

LEGAL STATUS OF OZONE THERAPY IN GERMANY¹

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- Based on “freedom of therapy” ozone therapy can be practiced without restrictions in Germany.
- German mandatory health insurances do not reimburse patients treated with ozone therapy since December 11, 2020.
- Based on ozone therapy papers prior to 1999, the authorities determined that “no guidelines or consensus articles could be found that recommend ozone therapy as a therapeutic measure.”
- Private insurance companies may offer their clients reimbursement for ozone therapy treatments.
- If current scientific papers, well founded and duly supported by research, were presented to the authorities, ozone therapy could once again be reimbursed by public and mandatory health insurance.

Germany: Origin of medical ozone therapy

Germany was the country where the ozone was synthesized in May 1840 by the chemist Christian Friedrich Schönbein; is the headquarters to large worldwide companies with great influence in the medical ozone equipment market; and is the place with the highest number of ozone therapists in the world. In 2011 [there were 11,000](#). Very surely the number of health professionals who practice ozone therapy today (2024), twelve years later, must be much higher.

Due to the German policy of “freedom of therapy” ozone therapy can be practiced without restrictions in Germany. Where there are restrictions is in the reimbursement of what the patient pays for ozone therapy.

Court decisions from 1995 and 1996

There are judicial decisions that could be applied to ozone therapy, based on the jurisprudence established by the Federal Court of Justice and the Federal Social Court.

[Three German authors](#) indicate that a ruling in July 1996 of the Federal Court of Justice (Bundesgerichtshof - BGH) and one from the Federal Social Court (Bundessozialgericht - BSG) of the same month but of the previous year, made “possible the acceptance of empirical medicine not only by the classical school but also by the legally recognized health insurance organizations.”

The condition, according to the Federal Court of Justice, is that the “treatment method is available and is used that is suited to provide relief for the disease concerned or to act against its aggravation” (BGH 1996). “This presupposes a success of the treatment method applied in a number of treated cases sufficient to establish a certain prognosis”.

According to the three German authors “it is thus possible to interpret § 2, Section 1, 3 SGB V in such a manner that such forms of treatment, even though they have not yet

¹ Chapter taken from the research “Ozone Therapy and Legislation - Analysis for its Regularization”. Roberto Quintero et al, AEPRMO, 11th. ed., 2023.

obtained recognition by the Federal Commission of Physicians and Health Insurance Organizations (Bundesausschuß der Ärzte und Krankenkassen), are still in agreement with regulations because proof of their efficacy in a guaranteed number of cases speaks in their favour, and because no serious objections exist against them in the context of quality (...)"

To demonstrate the efficacy of medical technology, the Federal Social Court has stated that the potential success must be based on "statistics on the number of treated cases and the efficacy of a new method conducted in a scientifically correct manner" (BSG 1995).

Both judicial decisions led to Beck et al. to extrapolate the case for ozone therapy, "provided that every case of successful treatment with ozone is documented statistically in the scientifically correct manner (...)"

Bearing in mind that the Social Legal Code (SGB) determines that it is no longer possible to base success on each and every individual case, the Medical Society for the Use of Ozone in Prevention and Therapy decided to publish statistical forms, for distribution to physicians upon request, to record the individual successes of the patients' treated with ozone therapy, to be duly registered. This will provide scientific basis for the successes obtained empirically and independently of the scientific research.

However, the statistical element referred to in 1996 by the Federal Court of Justice, and in 1995 by the Federal Social Court, seems not to be applicable today in Germany, in light of the decisions taken by the health authorities in the following years, and which we will examine below.

Ozone therapy is applied without restrictions but is not reimbursed by public health insurance

Germany does not currently have any governmental or parliamentary regulations on the regularization of the practice of ozone therapy. However, it is practiced without restrictions throughout its territory.

Reason why ozone therapy can be practiced without restrictions in Germany

The German drug and medical products supervisory body, the Federal Institute for Pharmaceuticals and Medical Products (Bundesinstitut für Arzneimittel und Medizinprodukte: the equivalent of the USA FDA, ANVISA in Brazil, COFIPRIS in Mexico, or the Spanish AEMPS, etc.), said, in a BBC news report, that "ozone is not an authorized medicine" in Germany. And it specified that in that country "there is the so-called 'freedom of therapy' ", which means "that a product does not necessarily need authorization as a medicine to be selected [by a doctor as therapy for a patient.](#)"

Freedom of therapy

Based on "freedom of therapy", ozone therapy can be practiced without restrictions in Germany.

Restriction on mandatory health insurance

Where there is an important restriction is in the mandatory health insurance that does not reimburse those who use medical ozone therapy. Therefore, it is advisable to briefly analyze the German legislation in relation to patients' medical insurance.

The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) [is a public legal entity](#) in charge of issuing “directives for the catalog of benefits of the official health insurance funds” and “thus specifies which healthcare services are reimbursed by the GKV [Gesetzliche Krankenversicherungen - Statutory Health Insurance Funds]”.

The importance of compulsory health insurance lies in the very high number of people who benefit from it. “About 73 million people” are insured “[by compulsory health insurance](#).”

The G-BA “is under the legal supervision of the Federal Ministry of Health” and its resolutions and directives “are audited by the Federal Ministry of Health”, to examine the legality of the decisions issued by the G-BA. If there are no objections or do not present any within the stipulated period, they are published, [on a mandatory basis, in the Federal Gazette](#).

For a therapy to be included in the “catalogue of benefits of the official health insurance funds” or excluded from it; and to determine which therapies are reimbursed by the GKV (Government Health Insurance Company) or a private health insurance (PKV) the G-BA requires that the diagnostic or therapeutic benefit of the therapy, and medical necessity, be demonstrated.

One of the elements that it takes into account the G-BA is the “evidence-based medicine” defined as follows by the same G-BA: “Base decisions regarding the expected benefit of a medical method on the body of current scientific knowledge. To achieve this, scientific studies on the relevant topic are systematically sought and their results are evaluated with respect to their plausibility [and applicability to the current topic](#).”

Ozone therapy is not reimbursed by public health insurance

Until 2000, public health insurance did include ozone therapy in its standard coverage, but as of the end of that year, it no longer does.

Indeed, on December 11, 2020, the G-BA included “ozone therapy, ozone autohemotherapy, oxygen-ozone autohemotherapy, oxyon therapy, hyperbaric ozone therapy”, in annex II of the “[Guideline Methods for Statutory Medical Care](#)” item 35.

This document lists (annex II) “lists the medical examination and treatment methods that, after review by the G-BA, cannot be provided as contracted medical services at the expense of statutory health insurance companies.”

To make this decision against ozone therapy being reimbursable by public health insurance, the G-BA made an analysis of the scientific basis of ozone therapy, which was published in a 33-page report on March 30, 2021.

The report notes that “no guidelines or consensus articles could be found recommending ozone therapy as a therapeutic measure.”

It states that “based on the discussion of the technical variants of ozone application and the scientific literature, the committee basically finds that there are no reasons that enable the practical implementation of a high-level scientific research, thus limiting methodological quality. It is necessary to evaluate the possible effectiveness and safety of the procedure through appropriate studies.”

“The committee reaches the following conclusions:

"1. The Committee has not received relevant studies on ozone therapy or other appropriate scientific research demonstrating effectiveness for any of the indicated indications, neither through the statements nor its own research.

"2. The scientific documents available so far have such serious deficiencies that they are in no way adequate to demonstrate the benefits, necessity and economic feasibility of ozone therapy for use within the framework of the compulsory health insurance.

"3. Contrary to claims in social litigation since around 1990, there have been no new relevant publications demonstrating a new state of knowledge. “The benefits, necessity and cost-effectiveness of ozone therapy have not been demonstrated.”

In conclusion, ozone therapy can be practiced without restrictions in Germany under the “freedom of therapy”. However, as of December 11, 2020, it is not refundable by mandatory health insurance. Private health insurance companies (PKV) can offer it to their clients [to be reimbursed for their ozone therapy treatments](#).

It should be noted that the G-BA report on ozone therapy was approved at the end of 2020 and the scientific papers on which it was based to make its decision were all prior to 1999. Since then, ozone therapy has evolved enormously; The number and quality of scientific research on ozone therapy has increased considerably. It could be likely that in the event of the presentation of current scientific articles, well founded and duly supported by research, ozone therapy could once again be reimbursed by public and compulsory health insurance.