Johner Institute

Can medical devices be reimbursed as assistive devices? Is that possible?

With Norbert Kamps , Prof. Dr. Christian Johner

Transcript

00:00:05 Speaker 1

Medical Device Insights.

00:00:08 Speaker 1

A podcast by the Ione Institute for medical device manufacturers, authorities and notified bodies.

00:00:17 Speaker 2

We here in the podcast talk regularly or almost exclusively about medical devices.

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One topic that is less discussed is the topic of

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Reimbursement of the financing of these medical devices.

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And now there is a very special class of products, namely the aids, which are also reimbursed in their own way.

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And here the only question is, are aids the same as medical devices or is it a disjoint set?

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When will they be reimbursed at all?

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These are all questions that we want to clarify in today's episode of the podcast.

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This time there are 2 people with me,

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that is Mr. Kamps and my colleague, Lea Wettlaufer.

00:01:00 Speaker 2

And because we want to welcome the guests first, I would suggest, Mr. Kamps, that you introduce yourself very briefly.

00:01:06 Speaker 1

Yes, my name is Norbert Kamps.

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Hello everyone, I am an engineer for medical physics.

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For about 30 years I have been moving in the field of aids, so I do in aids, as I always say so beautifully.

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And I'm a consulting engineer, which means I advise companies, I teach a little bit, I do a lot of training

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and the aids are my hobbyhorse, because this is the most exciting topic in the medical device sector.

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Yes, the first answers to our questions are already emerging, I'm looking forward to it.

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We also have the Lea Wettläufer with us.

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Lea, say something very briefly about yourself and maybe about the context why it is so important that you are here today.

00:01:42 Speaker 3

Thank you, Christian, and hello everyone.

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Yes, I am a team member in the Clinical Affairs department at the Juna Institute

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and support our customers with a focus on the preparation of the clinical evaluation and the clinical context of the medical devices.

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And the reason why I am here today is because I would like to share how clinical evaluation can help in the field of assistive devices.

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Yes, then let's start with the question, which already sounded a bit.

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So, how do aids and medical devices differ from each other?

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or perhaps they are aids about medical devices.

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Mr. Kamps, how would you compare or differentiate between them?

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Well, that's a very, very difficult question, because it's not that easy to define.

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So, they are both products, they are both material objects, software, for example, can also be an aid, all things that we also have with medical devices, of course.

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However, there are a few peculiarities that have been defined by case law, by law.

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Aids always serve to ensure the treatment of the sick, the curative treatment and one will say, medical products also work.

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But disability compensation, prevention of disability, we are slowly getting into such an area, where it sometimes gets tight with medical devices.

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Medical devices are rarely products that also facilitate care, prevent the need for care, at least in this sense, as the G.

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it understands.

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So here this independent, self-determined benefit under certain circumstances that they are necessary in the individual case.

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So very, very different requirements, actually more from a legal side.

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Of course, we have many aids that are also medical devices, quite often, but there are also many products that are not.

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Let's take therapy tricycles for children, adaptation aids for household items.

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If you have any screen readers for blind people, for example, or have visually impaired people, home emergency call devices, all of these are certainly important products in the field of assistive devices to be able to live independently and self-determined at home, but not medical devices in the true sense of the word.

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It just depends very much on the

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on the intended purpose, on the description, and there G.

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very, very much importance is attached to the fact that we demarcate that.

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So you can briefly say that aids are often medical devices, but not always.

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That's a very helpful answer, the mathematician's soul opens up right away.

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Yes, let's start with a topic that might now open or close the soul, I don't know, our favorite topic, the regulations.

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Of course, with all aids that are medical devices, it is clear that these regulations, which apply to medical devices, must probably be observed.

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But I suspect that there are still regulations for medical devices that have to be met.

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Which ones would be particularly important in your view, Mr. Kamps?

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Well, it is defined by paragraph 139 in SGB 5.

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The legislator actually says what an aid is or what an aid must fulfil, to be precise.

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and that was then filed again, made a little more precise in the list of aids by the G.K.V.

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umbrella association.

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So he interpreted it, so to speak, and the special requirements that are then placed on the aids, there are requirements for the special operational situations, that's how I would like to call it.

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So we don't have a secured, no closed, no defined area here, like a hospital, like a clinic,

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not in the doctor's office, but we have an area here that we don't know at all.

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We don't know where the products will be used.

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This can be at home, it can be at school, but it can also be during a walk in the forest.

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And these are special operational situations that must be taken into account.

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There are special requirements, for example in terms of equipment, certain functional properties, so that a product can then also be used independently of any energy supply, for example.

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The scope of delivery plays a very, very big role.

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There are also requirements, again from the G.K.V.

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umbrella association that very specific things must be included or may not be included at all, because they are more likely to serve the doctor.

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It is no longer an aid, because it is supposed to serve the patient.

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Often, it is not disposable products that G.K.V.

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umbrella association, but rather products that go into reuse, that can be refurbished.

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There are economic reasons for saying that it is probably cheaper in the long run.

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then the cleanability also plays a role.

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Of course, aids must be cleanable, just like medical devices, but with common household means, i.e. with the usual detergent that we have at home, with the usual washing-up liquid, which we use at home, can be used there and the products can be cleaned.

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Layman's safe operation is very important, of course, we have laymen here, we very rarely have professionals who use this and

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And here we come back into this unsecured environment.

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So, we don't have any security here in the sense that we always know, for example, what the electrical supply looks like.

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We don't have a central oxygen supply, for example, when it comes to breathing therapy equipment.

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We have to have everything decentralised and the layman-safe operation behind it, that's the important point.

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Yes, and very important, of course, it's about the medical benefit,

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which must be proven in broad application.

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It is not enough to have a single study, but it must really have already established itself in care.

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So to establish something new, a new examination and treatment method in the field of medical aids, that is damn difficult and you won't be able to do it with one or 2 simple studies, so to speak, but here you will have to gain experience over many years and only then will it be accepted for the supply of medical aids.

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Yes, and ultimately the very last requirement actually, these are the.

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yes, everyday objects of daily life that must be demarcated.

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So what we all use every day and the typical example of a medical device, what we often use, what everyone has at home, is a clinical thermometer.

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But this is also in the spirit of the G.K.V.

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is an object of daily use and therefore it is not remunerated.

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There is no reimbursement for these customers.

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Yes, that leads us straight into the next topic, namely pay.

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But perhaps a short follow-up question first.

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You have now mentioned above all those who have given the S.G.B.

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and the requirement of the G.K.V.s.

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Does the world of therapeutic products also know such things as standards, as the medical device manufacturers do, which could or perhaps even should be used to prove this requirement?

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Here I'll quickly straddle across, because you just said remedies.

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Yes, aids, definitely not cures.

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Remedies are services and here we have to distinguish very strongly from aids, which are always material things.

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Yes, of course there are also standards here.

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However, they are the well-known standards that we also know, be it 60 601, for example, for electrical safety, or others for special product-specific standards.

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We also know them here and they are also used and they are also demanded in part, but only in part, because the legislator has also clearly said here that they are not allowed.

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strict specifications in the sense that only very specific paths are possible here, but innovation should also be possible here, so that the manufacturer can also take other paths, can take paths outside certain standards, and therefore it is not a strict requirement, but in some points they are already required.

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Yes, thank you for this important addendum and thank you for the correction as well.

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To distinguish salvation and the image of help from each other is indeed extremely important for you.

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And yes, we follow that up to what you just said.

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It is now a question of payment, of reimbursement.

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So, you have already mentioned many, many prerequisites and who actually pays for it in the end or perhaps also, how do you get there?

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Yes, that doesn't have much to do with the list of aids.

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From a purely legal point of view, the list of aids is only a kind of yes source catalog, yes, as they say, as they say.

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So you can choose something from it,

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But there is still no relevance to the remuneration.

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Only when the product is needed later in the individual case and the health insurance companies have then also concluded contracts with the respective supplier and the aid is then dispensed, only then can it be reimbursed.

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But the whole thing is much easier if you have placed an aid in the list of aids and in this respect the list of aids has a great economic importance.

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So actually the basic prerequisite, you have to have recognition.

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legally as an aid and in order to be able to present this safely, the aid number naturally pays off very quickly.

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Because if you always have to show in individual cases that this is not a commodity, it is not a normal medical device, it is an aid, then it is damn time-consuming and that simply does not happen in individual cases in day-to-day business.

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And this can be shortened by entering products in the list of aids.

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Yes, and who will pay the health insurance companies then?

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It is a benefit in kind,

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This means that the insured person of the health insurance company submits an application to the health insurance company for care.

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This is usually done by a doctor's prescription, by prescription and then a cost estimate is submitted.

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The medical supply store that deals with this deals with the health insurance company, looks at the contracts and then a certain sum is reimbursed, which is negotiated in advance.

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And that's what the patient gets, namely the product at the end.

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You have just described that the

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Inclusion in the list of aids would not be absolutely necessary now in order to be reimbursable afterwards, but that it would be a very useful and helpful approach to choose this way.

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Of course, the question then arises directly, what do you have to do to be included in this directory.

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Yes, the first thing to do is of course submit an application, because nothing happens by itself, nothing goes automatically and the application is at the G.

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umbrella association.

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The National Association of Statutory Health Insurance Funds maintains the list of medical aids for all health insurance companies.

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He deals with it every day and he continues to write it.

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And here the application for admission must be submitted, which can be made informally.

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I always recommend using the forms that the National Association of Statutory Health Insurance Funds also publishes on its website, where it is already listed which documents and evidence you have to submit.

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sometimes it's more, sometimes less, it depends very much on the type of product we have.

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In principle, however, the regulations must always be submitted on the basis of Section 139 SGB 5 and here we have clear requirements that the manufacturer must prove, for example, for medical devices that a C.

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that he is a

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benefit must prove that it must also prove quality.

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How exactly this works is described in these applications, is described in the requirements of the National Association of Statutory Health Insurance Funds and typically one then submits a brochure, manufacturer documents such as instructions for use, cleaning instructions, labeling of course, the nameplate, packaging, product samples under certain circumstances.

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Special technical testing must be carried out by the

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test results are presented, for example in the case of wheelchairs or CPAP systems, they are required.

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And if you have put all this together, have also checked well, that is the most important recommendation of all, then you can also give the G.

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umbrella association and then he will take about 3 months, will check it and then hopefully you will be assigned an aid number.

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Yes, that would of course be the ideal result, let's look at one point right now.

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sound, but of course I also have to have a use for the thing somehow and of course the thought and association in the direction of the clinical evaluation rings a bell for me.

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Lea, would you see a clinical evaluation now in this context as a useful element to provide these useful evidence?

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Absolutely yes, the clinical evaluation has the goal or goal of proving the benefit of a medical device in the first place

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and will accordingly also refer to observational studies or, if necessary, clinical trial trials, which will ultimately also be used for the proof of benefit in the case of G.

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can be submitted to complete the application for medical aids listing.

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K., what would you do, Mr. Gams, if it wasn't a medical device and you therefore didn't have a clinical evaluation?

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What would be the alternative, the alternative process model?

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Yes, then of course it must also be shown in individual cases that the product has a benefit and here you have to look at the benefit first, a benefit in the sense of the G.K.V., so to speak.

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What is the task of the G.K.V., what, what must the G.K.V.

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and I have already hinted at this a bit, on the one hand there is the treatment of the sick, this is the disability compensation, we are very close to medical products, we will often have some there.

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But when we talk about disability compensation, we quickly get into the area of participation.

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and participation, that no longer necessarily has anything to do with illness.

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This no longer necessarily has anything to do with a medical device.

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So, if we have a product that, for example, enables a person in need of care to make an emergency call, then it is not necessarily disease-related and it does not necessarily have to be a medical device.

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And to prove the benefit here, that would be the important thing now and the best way to do that is to first carry out an application observation, by showing what is happening here in the first place.

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So, we've just written here for the

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Products in disability compensation, in the area of participation, not such high requirements that we have double-blind randomized trials, have to have controlled trials, but here it is sufficient if we actually simply show at a relatively low level that yes, is this a product that enables independent living, self-determined living at home.

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That sounds quite simple, but it's not that easy, because to show this effect, you have to do 23 things

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note.

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First of all, of course, what I have already indicated, consider the tasks of the GKV.

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The GKV is not responsible for everything.

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If you want to show that you can go to the cinema again with the product, that you can go to the theatre again, not a task of the statutory health insurance, yes, that doesn't do anything as proof of benefit, but you have to show that you can shop with it, that you can take it to the bakery, that you can go to the doctor.

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A task of the statutory health insurance must be completed and this is the first approach ever.

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The second approach is then really to represent a patient population,

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as the G.K.V.

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for example, not to bring in data that has nothing to do with this patient group.

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So really then also go for geriatric patients, for example, and that often goes wrong.

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And the third point is actually that it can also be transferred to our health system.

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This is always a problem when you bring in studies and observations from abroad.

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That is of course possible, there is no question about that.

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But

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You have to look at this again, can you transfer this to our health system.

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For example, we often have special nurses abroad who deal with these products.

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Here in Germany, however, it is required that it is laymen who deal with the product.

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And you have to pay attention to that too.

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And in this respect, you can‘t really give a blanket answer: What needs to be done?

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To look individually, to show, to work out the benefits, to present the benefits and to present them in such a way that I can understand them.

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this does not have to be done at the highest level of evidence, it can also be done at a lower, at the medium level of evidence, but this must of course happen.

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When we talk about medical devices, we need much higher evidence, then we also talk about controlled trials, let‘s talk about randomized trials, about double-blind studies and so on.

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Yes, then it looks completely different, but most of the aids, as I said, are also in the area of participation and disability and therefore the requirements are not quite as high.

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The clinical evaluation,

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which we don‘t have for these products, would of course be ideal for such a product.

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But we don't have it, because it is not demanded at all and in this respect it will not help us here.

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In the case of medical devices with a therapeutic benefit, with a medical benefit in the true sense of the word, the clinical evaluation is very, very important.

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Of course, it should fit there.

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They gave us a lot of tips and also told us what often goes wrong.

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One example was the

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non-representative population used in these studies or observations.

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What else often goes wrong?

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What are the typical problems they also encounter or where they have to help when manufacturers try in vain to get their product into the directory?

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Yes, I just touched on it a little bit, you don't pay attention to the tasks of the G.K.V., so to speak, what does this refund process look like, the right to benefits behind it?

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it is unfortunately the case that the right to benefits is not really only defined in the law, but has developed strongly over many, many decades through case law and you have to know a bit more about it.

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But it's just important that you only address the points that really make the G.

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yes.

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There is no goodwill regulation, we have a legally regulated area.

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and the tasks of the G.K.V.

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is the most important thing of all and this must be reflected in the wording, in the wording of the brochures, in the wording of the catalogues, in the wording of the instruction manual.

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If you write in the instructions for use that the products may only be used by nursing professionals, then the G.K.V.

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umbrella association quickly backtracked and said, wait a minute, we want to have this for nursing staff, for lay staff, not for nursing professionals.

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and just this little word „skilled workers“, which is introduced there, so to speak, can lead to an application being viewed with suspicion or even rejected.

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And these are often the instructions for use, very, very important point, central document, so to speak, when applying for aid numbers and that has to be right and the documents

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You can see that again and again, but unfortunately they are often not consistent.

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This means that statements in the instructions for use do not coincide with the statements in the brochures.

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The purpose looks a bit different and those are most of the problems we have.

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Now we have talked a lot about the problems that can arise if you want to be included in the directory.

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are there any that you still see afterwards, i.e. that perhaps even products disappear again, even though you have managed to be included in the list of aids?

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Well, the list of aids is actually just a ticket, that‘s all it is, it‘s a ticket to the game of patient care and if you have placed a product there, it doesn‘t mean that you get the orders, that you really reach the customer.

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So it may well happen that in the course of life

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the product is not sold so often anymore, because you simply don't work with the list of aids either.

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The product must then also be brought to the medical supply stores, it must also be economical for the health insurance companies, it must be reflected in the contracts and a manufacturer must actively take care of it.

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And if he doesn't do that, then it will perish.

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And if it goes down, then at some point the National Association of Statutory Health Insurance Funds will also find out, only this is not working at all, the product, it is not prescribed, it does not exist, it does not take place.

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And then there is an update and then such products are also removed from the directory and then all the work has been done in vain.

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Then it's gone again.

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So, products have to be prescribed and delivered.

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They must be reflected in the contracts.

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There is no automatic remuneration, there is no automatic payment, so to speak, just because a product is listed there.

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It's just the ticket, but the game itself has to be played by the manufacturer.

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Products have to prove themselves, again and again, and of course they are

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If it is the 4.5.

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product is then also registered of the same type, always in competition with each other and also there products have to prove themselves and also there you have to see that the customers are sometimes extremely critical, so especially when it comes to your own supply, where you can decide, do I take this wheelchair, do I take that walker, do I take this product, then it is very important that the products here always emphasize their special properties and

00:21:44 Speaker 1

And to present them and highlight the special properties, that's what the manufacturer should always do.

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He should always work out what the unique selling points are, because only then can you prove yourself in this whole round of the many, many medical devices and non-medical devices in the list of medical aids.

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Yes, the normal market rules also apply here, there is no exception, here too it is important to assert yourself.

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Yes, I think we have now addressed a lot of points, started with the distinction between aids and medical devices.

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how they have in common, how they differ, how they are paid, what typical mistakes arise or are made when trying to get into the list of aids.

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Yes, at the end I even talked about the fact that even this recording does not guarantee market success, but that there is still a lot more to do.

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So it's a big field and the fact that they've been working on it for decades also proves that it's not an easy one.

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Maybe, Lea, what would you recommend as a next step for people who want to go even deeper into the topic?

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Thank you, Christian, for asking.

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We have written a blog article in preparation for the podcast today and of course you have to read through it if you want more information.

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Yes, I think we have then reproduced a lot, also what we discussed today and also a little more, which I think is also exciting, also a link.

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how you can reach Mr. Kamps, who can help aid manufacturers in particular.

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So we at the Jona Institute are quite good at getting medical devices through to approval.

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We've done that thousands of times.

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When it comes to topics such as the inclusion of medical aids in the list of medical aids or if it is not medical devices, then there are better experts and one of these experts is Mr. Kamps.

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And that's why we have both in the article and at the bottom of the podcast

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in the show notes, his way of contacting him is still written in, so feel free to contact him, yes, there is still a lot for me to say to you, Lea, to them, Mr. Kamps and maybe soon until a continuation on this topic, because I think there is still a lot to say about it.

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Yes, thank you Christian for letting me be there today.

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Thank you very much that I was allowed to be there, it was exciting to look at it from the point of view of medical products

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And I would like to give one more thing, as a recommendation, so to speak: Always pay attention to your product and the unique selling points that your product has, and then it will also be something in the food directory.