Surgical Treatments for Lymphedema and Lipedema

Effective: August 1, 2020

Next Review: June 2021
Last Review: June 2020

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Lymphedema is an accumulation of fluid due to disruption of lymphatic drainage. Lymphedema can be caused by congenital or inherited abnormalities in the lymphatic system (primary lymphedema) but is most often caused by acquired damage to the lymphatic system (secondary lymphedema). Lipedema is a rare condition where increased fat tissue accumulates under the skin which causes non-pitting, bilateral swelling in the extremities.

MEDICAL POLICY CRITERIA

I. Lymphatic physiologic surgery with or without a microscope to treat lymphedema (including, but not limited to, lymphatico-lymphatic bypass, lymphatic-venous-lymphatic plasty, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer) is considered investigational.

II. Lymphatic physiologic surgery with or without a microscope performed during nodal dissection (e.g. axillary or groin) or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer is considered investigational.
III. Liposuction to treat lymphedema or lipedema (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) is considered investigational.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES
None

BACKGROUND

LYMPHEDEMA

A diagnosis of secondary lymphedema is based on history (e.g., cancer treatment, trauma) and physical examination (localized, progressive edema and asymmetric limb measurements) when other causes of edema can be excluded. Imaging, such as magnetic resonance imaging, computed tomography, ultrasound, or lymphoscintigraphy, may be used to differentiate lymphedema from others causes of edema in diagnostically challenging cases.

Breast Cancer-Related Lymphedema

Breast cancer treatment is one of the most common causes of secondary lymphedema. Both the surgical removal of lymph nodes and radiotherapy are associated with development lymphedema in patients with breast cancer.

In a systematic review of 72 studies (N=29,612 women), DiSipio (2013) reported that approximately 1 in 5 women who survive breast cancer will develop arm lymphedema.[1] Reviewers reported that risk factors for development of lymphedema that had a strong level of evidence were extensive surgery (i.e., axillary-lymph-node dissection, greater number of lymph nodes dissected, mastectomy) and being overweight or obese.

Management and Treatment

Early and ongoing treatment of lymphedema is necessary. Conservative therapy may consist of several features depending on the severity of the lymphedema. Patients are educated on the importance of self-care including hygiene practices to prevent infection, maintaining ideal body weight through diet and exercise, and limb elevation. Compression therapy consists of repeatedly applying padding and bandages or compression garments. Manual lymphatic drainage is a light pressure massage performed by trained physical therapists or by patients designed to move fluid from obstructed areas into functioning lymph vessels and lymph nodes. Complete decongestive therapy is a multiphase treatment program involving all of the previously mentioned conservative treatment components at different intensities. Pneumatic compression pumps may also be considered as an adjunct to conservative therapy or as an alternative to self-manual lymphatic drainage in patients who have difficulty performing self-manual lymphatic drainage. In patients with more advanced lymphedema after fat deposition and tissue fibrosis has occurred, palliative surgery using reductive techniques such as liposuction may be performed.

LIPEDEMA
Lipedema is a rare condition primarily seen in women where increased fat tissue accumulates under the skin which causes non-pitting, bilateral swelling typically seen in the lower extremities. Lipedema can also be seen in the upper extremities. The condition usually worsens gradually, although in some cases minor lipedema may stabilize. Lipedema is often painful and may be accompanied by easy bruising and joint problems. There is no known cause for lipedema.

Management and Treatment

Management of lipedema is complex and distinct from lymphedema. The proposed main conservative treatment is complete or complex decongestive therapy (CDT). CDT combines several approaches including manual lymph drainage (a massage technique), compression therapy, and physical mobilization. Liposuction has been proposed as an alternative treatment option for lipedema.

EVIDENCE SUMMARY

SURGICAL TREATMENT FOR LYMPHEDEMA

The purpose of physiologic microsurgery treatments and liposuction for lymphedema is to provide a treatment option that is an improvement on existing therapies such as conservative therapy with compression garments or bandages, manual lymph drainage or pneumatic pumps, and decongestive therapy. Both surgical treatment and radiotherapy for breast cancer can lead to lymphedema and is one of the most common causes of secondary peripheral lymphedema.

Multiple Techniques

Systematic Reviews

Markkula (2019) published a Cochrane systematic review to assess and compare the efficacy of surgical interventions for the prevention of the development of lymphedema (LE) in the arm after breast cancer treatment and to assess and compare the efficacy of surgical interventions for the treatment of established LE in the arm after breast cancer treatment. Reductive and reconstructive techniques were considered including liposuction, lymphaticovenular anastomoses (LVA), lymphatico-lymphatic bypass (LLB), and vascularized lymph node transfer (VLNT). Three studies which included two studies assessing the effectiveness of LVA as part of preventive management protocols in the prevention of breast cancer-related lymphedema and one study addressing the effectiveness of VLNT in the treatment of established breast cancer-related lymphedema. The authors concluded that there is not enough evidence to support the widespread adoption of liposuction, LVA, or VLNT techniques and that high-quality RCTs are needed.

A 2019 systematic review by Tyker aimed to evaluate the efficacy of a variety of surgical treatments for patients with lymphedema following head and neck cancer therapy. 26 studies met the inclusion criteria including 14 cohort studies, seven case reports, two RCTs, two systematic reviews, and one narrative review. Manual lymph drainage had the largest number of studies and participants and there was limited evidence evaluating the efficacy of liposuction and microsurgery techniques. The authors concluded that there is limited data from high-quality studies including RCTs and that more research is needed to understand the long-term efficacy of other treatment modalities.
A 2017 systematic review by Carl aimed to develop a treatment algorithm based on highest-quality lymphedema research.[4] The SR addressed lymphovenous anastomosis (LVA), vascularized lymph node transfer (VLNT), liposuction, excision, and combination surgical approaches for the treatment of lymphedema. Sixty-nine articles met inclusion criteria and were included in the review. In studies measuring excess volume reduction, the mean reduction was 96.6% for liposuction, 33.1% for LVA, and 26.4% for VLNT. Included excision articles did not report excess volume reduction. The authors stated that further studies with a focus on follow up after treatment will improve the validity of lymphedema surgery research.

There was significant heterogeneity of the included studies in terms of lymphedema stage and etiology, method of assessing surgical outcomes, and inconsistent reporting of complications and quality of life outcomes. Additional trials are needed that compare surgical treatments to conservative therapies which may help define the most appropriate interventions for patients according to their clinical stage.

Additional single-arm studies have been published on liposuction for the treatment of lymphedema.[5,6] However, these studies suffer from the same limitations as the studies included in the systematic reviews and do not capture longer periods of follow up and/or larger populations than the existing studies. Therefore, they are not discussed further.

**Surgeries That Reconstruct or Bypass Using Donor Lymph Vessels**

Leung (2015) reported on a systematic review of the surgical management of breast cancer-related lymphedema.[7] The search included studies reporting on the efficacy of surgical techniques used for the prevention or treatment of breast cancer-related lymphedema published between 2000 and 2014. Only one study on lymphatico-lymphatic bypass was identified and published since 2000. The study included seven patients followed for 2.6 years. One patient had "complete recovery" as measured by the circumference of the affected limb and the remaining six patients had a "reasonable outcome". Postsurgery complications were cellulitis, donor-site lymphorrhea, and transient edema of donor leg.

**Surgeries That Reconstruct or Bypass Using the Venous System**

**Systematic Reviews**

Two systematic reviews specifically evaluating microsurgical procedures using the venous system (lymphaticovenular anastomosis [LVA], lymphovenous bypass) have been reported.[8,9] Two broader systematic reviews of treatments for lymphedema including several microsurgical procedures have also been reported.[4,7] Corneilissen (2018) and Leung (2015) were limited to studies of breast cancer-related lymphedema but the remaining reviews were not.

Corneilissen (2018) reported on a systematic review assessing the effect of LVA in breast cancer-related lymphedema.[8] Fifteen observational studies were identified (11 prospective, 4 retrospective) with follow-up times ranging from two months to eight years. Although LVA surgery was performed in the included studies, the technical procedure differed among studies: six studies used only end-to-end anastomoses; four studies used both end-to-end and end-to-side anastomoses; one study used the "Octopus technique"; and four studies did not report the LVA technique used. Only two studies included a control group (bandaging, decongestive therapy).

Scaglioni (2017) reported on a systematic review of LVA for the treatment of lymphedema.[9] Reviewers noted significant variations in surgical techniques, numbers of anastomoses, and
supplementary interventions (i.e., compressive therapy, additional debulking surgery). Nine studies included secondary lymphedema alone, while eight studies included patients with both primary and secondary lymphedemas. The number of patients with breast cancer-related lymphedema was not described. As mentioned, the Carl (2017) and Leung (2015) reviews included multiple surgical techniques. Leung (2015) was limited to breast cancer-related lymphedema while Carl (2017) was not.

Basta (2014) published a systematic review which included 27 studies evaluating the efficacy and safety of microsurgical treatments for lymphedema. Lymphovenous shunt procedures were used in 22 studies and lymph node transfer was used in the remaining five studies. The primary endpoint was reduction in excess volume or circumference. The authors reported an excess circumference reduction of 48.8% and an absolute circumference reduction of 3.3 cm. The studies that reported excess volume reduction show a reduction of 56.6%. The rate of no improvement in the included studies was 11.8% and complications included infection, lymphorrhea, reexploration for flag congestion, and reoperation.

Randomized Controlled Trials

No RCTs were identified.

Nonrandomized Studies

Maruccia (2019) published a retrospective study comparing vascularized lymph node transfer (VLNT) to combined VLNT and axillary scar release. Thirty-nine patients were included and all had stage II or III breast cancer-related lymphedema. Primary outcomes were limb circumference and lymphedema-related quality of life. A significant difference between the circumference reduction rates at above elbow level was observed at three and six months of follow-up comparing the two groups, with higher values in the combined treatment group than VLNT alone. No significant difference was detected comparing reduction rate values at above and below elbow at 12 and 24 months postoperatively. Quality of life metrics showed significantly better scores in all domains at all follow-up appointments in the combined group.

Agko (2018) published a nonrandomized, noncomparative prospective study including 12 patients with lymphedema who received vascularized lymph node transfer followed by lipectomy. The primary outcomes were limb size and number of infectious episodes in addition to an evaluation of compression garment utilization. The authors reported a limb circumference reduction rate of 37.9% after the VLNT procedure and this was increased to a reduction rate of 96.4% after the lipectomy procedure. Only one patient reported an infectious episode after either of the treatments. It was noted that all patients were able to eventually discontinue the use of compression garments. Limitations of this study include the lack of a comparator group, small sample size, and no long-term follow-up.

Additional single-arm studies have been published since the systematic reviews. However, these studies suffer from the same limitations as the studies included in the systematic reviews and do not capture longer periods of follow-up and/or larger populations than the existing studies. Therefore, they are not discussed further.

Subsection Summary: Surgeries That Reconstruct or Bypass Using the Venous System

No controlled trials were identified evaluating the physiologic microsurgeries using techniques such as lymphovenous bypass or LVA that reconstruct or bypass the obstructed lymphatic vessels using the venous system. Systematic reviews have indicated that most of the available
evidence for these procedures comes from uncontrolled studies including fewer than 40 participants each, most of which lack adequate descriptions of how patients were selected for inclusion. Surgical technique, the severity of lymphedema, outcomes metrics, and follow-up times varied across studies making it difficult to synthesize the evidence. Surgical complications have been inconsistently reported but appear to be rare. RCTs of physiologic microsurgeries that bypass the obstructed lymphatic vessels using the venous system plus conservative therapy vs conservative therapy alone are needed.

SURGERIES THAT TRANSFER LYMPH TISSUE

Systematic Reviews

Systematic reviews evaluating microsurgical procedures that transfer lymph tissue (autologous lymph node transfer, vascularized lymph node transfer [VLNT]) have been reported. Ozturk (2016) reported on a systematic review of VLNT for treatment of lymphedema.[14] They included treatment for both primary and secondary lymphedema and as such comprised a heterogeneous population. However, 191 of 305 of the surgeries were for breast cancer-related lymphedema. Eighteen studies were identified (3 prospective, 15 retrospective). For breast cancer-related lymphedema, VLNT with a skin island or VLNT with an autologous flap was used. There was inconsistent reporting of the staging of lymphedema. Reviewers did not state whether any of the studies included a control group. Two systematic reviews of various surgical methods previously described also included a review of lymph node transfer.[4,7]

In addition to the systematic reviews of efficacy, Demiri (2018) reported on a systematic review of donor-site complications following autologous lymph node transfer for breast cancer-related lymphedema.[15]

Risk of bias was assessed in Ozturk (2016) using a checklist from the American Society of Plastic Surgeons guidelines for therapeutic studies. A summary of the assessment follows:

- 12 of 18 studies did not report whether patients were selected consecutively and one did not include consecutive patients;
- 13 of 18 studies had insufficient information on the surgical team;
- 3 of 18 studies had an insufficient follow-up to observe outcomes (ie, <1 year).

Randomized Controlled Trials

Dionyssiou (2016) reported on an RCT that evaluated VLNT plus physical therapy vs physical therapy alone for lymphedema in 36 women with stage II breast cancer-related lymphedema.[16] At 18 months, the reduction in the excess volume of the affected limb as a percentage of the intact limb was 57% in the VLNT group and 18% in the physical therapy group (treatment effect not reported, p<0.001). The mean number of lymphedema-related infections per patient per year was lower in the VLNT group (0.28 vs 1.16; treatment effect not reported, p=0.001). The trial had several limitations described in Tables 9 and 10. Notably, there was no description of allocation concealment and the trial was not blinded, possibly introducing both selection and ascertainment bias. The reporting did not describe the power calculations or justify a clinically important difference for the reported outcomes. The trial was not registered, so selective reporting cannot be ruled out.

Nonrandomized Studies
Additional single-arm studies have been published since the systematic reviews.[17-22] However, these studies suffer from the same limitations as the studies included in the systematic reviews and do not capture longer periods of follow-up and/or larger populations than the existing studies. Therefore, they are not discussed further.

Subsection Summary: Surgeries That Transfer Lymph Tissue

One RCT with 36 participants was identified evaluating VLNT that uses lymph tissue transfer in patients with breast cancer-related lymphedema. The trial reported reductions in the excess volume of the affected limb and rates of lymphedema-related infections for VLNT plus physical therapy compared with physical therapy alone. Systematic reviews have indicated that most of the remaining available evidence for these procedures comes from uncontrolled studies including fewer than 50 participants each, most of which lacked adequate descriptions of how patients were selected for inclusion. Surgical techniques, the severity of lymphedema, outcomes metrics, and follow-up times varied across studies. Although surgical complications were inconsistently reported, a systematic review of complications estimated that donor-site lymphedema occurs in approximately 2% of surgeries and seroma occurs in approximately 4%. Additional RCTs of physiologic microsurgeries that use lymph tissue transfer with conservative therapy vs conservative therapy alone are needed.

PHYSIOLOGIC MICROSURGERY TO PREVENT LYMPHEDEMA

The purpose of lymphatic physiologic microsurgery simultaneous to lymphadenectomy for breast cancer (e.g., the Lymphatic Microsurgical Preventing Healing Approach [LYMPHA]) is to prevent lymphedema in individuals who are being treated for breast cancer. While recommendations on preventive measures for lymphedema exist, such as avoiding needle sticks, limb constriction, and air travel, most recommendations are based on clinical opinion. A systematic review of preventive measures for lymphedema by Cemal (2011) found strong scientific evidence only for the recommendations to maintain a normal body weight or avoid weight gain and to participate in a supervised exercise regimen.[23]

LYMPHA is a preventive LVA procedure performed during nodal dissection or reconstructive surgery that involves anastomosing arm lymphatics to a collateral branch of an axillary vein.

Systematic Reviews

Jorgensen (2017) reported on a systematic review of prophylactic LVA and shunts for preventing cancer-related lymphedema, not limited to breast cancer.[24] Twelve articles were included in the qualitative analysis (5 specific to breast cancer) and four of those studies (2 specific to breast cancer) were included in a meta-analysis. Jorgensen (2017) performed a meta-analysis of the incidence of lymphedema that included 4 studies (2 specific to breast cancer) with a control group consisting of patients without prophylactic LVA. The relative risk for incident lymphedema was 0.33 (95% CI, 0.19 to 0.56) favoring prophylactic LVA vs control; however, because the incidence of lymphedema varies over time and the follow-up times varied across studies, it is not clear whether it would be appropriate to pool the risk including all time points.

Jorgensen (2017) also performed a risk of bias assessment of the included studies. They noted the following:

- None of the studies had allocation concealment or blinding;
- Only 1 study was randomized;
• None of the studies were registered;
• Only 4 studies had a control group. Selection of the control groups was unclear or a potential source of bias in all 4 controlled studies.

Randomized Controlled Trials

Boccardo (2011) reported on results of an RCT including 46 women referred for axillary dissection for breast cancer treatment between 2008 and 2009 who were randomized to LYMPHA or no preventive surgery (control).[25] All LVA procedures were performed by the same surgeon, reported to be skilled in lymphatic microsurgery. The LVA surgeon was not the same surgeon who performed lymph node dissection. The same axillary dissection treatment was performed in the 2 treatment groups. Lymphedema was diagnosed as a difference in excess volume of at least 100 mL compared with preoperative volume measurements. Lymphedema was diagnosed in 1 (4%) woman in the LYMPHA group and 7 women (30 %) in the control group by 18 months of follow-up. The change in volume with respect to baseline was reportedly higher in the control group than in the LYMPHA group at 1, 3, 6, 12, and 18 months (all p<0.01). The trial had several limitations described in Tables 15 and 16. Notably, the follow-up duration was only 18 months. Methods of randomization and allocation concealment were not described and there was no justification of the sample size. The patients and investigators were not blinded (ie, no sham procedure was performed) and there was no discussion of whether outcome assessors were blinded

Nonrandomized Studies

Additional single-arm studies have been published since the systematic reviews.[26] However, these studies suffer from the same limitations as the studies included in the systematic reviews and do not capture longer periods of follow up and/or larger populations than the existing studies. Therefore, they are not discussed further.

Section Summary: Physiologic Microsurgery to Prevent Lymphedema

One RCT was identified evaluating LYMPHA to prevent lymphedema in 49 patients referred for axillary dissection for breast cancer. The trial reported that lymphedema developed in 4% of women in the LYMPHA group and 30% in the control group by 18 months of follow-up. Longer follow-up is needed to observe incident lymphedema occurring after 18 months and assess the durability of the procedure. The trial had limitations that could have introduced bias: methods of randomization and allocation concealment were not described, and there was no sham procedure or blinding. Systematic reviews have indicated that most of the remaining available evidence for LYMPHA comes from uncontrolled studies, although two controlled observational studies in women with breast cancer have been performed. Selection of the control group was identified as a potential source of bias in both controlled studies. Outcomes metrics and follow-up times varied across studies. Additional RCTs of LYMPHA are needed and 1 such trial is underway (see NCT03428581).

SURGICAL TREATMENT FOR LIPEDEMA

The purpose of liposuction treatments for lipedema is to provide a treatment option that is an improvement on existing therapies such as complete decongestive therapy.

Systematic Reviews
The Canadian Agency for Drugs and Technology in Health (CADTH) published a rapid response report summarizing the evidence on liposuction for the treatment of lipedema.[27]

The report consists of five nonrandomized, uncontrolled studies that suggest liposuction may be effective in reducing extremity size and complaints related to lipedema. Complaints related to lipedema included spontaneous pain, easy bruising, sensitivity to pressure, impairment in quality of life, restrictions to mobility, edema, feeling of tension, and general impairment. Outcome data was collected via patient self-assessment using tools that have not been validated for lipedema related complaints. Additionally, all studies included were noncomparative, nonrandomized studies and did not include long-term follow up.

**Randomized Controlled Trials**

No RCTs were identified.

**Nonrandomized Studies**

No additional high-quality nonrandomized studies were identified that are not addressed above.

**Section Summary: Surgical Treatment for Lipedema**

The existing literature addressing liposuction techniques for the treatment of lipedema only includes nonrandomized, uncontrolled studies with no comparator group. The evidence is lacking and further research with longer-term outcomes and patient selection criteria are needed. High quality randomized trials or comparative studies are needed.

**PRACTICE GUIDELINE SUMMARY**

**NATIONAL LYMPHEDEMA NETWORK**

The National Lymphedema Network published a position paper on the diagnosis and treatment of lymphedema in 2011.[28] The paper stated the following on microsurgical procedures:

"Microsurgical and supramicrosurgical (much smaller vessels) techniques have been developed to move lymph vessels to congested areas to try to improve lymphatic drainage. Surgeries involve connecting lymph vessels and veins, lymph nodes and veins, or lymph vessels to lymph vessels. Reductions in limb volume have been reported and a number of preliminary studies have been done, but there are no long-term studies of the effectiveness of these techniques."

**INTERNATIONAL SOCIETY OF LYMPHOLOGY**

International Society of Lymphology published a consensus document on the diagnosis and treatment of peripheral lymphedema in 2016.[29] The document stated the following on lymphaticovenous (or lymphovenous) anastomoses (LVA):

"LVA are currently in use at multiple centers around the world. These procedures have undergone confirmation of long-term patency (in some cases more than 20 years) and some demonstration of improved lymphatic transport (by objective physiologic measurements of long-term efficacy)."

**NATIONAL CANCER INSTITUTE**
“Surgery is rarely performed on patients who have cancer-related lymphedema. The primary surgical method for treating lymphedema consists of removing the subcutaneous fat and fibrous tissue with or without creation of a dermal flap within the muscle to encourage superficial-to-deep lymphatic anastomoses. These methods have not been evaluated in prospective trials, with adequate results for only 30% of patients in one retrospective review. In addition, many patients face complications such as skin necrosis, infection, and sensory abnormalities. The oncology patient is usually not a candidate for these procedures. Other surgical options include the following: Microsurgical lymphaticovenous anastomoses in which the lymph is drained into the venous circulation or the lymphatic collectors above the area of lymphatic obstruction; liposuction; superficial lymphangieotomy; fasciotomy”.

**SUMMARY**

There is not enough research to show that physiologic microsurgeries including, but not limited to, lymphatico-lymphatic bypass, lymphatic-venous-lymphatic plasty, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer improve health outcomes for people with lymphedema. Therefore, physiologic microsurgeries including, but not limited to, lymphatico-lymphatic bypass, lymphatic-venous-lymphatic plasty, lymphovenous bypass, lymphaticovenous anastomosis, autologous lymph node transplantation, and vascularized lymph node transfer is considered investigational for all indications, including but not limited to lymphedema.

There is not enough research to show that lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer improves health outcomes. Therefore, lymphatic physiologic microsurgery performed during nodal dissection or breast reconstruction to prevent lymphedema (including, but not limited to, the Lymphatic Microsurgical Preventing Healing Approach) in individuals who are being treated for breast cancer is considered investigational.

There is not enough research to show that liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) to treat lymphedema or lipedema improves health outcomes. No clinical guidelines based on research recommend liposuction for the treatment of lipedema. Therefore, liposuction (including, but not limited to, lipectomy, suction-assisted protein lipectomy, and lymph-sparing liposuction) is considered investigational for patients with lymphedema or lipedema.

**REFERENCES**


17. Nguyen, AT, Suami, H, Hanasono, MM, Womack, VA, Wong, FC, Chang, EI. Long-term outcomes of the minimally invasive free vascularized omental lymphatic flap for the


**NOTE:** Reporting 38999 for the treatment of lipedema is not appropriate as it is not a disease of the lymphatic system.

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