

#LetHerDecide

BREAST CANCER PATIENT EQUITY ACT POLICY GUIDE

Establishing Medicare Coverage for Custom Breast Prostheses
116th Congress, S. 562/H.R. 1370 to 117th Congress, pending introduction

*For women striving to rebuild and return to activity
and quality of life after breast cancer.*



ISSUE SUMMARY

The Breast Cancer Patient Equity Act will allow Medicare to cover custom breast prosthesis as an eligible option for women post-mastectomy surgery. Currently, the options for breast replacement following mastectomy surgery are off-the-shelf breast prosthesis and surgical reconstruction. Not all women are candidates for surgery or would choose surgery if they had an option that would allow a better fit than what off-the-shelf prosthetics can provide.

While these options work for many women, there are some who would prefer a custom breast prosthesis, the missing option. The problem is Medicare doesn't cover custom breast prostheses. In fact, as we have researched—the breast is the only custom prosthetic body part that is not covered by Medicare. Legislation is needed for Medicare to include this as a covered benefit.

The goal of this bill is to make sure women have the choices they need when faced with making a decision for breast replacement after mastectomy surgery.

The Difference Between Surgical Reconstruction, Off-the-shelf Prostheses, and Custom Prostheses

Surgical Reconstruction	Off-the-Shelf Breast Prostheses	Custom Breast Prostheses
<ul style="list-style-type: none">• Not everyone is a good candidate• Requires multiple surgeries• Surgical procedures may include implants or may involve using tissue from another part of the body to create the breast. All new surgical procedure codes since 1998 have been allowed and have not required legislation to be covered by Medicare.	<p>Women are unique and come in all shapes and sizes. Off-the-shelf prostheses may not work the same for everyone.</p> <ul style="list-style-type: none">• Can shift• Symmetry isn't always possible• May not match skin tone• Requires a pocketed mastectomy bra 	<p>Certified mastectomy fitters can use a computer or tablet to scan a patient's chest wall to meet the exact shape of a patient, perfectly fitting her chest wall:</p> <ul style="list-style-type: none">• Minimizes shifting of the form• Gives patients symmetry• Matches skin tone 

Action Item

To establish custom breast prostheses as a Medicare-covered benefit, Congress must pass legislation.

- "Breast Cancer Patient Equity Act" will allow Medicare to establish coverage for this benefit.
- Women's Health and Cancer Rights Act of 1998 (WHCRA) allows for all surgical advancements to be covered since 1998; however, advancements in prosthetics have not been covered. Interpretation of prosthesis has only allowed for off-the-shelf.
- The breast is the only body part not allowed with a customized prosthetic replacement by Medicare.
- Billing code, L8035, and fee schedule were created in 1999.
- Medicare has deemed custom breast prosthesis as not medically necessary because it doesn't increase functionality. Eyes and ears are allowed a custom replacement even though they do not increase functionality.

One in eight women will be diagnosed with breast cancer in her lifetime. No one knows what choice they may need until they're in the situation.



MASTECTOMY SURGERY DATA

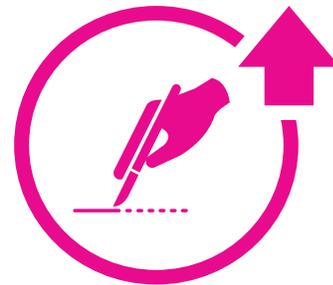
It is estimated there will be 281,550 women diagnosed with invasive breast cancer in the United States in 2021. Approximately 144,000 of those women will undergo mastectomy surgery. Below is information from CMS.

CMS Utilization Data

Sen. Grassley (R-IA), former Senate finance chairman, requested utilization data for mastectomy, surgical reconstruction, and off-the-shelf breast prosthetics for 2016-2018 from CMS. This data was provided from CMS based on Sen. Grassley's inquiry.

Total Mastectomies - Medicare Beneficiaries		
Year	Service Count	Cost*
2016	98,619	\$257,514,982
2017	98,806	\$209,819,202
2018	101,555	\$246,217,980

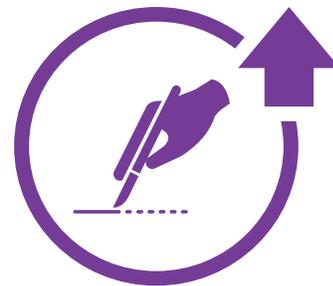
*Includes HCPCS codes: 19301, 19302, 19303, 19304, 19305, 19306, 19307



INCREASE IN PROCEDURES

Total Surgical Reconstruction Procedures - Medicare Beneficiaries		
Year	Service Count	Cost*
2016	9,066	\$38,484,218
2017	9,113	\$44,203,378
2018	9,560	\$52,128,570

Includes HCPCS codes: 19350, 19357, 19361, 19364, 19366, 19367



INCREASE IN PROCEDURES AND COST OVER THE LAST THREE YEARS

Total Off-the-Shelf Breast Prostheses Dispensed - Medicare Beneficiaries		
Year	Service Count	Cost*
2016	106,610	\$30,582,689
2017	98,483	\$29,115,586
2018	93,172	\$27,926,543

*Includes HCPCS codes: L8030, L8001, L8002



DECREASE IN COST AND UTILIZATION OVER THE LAST THREE YEARS

MASTECTOMY SURGERY DATA

Surgical Reconstruction or Custom Breast Prosthesis?



We know that surgical reconstruction can cost on average \$30,000 to \$40,000 depending on the woman.



These are just costs with the one billing code per procedure, not the cost of the entire procedure, which would include multiple billing codes.



Custom breast prosthesis is a non-surgical reconstruction option that will cost less than surgical reconstruction and will have fewer complications.

Benefits of Custom Breast Prostheses



No additional doctor visits once the surgery site is healed. Women are scanned and fitted for their prosthetics.



There is no risk of complications.



Custom breast prosthetics are considered DME and are subject to resupply every two years.

The Women's Health and Cancer Rights Act of 1998 requires U.S. health insurers and self-insured plans that cover mastectomy to also cover reconstruction and prostheses.



The billing code and fee schedule for custom breast prosthesis, L8035, was created in 1999, one year after the WHCRA.



All surgical procedures since 1998 have been allowed without need for legislation.



The breast is the only body part not allowed by Medicare as a custom replacement.

BREAST REPLACEMENT OPTIONS

Women who seek breast replacement after mastectomy deserve to have all the options available, recognizing that some women choose to go flat. The “good” and “best” options for breast replacement are covered by Medicare, but “better” is not. Stakeholders and patient advocacy groups are currently working to gain sponsors for the “Breast Cancer Patient Equity Act” to provide women with the “better” option. Let her decide what’s right for her.

	GOOD OPTION	BETTER OPTION	BEST OPTION
DESCRIPTION	Off-the-Shelf Prosthesis, L8030 Breast Prosthesis Without Adhesive	Custom Breast Prosthesis, L8035	Surgical Reconstruction
COVERED BY MEDICARE	✓	✗	✓
COST PER BREAST	\$315.48–\$420.63 (Based on 2021 CMS DMEPOS Fee Schedule)	\$3,291.75–\$4,388.99 (Based on 2021 CMS DMEPOS Fee Schedule)	\$5,000–\$15,000 (Initial surgery only)
REQUIRES ADDITIONAL PROCEDURES	✗	✗	✓ 2-4 additional surgeries
RISK OF COMPLICATIONS E.G., INFECTION	✗	✗	✓
RECOVERY TIME	None. Once mastectomy surgery site is healed, the breast prosthesis can be used.	None. Once mastectomy surgery site is healed, the custom breast prosthesis can be used.	Varies depending on procedure, multiple surgeries required, and lengthy recovery
TAILORED TO RESTORE THE PATIENT PROFILE	✗	✓	✓

Until faced with a breast cancer diagnosis, women don’t know what options they may need for their unique situation.

BILL TIMELINE

1998

[Women's Health and Cancer Rights Act of 1998](#) passed. Federal law requires coverage for all surgical reconstruction and prostheses, and treatment of physical complications of all stages of the mastectomy.

1999

Billing Code, L8035, and fee schedule created for Custom Breast Prosthesis

2012

S. 1217/H.R. 2233 Breast Cancer Patient Equity Act first introduced by Sen. Olympia Snowe (R-ME) and Rep. Mike Ross (D-AR).

2018

Nikki Jensen and Tom Powers meet with CMS Ombudsmen. Asked if CMS could make a regulatory change to their interpretation of the [Women's Health and Cancer Rights Act](#), to allow custom breast prostheses.

2018

S. 3687/H.R. 6980 Breast Cancer Patient Equity Act introduced in September 2018 near the end of the 115th Congress.

2019

S. 562/H.R. 1370 Breast Cancer Patient Equity Act reintroduced into 116th Congress.

2019

Sen. Grassley (R-IA) has a conversation with CMS in late 2019 to ask if they had regulatory authority to allow coverage for custom breast prosthesis and also requested the CMS utilization data for surgical procedures.

2020

Request for CBO score submitted by Senate Finance Committee staff.

2020

The state of Indiana passed a bill, [SB0239](#), to allow custom breast prosthesis as an eligible option for state employees. This legislation was found to be a no-cost bill.

2020

Pennsylvania passed a bill, [HB 1457](#), to allow custom breast prosthesis for patients who have had mastectomy surgery.

2020

CBO score received in late December, currently awaiting updated score following an update meeting with CBO representatives.

2021

We are currently working to reintroduce the legislation into the 117th Congress.