2022年11月 7日（月）17:00 ～ 18:30

German DiGA Process – Update 2022-

ー ドイツにおけるプログラム医療機器に関する保険償還 Update 2022 ー

本日の内容：

1. **EBCからご挨拶**
2. **DiGAに関する講演**（日本語通訳付き）
3. **Q&A**（日本語通訳付き）

講師：

Dr. Philipp Kircher

DiGA創設において、連邦保健省に助言を行ったThinkTank HIH（Health Innovation Hub；現在は解体）のﾒﾝﾊﾞｰ。弁護士としてDiGAのケースに関わっている。

本日はご参加いただき、誠に有難うございます。
いただいた質問への回答をシェアさせていただきます。

注意事項

- いただきましたご質問のうち、講演で触れられたものにつきましては

  以下のQ&Aでは触れておりませんのでご了解をお願いいたします。

Q&A 1：Acceptance of DiGA -1-

DiGAを利用した事業者からのフィードバック（良かった点、改善が必要な点）などありましたら、可能な範囲で教えてください。

Please share the feedback about DiGA (Positive aspects as well as negative one) from manufacturers ? (Acceptance of DiGA by manufacturers)

Manufacturers have been very excited early on that there is finally a reimbursement path for DiGA. (This is also shown by the many applications to the BfArM).

Recently, however, the market has become disillusioned, because increasingly strict requirements (especially in data protection) are being imposed. In addition, the BfArM is conducting increasingly strict tests and requiring many additional analyses. At the same time, the prices that are agreed after one year are significantly lower than the manufacturers had hoped. One hears again and again that manufacturers are thinking about reimbursing their products through selective contracts with individual health insurance companies.

However, manufacturers who have once mastered the process are increasingly coming to market with multiple DiGA.

Q&A 2: Acceptance of DiGA -2-

SaMDの臨床的有用性が確立していない中での保険適用となりますので、Evidence Based Medicineの原則からは医師側も患者もSaMDを使用するモチベーションが低いのではと懸念します。SaMDが使用されない、エビデンスが集まらないと言った問題が生じなかったか教えてください。また、SaMDの使用を促すために取った対応がございましたら教えてください。
企業側の値付けの患者の受容性とアプリの浸透度について教えてください。

Under DiGA process, during the 12 months test period, SaMDs are reimbursed before clinical usefulness is fully demonstrated.
With no proven evidence at hand, were there any cases in which physicians as well as patients have no ~ little motivation to use such SaMDs and clinical data were not collected in the 12 months period ?
How well producer-set-prices & SaMDs are accepted by users ?
Were there any measures to accelerate the usage of not-yet-proven DiGAs in the 12 months test period ?
(Acceptance of DiGA by physicians and patients)

Tabelle 7: DiGA-Nutzung und Gesamtkosten bis 31. Dezember 2021

DiGA	Listung	Aufnahme	Indikationsbereich[1]	Anteil Frauen[2]	Ø Alter in Jahren[2]	Ausgegebene Freischaltcodes[2]	Anteil an Gesamtvolumen	Kumulierter Anteil	Kosten (TK)
Vivira	vorläufig	22.10.2020	Muskeln, Knochen und Gelenke	66,1 %	47,3	3.947	20,7 %	20,7 %	947.122 €
Kalmeda	dauerhaft	25.09.2020	Ohren	51,0 %	52,1	3.450	18,1 %	38,9 %	703.697 €
M-sense	vorläufig	16.12.2020	Nervensystem	85,0 %	38,8	2.524	13,3 %	52,1 %	555.230 €
zanadio	vorläufig	22.10.2020	Hormone und Stoffwechsel	74,6 %	46,2	2.434	12,8 %	64,9 %	1.216.513 €
somnio	dauerhaft	22.10.2020	Psyche	65,4 %	47,3	2.211	11,6 %	76,6 %	820.813 €
Selfapy (Depression)[3]	vorläufig	16.12.2020	Psyche	69,8 %	38,2	1.222	6,4 %	83,0 %	659.880 €
deprexis	dauerhaft	20.02.2021	Psyche	63,2 %	42,8	1.167	6,1 %	89,1 %	347.183 €
velibra	dauerhaft	01.10.2020	Psyche	68,6 %	40,8	574	3,0 %	92,1 %	273.224 €
Invirto	vorläufig	03.12.2020	Psyche	61,3 %	35,1	243	1,3 %	93,4 %	104.101 €
Selfapy (Gen. Angststörung)[3]	vorläufig	19.06.2021	Psyche	81,1 %	38,9	203	1,1 %	94,5 %	109.620 €
Mika	vorläufig	25.03.2021	Krebs	75,3 %	51,7	197	1,0 %	95,5 %	82.543 €
elevida	dauerhaft	15.12.2020	Nervensystem	79,3 %	46,9	185	1,0 %	96,5 %	137.594 €
companion patella	vorläufig	04.10.2021	Muskeln, Knochen und Gelenke	59,3 %	35,3	155	0,8 %	97,3 %	53.491 €

According to the DiGA Report 2022 of one of the largest health insurers in Germany (Techniker Krankenkasse), **6 of the 10 most often prescribed DiGAs are only provisionally listed** in the DiGA directory for trial use . I cannot see any indication of fear of a lack of proven benefit in this. The SaMDs are - regardless of whether you have proven a positive care effect at the BfArM - safe and efficient according to the regulations of the medical device law.

Prices have been the subject of much discussion. However, patients with statutory health insurance in Germany do not bear the costs of the therapy and may not even know the prices. Therefore, it does not have a significant impact on them, if the prices are high.

Q&A 3: Proof during test period

DiGAの仮登録の間に求められる臨床効果の証明について、どの程度RCT等の前向き試験を求めているのか。また、他の医療機器よりも柔軟な基準で認めているのか。そうだとすると、他の医療機器と同等程度に厳格である必要がないとするのはどのような考え方に基づくものか。

During the test period of 12 months, what kinds of medical evidence need to be generated ? Is prospective study such as RCT required ? Or are the requirements less strict ?
In case of latter (less strict requirements), what are the rationales behind that (less strict requirements accepted for DiGA)?

The requirements for demonstrating a positive supply effect are found in **Section 10 DiGAV**:

(1) The manufacturer shall submit a **comparative study** to prove the positive supply effects specified in accordance with Section 9 (1), which shows that the use of the digital health application is **better than its non-use**. Comparative studies within the meaning of sentence 1 are **retrospective comparative studies including retrospective studies with intraindividual comparison**.
(2) To demonstrate the positive health care effects specified in accordance with Section 9 (1), the manufacturer **may also submit prospective comparative studies** as an alternative to the studies in accordance with (1).
(3) Regardless of whether methods of clinical research or methods of other scientific fields such as, in particular, health services research or social research are used within the scope of the studies according to Paragraphs 1 and 2, **quantitative comparative studies must be submitted**. The methodological approach chosen must be appropriate to the positive health care effect to be demonstrated.
(4) The non-application according to paragraph 1 sentence 1 may be a **non-treatment or a treatment without digital health application**. The selection of the **comparator must correspond to the reality of care**. In deviation from sentence 1, the non-application **may also be a treatment with another comparable digital health application**. The other digital health application in accordance with sentence 3 must be definitively listed in the directory for digital health applications in accordance with Section 139e (2) and (3) of the Fifth Book of the German Social Code at the time of application.

Note: The text has been translated automatically.

Q&A 4: Producer-set-price -1-

保険の仮収載の際、企業の必要以上に高額な値付けを牽制する仕組みにはどのようなものがありますでしょうか？・保険の仮収載から本収載までの期間の定め、及び適切な収載額の評価方法は公開されていますか？・単回使用の医療機器ではなく、技術料に包括され繰り返して使用される医療機器（プログラム医療機器含む）も、DiGAの制度で評価されますか？もし評価される場合、仮収載、本収載それぞれにおける技術料の評価方法は公開されていますか？

Are there any mechanisms to have acceptable price (not too high) for producer-set-price ?
Are repeatedly used SaMD also applied to DiGA process ? If yes, how are the value of such SaMD assessed ?

In the first year, pricing is basically free, unless there are several comparable DiGAs, in which case there may be a **maximum amount for the group of DiGAs** (ceiling amount) if a DiGA was prescribed more than 2000 times in the first year. The health insurance company will not reimburse the manufacturer more than this maximum amount.
A lowered ceiling amount (80% of the group-specific ceiling amount) applies to provisionally listed DiGAs for trial use. If a DiGA is prescribed more than 10,000 times, the ceiling amount is reduced to 75% of the group-specific ceiling amount.

However, if prices are out of proportion, physicians may not prescribe DiGA and health insurers may not approve it. Otherwise, there may be recourse against the prescribing physicians. The „**general efficiency principle**“ applies in the SHI system.

There is no special evaluation method for **technical effort**. Prices are negotiated between the manufacturer and the German National Association of Statutory Health Insurance Funds, usually on the basis of use for 90 days. After that, a new prescription is in most cases necessary, which can trigger the costs again. It would be conceivable to make a follow-up prescription cheaper than an initial prescription or vice versa. Volume pricing or pay-for-use / pay-for-performance pricing models would also be possible. The law permits the processing of additional personal data required for this purpose.

Q&A 5: Impact on Business

DiGAは、SaMD開発企業にとって非常に魅力的に映ると思います。この制度により、海外企業が製品の展開先としてドイツを選択する、開発拠点をドイツに作るといった呼び込み効果があったか教えてください。

DiGA is considered to be a very attractive system for SaMD developers. Have DiGA had any positive economic impact for Germany to have developers launch their products first in Germany or to locate their development center in Germany ?
If yes, please share such examples with us.

Out of 34 DiGA in the DiGA directory, only 2 are from manufacturers based abroad (Romania and Czech Republic). Manufacturers located outside the EU in countries without a data protection level for which the EU Commission has not adopted an adequacy decision cannot currently be included in the DiGA directory. I know that companies from other countries have applied for inclusion (e.g. Switzerland) and other companies are currently targeting the market (e.g. Sweden, Denmark). Whether companies have relocated to Germany specifically for this purpose is not known to me.

Q&A 6: Program for physicians

DiGAは、「患者が中心となって使用するSaMD」を対象とした制度ですが、医師が使用する診断用AIなどDiGAの対象となりませんが開発が活発な領域もあります。ドイツにおいてこのような診断用AIを支援する施策がございましたら教えてください。

DiGA法の対象は、デジタルヘルスプログラム一般ではなく、患者が主に使用するものとなっているが、それはどのような考えに基づくものか。医師が診断に用いるようなものが対象になっていないのはなぜか。

DiGA is a process for SaMDs used by patients.

1) Are there any process/system which support the development of SaMDs for physicians' use such as AIs for diagnosis ?
2) What are the rationales of this concept ? Why are the programs used by physicians not included in DiGA process ?

1) Yes, there are also DiGAs that want to make it easier for physicians to make diagnoses or optimize therapy. So far, however, these DiGA have not been successful in the process. The BfArM is of the opinion that the DiGA must not be primarily helpful for physicians. (I see this differently, by the way. The law is much less strict here than most make it out to be).

2) The respective practice is responsible for equipping a practice with medical devices. It has to bear the costs itself. The DiGA follows the same logic as medicinal products. They are prescribed by physicians, but used by patients.

Q&A 7: Risk of DiGA usage

DiGAで仮登録された医療機器の使用に際して、従来の治療の追加的処置なのか、代替的処置なのか。代替的処置の場合、従来の治療とのトレードオフの関係になるが、従来の治療を受けられないリスクをどのように考えているのか

Are the DiGA usages during the 12 month test period considered as additional treatment or as alternative treatment (to normal therapy) ?
If latter (alternative treatment), how is the risk of not having normal therapy handled/accepted?

The law simply sees DiGA as another option along with assistive devices, physical therapy, pharmaceuticals, etc. If the DiGA requires additional medical care according to its own risk assessment, this can be provided by physicians. Reimbursements are created for this purpose. Whether the DiGA is used in addition or as a substitute depends on the DiGA. The German National Association of Health Insurance Funds is of the opinion that DiGA can only be considered in addition. I do not share this view, as it does not follow from the law.

Q&A 8: Limit of reimbursement

前回Webinarでは、「仮償還価格が企業側の提案で決めることが出来て、医療財政上は問題ないなのか？何か医師が利用請求する上での制限はないのか？」という質問に対して、実際にはこの請求をする医師側に「保険償還請求できる年間トータルの金額制限がある」という説明がありました。この年間の利用制限について、今回はもっと詳しく説明頂けることを期待しております。

『DiGA対象プログラムだけの制限なのか？』、『疾患毎の治療に係る制限なのか？』等、制限の対象、請求できなくなっても患者は来ると思うが、その場合にはどうするのか？等、もう少し具体的な状況が分かると行政との交渉にも役立つと思う。

In webinar last year, we learned that physicians have some limitation for reimbursement (of DiGA?).
Is it true ? If yes, is it only for DiGA or for each individual disease (or treatment)?
Patients will come to physicians, even when the limit is exceeded. What do physicians do in such cases ?

There are different reimbursement systems for physician actions and DiGA. Physicians who participate in the care of SHI patients are compensated according to their activities. However, basically the amount of money per year is capped for all physicians (except hospitals). Roughly speaking, physicians accumulate points over the year for their activities. The available money is divided at the end according to the distribution of points. For DiGA, compensation has not been capped to date. More prescribed DiGA could also mean higher costs.

Q&A 9: Regulation of positive effect

DiGAの仮登録にあたり求められる有効性について、どの程度の有効性が推定されれば仮登録が認められるのか。他の医療機器よりも柔軟な基準で認めているのか。
また、仮登録の承認書（仮登録にあたり規制当局側が許可したものとして発行するものをイメージ）には、有効性についてどのように記載されているのか。

What are the criteria of positive care effect (medical benefit) for being approved for DiGA ? Are they less strict than those for usual medical device?
How are the positive care effect (esp. medical benefit) described in the regulatory document/certificate issued by authorities ?

DiGAs do not necessarily have to show medical benefit. The term "**positive health care effect**" includes both a medical benefit or so-called "patient-relevant procedural and structural improvements".

The **medical benefit** in the sense of this regulation is the patient-relevant effect, in particular with regard to the improvement of the state of health, the shortening of the duration of illness, the prolongation of survival or an improvement in the quality of life.

Patient-relevant structural and procedural improvements in care, as defined in this regulation, are, in the context of the detection, monitoring, treatment, or palliation of disease or the detection, treatment, palliation, or compensation for injury or disability, directed toward supporting patients' health care actions or integrating processes between patients and providers, and specifically include the areas of.

1. Coordination of treatment processes,
2. Alignment of treatment with guidelines and accepted standards,
3. Adherence,
4. Facilitating access to care,
5. Patient safety,
6. Health literacy,
7. Patient sovereignty,
8. Coping with disease-related difficulties in daily life, or
9. Reduction of therapy-related expenses and burdens for patients and their relatives.

Note: The text has been translated automatically.

Q&A 10: Examination process

DiGAを利用することにより、認証までの期間、保険適用までの期間（中間値）はそれぞれいかほどになったでしょうか。
DiGAを利用するにあたり、通常の審査等に加え、付加的な費用は発生するでしょうか

What is the impact of DiGA process on the examination time frame?
Does application for DiGA incur any additional fee for examination?

The law provides that if a full application for permanent listing on the DiGA is received, the process is completed within three months. In the case of a trial, it would take three months to be provisionally listed. If necessary, the trial can be extended for up to twelve months. Subsequently, the BfArM would again have three months to evaluate the evidence. The trial process therefore consists of the individual trial period and the planned 6-month approval process. Mathematically, the procedure should not take longer than a maximum of 30 months. However, the deadlines cannot always be met. This may be due to incomplete documents, additional analyses required, appeal procedures and probably also a lack of personnel.