OH.CLI.1378 Breast Reconstruction

Effective Date:	January 12, 2024	Accountable Dept.:	Medicaid Clinical Delivery Experience 10585
Last Reviewed Date:	November 28, 2023		

Summary of Changes:

None – new policy created H1378.

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 on a case-by-case basis, based on the information provided on the member's health status.

For the following Breast Reconstruction HCPCS Code, S2068, Humana Healthy Horizons™ in Ohio uses the below coverage determination criteria.

Providers may submit authorization request(s) through the provider portal.

Providers may access physical and behavioral health 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 also 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 OHMCDUM@humana.com.

Description:

Breast Reconstruction HCPCS Code(s)	
HCPCS Code(s) Summary	S2068 *Other related codes may be found in other policies
HCPCS Code(s)	**Description**
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

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.

Various technologies may be utilized in conjunction with breast reconstruction procedures.

Procedures:

1. The Plan covers all benefits and services required in OAC chapter 5160 in the amount, duration, and scope for the same services furnished to members under the fee-for-service (FFS) Medicaid.
2. When applying coverage policies and medical necessity criteria, the Plan will consider individual member needs and an assessment of the local delivery system.
3. The Plan uses the following hierarchy of guidelines to review for medical necessity:
    - 3.1 Federal or state regulation, including medical criteria published in the Ohio Administrative Code, Chapter 5160.
    - 3.2 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).
    - 3.3 Humana Healthy Horizons™ in Ohio clinical policies
    - 3.4 In the case of no guidance from above, additional information that the clinical reviewer will consider, when available, includes;
        - 3.4.1 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;
        - 3.4.2 Professional standards for safety and effectiveness recognized in the US for diagnosis, care, or treatment;
        - 3.4.3 Medical association publications;
        - 3.4.4 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.;
        - 3.4.5 Published expert opinions;
        - 3.4.6 Opinion of health professionals in the area of specialty involved;
        - 3.4.7 Opinion of attending provider;
    - 3.5 Dental: DentaQuest coverage guidelines and policies
      Dental Coverage - Humana Healthy Horizons in Ohio | Humana
    - 3.6 Vision: EyeMed coverage guidelines and policies
      Vision Care - Humana Healthy Horizons - Ohio Medicaid | Humana
4. 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 medical necessity determination.

Only practitioners with the appropriate clinical expertise can make the decision to deny or reduce the amount, duration or scope of the services being requested.

Humana Healthy Horizons™ in Ohio requires prior authorization on all "Miscellaneous," "Unlisted," and "Not Otherwise Specified" codes. Medical necessity documentation and rationale must be submitted with the prior authorization request. The Medical Director adheres to the above process to align criteria based on the information provided on the member's health status.

Coverage Determination Criteria:

Humana Healthy Horizons™ in Ohio members: 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.

Any mandates from the State of Ohio for breast reconstruction take precedence over this medical coverage policy.

Humana Healthy Horizons™ in Ohio 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 for Humana Healthy Horizons™ in Ohio members)

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 the Plan's medical necessity language and does not include procedures to fill the flap donor site.

Capsulectomy, Capsulotomy, Breast Implant Removal

Humana Healthy Horizons™ in Ohio 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 (non-cosmetic) surgery;

AND any of the following

o Capsular contracture (Baker grade III or IV); OR

o Extrusion; OR

o Rupture of saline filled, silicone gel or alternative breast implant (confirmed by imaging such as magnetic resonance imaging [MRI] or ultrasound); OR

o Implant infection refractory to medical management (e.g., 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

Humana Healthy Horizons™ in Ohio 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; 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 Healthy Horizons™ in Ohio 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 Healthy Horizons™ in Ohio members may be eligible under the Plan for reinsertion of breast implants following a medically necessary removal.

Coverage Limitations:

Humana Healthy Horizons™ in Ohio 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 may not be eligible under the plan upon review for medical necessity.

Humana Healthy Horizons™ in Ohio 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 Healthy Horizons™ in Ohio 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.

Background:

Additional information about breast cancer, breast conditions, breast reconstruction and breast surgeries may be found from the following websites:

- American Cancer Society
- National Cancer Institute
- National Library of Medicine

Additional information about breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) or breast implant-associated squamous cell carcinoma (BIASCC) may be found from the following websites:

- American Cancer Society
- American Society of Plastic Surgeons
- US Food & Drug Administration

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 an 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:
        a. It meets generally accepted standards of medical practice;
        b. It is clinically appropriate in its type, frequency, extent, duration, and delivery setting;
        c. It is appropriate to the adverse health condition for which it is provided and is expected to produce the desired outcome;
        d. It is the lowest cost alternative that effectively addresses and treats the medical problem;
        e. It provides unique, essential, and appropriate information if it is used for diagnostic purposes; and
        f. 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.

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Appendix: A

Baker Grading Scale

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

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Accountable VP / Director:	Patricia Jones		

Version Control:

11/28/2023 - Code S2068 from Humana Healthy Horizons™ in Ohio policy H1228 was placed into this new policy (H1378) and coverage criteria was written for determining medical necessity. – M. Joyce Medicaid Clinical Delivery Experience