necessary reduction mammoplasty, these procedures are generally considered not medically necessary in other circumstances.

Complications of breast implants are common and may require explantation of the implant.¹ Determining the medical necessity of explantation requires documentation of the type of implant and its original indication; ie, whether reconstructive or cosmetic.

Rupture of the breast implant may be difficult to document, but physical exam, mammography, ultrasonography, or MRI have been used. There is no consensus on which method affords the best sensitivity and specificity.²⁻⁵ Although it has been suggested that older implants are associated with a higher incidence of rupture, there is no consensus that screening implants for rupture is warranted. Specifically, in the hearings on breast implants by the U.S. Food and Drug Administration (FDA) held in 1992, the FDA did not recommend screening for asymptomatic ruptures. Instead, work-up for a potential rupture is typically initiated at the onset of local symptoms, such as sudden change in the size or consistency of an implant, or the development of local pain.

Contracture is a more subjective finding, which is graded according to the Baker Classification.⁶ Baker Classification ranges from Grade I, describing a normal implant, to Grade IV, which describes an implant that is hard, cold, painful, tender, and distorted.

Potential systemic complications of implants, most prominently various connective tissue diseases or chronic fatigue syndrome, have been hotly debated for the past five years. In particular, it has been hypothesized that leakage of silicone, due either to an implant rupture or to “bleeding” of silicone through an intact capsule, may incite an autoimmune response with the



development of systemic symptoms. However, to date, large epidemiologic studies have not demonstrated that women with breast implants are over-represented among all those with connective tissue disease.⁸⁻¹¹ In addition, there are inadequate empiric studies to demonstrate that removal of breast implants is associated with resolution of systemic symptoms.

Patients with cosmetic implants may develop breast cancer. While lumpectomy can be accomplished without removal of the implant, in general, explantation as an adjunct to surgical treatment for breast cancer would be considered medically necessary. However, explantation may not be necessary in patients who are undergoing only chemotherapy or radiation therapy for breast cancer.¹²

Once an implant has been removed, patients who originally underwent reconstructive implantation are candidates for additional reconstructive breast surgery, either insertion of another breast implant or for autologous reconstruction of the breast as described above. Patients who originally underwent implantation of a cosmetic breast implant are not candidates for additional reconstructive breast surgery after explantation.¹³

In 2009, Kreymerman and colleagues reviewed their experience with using breast magnetic resonance imaging to evaluate breast implant integrity and to offer a decision tree to assist physicians in managing these patients. Data were available for 81 patients with 146 implants placed either unilaterally or bilaterally for either cosmesis or breast reconstruction. The chief complaint for a majority of patients (n = 24) was breast pain. Thirty-two patients were found to have 44 ruptured implants, the majority of whom were found to have either contracture (n = 7) or negative findings (n = 7) on physician examination. The likelihood of rupture increased with number of years in place. The number of years in place was available for 120 implants; the median was 18 years (range 1-45years); 98% of implants were intact at five years; 94% at 10 years; and 59% at more than 20 years. When a patient presents for a possible implant rupture, the initial concern is to rule out malignancy but clinical and radiologic findings are often convoluted and complicated. A management algorithm may be useful to help determine which imaging modality is appropriate and when to use MRI in the implant evaluation process.¹⁴

In 2011, Cassileth and colleagues acknowledged that the current standard of care for breast implant reconstruction after mastectomy is 2-stage reconstruction with placement of tissue expanders followed by implants. However, the immediate use of implants at the time of mastectomy, which eliminates the need for a second operative procedure, has been sparsely reported and is not yet accepted as the standard of care. They published a study describing a 1-stage immediate implant reconstruction technique and evaluated its risks.¹⁵

Between 2005 and 2010, immediate implant reconstruction was performed in 43 sequential patients on a total of 78 breasts. Permanent silicone implants were placed at the time of



mastectomy with the assistance of acellular dermal matrix (ADM). Follow-up was for an average of 575 days. Implant sizes varied widely from 175 to 800 mL. In order to create the correct breast shape and implant placement, specific techniques of acellular dermal matrix placement in the reconstruction were critically important. Aesthetic evaluation of the patients was performed, evaluating pre- and postoperative photos by 20 evaluators. Pictures were rated according to a 4-point Harris breast scale. A 2-sided paired test was then used to compare the rating scores.

Cassileth and colleagues reported complication rates as follows: seroma occurred in 6.4% of breasts; infection resolving with antibiotics occurred in 2.6%; infection requiring implant removal occurred in 3.8%; and hematoma occurred in 1.3%. Neither preoperative breast size nor implant size correlated to an increased risk of complications. Complication rate increased with age. The average score for the preoperative images was 2.1, whereas the postoperative average was 2.4. This represented a statistically significant improvement above the baseline (preoperative) breasts with a $P < 0.001$, according to a 2-sided paired test.

They concluded that with complication rates similar to previously reported tissue expander reconstructions, immediate implant reconstruction is a viable alternative to 2-stage expander reconstruction, presenting many advantages over expander reconstruction while offering the same risk profile and eliminating the additional risks, costs, and discomfort of a second procedure. Additionally, they stated that aesthetic results were highly satisfactory according to patients themselves and based on evaluation by independent observers.

Medicare National Coverage

The Medicare NCD states that "Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason. Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage)."¹⁷

Regulatory Status

U.S. Food and Drug Administration (FDA). Regulatory history of breast implants in the U.S.

Source URL:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064461.htm>, accessed May 2018.



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19. BlueCross BlueShield Association (BCBSA). Medical Policy Reference Manual, Reconstructive Breast Surgery/Management of Breast Implants – Archived. Policy No. 7.01.22, 2012

History

Date	Comments
02/97	New Policy. Add to Surgery section.
06/25/98	Replace Policy. Reviewed with changes; discussion of reconstructive breast surgery, revised indications for removal of breast implants.
12/07/99	Replace Policy. Policy description revised.
12/10/02	Replace Policy. Policy reviewed without literature review; new review date only
10/16/03	Replace Policy. Policy reviewed by consensus without literature review; new review date only.
02/06/06	Disclaimer and Scope Update
06/09/06	Codes updated. No other changes.
07/10/07	Policy renumbered. Replaces BC.7.01.22. Policy updated with literature review; references added. Policy statement revised to indicate medical necessity for reconstructive surgery as a result of mastectomy or trauma, and explantation of implants as medically necessary if the original surgery met medically necessary criteria; explantation as not medically necessary under indicated circumstances; and as a contract exclusion based upon cosmetic purposes. Benefit Application section updated with definitions for cosmetic, physical functional impairment and reconstructive surgery.
08/24/07	Cross Reference Update. No other changes.
11/13/07	Cross Reference Update. No other changes.
05/13/08	Cross Reference Update. No other changes.
08/12/08	Policy updated with literature search. Policy statement updated to include "or other malignancies involving the breast" under the reconstructive and cosmetic purposes criteria. Under Cosmetic Purposes "irrespective of the existence of any medical necessity criteria described in the section devoted to explantation of implants placed for reconstructive purposes above" was added to the last statement. Codes added, effective 10/1/08.
06/09/09	Replace Policy. Replace Policy. Policy updated with literature search. No change to policy statements. Codes added.
05/11/10	Replace Policy. Policy updated with literature search. No change to policy statements.



Date	Comments
11/09/10	Replace Policy. Policy statement revised to allow lumpectomies, previously not addressed, as a medically necessary indication for reconstructive breast surgery.
09/15/11	Replace Policy. Policy updated with literature search. Reference added. No change to the policy statement. Related Policies updated; 10.01.514 added.
03/23/12	Replace Policy – Policy updated with literature search. No change to the policy statement.
04/16/12	Related Policies updated: 7.01.09 removed as this policy has been archived.
03/08/13	Replace policy. Policy updated with literature search. No change to the policy statement. Reference 15 added.
05/02/14	Annual review. Moved definition of terms from Benefit Application to Policy Guidelines section. Added links to AK & WA state laws on breast reconstruction. A literature search through March 2014 did not prompt any changes to the rationale section. No new references added. Minor edits for readability. Policy statement unchanged.
10/13/14	Interim Review. Added clarifying policy statements to indicate the services are considered cosmetic when medical necessity criteria are not met.
06/17/15	Annual Review. Policy statements unchanged. Informational codes removed (not reviewed); ICD-9 diagnosis codes and procedure codes also removed as they are not used in adjudication.
12/15/15	Update Related Policies. Remove 7.01.129 as it is archived.
02/09/16	Annual Review. Policy updated with literature search; references 5, 17-18 added. Policy statement unchanged.
03/01/17	Annual Review, approved February 14, 2017. Policy updated with literature search. Policy moved into new format; no change to policy statements.
03/24/17	Minor formatting update.
06/01/17	Interim Review, approved May 23, 2017. Policy section updated; procedures in this policy are considered not medically necessary when criteria in this policy are not met. Clarification and simplification of coverage statements made. Change from a medical policy to a benefit coverage guideline.
08/18/17	Coding update, added CPT code 11921.
11/01/17	Interim Review, approved October 19, 2017. Added indications to medical necessity criteria: reduce risk of breast cancer occurrence, and treat disease (severe fibrocystic disease unresponsive to medical therapy).
06/01/18	Annual Review, approved May 3, 2018. Policy reviewed with literature search. No references added. Policy statement unchanged. Added HCPCS codes S2067 and S2068.
06/19/18	Added Site of Service information to the policy.
09/07/18	Coding update, added CPT codes 11922, 11960, 11970, 11971, 19303, 19304, 19324,



Date	Comments
	and 19325.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.



Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified sign language interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

አማርኛ (Amharic):

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀዳሾች ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፋፈል እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

العربية (Arabic):

يحتوي هذا الإشعار على معلومات هامة. قد يحتوي هذا الإشعار على معلومات مهمة بخصوص طلبك أو التغطية التي تزيد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تواريخ مهمة في هذا الإشعار. وقد تحتاج لاتخاذ إجراء في تاريخ معينه للحفاظ على تغطيتك الصحية أو المساعدة في دفع التكاليف. يحق لك الحصول على هذه المعلومات والمساعدة بلغتك دون تكبد أية تكلفة. اتصل بـ 800-722-1471 (TTY: 800-842-5357)

中文 (Chinese):

本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或者費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Oromoo (Cushite):

Beeksisni kun odeeffannoo barbaachisaa qaba. Beeksisti kun sagantaa yookan karaa Premera Blue Cross tiin tajaajila keessan ilaalchisee odeeffannoo barbaachisaa qabaachuu danda'a. Guyyaawwan murteessaa ta'an beeksisa kana keessatti ilaalaa. Tarii kaffaltiidhaan deeggaramuuf yookan tajaajila fayyaa keessaniif guyyaa dhumaa irratti wanti raawwattan jiraachuu danda'a. Kaffaltii irraa bilisa haala ta'een afaan keessaniin odeeffannoo argachuu fi deeggarsa argachuuf mirga ni qabaattu. Lakkoofsa bilbilaa 800-722-1471 (TTY: 800-842-5357) tii bilbilaa.

Français (French):

Cet avis a d'importantes informations. Cet avis peut avoir d'importantes informations sur votre demande ou la couverture par l'intermédiaire de Premera Blue Cross. Le présent avis peut contenir des dates clés. Vous devez peut-être prendre des mesures par certains délais pour maintenir votre couverture de santé ou d'aide avec les coûts. Vous avez le droit d'obtenir cette information et de l'aide dans votre langue à aucun coût. Appelez le 800-722-1471 (TTY: 800-842-5357).

Kreyòl ayisyen (Creole):

Avi sila a gen Enfòmasyon Enpòtan ladann. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kèk aksyon avan sèten dat limit pou ka kenbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rele nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Diese Benachrichtigung enthält wichtige Informationen. Diese Benachrichtigung enthält unter Umständen wichtige Informationen bezüglich Ihres Antrags auf Krankenversicherungsschutz durch Premera Blue Cross. Suchen Sie nach eventuellen wichtigen Terminen in dieser Benachrichtigung. Sie könnten bis zu bestimmten Stichtagen handeln müssen, um Ihren Krankenversicherungsschutz oder Hilfe mit den Kosten zu behalten. Sie haben das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Rufen Sie an unter 800-722-1471 (TTY: 800-842-5357).

Hmoob (Hmong):

Tsawb ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb. Tej zaum tsawb ntawv tshaj xo no muaj cov ntshiab lus tseem ceeb txog koj daim ntawv thov kev pab los yog koj qhov kev pab cuam hnu ntawm Premera Blue Cross. Tej zaum muaj cov hnuv tseem ceeb uas sau rau hauv daim ntawv no. Tej zaum koj kuj yuav tau ua qee yam uas pab kom koj ua tsis pub dhau cov caij nyuog uas teev tseg rau hauv daim ntawv no mas koj thiaj yuav tau txais kev pab cuam kho mob los yog kev pab them tej nqi kho mob ntawd. Koj muaj cai kom lawv muab cov ntshiab lus no uas tau muab sau ua koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):

Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyonyo wenna coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salun-ato wenna tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a pagsasao nga awan ti bayadanyo. Tumawag iti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente. Chiama 800-722-1471 (TTY: 800-842-5357).

日本語 (Japanese):

この通知には重要な情報が含まれています。この通知には、Premera Blue Cross の申請または補償範囲に関する重要な情報が含まれている場合があります。この通知に記載されている可能性がある重要な日付をご確認ください。健康保険や有料サポートを維持するには、特定の期日までに行動を取らなければならない場合があります。ご希望の言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):

본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조치를 취해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 도움을 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357) 로 전화하십시오.

ລາວ (Lao):

ແຈ້ງການນີ້ມີຂໍ້ມູນສໍາຄັນ. ແຈ້ງການນີ້ອາດຈະມີຂໍ້ມູນສໍາຄັນກ່ຽວກັບຄໍາຮ້ອງສະໝັກ ຫຼື ຄວາມຄົມຄອງປະກັນໄພຂອງທ່ານຜ່ານ Premera Blue Cross. ອາດຈະມີວັນທີ່ສໍາຄັນໃນແຈ້ງການນີ້. ທ່ານອາດຈະຈຳເປັນຕ້ອງດໍາເນີນການຕາມກຳນົດ ເວລາສະເພາະເພື່ອຮັກສາຄວາມຄົມຄອງປະກັນສະພາບ ຫຼື ຄວາມຊ່ວຍເຫຼືອເວັ້ນເວົ້ອງຄ່າໃຊ້ຈ່າຍຂອງທ່ານໄດ້. ທ່ານມີສິດໄດ້ຮັບຂໍ້ມູນນີ້ ແລະ ຄວາມຊ່ວຍເຫຼືອເປັນພາສາຂອງທ່ານໂດຍບໍ່ເສຍຄ່າ. ໃຫ້ໃບທາ 800-722-1471 (TTY: 800-842-5357).

ភាសាខ្មែរ (Khmer):

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ឆ្លើយតបនឹងសំណួរ ឬប្រាកដន្នយុទ្ធសាស្ត្រ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដំណោះស្រាយសំណួររបស់អ្នកដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

ਪੰਜਾਬੀ (Punjabi):

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਰਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

فارسی (Farsi):

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

Polskie (Polish):

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

Română (Romanian):

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

Русский (Russian):

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Fa'asamoa (Samoan):

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือนี้ในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

Український (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).