



AMERICAN SOCIETY OF
PLASTIC SURGEONS®



THE PLASTIC SURGERY
FOUNDATION®

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August 5, 2019

Kevin Olson, MD
Chair, Value-based Benefits Subcommittee
Health Evidence Review Commission
Oregon Health Authority
Salem, OR 97301

RE: **Biologic matrix for breast reconstruction**

Dear Chair Olson:

I am writing on behalf of the American Society of Plastic Surgeons (ASPS) regarding the Value-based Benefits Subcommittee's (VbBS) review of whether acellular dermal matrix (ADM) should be covered by the Oregon Health Plan (OHP). ASPS is the largest association of plastic surgeons in the world, representing more than 7,000 members and 93 percent of all board-certified plastic surgeons in the United States – including 88 board-certified plastic surgeons in Oregon. ASPS member surgeons perform nearly 400,000 breast implant related procedures annually nationwide, including many that utilize ADMs in post-mastectomy breast reconstruction. Our mission is to advance quality care for plastic surgery patients and promote public policy that protects patient safety.

Breast reconstruction in today's practice would not be possible without acellular dermal matrices, which have been used for nearly two decades in post-mastectomy procedures and become the standard of care. Of the approximately 102,000 breast reconstructions performed by ASPS member surgeons in 2018, about 62,000 (roughly 74%) utilized ADM.ⁱ With increasing frequency, surgeons are electing to use ADMs to assist with tissue expander or implant-based primary breast reconstruction.^{ii,iii} The use of ADMs allows for a one stage procedure as opposed to expander based reconstructions that require several inflations in clinic and a second operation to exchange the expander to a silicone implant.^{iv} The use of ADMs can also limit inflammatory changes believed to play a role in capsular contracture – a common complication of implant-based breast reconstruction^v – as well as decreased risk of all complications related to radiation.^{vi} Multiple authors have reported favorable outcome studies using ADMs,^{vii,viii,ix,x,xi,xii,xiii} and rapid early expansion has led to improved cosmetic outcomes.^{xiv,xv,xvi,xvii}

The introduction of human ADMs has provided surgeons with alternative means of obtaining sufficient vascularized soft tissue to cover the breast implant and provide appropriate support, thereby alleviating some complications. This process of covering the breast implant and providing support is consistent with the "basic function" of skin, as supported by the clinical evidence^{xviii,xix} and as defined in the final guidance *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use* (November 2017, corrected December 2017). Specifically, as part of that guidance, the Food and Drug Administration provided its rationale with respect to the homologous use of dermis by stating the following:

The basic functions of skin include covering, protecting the body from external force, and serving as a water-resistant barrier to pathogens or other damaging agents in the external environment. The dermis is the elastic connective tissue layer of the skin that covers, provides support and protects the body from mechanical stress.

Thus, by using skin to cover and support the implant, plastic surgeons are using it in the same basic function as within the human body, ensuring that it is used in a homologous manner. Therefore, the use of human ADMs for breast reconstruction is, by definition, a homologous use.

In recognition that breast reconstruction, including reconstruction using human ADMs, plays an essential role in both physical and psychological healing following mastectomy, federal law requires health insurers to cover for breast reconstruction.^{xx} States have enacted separate legislation^{xxi} to further clarify coverage, including Oregon's Chapter 163, signed by Governor Brown in 2017. Due to these state and federal mandates, the vast majority of insurance companies cover the procedure.^{xxii,xxiii,xxiv,xxv,xxvi,xxvii} However, if the OHA chooses not to cover human ADMs, private insurance companies in the state are likely to follow suit. Patient access to care would be limited and surgeons would not be able to provide patients with effective alternatives. Therefore, due to the current reliance on the use of ADMs for breast reconstructive surgery, it's imperative that these products remain available to all patients – regardless of income – and that ADMs for breast reconstruction are added to the breast cancer line for post-mastectomy reconstruction.

Oregon would be out of step with national standards if the state chose to stop coverage of ADMs. While the U.S. Food and Drug Administration (FDA) has not approved the use of ADMs in breast surgery, the FDA still permits the off-label use of ADMs. Surgeons who use ADMs "off-label" in breast reconstruction or other breast surgery are entirely within their discretion under in the practice of medicine, which is not regulated by the FDA. The FDA has confirmed that hospitals and facilities may continue to purchase ADMs and make them available to surgeons who wish to use them for breast surgery. To be clear, the FDA has not banned the use of ADMs.

ASPS believes that state governments should continue to encourage coverage of ADMs, as it has been the standard of care for over two decades. For the reasons outlined above, we urge the VbBS and the Health Evidence Review Commission to recommend that the OHP cover the use of ADMs in breast surgery. Thank you for your consideration of our comments. Please do not hesitate to contact Patrick Hermes, Director of Advocacy and Government Relations, at phermes@plasticsurgery.org or (847) 228-3331 with any questions or concerns.

Sincerely,

A handwritten signature in black ink that reads "Alan Matarasso, MD". The signature is written in a cursive, flowing style.

Alan Matarasso, MD, FACS
President, American Society of Plastic Surgeons

cc: Members, Value-based Benefits Subcommittee

- ⁱAmerican Society of Plastic Surgeons: Reconstructive Breast Surgery Statistics 2018. Available at <https://www.plasticsurgery.org/documents/News/Statistics/2018/plastic-surgery-statistics-report-2018.pdf>. Accessed 16 April 2019.
- ⁱⁱSbitany H, Sandeen SN, Amalfi AN, Davenport MS, Langstein HN. Acellular dermis-assisted prosthetic breast reconstruction versus complete submuscular coverage: a head-to-head comparison of outcomes. *Plast Reconstr Surg*. Dec 2009;124(6):1735-40.
- ⁱⁱⁱSpear SL, Parikh PM, Reisin E, Menon NG. Acellular dermis-assisted breast reconstruction. *Aesthetic Plast Surg*. May 2008;32(3):418-25.
- ^{iv}Kiernan T, Martin L (2013) Use of Acellular Dermal Matrix is Comparable to Expander Based Breast Reconstructions for Post Operative Physiotherapy Requirements. *Surgery Curr Res* 3:136. doi: 10.4172/2161-1076.1000136. <http://omicsonline.org/use-of-acellular-dermal-matrix-is-comparable-to-expander-based-breast-reconstructions-for-post-operative-physiotherapy-requirements-2161-1076.1000136.php?aid=15706>
- ^vLeong M, Basu CB, Hicks MJ. Further Evidence that Human Acellular Dermal Matrix Decreases Inflammatory Markers of Capsule Formation in Implant-Based Breast Reconstruction. *Aesthet Surg J*. 2015 Jan;35(1):40-7.
- ^{vi}Seth AK, Hirsch EM, Fine NA, Kim JY. Utility of acellular dermis-assisted breast reconstruction in the setting of radiation: a comparative analysis. *Plast Reconstr Surg*. 2012 Oct;130(4):750-8.
- ^{vii}Breuing KH, Warren SM. Immediate bilateral breast reconstruction with implants and inferolateral AlloDerm slings. *Ann Plast Surg*. Sep 2005;55(3):232-9.
- ^{viii}Bindingavele V, Gaon M, Ota KS, Kulber DA, Lee DJ. Use of acellular cadaveric dermis and tissue expansion in postmastectomy breast reconstruction. *J Plast Reconstr Aesthet Surg*. 2007;60(11):1214-8.
- ^{ix}Salzberg CA. Nonexpansive immediate breast reconstruction using human acellular tissue matrix graft (AlloDerm). *Ann Plast Surg*. Jul 2006;57(1):1-5.
- ^xSpear SL, Parikh PM, Reisin E, Menon NG. Acellular dermis-assisted breast reconstruction. *Aesthetic Plast Surg*. May 2008;32(3):418-25.
- ^{xi}Topol BM, Dalton EF, Ponn T, Campbell CJ. Immediate single-stage breast reconstruction using implants and human acellular dermal tissue matrix with adjustment of the lower pole of the breast to reduce unwanted lift. *Ann Plast Surg*. 2008 Nov;61(5):494-9. *Ann Plast Surg*. 2008 Nov;61(5):494-9. doi: 10.1097/SAP.0b013e31816d82d9.
- ^{xii}Preminger BA, McCarthy CM, Hu QY, Mehrara BJ, Disa JJ. The influence of AlloDerm on expander dynamics and complications in the setting of immediate tissue expander/implant reconstruction: a matched-cohort study. *Ann Plast Surg*. May 2008;60(5):510-3.
- ^{xiii}Sbitany H, Sandeen SN, Amalfi AN, Davenport MS, Langstein HN. Acellular dermis-assisted prosthetic breast reconstruction versus complete submuscular coverage: a head-to-head comparison of outcomes. *Plast Reconstr Surg*. Dec 2009;124(6):1735-40.
- ^{xiv}Spear SL, Parikh PM, Reisin E, Menon NG. Acellular dermis-assisted breast reconstruction. *Aesthetic Plast Surg*. May 2008;32(3):418-25
- ^{xv}Breuing KH, Warren SM. Immediate bilateral breast reconstruction with implants and inferolateral AlloDerm slings. *Ann Plast Surg*. Sep 2005;55(3):232-9.
- ^{xvi}Salzberg CA. Nonexpansive immediate breast reconstruction using human acellular tissue matrix graft (AlloDerm). *Ann Plast Surg*. Jul 2006;57(1):1-5.
- ^{xvii}Bindingavele V, Gaon M, Ota KS, Kulber DA, Lee DJ. Use of acellular cadaveric dermis and tissue expansion in postmastectomy breast reconstruction. *J Plast Reconstr Aesthet Surg*. 2007;60(11):1214-8.
- ^{xviii}The dermis contains tough connective tissue. <http://www.webmd.com/skin-problems-and-treatments/picture-of-the-skin>
- ^{xix}The dermis is the vascular area of connective tissue of skin. *Illustrated Dictionary of Podiatry and Foot Science* by Jean Mooney © 2009 Elsevier Limited. All rights reserved.
- ^{xx}Women's Health and Cancer Rights Act of 1998, PL 105-277.
- ^{xxi}<http://www.plasticsurgery.org/reconstructive-procedures/breast-reconstruction/breast-reconstruction-resources/state-laws-on-breast-reconstruction.html>

^{xxii}“Breast Implants and tissue expanders post mastectomy with or without skin substitutes, approved by the FDA, including but not limited to: Alloderm, Allomax or FlexHD are a covered benefit.”
https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/Medical%20Policies/Medical%20Policies/BreastReconstruction_CD.pdf

^{xxiii}Following Medically Necessary removal of all or part of a breast, we cover reconstruction of the breast, surgery and reconstruction of the other breast to produce a symmetrical appearance, and treatment of physical complications, including lymphedemas.
http://info.kaiserpermanente.org/info_assets/child_health_plan/pdfs/membership_agreement_eoc.pdf.

^{xxiv}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.
<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=64&ncdver=1&bc=AgAAQAAAAAAAA&>

^{xxv} The use of the following acellular dermal matrices are considered medically necessary for breast reconstruction: Alloderm (LifeCell Corp., Branchburg, NJ), Alloderm-RTU (LifeCell Corp., Branchburg, NJ), FlexHD (Musculoskeletal Transplant Foundation/Ethicon, Inc., Somerville, NJ), DermaMatrix (Musculoskeletal Transplant Foundation/Synthes CMF, West Chester, PA), AlloMax (formerly NeoForm) (Davol, Inc., Warwick, RI), Strattice (LifeCell Corp., Branchburg, NJ) and SurgiMend (TEI Biosciences, Boston, MA).
http://www.aetna.com/cpb/medical/data/100_199/0185.html

^{xxvi}Reconstructive surgery refers to surgical procedures and other techniques, undertaken in the context of breast cancer, to rebuild breast contour and, when necessary, reconstitute the areola and nipple. <https://www.caresource.com/documents/breast-reconstruction-surgery-following-mastectomy/>

^{xxvii}Restoration of a normal breast form through breast reconstruction is performed for patients undergoing mastectomy or lumpectomy. The manner of breast reconstruction is an individualized decision between the patient and their physician.
https://my.cigna.com/teamsite/health/provider/medical/procedural/coverage_positions/medical/mm_0178_coverage_positioncriteria_breast_reconstruction_follow_mast_lump.pdf