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Possibilities and obstacles of the German Reimbursement System (G-DRG) for the implementation of guideline-recommended adjunctive technical devices for percutaneous coronary interventions

Since the publication of the first guidelines of the European Society of Cardiology (ESC) for percutaneous coronary interventions (PCI) in 2005[1] and their update in 2010,[2] several adjunctive technical devices (e.g., drug-eluting stents [DES] and drug-eluting balloons [DEB]) have been recommended to improve patients' outcome after PCI. The desired widespread implementation of these techniques, however, can only be achieved if an adequate reimbursement of the materials is guaranteed.

The Concept behind the reimbursement system in Germany

Reimbursement for in-hospital PCI in Germany is processed by the German Diagnosis Related Groups (G-DRG) System, which is independent of the type of insurance a patient may have (social or private) and comprises a mixture of flat-rate reimbursements. For some devices, a fixed amount is paid in addition to monies provided by the DRG. The following overview describes how specific, important adjunctive PCI devices are evaluated and considers the extent to which they are currently covered by the reimbursement system in Germany.

Individual PCI procedures are described by an OPS (Operationen und Prozedurenschlüssel) code. The amount of reimbursement provided by the DRG for a specific procedure depends on the type and complexity of the procedure, the number of implanted stents, the morbidity of the patient and the length of the patient's hospital stay.

However, for the reimbursement of adjunctive PCI devices, there are, in essence, three different possibilities, which will be referred to as 'Modes' in this article and are defined as follows:

Mode A: direct payment of the device

For the given device, the payment of a fixed amount in addition to the DRG. This fixed amount can be either a *'Zusatzentgelt'* (additional payment) for established devices or a NUB (Neue Untersuchungs- und Behandlungsmethoden) for new devices whose use is not yet established in clinical practice. The reimbursement of these 'top-up' direct payments are independent of the morbidity of the patients and independent of the length of the hospital stay

Mode B: indirect 'payment' of the device

Payment for the device through an upgrade of the DRG category: this DRG change is triggered by the procedure-specific OPS code. Thus, some adjunctive PCI devices can be indirectly 'reimbursed', if the OPS code for the specific procedure leads to an increase of the DRG

Mode C: no payment of the device

Occuring when a procedure-specific OPS code does not trigger a change in the DRG category. In this instance, the technical device must be paid in full by the hospital

Let us now look at how these 'Modes' are applied across a range of devices used in clinical practice in Germany.

Therapeutic adjunctive devices

DES and DEB:

DES are accepted adjunctive devices and are reimbursed by direct payment for each single implanted DES, independent of the length of stay

in hospital (an example of 'Mode A' reimbursement). The amount of this flat rate is pre-specified for each year and is the same for all patients in Germany. However, it is important to note that there has been a notable decline in this flat rate over recent years, as can be seen in table 1. DEB also are reimbursed by 'Mode A', again at a pre-specified amount, which is €929.97 per procedure for 2013.

table 1

'Mode A' reimbursement for DES, whereby a fixed amount is reimbursed for each implanted DES. Note the decline in flat rate from 2008 to 2013.

Year	Fixed reimbursement for each DES
2008	€936.57
2009	€693.11
2010	€572.68
2011	€469.47
2012	€384.58
2013	€333.51

Examples of NUB ("New Diagnostic and Treatment Methods") 'Mode A' reimbursement include DES specifically engineered for bifurcations and stents that capture circulating CD34+ endothelial progenitor cells (Genous stent; OrbusNeich, Hong Kong). In these cases, for example, the amount of reimbursement is individually negotiated by each hospital with healthcare insurers; in our hospital, these stents are reimbursed at a rate of €700 and €615, respectively.

Other therapeutic adjunctive devices:

For the use of therapeutic adjunctive devices other than DES and DEB, there is considerable variation in reimbursement; these devices are classified under 'Mode B' or 'Mode C'. Large differences in reimbursement for a given procedure may be due to the number of stents used or the length of hospital stay. Below, we discuss some examples of this type of reimbursement.

Rotablation is a guideline-recommended procedure for the "preparation of heavily calcified or severely fibrotic lesions that cannot be crossed by a balloon or adequately dilated before planned stenting". The cost of such procedures is often indirectly reimbursed for the use of at least one burr. However, payments are dependent on the number of implanted stents and the length of the patient's hospital stay (Mode B reimbursement). For example, if the patient received two stents and stays in hospital for only one night, the rotablation is not fully reimbursed, despite the use of only one burr (table 2).

Thrombus aspiration catheters are also reimbursed according to 'Mode B'. As can be seen in table 3, the procedure is notably overpaid if only one stent is implanted, but quite balanced with the implantation of two stents.

There are also a number of devices and procedures for which no reimbursement is received. Distal

table 2

'Mode B' reimbursement for rotablation in patients with stable coronary artery disease. Depending on the number of implanted stents and the length of the patient's hospital stay, the costs of the procedure is, in the majority of cases, reimbursed for one burr. If the patient received two stents and stays in hospital for only one night, the rotablation is not fully reimbursed, despite the use of only one burr.

Mean cost of the rotablation material (€)	OPS code for the use of the rotablation catheter	Invasive procedure and length of stay	Change of DRG code triggered by the OPS code	Reimburse-ment of DRG (€)	Difference of DRG change (€)	Difference of DRG change minus device costs (€)	Comment
1,440 (Rotawire and 1 burr) and 1,250 for each additional burr	8-837.50	PCI 1 stent/ 1 night	From F58B to F19C	2,031.25 3,452.23	1,420.98	–19	One burr reimbursed
		PCI 1 stent/ 2 nights	From F58B to F19C	2,782.12 5,390.74	2,608.62	+1,168	One burr reimbursed, two burrs possible
		PCI 2 stents/ 1 night	From F56B to F19C	2,578.70 3,452.23	873.53	–566	Rotablation not reimbursed
		PCI 2 stents/ 2 nights	From F56B to F19C	3,640.69 5,390.74	1,750.05	+310	One burr reimbursed, second burr not reimbursed

table 3

'Mode B' reimbursement for the use of thrombus aspiration catheters in patients with 3-vessel disease (3-VD) ST segment elevation myocardial infarction (STEMI). Depending on the number of implanted stents, the costs of the thrombus aspiration catheter is either extremely overpaid or reimbursed.

Mean cost of the thrombus aspiration catheter (€)	OPS code for the use of the thrombus aspiration catheter (€)	Invasive procedure and length of stay	Change of DRG code triggered by the OPS code	Reimburse-ment of DRG (€)	Difference of DRG change (€)	Difference of DRG change minus device costs (€)	Comment
400	8-837.t	PCI in STEMI (3-VD) 1 stent/ ≥2 nights	From F52B to F19C	3,975.74 5,390.74	1,415	+1,015	Thrombus aspiration catheter is extremely overpaid
		PCI in STEMI (3-VD) 2 stents/ ≥2 nights	From F24B to F19C	4,986.88 5,390.74	403.86	+3.86	Thrombus aspiration catheter is reimbursed

embolic protection devices, which are guideline-recommended for PCI of venous bypass grafts to prevent a myocardial infarction, are not reimbursed at all, despite the existence of a specific OPS code (8-83b.9). Therefore, the average material costs of €720–1,000 must be paid by the hospital.

Although the 'cutting or scoring balloon' is guideline-recommended for "dilatation of in-stent restenosis, to avoid slipping-induced vessel trauma of adjacent segments", there is no direct payment and its OPS code (8-837.q) in most cases (except for 1 stent/1 night) does not lead to a change of the DRG ('Mode C'). The mesh-based embolic protection MGuard stent which is guideline-recommended for "highly thrombotic or SVG lesions" is not at all reimbursed. Similarly, arterial puncture closure devices are not reimbursed, as their specific OPS code (8-83b.c6) does not change any DRG. The average costs of €100–130 must be paid in full by the hospital.

Diagnostic adjunctive devices

Fractional flow reserve (FFR):

The measurement of FFR has been guideline-recommended since 2005 and received an 'IA' recommendation in 2010 for "the detection of ischaemia-related lesion(s) when objective evidence of vessel-related ischaemia is not available". FFR-guided PCI has been shown to improve clinical outcome compared with angiography-guided PCI and improved the clinical outcome compared with conservative treatment.

Although FFR measurement can provide cost savings by avoiding unnecessary stent implantations, the cost of the FFR catheter is reimbursed by 'Mode B' only in an unrealistic scenario. As we can see in table 4, if a lesion is characterized as not being of prognostic significance by FFR, and the patient leaves the hospital the next day, the FFR catheter is not reimbursed. For reimbursement to occur, the patient would have to stay in hospital for three nights. This is unrealistic and, even if the patient were to do so, the longer hospital stay would be cancelled retrospectively by the healthcare insurance providers. Furthermore, no reimbursement for the FFR catheter is received if a diagnostic catheterization is made during an outpatient appointment. If the FFR measurement leads to a stent implantation, the FFR catheter is effectively reimbursed only if a single stent is implanted and the patient stays in hospital for two nights. However, if two stents are implanted, the FFR catheter is not reimbursed and the hospital has to pay for it (table 4).

In summary, FFR that avoids unnecessary stent implantations is not reimbursed. Moreover, if FFR helps to stent selected significant prognostic lesions, it will be reimbursed only if one single stent is implanted and the patient stays in hospital for two nights.

Intravascular ultrasound (IVUS) and optical coherence tomography (OCT):

IVUS and OCT are useful for characterizing lesions and checking the quality of stent implantation, especially in detecting malappositions. The situation for IVUS is the same as for FFR ('Mode B'). Although

table 4

'Mode B' reimbursement for the use of FFR catheters in patients with stable coronary artery disease. Depending on the type of procedure, number of implanted stents and the length of the patient's hospital stay, the cost of the FFR catheter is either "reimbursed" or must be paid in full by the hospital.

Mean cost of the FFR catheter (€)	OPS code for the use of the FFR catheter (€)	Invasive procedure and length of stay	Change of DRG code triggered by the OPS code	Reimburse-ment of DRG (€)	Difference of DRG change (€)	Difference of DRG change minus device costs (€)	Comment
700	1-279.a	**FFR without PCI:**					
		Diagnostic catheter only, 1 night	From F49G to F49G	1,235.50 1,235.50	0.0	–700	FFR catheter not reimbursed
		Diagnostic catheter only, 2 nights	From F66B to F66B	1,414.99 1,414.99	0.0	–700	FFR catheter not reimbursed
		Diagnostic catheter only, 3 nights (unrealistic)	From F49E to F49D	2,450.06 3,652.66	1,202.60	+502.60	FFR catheter extremely overpaid
		FFR with PCI:					
		PCI 1 stent/ 1 night	From F58B to F56B	2,031.25 2,578.70	547.45	–153	FFR catheter almost not reimbursed
		PCI 1 stent/ 2 nights	From F58B to F56B	2,782.12 3,640.69	858.57	+159	FFR catheter slightly overpaid
		PCI 2 stents/ 1 night	From F56B to F56B	2,578.70 2,578.70	0.0	–700	FFR catheter not reimbursed
		PCI 2 stents/ 2 nights	From F56B to F56B	3,640.69 3,640.69	0.0	–700	FFR catheter not reimbursed

an OPS code exists (3-05g.0), the hospital, in many circumstances, has to pay approximately €700 for the IVUS catheter (table 4). Although OCT has its own OPS code (3-300), it is not reimbursed at all.

Conclusion

The German reimbursement system makes sense only for DES, DEB and Mode A devices covered by NUB. Many other guideline-recommended PCI devices are reimbursed only with the wrong incentives or must be paid in full by the hospital. The German System should be improved by separating the reimbursement for material costs (like FFR catheter) from the procedural costs to avoid wrong incentives.

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