MEDICAL POLICY	Autologous Fat Transfer
Effective Date: 3/1/2021  3/1/2021 Medical Officer Date	Medical Policy Number: 9 Technology Assessment Committee Approved Date: 7/11; 2/12; 9/12; 7/13; 10/13; 1/14; 8/14; 8/15; 12/15; 3/16 Medical Policy Committee Approved Date: 4/17; 4/18; 8/19; 11/19; 2/2020; 2/2021

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

I. Autologous fat transfer for breast reconstruction is considered **medically necessary and covered** for breast reconstruction related to **any** of the following (A.-C.):

   A. Lumpectomy, or a partial or total mastectomy; **or**
   B. Traumatic injury or surgery of the affected breast which results in an asymmetrical change in breast shape or development compared to the contralateral breast; **or**
   C. To correct a congenital or developmental breast abnormality, which is known to affect normal breast growth.

II. Autologous fat transfer for gender assignment surgical interventions may be considered **medically necessary and covered**.

III. Autologous fat transfer associated with breast reconstruction that does not meet criterion I. or II. above is considered **cosmetic and is not covered**.

BILLING GUIDELINES

CPT codes 15770 and 15877-15879 should not be used to bill for autologous fat transfer. These codes will be denied as not medically necessary if billed for this service.

CPT CODES

All Lines of Business	
Prior Authorization Required	
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
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)
No Prior Authorization Required	
~~20926~~	Termed 12/31/2019 ~~Tissue grafts, other (eg, paratenon, fat, dermis)~~
Not Covered *Note: The following codes may be considered medically necessary and covered when billed with diagnosis code F64.0, F64.1, F64.8 or F64.9*	
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)

DESCRIPTION

Autologous Fat Grafting for Breast Reconstruction

According to a 2017 Hayes technology review:[1]

> "Autologous fat grafting (AFG) uses the patient's own body fat to fill and correct volume loss or contour deformities of the breast caused by surgical tumor removal and/or breast reconstruction procedures. The procedure involves harvesting fat from the abdomen, thighs,

buttocks, or flank; processing the harvested fat to remove blood, oil, and debris; and injecting the processed fat into the target breast area(s). Despite a growing uptake in the use of AFG among patients having undergone surgery for breast cancer, questions remain regarding the safety of the procedure. Some in vitro studies have indicated that adipocytes and their associated milieu may directly stimulate tumor growth and progression, and adipose-derived stem cells within the graft may increase the risk of malignant transformation."[1]

The medical necessity criteria regarding the use of autologous fat transfer for breast reconstruction are primarily based on the Women's Health and Cancer Rights Act (WHCRA) of 1998. The WHCRA requires all insurance carriers that cover mastectomies to also cover the following, in consultation with the attending physician and patient:[2,3]

> "All stages of reconstruction of the breast on which the mastectomy was performed, surgery and reconstruction of the other breast to produce a symmetrical appearance, prostheses and treatment of physical complications of the mastectomy, including lymphedema."

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of autologous fat transfer for conditions other than breast reconstruction. Below is a summary of the available evidence identified through December 2019.

- In 2018, Krastev and colleagues conducted a systematic review and meta-analysis evaluating the efficacy of autologous fat transfer (AFT) for the correction of contour deformities in the breast.[4] Investigators systematically searched the literature through August 2017, identified eligible studies, assessed study quality, extracted data and pooled results. In total, 89 studies evaluating 5,350 patients were included for review. Mean follow-up was 1.9 years. Outcomes of interest included patient satisfaction, surgeon satisfaction and Breast-Q scores.

  Meta-analysis yielded an overall score of 73.0 (95% CI 67.7-78.4), indicating a moderate to good satisfaction with breasts and breast-related quality of life. At one-year follow-up, long-term volume retention showed a gradual decrease of the initially grafted volume to 52.4% (95% CI 45.0-59.8), reaching a plateau at approximately 505% when extrapolated to the long term. The overall mean number of AFT sessions was 1.5 (95% CI 1.4-1.6), with a mean injected volume of approximately 100ml. In total, 5% percent of procedures resulted in clinical complications and 8.6% of breasts required biopsy due to abnormal clinical or radiological findings. Limitations include the low-quality of evidence (i.e. lack of RCTs), lack of long-term follow-up, and heterogeneous study design and patient characteristics. Nonetheless, investigators concluded that AFT was safe, and highly effective in correcting contour deformities in breast reconstruction, as assessed by volume retention, and patient and surgeon satisfaction.

- In 2018, Krastev and colleagues conducted a systematic review and meta-analysis evaluating the oncological safety of autologous fat transfer after breast cancer.[5] Investigators systematically searched the literature through August 2017, identified eligible studies, assessed study quality, extracted data and pooled results. The primary outcome of interest was the difference in incidence rate of locoregional recurrence between patient who had autologous fat transfer and

controls. In total, 59 studies assessing 4,292 were included for review (7 matched cohort studies, 12 cohort studies and 40 case series). Mean follow-up was 5.7 years from the date of primary cancer surgery and 2.7 years after AFT. Meta-analysis yielded a not statistically significant incidence rate difference of -0.15% per year (95% CI -0.36 to 0.07; *p*-value (0.419). Limitations included the lack of high-quality studies included for review, and heterogenous follow-up periods between studies. Investigators concluded that ATF can be performed safely in breast reconstruction as it did not appear to increase patients' likelihood of locoregional recurrence in breast cancer patients.

- In 2015 (updated 2017; archived 2018), Hayes conducted an evidence review evaluating autologous fat grafting (AFG) for breast reconstruction after breast cancer surgery.[1] Searching the literature through June 2017, investigators identified 11 studies (3 case-control studies; 2 controlled retrospective cohort studies; 2 uncontrolled retrospective cohort studies, and 4 case series). Sample sizes across studies ranged from 59 to 963. Follow-up ranged from 19.2 months to 10 years. Outcomes of interest included breast cancer recurrence, procedural effectiveness, complications, and imagine abnormalities. Collectively, results across studies suggested that AFG was an effective and relatively safe procedure for achieving acceptable and durable breast appearance, without a concomitant increase in the risk of locoregional cancer recurrence. Four retrospective comparative studies reported similar rates of cancer recurrence between the AFG versus the control groups at 33-month follow-up. Additional studies reported success in patients' fat resorption, patient satisfaction with breast appearance, and low rates of complications and imaging abnormalities.

  Nonetheless, Hayes assessed the overall body of evidence as being of "very-low" quality. Limitations included studies' retrospective design, lack of randomization, selected samples, sample overlap, heterogenous patient characteristics, and potential reporting and selection biases. Patient selection criteria has also not been established, although low-quality evidence suggests that certain subpopulations (patients with lobular intraepithelial neoplasia (LIN) or ductal intraepithelial neoplasia (DIN)) may have a greater risk of cancer recurrence as a result of AFG. Due to the consistent but "very poor quality" body of evidence, Hayes ultimately assigned a "C" rating (potential but unproven benefit) for AFG for breast reconstruction after breast cancer surgery in patients with diagnoses other than LIN and DIN. Investigators called for large, higher-quality studies (e.g. prospective, randomized comparisons), with standardized AFG protocols and reporting of results to confirm findings to date.

- In 2020, Hayes published a health technology assessment on autologous fat grafting (AFG) for breast reconstruction after breast cancer surgery.[6] Searching the literature through August 2015, investigators identified 11 studies (9 retrospective comparative cohort studies, 2 retrospective case series). All studies compared AFG to no AFG and mean/median follow-up time from procedure ranged from 18.4 to 60 months. Across the 9 comparative studies, no difference in recurrence or survival were observed between AFG and non-AFG treatment groups. One study found significantly lower rates of breast-cancer related mortality and overall mortality in the AFG-treated group compared to the non-AFG treated group.

  Hayes found that the quality of evidence was moderate in size and quality. While there was only moderate follow up in some trials, moderate heterogeneity among trials, and limited data on patient-centered outcomes such as quality of life, Hayes found that a moderate-quality body of

evidence shows that AFG does not increase risk of breast cancer recurrence or breast cancer mortality in women undergoing breast reconstruction following breast cancer surgery. Hayes gave AFG a B rating, suggesting some proven benefit.

- In 2020, Tayeh and colleagues published a systematic review on the safety of autologous fat grafting following breast conserving surgery for breast cancer.[7] Twenty-six studies were included in the review, 11 of which were case-control studies and 15 of which were case series, with a total of 1640 patients. A meta-analysis was run on the case-control studies on locoregional recurrence rates (RR) between AFG and the control groups. No significant difference was found in locoregional RR between AFG and control groups (RR=0.82; 95% CI: 0.41-1.66). Case control studies were considered to be good quality with low risk of bias. The authors concluded that the results of the review adds additional support to the safety of AFG after breast conserving surgery, not leading to increased risk of locoregional RR, but prospective data should be collected and analyzed to further assess the oncological safety of AFG, particularly in high-risk groups.

CLINICAL PRACTICE GUIDELINES

American Society of Plastic Surgeons

In 2015, the ASPS Patient Safety committee reaffirmed the conclusions published in a 2012 evidence review on AFG. The ASPS published the following principles for postmastectomy AFG:[8]

- Evidence suggests that, as an adjunct to postmastectomy breast reconstruction, AFG leads to moderate to significant aesthetic improvement in breast volume, contour, and superomedial fullness and patient satisfaction. Serial grafting significantly improves cosmetic results.
- Evidence suggests that, in postmastectomy breast cancer patients, AFG does not increase the risk of breast cancer recurrence, does not delay the diagnosis of breast cancer recurrence, or, when interpreted by experienced radiologists, does not impede the differentiation between benign lesions and breast cancer recurrence.
- Evidence suggests that postmastectomy breast reconstruction with AFG is effective, is associated with a low risk for complications, and may be effective for treating postmastectomy pain syndrome.
- Increasing evidence indicates that the risk for complications is not increased when AFG is used in the presence of previously irradiated tissue.
- Evidence suggests that the number of AFG sessions needed varies per patient, that most patients require > 1 AFG sessions, and that each additional AFG session contributes to gradual improvement in overall outcome.[8]

National Institute for Health and Care Excellence (NICE)

In 2012, NICE published a guideline on the use of lipomodelling (i.e. AFG) for breast reconstruction after breast cancer treatment. Authors published the following conclusions:[9]

- Current evidence on the efficacy of lipomodelling after breast cancer treatment is adequate and evidence on the safety of the procedure raises no major safety concerns. Therefore, the

procedure may be used when normal arrangements for the clinical governance, consent and audit are in place.

- There is theoretical concern regarding the potential influence of lipomodelling in this setting on breast cancer recurrence, but there is no evidence of increased recurrence in published reports. Therefore, the NICE encourages the collection of long-term data on the procedure.
- Patient selection for lipomodelling after breast cancer treatment should be determined by a breast cancer multidisciplinary team.
- Breast reconstruction using lipomodelling after breast cancer treatment should be performed by surgeons with specialist expertise in the procedure.

POLICY SUMMARY

Consistent, albeit low-quality evidence suggests that autologous fat grafting after breast cancer treatment is a safe and effective method of breast reconstruction. While the evidence base is limited to largely retrospective studies assessing patients with varying baseline characteristics, studies consistently report improvement in breast volume retention and patients' satisfaction with breast appearance. Moreover, no significant increase in rates of locoregional cancer recurrence have been reported. Two clinical practice guidelines have also endorsed the use of AFG following breast cancer.

There is a paucity of evidence evaluating the use of autologous fat grafting to treat conditions not associated with breast reconstruction. Studies are limited by small sample size, short-term follow-up, heterogeneity of conditions treated, lack of comparison group and lack of randomization. Further prospective studies are needed to understand the clinical utility of fat transfer as a treatment of conditions not associated with breast reconstruction after lumpectomy, partial or total mastectomy.

CENTERS FOR MEDICARE & MEDICAID

As of 12/28/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses autologous fat transfer for any condition, including breast reconstruction.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

MEDICAL POLICY CROSS REFERENCES

- Breast Reconstruction
- Cosmetic and Reconstructive Procedures (All Lines of Business Except Medicare)
- Cosmetic and Reconstructive Procedures (Medicare only)
- Gender Affirming Surgical Interventions

REFERENCES

1. Hayes Inc. Autologous Fat Grafting For Breast Reconstruction After Breast Cancer Surgery. https://evidence.hayesinc.com/report/htb.autologous2161. Published 2015 (updated 2017; archived 2018). Accessed 12/28/2020.
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3. U.S. Department of Labor - Employee Benefits Security Administration. FAQs about Women's Health and Cancer Rights. https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/whcra.pdf. Accessed 12/28/2020.
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9. National Institute for Health and Care Excellence (NICE). Breast reconstruction using lipomodelling after breast cancer treatment. https://www.nice.org.uk/guidance/ipg417/chapter/1-guidance. Published 2012. Accessed 12/28/2020.