Breast Reconstruction

Humana

Medicaid Medical Coverage Policy

Original Effective Date: 01/01/2025
Effective Date: Click or tap to enter a date.
Review Date: 10/01/2024
Policy Number: HUM-2030-000
Line of Business: Medicaid
State: OH

Table of Contents

Scope

This policy applies to all physical and behavioral health prior authorization requests received by Humana Healthy Horizons™ in Ohio.

Policy

Humana Healthy Horizons™ in Ohio uses established criteria guidelines to make medical necessity decisions and follows the below procedure. Decisions are made on a case-by-case basis, utilizing the information provided about the member's health status and an assessment of the local delivery system. Emergent services do not require a referral or preauthorization.

The Plan covers all benefits and services required in Ohio Administrative Code (OAC) chapter 5160 in the amount, duration, and scope for the same services furnished to members under the fee-for-service (FFS) Medicaid.

When the plan receives a request for a primary code that requires prior authorization and the primary code is denied for lack of medical necessity, any related secondary codes submitted on the authorization request will be denied based on lack of medical necessity. When a primary code is approved, related secondary codes requiring prior authorization will be reviewed individually for medically necessity determinations.

Please see Ohio Medicaid Prior Authorization and Notification List for a list of CPT and HCPCS codes that require prior authorization.

Humana Healthy Horizons™ in Ohio will review requested non-MCO covered codes and services as required for Early and Periodic Screening, Diagnostic and Treatment (EPSDT) for medical necessity to ensure children and adolescents receive appropriate and preventative, dental, mental health, developmental and specialty services.

Humana Healthy Horizons™ in Ohio does not cover services, items or devices that have not been approved by the Food and Drug Administration (FDA). Other factors affecting reimbursement supersede this policy. These factors include but are not limited to Federal and/or State statutes and regulations, the State Plan, the MCE Manual, physician or other provider contracts, the beneficiaries' benefit coverage documents, and/or other reimbursement, medical or drug policies.

Providers may submit authorization request(s) through the provider portal. A provider may request an urgent prior authorization in situations where the provider considers a delay in providing services, supplies or prescription drugs requiring prior authorization to be detrimental to the health of the member. The absence of authorization and/or notification prior to the date of a service could result in financial penalties for the practice and reduced benefits for the member, based on the healthcare provider's contract and the member's Certificate of Coverage. Services or medications provided without preauthorization may be subject to retrospective medical necessity review. We recommend individual practitioners making specific requests for services or medications verify benefits and preauthorization requirements with Humana prior to providing services.

Medical necessity documentation and rationale must be submitted with the prior authorization request. Providers may access physical and behavioral clinical coverage policies and medical necessity criteria at the below links.

Physical Health:
www.humana.com/provider/medical-resources/ohio-medicaid/physical-health-clinical-coverage-policies

Behavioral Health:
www.humana.com/provider/medical-resources/ohio-medicaid/behavioral-health-clinical-coverage-policies

Members may request a copy of the medical necessity criteria by calling member services at 877-856-5702 (TTY:711), Monday-Friday, 7AM to 8PM EST.

Providers may request a copy of the medical necessity criteria by calling provider services at 877-856-5707 (TTY:711), Monday-Friday, 7AM to 8PM EST or emailing the request to ODMCDUM@humana.com.

Description

Breast reconstruction surgery rebuilds a breast's shape following a mastectomy or trauma and may be performed immediately, be delayed or be completed in stages. The surgeon forms a breast mound by using

autologous tissue taken from other areas of an individual's body (abdomen, back, buttocks, thighs), placing an artificial implant, or using a tissue expander if necessary, depending on the final desired breast size.

Breast implants are silicone sacs filled with saline (salt water) or silicone gel. The development of scar tissue around a breast implant may necessitate a capsulotomy (surgical opening and release of scar tissue) or capsulectomy (surgical removal of the entire capsule containing the breast implant surrounded by abnormally thick, hardened tissue).

The type of reconstruction recommended (autologous tissue or implants) depends on an individual's age, body composition, general health status, method of planned cancer treatment or other reason for reconstruction.

Breast reconstruction may require multiple surgeries, such as:

- Nipple and areola reconstruction and tattoo pigmentation
- Revision surgery involving the breast and/or donor site
- Surgery on the opposite breast to correct asymmetry

Autologous fat graft, autologous fat transplant (lipoinjection or lipomodeling) via excision lipectomy, suction lipectomy or liposuction involves the removal of adipose tissue (fat) from another area of the body (abdomen, buttocks, thighs, etc.) which is then transferred to the breast(s) during initial reconstructive surgery.

Chest wall reconstruction with flat closure is a reconstructive surgery option for an individual who is not a candidate for or has chosen not to undergo breast reconstruction with autologous tissue or an implant. The procedure may be done at the time of mastectomy or may be delayed and involves the removal and tightening of extra tissue to create a flat chest wall contour.

Oncoplastic surgery refers to integrating tumor removal and immediate breast reconstruction into the initial surgical procedure. Generally, the surgical oncologist removes the tumor, and the plastic surgeon immediately begins reconstruction.

Examples of breast reconstruction techniques (also called flaps) that use **autologous tissue** include, but may not be limited to:

- **Deep circumflex iliac artery (DCIA)/Ruben's free flap**
- **Deep inferior epigastric perforator (DIEP)**
- **Gluteal artery perforator (GAP)**
- **Latissimus dorsi (LD)**
- **Profunda artery perforator (PAP)**
- **Superficial inferior epigastric artery (SIEA)**
- **Thoracodorsal artery perforator (TAP or TDAP)**
- **Transverse gracilis (TUG)**
- **Transverse rectus abdominus muscle (TRAM)**

The flap description and name are related to the muscles or blood-supplying vessels used and involve surgically removing tissue, typically fat, skin and muscle, from one area of the body and reattaching it to the chest. Pedicled flaps are positioned with the corresponding vascular origin intact while free flaps require microsurgery to connect the tiny blood vessels needed to supply the transplanted tissue.

Other technologies used or being studied for use in conjunction with breast reconstruction procedures include, but may not be limited to:

Intraoperative tissue perfusion assessment methods have been developed to assist surgeons in determining the viability of tissue-transfer circulation during micro, plastic and reconstructive surgery. The suggested benefits involve reducing tissue necrosis (death) and decreasing the need for a second corrective procedure.

- One method, **indocyanine green (ICG) fluorescence angiography**, also referred to as **fluorescent angiography** or **spy angiography**, involves intravenous injection of ICG dye during surgery. The ICG dye binds to proteins in the blood and emits light when stimulated by a low energy laser or near infrared light. The emitted light facilitates visualization of blood flow through the operative tissue, thus determining perfusion and viability. Examples of US Food & Drug Administration (FDA)-approved imaging devices or systems used to capture fluorescent images for this purpose include, but may not be limited to, Explorer Air II, FloNavi, Fluobeam LM, Infrared 800 with Flow 800 option, Leica FL 800, PDE-Gen3, SPY fluorescent imaging systems (SPY Elite, SPY-PHI) and EleVision IR Platform (including the VS3-Iridium System).

- **Multispectral imaging** involves taking several photographs under many different wavelengths of light in order to ascertain tissue oxygenation measurements for selected tissue regions. The camera determines the approximate values of oxygen saturation (StO_2), relative oxyhemoglobin (HbO_2) and deoxyhemoglobin levels (Hgb) in superficial tissues and displays a two-dimensional color-coded image of tissue oxygenation. The $Snapshot_{NIR}$ is an example of an FDA-approved multispectral imaging device.

- **Near-infrared spectroscopy (NIRS)** technology is being explored to assess circulation or perfusion in tissue samples. While near-infrared light is scattered in human tissue, some structures, such as hemoglobin, absorb it. NIRS technology uses reflected light to determine the ratio of oxyhemoglobin ($HgbO_2$) and deoxyhemoglobin (Hgb) to permit real-time measurement of tissue oxygen saturation (StO_2) within the selected tissue. The T.Ox and its newer modifications the Intra.Ox and Intra.Ox 2.0 are examples of FDA-approved devices that measure tissue oximetry.

- **Visible light spectroscopy (VLS)** uses a sensor with a white LED light to illuminate target tissue and a light detector that captures reflected light. The sensor is connected to a software-based system using a range of reflected light values from visible light wavelengths. The single-use surface sensors are intended to measure percent tissue oxygen saturation (StO_2) on any skin surface to purportedly assist with monitoring skin flap perfusion after microvascular reconstructive procedures. The T-Stat is an example of an FDA-cleared device.

Lymphatic microvascular surgery is proposed in conjunction with reconstructive surgery to prevent the development of lymphedema that may occur following a mastectomy with axillary lymph node dissection.

Lymphatic microsurgical preventive healing approach (LYMPHA) procedures include, but may not be limited to, lymphaticovenous anastomosis (LVA), lymphaticovenous bypass (LVB) or lymph node transfer. **(Refer to Coverage Limitations section)**

Procedures

1. The Plan uses the following hierarchy of guidelines to review for medical necessity:

   1.1 Federal or state regulation, including medical criteria published in the Ohio Administrative Code, Chapter 5160.

   1.2 Nationally accepted evidence based clinical guidelines: MCG (formerly Milliman Care Guidelines), American Society of Addiction Medicine (ASAM) Level of Care Adolescent Guidelines and American Society of Addiction Medicine (ASAM) Patient Placement Criteria (ASAM Admission Guidelines).

   1.3 Humana Healthy Horizons™ in Ohio clinical policies

   1.4 In the case of no guidance from above, additional information that the clinical reviewer will consider, when available, includes;

      1.4.1 Clinical practice guidelines and reports from peer reviewed medical literature, from which a higher level of evidence and study quality is more strongly considered in determinations;

      1.4.2 Professional standards for safety and effectiveness recognized in the US for diagnosis, care, or treatment;

      1.4.3 Medical association publications;

      1.4.4 Government-funded or independent entities that assess and report on clinical care; Decision and technology such as Agency for Healthcare Research and Quality (AHRQ), Hayes Technology Assessment, Up-To-Date, Cochrane Reviews, National Institute for Health and Care Excellence (NICE), etc.;

      1.4.5 Published expert opinions;

      1.4.6 Opinion of health professionals in the area of specialty involved;

      1.4.7 Opinion of attending provider;

   1.5 Dental: DentaQuest coverage guidelines and policies
   Dental Coverage - Humana Healthy Horizons in Ohio | Humana

   1.6 Vision: EyeMed coverage guidelines and policies
   Vision Care - Humana Healthy Horizons - Ohio Medicaid | Humana

Coverage Determination

Requests for autologous fat graft, autologous fat transplant (lipoinjection or lipomodeling) via excision lipectomy, suction lipectomy or liposuction as stand-alone procedures (not in conjunction with other breast reconstruction techniques) require review by a medical director.

Humana members may be eligible under the Plan for **breast reconstruction** following, or in conjunction with:

- A medically necessary mastectomy or lumpectomy (regardless of the date of the mastectomy or lumpectomy); **OR**
- A medically necessary prophylactic mastectomy; **OR**
- Trauma (within 12 months postinjury);

AND for surgical procedures including, but may not be limited to:

- Chest wall reconstruction with flat closure; **OR**
- Free or pedicled flap (DIEP, GAP [IGAP, SGAP], LD, PAP, Ruben's, SIEA, TAP, TDAP, TUG, TRAM, or others); **OR**
- Insertion of breast implants; **OR**
- Insertion of tissue expanders; **OR**
- Mastopexy (including prior to a nipple-sparing mastectomy); **OR**
- Nipple reconstruction and repigmentation (tattoo); **OR**
- Reduction mammaplasty only if necessary to preserve nipple viability prior to a nipple-sparing mastectomy **(medical director review required)**

Correction of Breast Asymmetry
Breast reconstruction surgery to correct breast asymmetry is considered cosmetic except for:

- A medically necessary lumpectomy that results in a deformity; **OR**
- A medically necessary mastectomy; **OR**
- Complications with or removal of breast implant(s) following a medically necessary mastectomy; **OR**

- Trauma (within 12 months postinjury)

Further modification related to achieving symmetry is subject to medical necessity and does not include procedures to fill the flap donor site.

Capsulectomy, Capsulotomy, Breast Implant Removal

Humana members may be eligible under the Plan for **capsulectomy, capsulotomy or breast implant removal** when the following criteria are met:

- Breast implants were placed in conjunction with a medically necessary (noncosmetic) surgery;

  AND any of the following

  - Capsular contracture (Baker grade III or IV); **OR**
  - Extrusion; **OR**
  - Rupture of saline filled, silicone gel or alternative breast implant (confirmed by imaging such as magnetic resonance imaging [MRI] or ultrasound); **OR**
  - Implant infection refractory to medical management (eg, antibiotics) unless contraindicated;

    AND either:

    - Infection confirmed by microbiological analysis of peri-implant fluid aspirate; **OR**
    - Presence of symptoms such as fever, redness, elevated white blood cell (WBC) count

Breast Implant Associated Anaplastic Large Cell Lymphoma

Note: The following criteria applies **ONLY** to implant removal related to breast implant associated anaplastic large cell lymphoma BIA-ALCL, as total capsulectomy (complete surgical resection) is the only recommended treatment.[4,24,28,47]

Humana members may be eligible under the Plan for **total capsulectomy with breast implant removal** for the following indications:

- Pathologic confirmation of breast implant associated anaplastic large cell lymphoma BIA-ALCL by cytological evaluation of seroma fluid or mass with Wright Giemsa stained smears and cell block immunohistochemistry/flow cytometry testing for cluster of differentiation (CD30) and anaplastic lymphoma kinase (ALK) markers[47]; **OR**
- Removal of Allergan BIOCELL textured breast implants and tissue expanders (due to increased risk of breast implant-associated anaplastic large cell lymphoma [BIA-ALCL])

Breast Implant Associated Squamous Cell Carcinoma
Humana members may be eligible under the Plan for **total capsulectomy with breast implant removal** for a confirmed diagnosis of breast implant associated squamous cell carcinoma.

Humana members may be eligible under the Plan for **reinsertion of breast implants** following a medically necessary removal.

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **breast reconstruction, capsulectomy, capsulotomy or breast implant removal** procedures other than those listed above, or for any indications other than those listed above. All other indications are considered not medically necessary.

Humana members may **NOT** be eligible under the Plan for **nipple reconstruction for inverted nipples or breast reconstruction for naturally occurring breast asymmetry** as these are considered cosmetic.

Humana members may **NOT** be eligible under the Plan for **lymphatic microvascular surgery** in conjunction with breast reconstruction to prevent lymphedema. This is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Autologous fat graft, autologous fat transplant (lipoinjection or lipomodeling) via excision lipectomy, suction lipectomy or liposuction when performed in conjunction with other breast reconstruction techniques is considered integral to the primary procedure and not separately reimbursable.

Intraoperative assessment of tissue perfusion by any technology including, but not limited to, fluorescence angiography, fluorescent angiography, multispectral imaging, near-infrared spectroscopy, oximetry or visible light spectroscopy is considered integral to the primary procedure and not separately reimbursable.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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)	
11970	Replacement of tissue expander with permanent implant	
11971	Removal of tissue expander without insertion of implant	
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less	
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm	
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate	
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)	
15877	Suction assisted lipectomy; trunk	
19316	Mastopexy	
19318	Breast reduction	
19325	Breast augmentation with implant	
19328	Removal of intact breast implant	
19330	Removal of ruptured breast implant, including implant contents (eg, saline, silicone gel)	
19340	Insertion of breast implant on same day of mastectomy (ie, immediate)	
19342	Insertion or replacement of breast implant on separate day from mastectomy	
19350	Nipple/areola reconstruction	
19355	Correction of inverted nipples	
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)	
19361	Breast reconstruction; with latissimus dorsi flap	
19364	Breast reconstruction; with free flap (eg, fTRAM, DIEP, SIEA, GAP flap)	
19367	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap	

19368	Breast reconstruction; with single-pedicled transverse rectus abdominis myocutaneous (TRAM) flap, requiring separate microvascular anastomosis (supercharging)	
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap	
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy	
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents	
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)	
19396	Preparation of moulage for custom breast implant	
19499	Unlisted procedure, breast	
76499	Unlisted diagnostic radiographic procedure	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
C1789	Prosthesis, breast (implantable)	
L8600	Implantable breast prosthesis, silicone or equal	
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral	
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	

References

1. Agency for Healthcare Research and Quality (AHRQ). Comparative Effectiveness Review. Breast reconstruction after mastectomy: a systematic review and meta-analysis. https://www.ahrq.gov. Published July 2021. Updated October 2021.

2. American Society of Addiction Medicine. https://asam.org.

3. American Society of Plastic Surgeons (ASPS). ASPS statement on breast implant associated squamous cell carcinoma (BIA-SCC). https://www.plasticsurgery.org. Published September 8, 2022.

4. American Society of Plastic Surgeons (ASPS). BIA-ALCL summary and quick facts. https://www.plasticsurgery.org. Published March 21, 2018. Updated February 24, 2020.

5. American Society of Plastic Surgeons (ASPS). Evidence-Based Clinical Practice Guideline. Autologous breast reconstruction with DIEP or pedicled TRAM abdominal flaps. https://www.plasticsurgery.org. Published November 2017.

6. American Society of Plastic Surgeons (ASPS). Evidence-Based Clinical Practice Guideline (ARCHIVED). Breast reconstruction with expanders and implants. https://www.plasticsurgery.org. Published March 2013.

7. American Society of Plastic Surgeons (ASPS). Guiding Principles. Post-mastectomy fat graft/fat transfer. https://www.plasticsurgery.org. Published December 2012. Updated June 2015.

8. American Society of Plastic Surgeons (ASPS). Statement on breast implant specimens and pathology. Published 2016. https://www.plasticsurgery.org.

9. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD). Breast reconstruction following mastectomy (140.2). https://www.cms.gov. Published January 1, 1997.

10. ClinicalKey. Schaverien M, Raine C. Breast reconstruction. In: Dixon J and Barber M. *Breast Surgery: A Companion to Specialist Surgical Practice*. 7th ed. Elsevier; 2024:140-155.e2. https://www.clinicalkey.com.

11. ECRI Institute. Clinical Evidence Assessment. Lymphatic microsurgical preventive healing approach (LYMPHA) for preventing lymphedema. https://www.ecri.org. Published June 16, 2020.

12. ECRI Institute. Clinical Evidence Assessment. Spy Elite system (Stryker) for assessing tissue perfusion during plastic and reconstructive surgery. https://www.ecri.org. Published April 11, 2011. Updated April 25, 2022.

13. ECRI Institute. Hotline Response (ARCHIVED). Cosmetic areola micropigmentation after postmastectomy breast reconstruction. https://www.ecri.org. Published May 5, 2017.

14. ECRI Institute. Product Brief (ARCHIVED). PDE-Neo (Mitaka USA/Hamamatsu Photonics) versus Spy Elite system (Novadaq Technologies) for visualizing intraoperative blood flow during breast reconstructive surgery. https://www.ecri.org. Published February 4, 2015.

15. ECRI Institute. Product Brief (ARCHIVED). T.Ox tissue oximeter (ViOptix, Inc.) for assessing tissue viability in breast reconstruction. https://www.ecri.org. Published February 27, 2014. Updated February 28, 2018.

16. ECRI Institute. Product Brief (ARCHIVED). T-Stat VLS tissue oximeter (Spectros Corp.) for monitoring postsurgical tissue viability. https://www.ecri.org. Published May 21, 2018.

17. Gutowski K. Current applications and safety of autologous fat grafts: a report of the ASPS Fat Graft Task Force. *Plast Reconstr Surg.* 2009;124:272-280.

18. Hayes, Inc. Evidence Analysis Research Brief. Fluorescence angiography for mastectomy breast flap perfusion. https://evidence.hayesinc.com. Published August 2, 2022. Updated May 3, 2023.

19. Hayes, Inc. Health Technology Assessment. Autologous fat grafting for breast reconstruction after breast cancer surgery. https://evidence.hayesinc.com. Published October 21, 2020. Updated November 13, 2023.

20. Hayes, Inc. Health Technology Assessment. Microsurgery for primary prevention of breast cancer associated lymphedema. https://evidence.hayesinc.com. Published October 15, 2019. Updated November 14, 2022.

21. Hayes, Inc. Health Technology Brief. Superficial inferior epigastric artery (SIEA) flap procedure for postmastectomy breast reconstruction. https://evidence.hayesinc.com. Published November 20, 2014. Updated October 12, 2016.

22. MCG Health.https://humana.access.mcg.com/index.

23. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Breast cancer. https://www.nccn.org. Published March 11, 2024.

24. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. T-cell lymphomas. https://www.nccn.org. Published May 28, 2024.

25. Ohio Administrative Code Chapter 5160 Ohio Department of Medicaid. Chapter 5160 - Ohio Administrative Code | Ohio Laws.

26. Ohio Administrative Code 5160-1-01 Medicaid medical necessity: definitions and principles. Rule 5160-1-01 - Ohio Administrative Code | Ohio Laws.

27. Ohio Administrative Code 5160-26-01 Managed care: definitions. Rule 5160-26-01 - Ohio Administrative Code | Ohio Laws.

28. UpToDate, Inc. Breast implant-associated anaplastic large cell lymphoma. https://www.uptodate.com. Updated April 2024.

29. UpToDate, Inc. Breast implant infections. https://www.uptodate.com. Updated April 2024.

30. UpToDate, Inc. Complications of reconstructive and aesthetic breast surgery. https://www.uptodate.com. Updated April 2024.

31. UpToDate, Inc. Implant-based breast reconstruction and augmentation. https://www.uptodate.com. Updated April 2024.

32. UpToDate, Inc. Oncoplastic breast surgery. https://www.uptodate.com. Updated April 2024.

33. UpToDate, Inc. Options for autologous flap-based breast reconstruction. https://www.uptodate.com. Updated April 29, 2024.

34. UpToDate, Inc. Overview of breast reconstruction. https://www.uptodate.com. Updated April 2024.

35. UpToDate, Inc. Overview of flaps for soft tissue reconstruction. https://www.uptodate.com. Updated April 2024.

36. US Food & Drug Administration (FDA). 510(k) summary: Fluobeam 800. https://www.fda.gov. Published May 7, 2014.

37. US Food & Drug Administration (FDA). 510(k) summary: Infrared 800 with flow 800 option. https://www.fda.gov. Published March 3, 2010.

38. US Food & Drug Administration (FDA). 510(k) summary: Kent Camera. https://www.fda.gov. Published May 5, 2017.

39. US Food & Drug Administration (FDA). 510(k) summary: Leica FL 800. https://www.fda.gov. Published May 9, 2008.

40. US Food & Drug Administration (FDA). 510(k) summary: ODISsey Tissue Oximeter (T.Ox). https://www.fda.gov. Published July 1, 2014.

41. US Food & Drug Administration (FDA). 510(k) summary: PDE Neo. https://www.fda.gov. Published March 27, 2014.

42. US Food & Drug Administration (FDA). 510(k) summary: SPY fluorescent imaging system. https://www.fda.gov. Published September 7, 2007.

43. US Food & Drug Administration (FDA). 510(k) summary: SPY PHI open field handheld fluorescence imaging system. https://www.fda.gov. Published January 11, 2017.

44. US Food & Drug Administration (FDA). 510(k) summary: T-Stat microvascular tissue oximeter. https://www.fda.gov. Published July 28, 2008.

45. US Food & Drug Administration (FDA). 510(k) summary: VS3-IR-MM. https://www.fda.gov. Published June 17, 2015.

46. US Food & Drug Administration (FDA). Risks and complications of breast implants. https://www.fda.gov. Updated December 15, 2023.

47. US Food & Drug Administration (FDA). Safety Communication (ARCHIVED). The FDA requests Allergan voluntarily recall Natrell BIOCELL textured breast implants and tissue expanders from the market to protect patients. https://www.fda.gov. Published July 24, 2019. Updated June 1, 2020.

48. US Food & Drug Administration (FDA). Safety Communication. Update: reports of squamous cell carcinoma (SCC) in the capsule around breast implants. https://www.fda.gov. Updated March 22, 2023.

Definitions

1. Adverse Benefit Determination – As defined in OAC rule 5160-26-01, is a managed care entity's (MCEs):
   1) Denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit;
   2) Reduction, suspension, or termination or services prior to the member receiving the services previously authorized by the MCE;
   3) Failure to provide services in a timely manner as specified in rule 5160-26-03.1 of the Administrative Code;
   4) Failure to act within the resolution timeframes specified in rule 5160-26-08.4 of the Administrative Code;
   5) Denial of a member's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other member financial liabilities, if applicable; or
   6) Denial, in whole or part, of payment for a service. A denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a "clean claim" as defined in 42 C.F.R. 447.45(b) (October 1, 2021) is not an adverse benefit determination).
2. American Society of Addiction Medicine (ASAM) – a professional medical society representing over 7,000 physicians, clinicians, and associated professionals in the field of addiction medicine. ASAM produces a comprehensive set of standards for placement, continued stay, transfer or discharge of patients with addiction and co-occurring conditions used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the

requestor.

3. MCG – are nationally recognized guidelines used by clinical staff to determine whether to refer a service request for physician review based upon the clinical information submitted by the requestor.
4. Medically Necessary or Medical Necessity – Has the same meaning as OAC rule 5160-1-01:
   A. Medical necessity for individuals covered by early and periodic screening, diagnosis, and treatment (EPSDT) is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate, correct, ameliorate, or treat as adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability.
   B. Medical necessity for individuals not covered by EPSDT is criteria of coverage for procedures, items, or services that prevent, diagnose, evaluate or treat an adverse health condition such as an illness, injury, disease or its symptoms, emotional or behavioral dysfunction, intellectual deficit, cognitive impairment, or developmental disability and without which the person can be expected to suffer prolonged, increased, or new morbidity; impairment of function; dysfunction of a body organ or part; or significant pain and discomfort.
   C. Conditions of medical necessity for a procedure, item, or service are met all the following apply:
      1) It meets generally accepted standards of medical practice;
      2) It is clinically appropriate in its type, frequency, extent, duration, and delivery setting;
      3) It is appropriate to the adverse health condition for which it is provided and is expected to produce the desired outcome;
      4) It is the lowest cost alternative that effectively addresses and treats the medical problem;
      5) It provides unique, essential, and appropriate information if it is used for diagnostic purposes; and
      6) It is not provided primarily for the economic benefit of the provider nor for the sole convenience of the provider or anyone else other than the recipient.
   D. The fact that a physician, dentist, or other licensed practitioner renders, prescribes, orders, certifies, recommends, approves, or submits a claim for a procedure, item, or service does not, in and of itself make the procedure, item, or service medically necessary and does not guarantee payment.
   E. The definition and conditions of medical necessity articulated in this rule apply throughout the entire medicaid program. More specific criteria regarding the conditions of medical necessity for particular categories of service may be set forth within the Ohio Department of Medicaid (ODM) coverage policies or rules.

Appendix

Appendix A – Baker Grading Scale[46]

Grade	Breast appearance
Grade I	Breast is normally soft and appears natural
Grade II	Breast is firm but appears normal
Grade III	Breast is firm and appears abnormal
Grade IV	Breast is hard, painful and appears abnormal

Appendix B – Autologous Tissue Procedures

Flap Name	Description
Deep circumflex iliac artery (DCIA), also called Ruben's flap	Tissue overlying or just above the iliac crest (hip) along with a DCIA perforator vessel are harvested for use in cases when the abdominal tissue is insufficient due to a previous abdominoplasty or TRAM procedure
Deep inferior epigastric perforator (DIEP)	Fat and skin are moved to the chest from the lower abdominal wall with the vessel in the transplanted tissue reconnected to a vessel under the arm to provide blood supply
Gluteal artery perforator (GAP)	Tissue is harvested from the buttocks with perforating vessels from either the superior gluteal artery (SGAP) or inferior gluteal artery (IGAP) as the blood supply for the transplanted tissue
Latissimus dorsi (LD)	Harvested tissue (skin and muscle) from the back is tunneled through the axilla (underarm) with the blood supplying vessels (the thoracodorsal artery and vein) intact
Profunda artery perforator (PAP)	Skin, fat and blood vessels from the back of the upper thigh are transplanted to the chest
Superficial inferior epigastric artery (SIEA)	Uses the same abdominal tissue as the DIEP flap but different blood supplying vessels
Thoracodorsal artery perforator (TAP or TDAP)	Tissue retrieved from the same anatomical area as the LD flap however, only skin and subcutaneous tissue are harvested, leaving the latissimus dorsi muscle intact
Transverse gracilis (TUG) flap	Tissue retrieved from the upper posterior thigh and lower buttock area for individuals with insufficient lower abdominal fat
Transverse rectus abdominus muscle (TRAM)	Skin, fat, blood vessels and at least one abdominal muscle are moved from the lower abdomen to the chest area and the tissue volume is often sufficient enough to shape the breast without an implant

Change Summary

01/01/2025 New Policy.