Guideline

of the Joint Federal Committee
on quality assurance measures for liposuction procedures ~~in stage III~~ lipedema

(Quality Assurance Guideline for Liposuction ~~in Stage III~~ Lipoedema / QS-RL Liposuction)

in the version dated September 19, 2019
published in the Federal Gazette BAnz AT 06.12.2019 B4
entered into force on December 7, 2019

last amended on June 18, 2020
published in the Federal Gazette (BAnz AT 15.09.2020 B1)
entered into force on September 16, 2020

Note

Approved amendments are shown in amendment mode,

Text in black font is currently valid and will not be changed.

Contents

§ 1 Legal basis and subject matter of the guideline on the use of the " " (surgical prosthesis)

(1) The Joint Federal Committee adopts this guideline as a quality assurance measure based on Section 136(1) sentence 1 no. 2 of the German Social Code, Book V (SGB V), which establishes eligibility criteria and minimum requirements for the structural and process quality of the indication, implementation, and care of patients undergoing liposuction for the treatment ~~of stage III~~ lipedema.

(2) [1]The guideline is intended for hospitals approved in accordance with Section 108 of the German Social Code, Book V (SGB V), as well as service providers participating in the statutory health insurance system. [2]All service providers who perform liposuction at the expense of health insurance funds must ensure that the eligibility requirements are met and that the minimum requirements are fulfilled. (~~3~~)Hospitals must meet the minimum requirements at their location. (~~4~~)The definition of hospital locations is based on ~~the agreement pursuant to~~ Section 2a ~~(1)~~ KHG in conjunction with the list of locations pursuant to Section 293 (6) SGB V.

(3) The titles of specialist physicians are based on the (model) further training regulations of the German Medical Association and also include physicians who hold a corresponding title under the old law.

§ 2 Objectives

[1]The objectives of this guideline are to ensure high-quality care and the safety of patients undergoing liposuction. [2]Surgical liposuction ~~for stage III~~ lipedema should contribute ~~in particular~~ to pain relief and eliminate any existing movement restrictions, thereby enabling an increase in physical activity.

§ 3 e method

(1) [1]Liposuction for the treatment of ~~stage III~~ lipedema must be performed as tumescent liposuction. [2]Dry suction methods are not permitted.

(2) Tumescent liposuction may be performed using water-jet assisted systems or vibration cannulas.

(3) A liposuction treatment may several consecutive partial procedures.

§ 4 Diagnosis and examination of the prerequisites for ~~liposuction Indication~~

(1) [1]The method may be used to treat lipedema at the expense of health insurance companies if ~~stage III~~ lipedema has been diagnosed, the indications have been checked, and liposuction has been indicated. (~~2~~)~~According to ICD-10-GM, stage III lipedema is characterized by localized, painful, symmetrical lipohypertrophy of the extremities with edema, marked circumferential enlargement, and large, flabby overhanging tissue of the skin and subcutis.~~Lipedema is diagnosed by a specialist in internal medicine and angiology, physical and rehabilitative medicine, or skin and sexually transmitted diseases, or by a specialist with additional training in phlebology.

and sexually transmitted diseases, or by a specialist with additional training in phlebology.

(2) For a diagnosis ~~of stage III~~ lipedema~~,~~ all of the following criteria must be met:

a) Disproportionate, symmetrical increase in fatty tissue ~~(extremities and trunk) with large, sagging areas of skin and subcutaneous tissue~~ that only affect the extremities.

b) No involvement of the hands and feet. and

c) Pain on pressure or touch in the soft tissue of the affected extremities.

(3) After diagnosis in accordance with paragraph 2, liposuction may be indicated if a doctor has determined that all of the following conditions are met

a) Despite continuous, medically prescribed conservative therapy within the last six months prior to the indication, the symptoms of the disease could not be sufficiently alleviated.

b) There has been no weight gain in the 6 months prior to the indication for liposuction.

~~b) Patients with a body mass index (BMI) of 35 kg/m2 or higher will receive treatment for obesity.~~

~~c)~~ Liposuction for BMI values between 32 kg/m² and 35 kg/m² is only permitted if the excess weight is predominantly caused by fat deposits on the legs and upper arms resulting from lipedema. This can be assumed if the waist-to-height ratio (WHtR) does not exceed the following age-appropriate limit values:

- 40 years and younger: 0.5
- 41 to 49 years: increase of 0.01 for each additional year of life
- 50 years and older: 0.6

Liposuction is not permitted if the BMI is greater than 35 kg/m².

If the above BMI or WHtR limits are exceeded, obesity must first be treated until the limits are no longer exceeded over a period of 6 months prior to the indication for liposuction.

~~b)~~d) The medical history should include any psychological factors that may play a role in the clinical picture.

(4) ~~Liposuction should not be performed if the BMI is 40 kg/m²or higher.~~

(4) The criteria listed in paragraphs 2 and 3 must be documented in the patient's medical records.

§ 5 Indications for liposuction and procedure-related quality assurance

(1) [1]The method may, in principle, be provided in accordance with the minimum requirements of this guideline both in contract-based medical care and as part of hospital treatment. (2)Liposuction for lipedema performed on an outpatient basis as part of contract-based medical care is an outpatient operation within the meaning of the agreement on quality assurance measures pursuant to Section 135(2) of the German Social Code, Book V (SGB V) on outpatient surgery.

(2) [1]The indication for liposuction is made by the operating physician after referral or hospital admission on the basis of the diagnostic criteria and indication requirements specified in § 4 (2) and (3), which have been previously determined by another physician with qualifications in accordance with § 4 (1) ~~and which~~. (2)The procedure shall be performed by specialists in plastic, reconstructive, and aesthetic surgery, other specialists in the field of surgery, and ~~other groups~~ of specialists ~~who perform surgery~~, such as specialists in dermatology and venereology. (3)Specialists other than those mentioned in sentence 2 who were already authorized to perform the method in accordance with this guideline before [insert date of entry into force of this amendment] shall continue to be authorized to do so.

(3) Before performing the procedure for the first time, physicians must be able to demonstrate experience in accordance with one of the following points based on these guidelines:

a) Independent performance of liposuction for lipedema in 50 or more cases prior to [insert date of entry into ~~force of~~ this ~~amendment~~].

b) Performance of liposuction for lipedema in 20 or more cases within two years under the supervision of an experienced user in the case of first-time use. Users who have independently performed liposuction for lipedema in 50 or more cases are authorized to provide supervision.

(4) [1] Comprehensive surgical planning must be carried out before the first procedure. [2] The number of individual procedures, the volume of fat to be removed in each procedure, and the areas to be treated must be planned, taking into account the risks involved. (3)As part of the procedure-related risk assessment, the maximum infiltration volume of the tumescent solution must also be determined and documented, taking into account the maximum active ingredient dosage if a local anesthetic is added.

(5) [1]More than 3,000 ml of pure fatty tissue per partial procedure may only be aspirated if postoperative follow-up for at least 12 hours is ensured. [2]The maximum volume of fat that can be removed per session is 8–10% of body weight in liters.

(6) No further liposuction may be performed in an area that has already been treated with liposuction.

(7)~~(6)~~ The service provider must ensure, through appropriate organization and infrastructure, that emergency plans (SOPs) and the equipment and medication required for resuscitation and other emergencies are available on site.

(8)~~(7) (~~[1]The service provider must ensure, through appropriate organization and infrastructure, that intensive medical treatment is available and that emergency inpatient surgery is possible. ([2])Facilities that do not have an intensive care unit and the continuous possibility of inpatient emergency surgery must ensure, through organizational measures, that any intensive medical or surgical treatment required by the patient is provided in cooperation with another facility.

§ 6 Verification procedure

(1) Compliance with the minimum requirements pursuant to § 5 (2) sentence 2, (3),~~ 76~~, and
~~87~~ must be verified before the service covered by this guideline is provided for the first time.

(2) [1]Liposuction may only be provided to patients as part of hospital treatment at the expense of health insurance funds once the evidence specified in paragraph 1 has been provided. [2]Hospitals shall provide the evidence specified in paragraph 1 to the state associations of health insurance funds and to the substitute health insurance funds in the federal state in which the respective hospital is located using the form set out in Appendix I. ([3]) The proof may be provided in writing or in electronic form using an advanced electronic signature. ([4]) The GKV-Spitzenverband shall publish a binding list of the state associations of health insurance funds and substitute health insurance funds on its website on January 1 of each calendar year. ([5])The list shall contain the names and addresses of the state associations of health insurance funds and substitute health insurance funds, the responsible departments, and the corresponding email addresses. ([6])Hospitals must also demonstrate compliance with the minimum requirements pursuant to Section 5 (2) sentence 2, (3), (~~67~~) and (~~78)~~ annually between November 15 and December 31 of the calendar year following the initial verification pursuant to sentence 1.

(3) [1]The performance and billing of services covered by this guideline within the scope of contract-based medical care by physicians participating in contract-based medical care is only permitted after approval has been granted by the relevant Association of Statutory Health Insurance Physicians. ([2]) Approval shall be granted if the participating physician proves to the Association of Statutory Health Insurance Physicians that the requirements set out in paragraph 1 are met in detail.

(4) [1]Service providers who no longer meet the minimum requirements pursuant to Section 5 (2) sentence 2, (3), (67) and (78) for a period of more than one month must notify the competent authorities thereof in accordance with paragraphs 2 and 3 by the end of this period. [2]Section 9 (3) remains unaffected by this.

Section 7 Specific bodies pursuant to Section 2 (3) No. 4 and Section 6 (3) QFD- RL

The bodies responsible for determining non-compliance with the minimum requirements and for determining and enforcing the consequences of non-compliance in accordance with Section 2 (3) No. 4 and Section 6 (3) of the Quality Promotion and Enforcement Directive (QFD-RL) are

towards hospitals, the health insurance funds, and towards contracted physicians, the respective Association of Statutory Health Insurance Physicians.

§ 8 Verification of compliance with the quality requirements of the German Hospital Federation ( )

(1) Checks on compliance with the minimum requirements are carried out in hospitals by the Medical Service on the basis of the guidelines for checks by the Medical Service ~~of the Health Insurance Funds~~ (MDK-QK-RL).

(2) [1]The associations of statutory health insurance physicians shall verify compliance with the minimum requirements pursuant to § 3 (1), § 4 (2) and (3) (a) to (c) and § 5 (2) sentence 1, (4) ~~and~~ (5) 6 of the services provided in contract medical care in accordance with these guidelines, including the services provided by affiliated physicians, by means of quality checks in individual cases (random checks) on the basis of § 135b (2) SGB V. [2]Sections 2 and 4 of the Quality Control Guideline for Contractual Medical Care (QP-RL) shall apply mutatis mutandis to the random checks. (3)The subject of the random check is the fulfillment of each minimum requirement in accordance with sentence 1. The Association of Statutory Health Insurance Physicians shall notify the physician of the result of the random check in a decision.

§ 9 Consequences of non-compliance with minimum requirements pursuant to Section

(1) ~~-~~The provisions in § 3 (1), § 4 (2) and ~~§-~~ (3) (a) to (c) as well as ~~-~~ e 5 (2) to (~~7)~~ 8 are minimum requirements.

(2) The non-fulfillment of minimum requirements leads to a loss of entitlement to remuneration.

(3) In the event of non-compliance with minimum requirements, liposuction may not be performed on patients at the expense of health insurance companies.

§ 10 Publication and transparency of the " "

(1) The implementation of these regulations must be presented in a structured quality report in accordance with the regulations of the Joint Federal Committee on the Quality Report for Hospitals based on Section 136b (1) sentence 1 number 3 SGB V.

(2) [1]Each year by April 30, the associations of statutory health insurance physicians shall transmit the following data from the previous year to the National Association of Statutory Health Insurance Physicians:

- Number of physicians authorized to perform liposuction based on these guidelines
- Number of authorizations granted and revoked,
- The results of the reviews pursuant to Section 8(2).

[2]The National Association of Statutory Health Insurance Physicians shall transmit the data to the office of the Joint Federal Committee by June 30.

~~§ 11 Transitional provision~~

~~Service providers who have already provided the service covered by this guideline between December 7, 2019, and September 16, 2020, must provide the proof in accordance with Section 6(1) by January 16, 2021.~~

Appendix I Checklist for checking the quality criteria of the guideline on quality assurance measures for liposuction procedures ~~in stage III~~ lipedema

Self-assessment:

The medical facility

_____

in _____

_____

(number/identification number of the location in accordance with the list of locations pursuant to Section 293 (6) SGB V)

meets the requirements for performing liposuction for ~~stage III~~ lipedema when providing the service.

General information:

All documents necessary to assess the accuracy of the following information must be submitted to the Medical Service (MD) in the event of an inspection to verify compliance with the quality requirements.

The specialist titles are based on the (model) training regulations of the German Medical Association and also include doctors who hold a corresponding title under the old law.

1 Availability and qualifications of medical staff

The indication for liposuction and the performance of liposuction shall be carried out by one of the following specialists.

• Specialists in plastic, reconstructive, and aesthetic surgery, • , other specialists in the field of surgery, • ~~or other specialist groups performing surgical procedures~~ Specialists in dermatology and venereology or • Specialists from other surgical specialist groups, provided that the respective physician was already authorized to perform the method in accordance with this guideline prior to [insert date of entry into force of this amendment].	□ Yes	□ No

Before performing the method for the first time on the basis of this guideline, the physician may demonstrate experience in accordance with one of the following points:

- Independent performance of liposuction for lipedema in 50 or more cases prior to [insert date of entry into force ~~of~~ this ~~amendment decision~~] or - Performance of liposuction for lipoedema in 20 or more cases within two years under the supervision of an already experienced user in the case of new application. *Users who have independently performed liposuction for lipedema in 50 or more cases are authorized to provide guidance.*	□ Yes	□ No

2 Structural requirements

- Emergency plans (SOP) and equipment and medication required for resuscitation and other emergencies are available on site.	□ Yes	□ No
- Intensive care treatment and inpatient emergency surgery are available. *Facilities that do not have an intensive care unit and the continuous possibility of inpatient emergency surgery must ensure that, if necessary, the patient receives intensive medical or surgical treatment through cooperation with another facility.*	□ Yes	□ No

Sign

The accuracy of the above information is hereby confirmed:

Place	Date	Medical director of the department providing the service

Place	Date	Management or administrative director of the hospital