MTRC

Market Access for Medical Technologies in Austria

Prepared for

BVMed
Bundesverband
Medizintechnologie e.V.

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Reimbursement Represents the Key Major Market Access Hurdle in Austria

Reimbursement	Acceptance by payers	Stand-alone HTA
Mechanism to pay for technology or medical procedure	**Independent acceptance by payers or national decision-makers**	**Stand-alone health technology assessment**
○ A DRG-adjusted budget allocation to hospitals in hospital, day case, and hospital-based outpatient specialist settings ○ Fee-for-service model for outpatient visits and minor procedures	○ Does not exist in Austria	○ HTA by the Austrian Institute for Health Technology Assessment (AIHTA) is integrated into reimbursement decision-making

Federal and Social Insurance Stakeholders Jointly Shape Hospital Reimbursement

Payers

Sickness funds
Five sickness funds were established following the 2020 structural reform of payers. Distribute money to state funds to pay hospitals within the statutory health insurance system. Directly pay for out-patient and GP care

Policy-makers

Bundesministerium
Arbeit, Soziales, Gesundheit,
Pflege und Konsumentenschutz

Federal Ministry of Labor, Social Affairs, Health, Care, and Consumer Protection (BMASGPK)
The highest governing body, responsible for regulatory affairs, supervision of national healthcare, national clinical guidelines, and strategies. Superior to the **Federal Health Agency**, which is part of the ministry in charge of health

Bundesministerium
Arbeit, Soziales, Gesundheit,
Pflege und Konsumentenschutz

Federal Health Commission
Develops key policies in the healthcare system. Involved in the approval of the procedural classification and DRG system. Part of the **Federal Health Agency**. Includes representatives of key stakeholders

Österreichische
Sozialversicherung

The umbrella organization of Austrian Social Security Institutions (Dachverband)
Coordinating activities and producing policy guidelines. Negotiates collective contracts in the ambulatory sector. Develops HTAs

Decision influencers

Austrian Medical Chamber
Legal representative body of physicians. Participates in the creation of agreements regulating relations between physicians and social security institutions. Negotiates collective contracts in the ambulatory sector

Austrian Institute for Health Technology Assessment (AIHTA)
Health technology assessment to support decisions about the introduction of novel procedure codes into the Austrian system. Main HTA organization in Austria

Austrian Health Institute (GÖG)
Research and planning for health care, creates HTA reports, economic analyses, quick assessments, and national clinical guidelines on the benefits and risks of different therapies

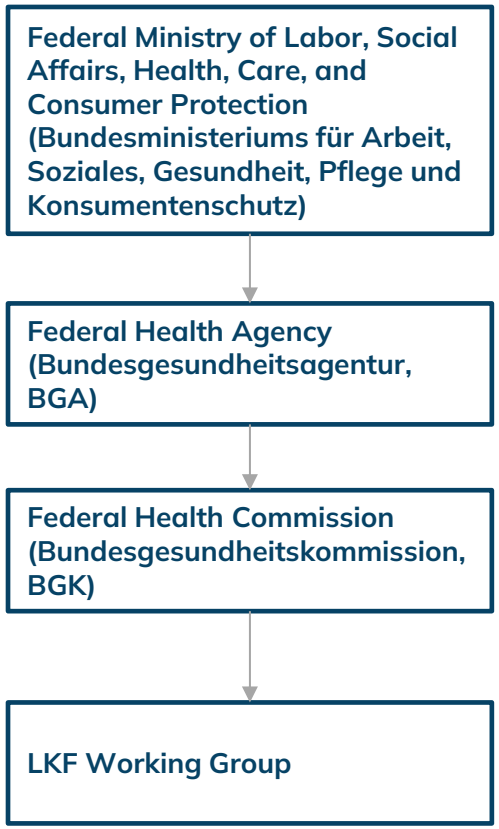
Institute of Technology Assessment
Has a counseling role for scientific policy

Technical support

Bundesministerium
Arbeit, Soziales, Gesundheit,
Pflege und Konsumentenschutz

LKF Working Group
Develops procedural classification and DRG system in Austria. Supervised by the Federal Health Commission

Federal Health Bodies Govern LKF Policy and Procedure Code Decisions

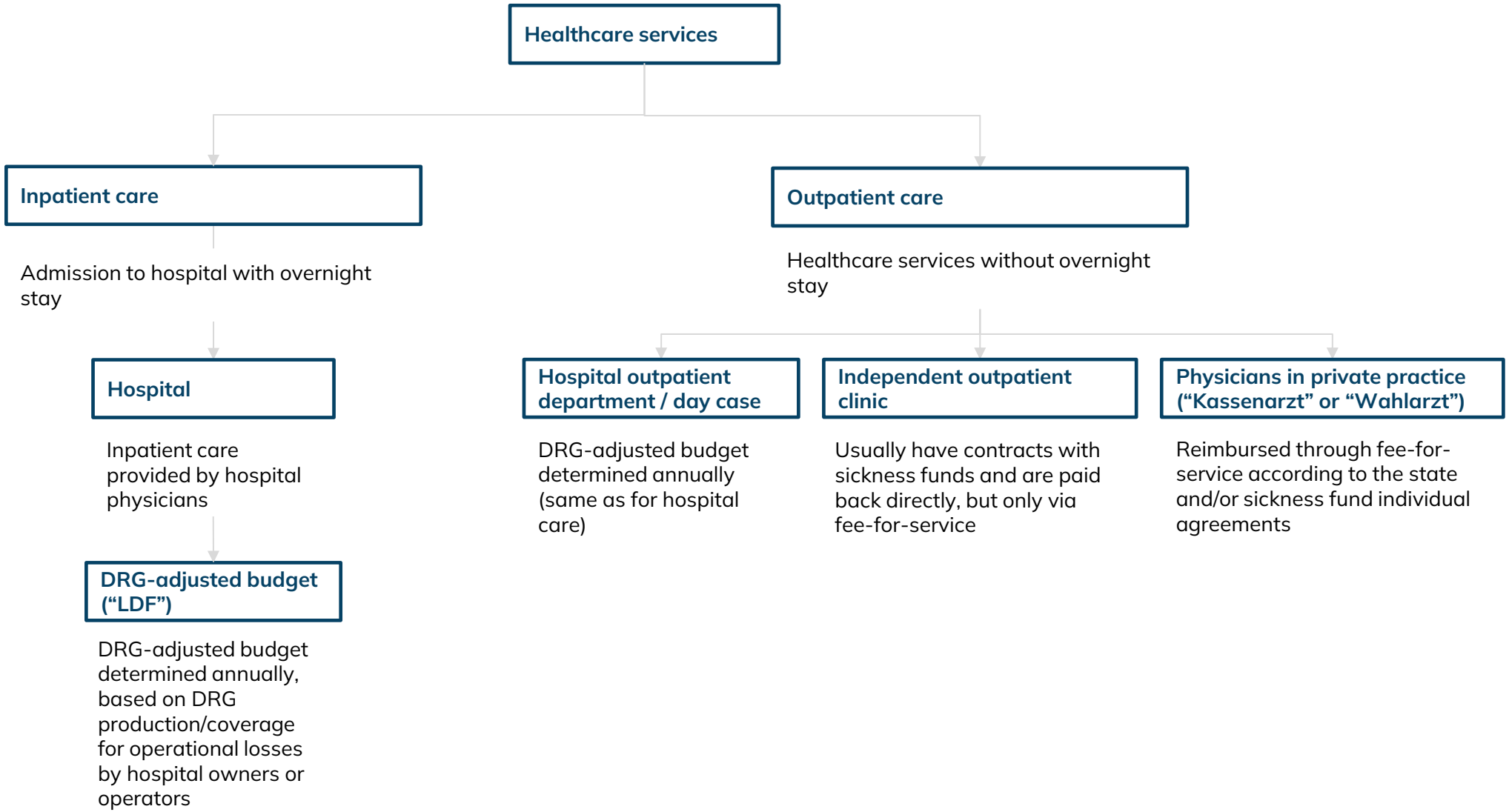


Distributes the federal funds for financing the public hospitals to the nine state health funds

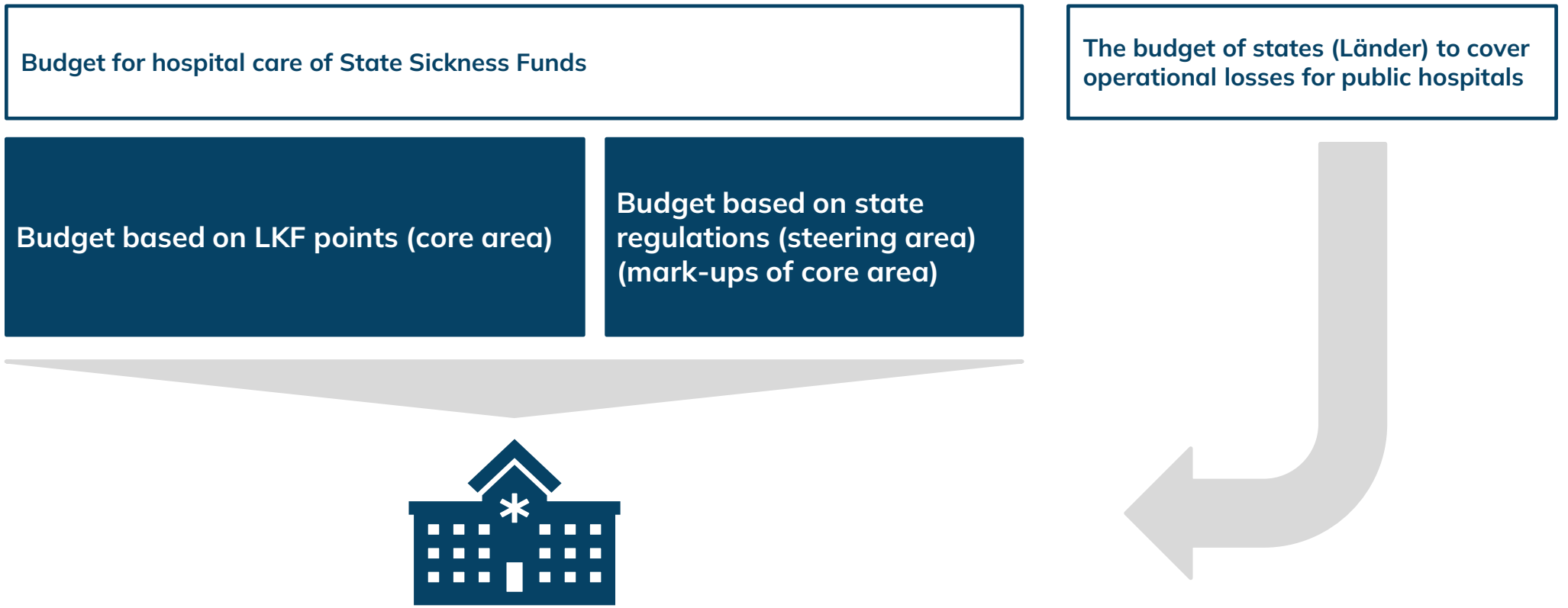
Advisory body for local authorities and sickness funds on health policy issues. Includes representatives of the federal government, social security, all states, the interest groups of the cities and municipalities, the confessional hospitals, patient representatives, and the Austrian Medical Association, as well as other non-voting members

The actual developer of the DRG (LKF) system

Austrian Payment Logic Differs by Inpatient, Hospital Outpatient, and Ambulatory Settings



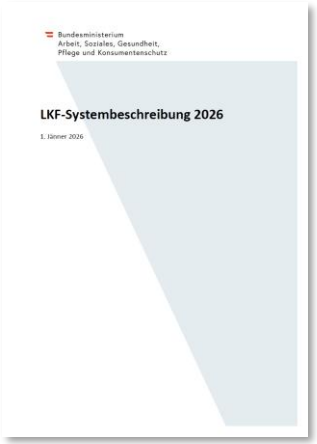
LKF Points Allocate Fixed Hospital Budgets Rather Than Direct Case Payments



The system is used to allocate a limited, fixed budget to hospitals. As the activities of hospitals vary, the hospitals can typically (but not always) have a deficit of funds. This deficit is covered by the steering area of the State Health Funds or extra payments by states to cover operational losses (Betriebsabgangsdeckung)

LKF Functions as a DRG-Like Budget Allocation System for Inpatient Care

- Austrian hospitals operate within an annual budget, which is calculated based on their production in the previous year, which is documented via the LKF system
- The LKF system is a DRG-like performance-oriented financing system
- It has been used for the financing of inpatient services since 1997
- The LKF catalog includes procedures that are obligatory to be performed in inpatient settings and those that can be performed as ambulatory services, optionally
- Changes to the LKF take effect on January 1st of each year. As a basis for decisions on model changes, the planned modifications are defined by May 31st, and simulation calculations are prepared by June 30th of the year preceding the billing year
- Since 2017, the final model specification must be completed by July 15th by the Standing Coordination Committee commissioned for this purpose by the Federal Target-Based Governance Commission (Bundes-Zielsteuerungskommission, B-ZK)
- The required model descriptions and LKF point-allocation programs are made available to the federal states and/or the state health funds by September 30th
- An updated version of the LKF catalog is released by the Federal Ministry of Labor, Social Affairs, Health, Care, and Consumer Protection annually. It comes into effect on January 1st of each calendar year. Procedures and DRGs are approved by the Federal Health Commission



Austrian DRGs Are Determined by MEL Codes, Diagnoses, and Patient Parameters

- The LKF Working Group (under the Federal Health Commission) is the main administrator of the LKF/DRG system
- The system is used for the calculation of the hospital budget
- DRGs are defined by a combination of
  - Diagnosis codes (International Classification of Diseases; ICD-10)
  - Procedure codes (Austrian Individual medical procedure; MEL)
  - Patient-specific parameters (e.g., age, length of stay, sex)
- The combination of codes and patient characteristics will result in a specific DRG associated with points (cost weight). These DRG points are multiplied by a monetary base rate that differs between federal states and even hospitals within states
- Cost weights are determined based on the micro-costing method using data from selected reference hospitals
- Monetary base rates are determined based on reference cost weights from previous years
- Data about the usage of codes and DRGs is collected by the Ministry through the data warehouse “DIAG” and analyzed by the LKF Working Group
- The LKF model differentiates between procedure-related groups (medizinische Einzelleistungen, MEL) and main diagnostic groups (Hauptdiagnose-Gruppen, HDG), leading to MEL groups or HDG groups. These groups are given specific LDF points
- Intensive care treatment is covered by daily supplements

Aortic Valve Replacement Illustrates How LKF Points Translate into Hospital Payment

- Example of calculation of reimbursement tariff for open aortic valve replacement
  - Primary procedure code: DB070 “Replacement of aortic valve with stentless valve”
  - Diagnosis code: I35.0 “Aortic stenosis”
  - Age – 55
  - Sex – female
  - Discharge status – home
  - Type of setting – in-patient
  - Length of stay: 7 days
  - Type of care – elective admission

  - **Resulting DRG: MEL08.03A “Intervention on the heart valves and ascending aorta with the heart-lung machine”**
    - Cost weight is 16,646 points, composed of
      - 7,524 points for the ward component (TK-Anteil)
      - 9,122 procedural component (LK-Anteil)
    - Cost weight is multiplied by the base rate. As an example, for AMEOS Klinikum Bad Aussee in 2024, this is €1.04 per point
    - The reimbursed tariff is €17,312 (= 16,646 * €1.04)
    - This amount will cover every aspect of care from admission until discharge

This example was developed based on 2024 data

Provisional Procedure Codes Enable Tracking but Usually Provide Insufficient Funding

- Provisional statement of a procedure is the outcome of a standard application for a new procedure code, in case a procedure is promising but the evidence is regarded as insufficient
- Provisional codes (beginning with XN) may be assigned to high-cost, innovative procedures if sufficient evidence is not yet provided due to, e.g., a small sample size in the studies. They are used during the time further evidence is collected, and make it possible to data-track a new technology
- A provisional code can be used by any Austrian hospital (not only by those who submitted the application) once it is integrated into the procedure code catalog. However, hospitals need approval from the state sickness funds to provide and charge for provisional procedures
- Provisional procedure codes are grouped into existing DRGs, meaning that the reimbursement tariff is usually insufficient
- If sufficient evidence could be established, the Federal Ministry of Labor, Social Affairs, Health, Care, and Consumer Protection will, without a need for a further application, transfer the code into a regular one and create a new DRG which will be available on January 1st one year later. Otherwise, the provisional procedure code can be extended for another year or deleted/removed from the catalog
- In practice, however, provisional codes are often not used so that no evidence can be collected, and codes stay in their provisional state for multiple years. There is no possibility for manufacturers to impact the process of annual re-evaluation
- Provisional codes are listed in Chapter 22 of the Procedure Codes Catalog (see next slide)

Provisional Codes Cover Selected High-Cost Innovative Procedures

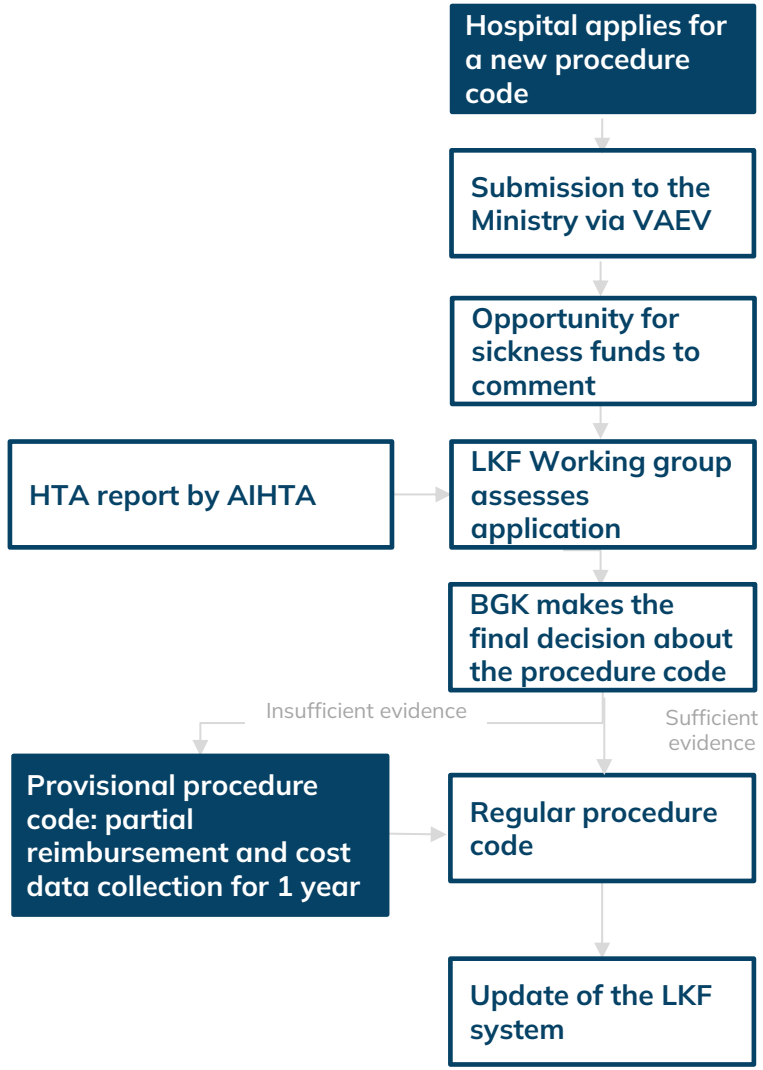
Code	Name of procedure (English)	Name of procedure (German)
XN030	Implantation of a stent graft in the ascending aorta (LE = per session)	Implantation eines Stentgrafts in die Aorta ascendens (LE=je Sitzung)
XN050	Mitral valve reconstruction – catheter-based, transvascular (LE = per session)	Rekonstruktion der Mitralklappe – kathetergestützt, transvaskulär (LE=je Sitzung)
XN051	Tricuspid valve reconstruction – catheter-based, transvascular (LE = per session)	Rekonstruktion der Trikuspidalklappe – kathetergestützt, transvaskulär (LE=je Sitzung)
XN055	Mitral valve replacement – catheter-based, transapical (LE = per session)	Ersatz der Mitralklappe – kathetergestützt, transapikal (LE=je Sitzung)
XN056	Mitral valve replacement – catheter-based, transvascular (LE = per session)	Ersatz der Mitralklappe – kathetergestützt, transvaskulär (LE=je Sitzung)
XN057	Tricuspid valve replacement – catheter-based, transvascular (LE = per session)	Ersatz der Trikuspidalklappe – kathetergestützt, transvaskulär (LE=je Sitzung)
XN060	Catheter ablation of the renal sympathetic nerve plexus (LE = per session)	Katheterablation des renalen Sympathikus-Nervengeflechtes (LE=je Sitzung)
XN080	Percutaneous transluminal angioplasty (PTA) of intracranial vessels (LE = per session)	Perkutane transluminale Angioplastie (PTA) an intrakraniellen Gefäßen (LE=je Sitzung)
XN090	Percutaneous transluminal recanalization with stent implantation of intracranial vessels (LE = per session)	Perkutane transluminale Rekanalisation mit Stentimplantation an intrakraniellen Gefäßen (LE=je Sitzung)
XN100	Percutaneous transluminal embolization of cerebral aneurysms using a flow diverter (LE = per session)	Perkutane transluminale Embolisation cerebraler Aneurysmen mittels Flow Diverter (LE=je Sitzung)
XN110	Implantation of a permanent embolic protection system into the left atrial appendage (LE = per session)	Implantation eines permanenten Embolieprotektionssystems in das linke Herzohr (LE=je Sitzung)

Provisional Codes Cover Selected High-Cost Innovative Procedures

Code	Name of procedure (English)	Name of procedure (German)
XN120	Implantation of a fully bioresorbable stent into the coronary vessels (LE = per stent)	Implantation eines vollständig bioresorbierbaren Stents in die Koronargefäße (LE=je Stent)
XN130	Implantation of a leadless pacemaker – percutaneous (LE = per session)	Implantation eines sondenlosen Herzschrittmachers – perkutan (LE=je Sitzung)
XN140	Implantation of a system for telemedicine monitoring of pulmonary arterial pressure (LE = per session)	Implantation eines Systems für ein telemedizinisches Monitoring des pulmonal-arteriellen Druckes (LE=je Sitzung)
XN170	Minimally invasive implantation of self-expanding prostheses into the anal sphincter apparatus (LE = per session)	Minimalinvasive Implantation selbstexpandierender Prothesen in den analen Sphinkterapparat (LE=je Sitzung)
XN180	Monoclonal antibodies for Covid-19 (LE = per application)	Monoklonaler Antikörper bei Covid-19 (LE=je Applikation)
XN190	Implantation of a fenestrated stent graft – aortic arch (LE = per session)	Implantation eines gefensterten Stentgrafts – Aortenbogen (LE=je Sitzung)
XN200	Implantation of a pacemaker, HIS bundle pacing (LE = per session)	Implantation eines Herzschrittmachers, HIS Bündel Pacing (LE=je Sitzung)
XN210	Implantation of a system for respiratory-controlled stimulation of the hypoglossal nerve (LE = per session)	Implantation eines Systems zur atmungsgesteuerten Stimulation des Nervus hypoglossus (LE=je Sitzung)
XN220	Percutaneous aspiration thrombectomy of the pulmonary artery (LE = per session)	Perkutane Aspirationsthrombektomie der Pulmonalarterie (LE=je Sitzung)
XN230	Percutaneous aspiration thrombectomy of the heart/large veins with extracorporeal circulation (LE = per session)	Perkutane Aspirationsthrombektomie Herz/große Venen mit extrakorporaler Zirkulation (LE=je Sitzung)

LKF Integration Requires Hospital-Led Application and AIHTA Review for Innovative Procedures

- The introduction of a new procedure code (MEL) requires high-level clinical evidence
- Hospitals or their operators can submit proposals for a new procedure by September 30th of each year through an internet-based system (VAEV) to the Federal Ministry of Labor, Social Affairs, Health, Care, and Consumer Protection
- Experts from the Austrian sickness fund (ÖGK) and private hospital financing fund (PRIKRAF) contribute to the review of the proposals
- LKF Working Group assesses proposals and gives suggestions to the Federal Health Commission (BGK), which makes the final decision about the creation of new procedure codes
- In the case of innovative technologies, the Austrian Institute for Health Technology Assessment (AIHTA) conducts a systematic, scientific review of papers (HTA reports) with a focus on the efficacy and safety of the technology
- A permanent code is established if sufficient evidence is found. If evidence is insufficient but technology is promising, a provisional code (NUB) can be created
- The annual release of the catalog of procedures by the Federal Ministry of Labor, Social Affairs, Health, Care, and Consumer Protection becomes effective on January 1st

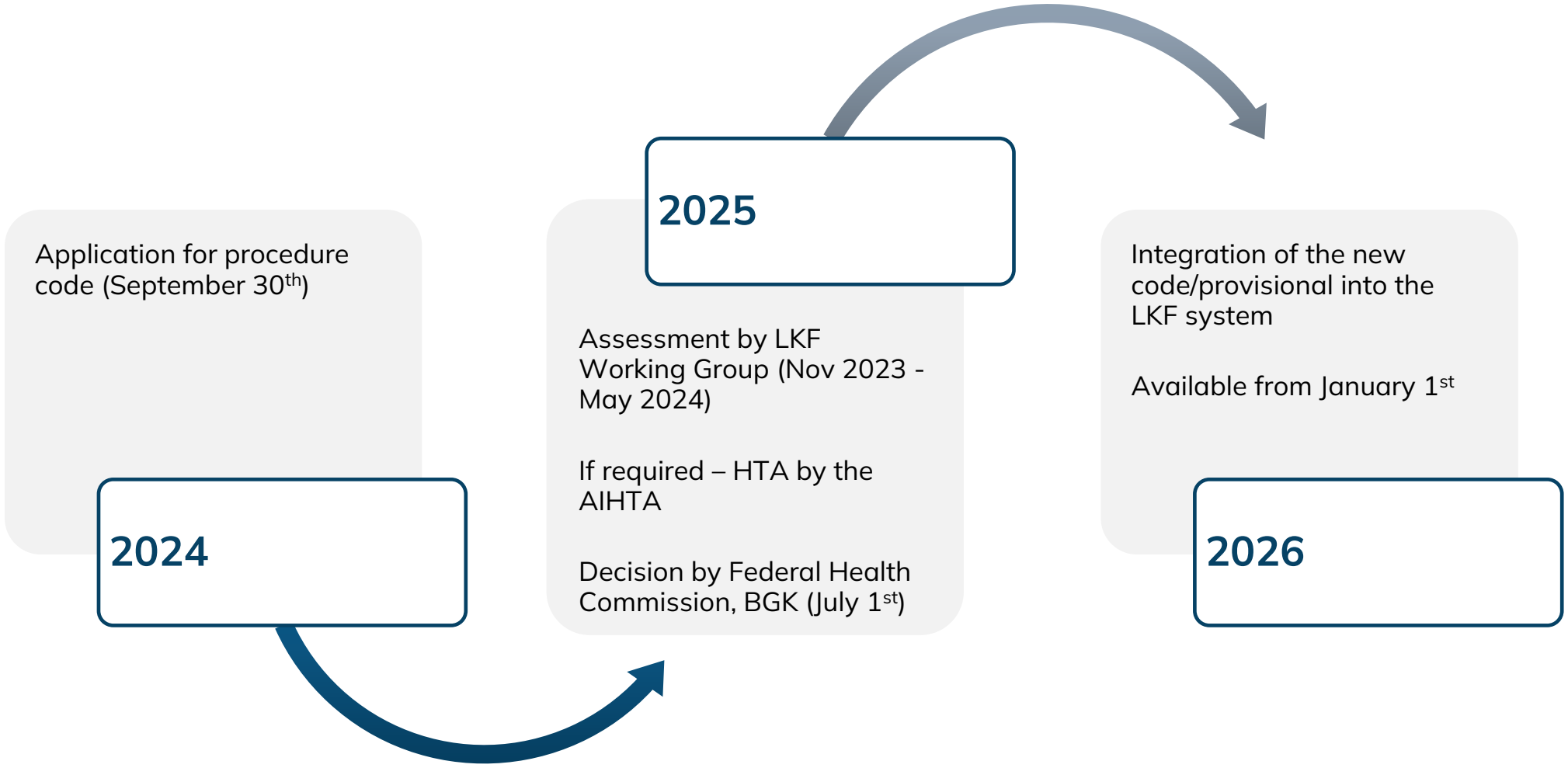


Novel Procedure Acceptance Depends on Clinical Definition, Evidence, and Economic Relevance

- For procedures to be included in the catalog, the following criteria generally must be met:
  - The procedure is new (newly developed) or necessary to reflect medical progress
  - The procedure is clinically established
  - Adequate scientific evidence is available
  - There is a clearly defined medical indication for the procedure
  - The procedure and its corresponding performance unit are clearly defined and can be distinguished from other catalog procedures
  - The procedure is economically relevant in terms of costs and/or frequency of use

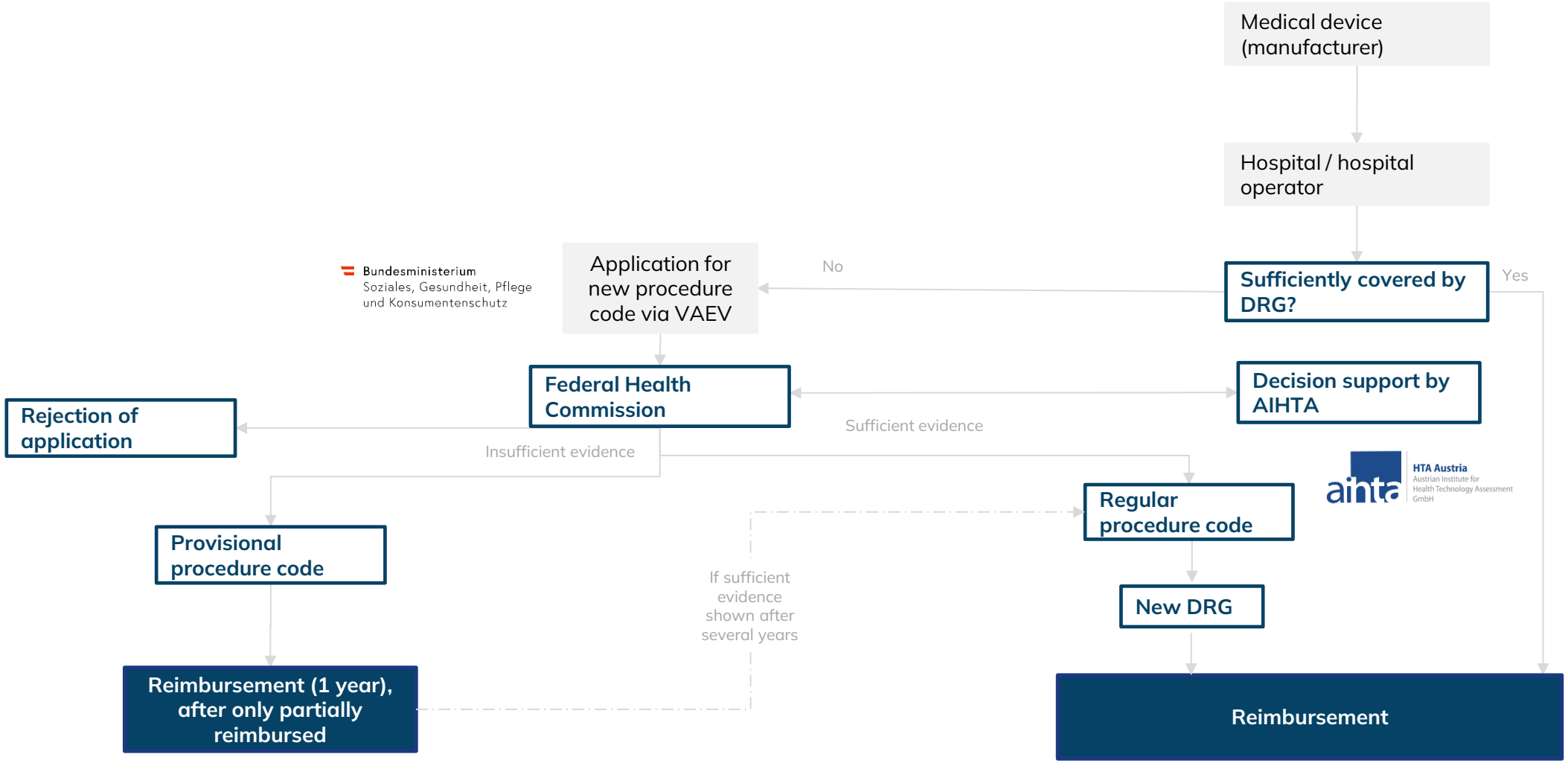
- The following proposals are not included in the catalog:
  - Incomplete proposals
  - Diagnostic examination and treatment procedures that are typical and routinely recurring components of various diagnostic or therapeutic procedures
  - Procedures that are already covered within existing case-based payment categories
  - Different surgical techniques used to perform the same procedure
  - Pharmaceuticals (except for oncological products)
  - Procedures containing manufacturer-specific references to pharmaceuticals, medical devices, or other materials

LKF Code Integration Takes Around 14 Months Under the Standard Annual Cycle



The integration of a novel procedure code into the LKF system takes around 14 months. The timing of permanent integration of provisional codes depends on the progress in evidence collection

Austrian Reimbursement Pathways Depend on Evidence Sufficiency and DRG Coverage



AIHTA Evidence Reviews Strongly Influence MEL Code Inclusion

- HTA has gained considerable importance in Austria. It is increasingly used as a basis for reimbursement decisions, particularly for innovative and invasive procedures
- Between 2006 and 2020, the main health technology appraisal body in Austria was the Ludwig Boltzmann Institute (LBI-HTA). In March 2020, the Austrian Institute for Health Technology Assessment (AIHTA) was founded as the direct successor of the LBI-HTA. It is an independent organization that, on request, provides scientific support for decision-making regarding the inclusion of health technologies (medical devices and in-vitro diagnostics) into the procedures catalog by the Federal Ministry of Labor, Social Affairs, Health, Care, and Consumer Protection
- At the request of the LKF-Working Group, the AIHTA prepares HTA reports (so-called “decision support documents”). Recommendations about the inclusion of the procedure (MEL) code into the DRG system of AIHTA are typically followed by the decision-makers. AIHTA typically uses a systematic literature review methodology of clinical (not economic) studies
- Significant attention is paid by the AIHTA to ongoing studies. In the cases when evidence is insufficient to recommend the inclusion of the method in the DRG system, AIHTA often recommends re-evaluation (and this regularly happens) when new evidence becomes available
- Furthermore, all the clinical criteria for the creation of a new MEL code must be fulfilled (the procedure is newly developed or required to reflect medical progress, it is well established, there is a clearly defined medical indication for the procedure, the procedure is clearly defined and distinctive from other procedures)

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