MTRC

Market Access for Medical Technologies in Switzerland

Prepared for

BVMed
Bundesverband
Medizintechnologie e.V.

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Switzerland Has Two Market Access Barriers for Medical Technologies, with Reimbursement Being at the Center of the Market Access Strategy

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**
○ DRG reimbursement for hospital care, including explicitly one-day DRGs ○ Add-on reimbursement for the procedures requiring extra resources or using expensive technologies (Zusatzentgelt, ZE)	○ In accordance with “the principle of trust”, medical devices and procedures are automatically reimbursed via DRGs in the inpatient sector unless coverage is challenged by insurance companies or other stakeholders in the system ○ In case technology is questioned, the Federal Office for Public Health (FOPH) performs a formal evaluation to define the coverage status ○ Explicitly evaluated technologies and their coverage status are documented in Annex 1 of the Healthcare Benefits Ordinance (KLV)	○ Generally, not relevant in Switzerland, as the HTA activities are integrated into coverage decisions ○ The National HTA program mainly serves to review already covered services

Market Access in Switzerland is Driven by Multiple Interconnected Stakeholders

Policy-makers

Swiss Confederation
Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH

Federal Office for Public Health (FOPH)
The supreme body in the Swiss healthcare system. Part of the Federal Department of Home Affairs (FDHA), together with other offices. Develops key policy documents and decisions about coverage of services within the statutory health insurance

Payers

Health insurance companies
Statutory and private health insurance companies that are payers to the public healthcare providers

Technical support

Bundesinstitut für Arzneimittel und Medizinprodukte

BfArM Cologne Office (ex DIMDI)
Maintains and develops German ICD-10 version, which is used in Switzerland

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Statistical Office (BFS/UFS)
Responsible for the development of inpatient classification of procedures (CHOP). Under the direct supervision of the Federal Department of Home Affairs

Payment system administrators
SwissDRG maintains the Swiss hospital reimbursement system (SwissDRG), while OAAT is developing new outpatient reimbursement systems

Decision-influencers

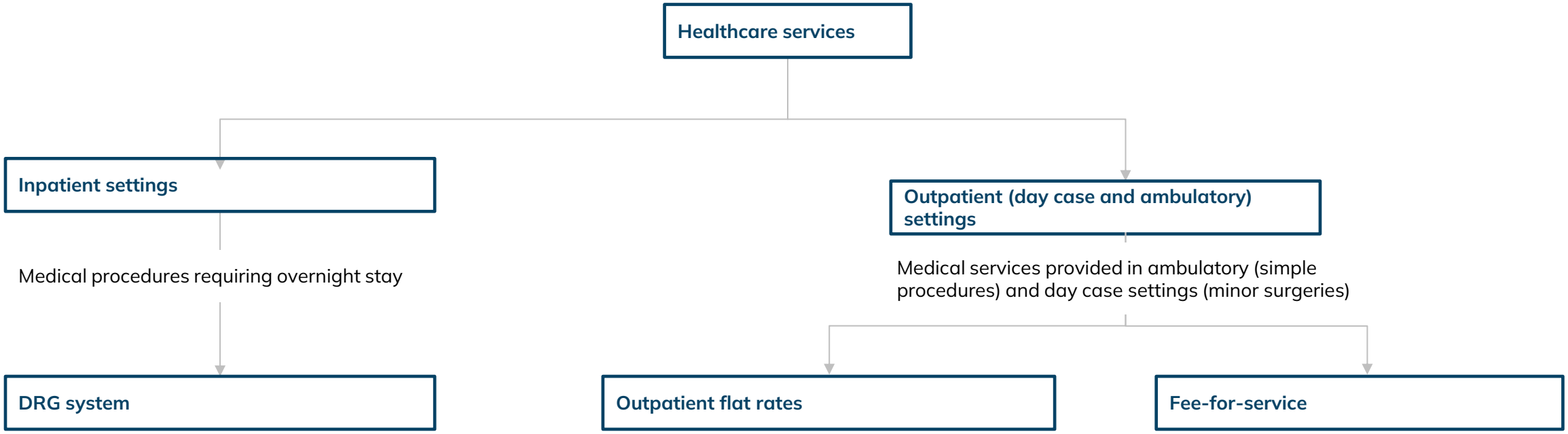
Swiss Conference of the Cantonal Ministers of Public Health (GDK/CDS)
Partner of SwissDRG, which promotes collaboration among cantons. Can make binding decisions regarding highly specialized healthcare

Swiss Association of Hospitals (H+)
Partner of SwissDRG and OAAT. Represents the interests of all hospitals in Switzerland

Medical Tariff Commission (MTK/CTM)
Partner of SwissDRG and OAAT. Part of the Swiss National Accident Insurance Fund (SUVA). Deals with issues related to mandatory accident insurance, military, and invalidity insurance

Associations of Swiss Health Insurance Companies
Take part in developing the payment systems. The most important ones are prior.swiss and santésuisse. Influence the tariff setting by fighting for the interests of health insurance companies. Partners of SwissDRG and OAAT

Swiss Reimbursement Combines DRG-Based Inpatient Funding with Reforming Outpatient Tariffs



Both tariff structures comprising the new Swiss outpatient reimbursement system are governed by a single, unified service catalog - the Service Catalog of Outpatient Medical Tariffs (LKAAT), which integrates all TARDOC and outpatient flat-rate trigger codes. For each service, LKAAT specifies whether the code represents an individual medical service or a flat rate “trigger position”. The treatment case is reimbursed via an outpatient flat rate if a trigger position code is recorded

SwissDRG Covers All Statutory Inpatient Admissions

- The Swiss DRG model (SwissDRG) covers 100% of hospital admissions within the statutory health insurance
- SwissDRG is based on the German G-DRG system, adjusted to Swiss settings
- The national DRG catalog is updated annually by the SwissDRG AG
- The Swiss Conference of the Cantonal Ministers of Public Health (GDK/CDS), the association of health insurers santésuisse, Swiss Association of Hospitals (H+) and Physicians (FMH), and medical tariff commissions (MTK/CTM) are the partners of SwissDRG and thus influence the development of the system
- This document includes DRG tariffs and lists of add-on reimbursements (ZE)
- The new DRG systems become effective each year on the 1st of January

Hospital Reimbursement in Switzerland Is Governed by the DRG System

Swiss DRG system has two main components

Diagnosis-Related Groups (DRGs)

- Core inpatient reimbursement mechanism covering therapeutic and diagnostic services
- DRGs are designed to cover all costs of care, including medical devices and capital equipment
- Each DRG has a cost weight, multiplied by a base rate to determine reimbursement
- Base rates vary across cantons and, within cantons, by hospital and by reference insurance corporation
- SwissDRG is based on the German G-DRG system, adjusted to Swiss settings
- DRGs are defined based on:
  - ICD-10-GM diagnosis codes (from Germany, BfArM)
  - CHOP procedure codes
  - Patient-specific parameters (e.g., age, length of stay, gender)

Add-on reimbursement (ZE)

- Applies to technologies not sufficiently covered by DRG tariffs
- Typically granted to devices and procedures that are cost outliers with uneven cost distribution across hospitals
- Tariff is typically determined on the national level by SwissDRG

All hospital care is reimbursed via the DRG system, which is updated annually by SwissDRG AG. The new DRG systems become effective each year on the 1st of January

Mechanical Thrombectomy Illustrates How SwissDRG Cost Weights Translate Into Tariffs

- Example of calculation of reimbursement tariff for mechanical thrombectomy of a single intracranial artery
  - Primary procedure code (+ additional procedure codes): 39.77.62 + 00.40 + 00.4F.21 (Percutaneous thrombectomy of the intracranial vessel(s) + procedure on a single vessel + use of one catheter-guided thrombus and foreign body removal system)
  - Diagnosis code: I63.9 (cerebral infarction, unspecified)
  - Age – 50 years
  - Sex – male
  - Discharge method – Normal
  - Type of setting – Hospital
  - Length of stay: 3 days

  - **Resulting DRG B20C (Specific or complex intracranial interventions or major spinal surgery with a complex procedure or IntK > 119 effort points, age > 15 years):**
    - Cost weight is 2.112
    - To calculate the tariff, the cost weight is multiplied by the base rate, which differs among the cantons. Moreover, within the same canton, weights are defined for every single hospital and vary depending on the reference insurance corporation
    - Considering the base rate of 10,103 CHF (the average base rate of the three most populated cantons – Zurich, Bern, and Vaud), the reimbursement tariff is 21,337.6 CHF
    - This amount will cover every aspect of care from admission until discharge

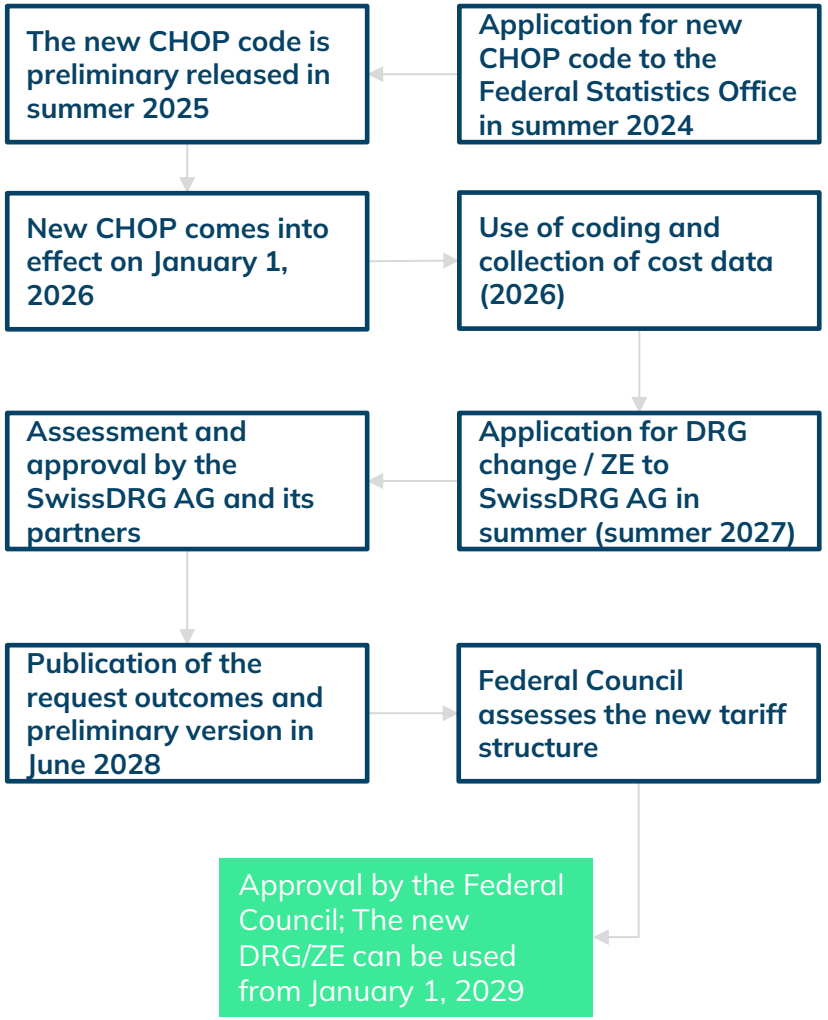
New CHOP Codes and DRG Changes Require Stakeholder-Led Applications

- The SwissDRG system is the ultimate pathway for reimbursement of inpatient procedures in Switzerland
- The process of changing the DRG system might include two steps:
  - Creation of a new CHOP procedure code via the Federal Statistics Office (BFS/UFS). The submission period is usually summer (June to early September)
  - DRG change process (including establishing of add-on reimbursement, ZE) via SwissDRG AG. The submission period is usually summer (June to early July)
- It is relatively easy to create a CHOP code. The applications are made via the online platform eMedClassCon. The application can be made only on behalf of one of the following organizations: FMH, H+, GDK/CDS, MTK/CTM, SwissDRG, and health insurance companies. Thus, collaboration with a physician is necessary
  - In 2022, 35 applications were made on behalf of H+, 15 on behalf of FMH, and one by a health insurance company (51 requests in total; one request can concern several CHOP codes)
- Applications for the change of the DRG system are typically made by clinical societies or hospitals but must be supported by a relevant umbrella organization – one of the partners of the SwissDRG system
- The SwissDRG system, including the accompanying measures indicated by the legislator, must be approved by the Federal Council before implementation

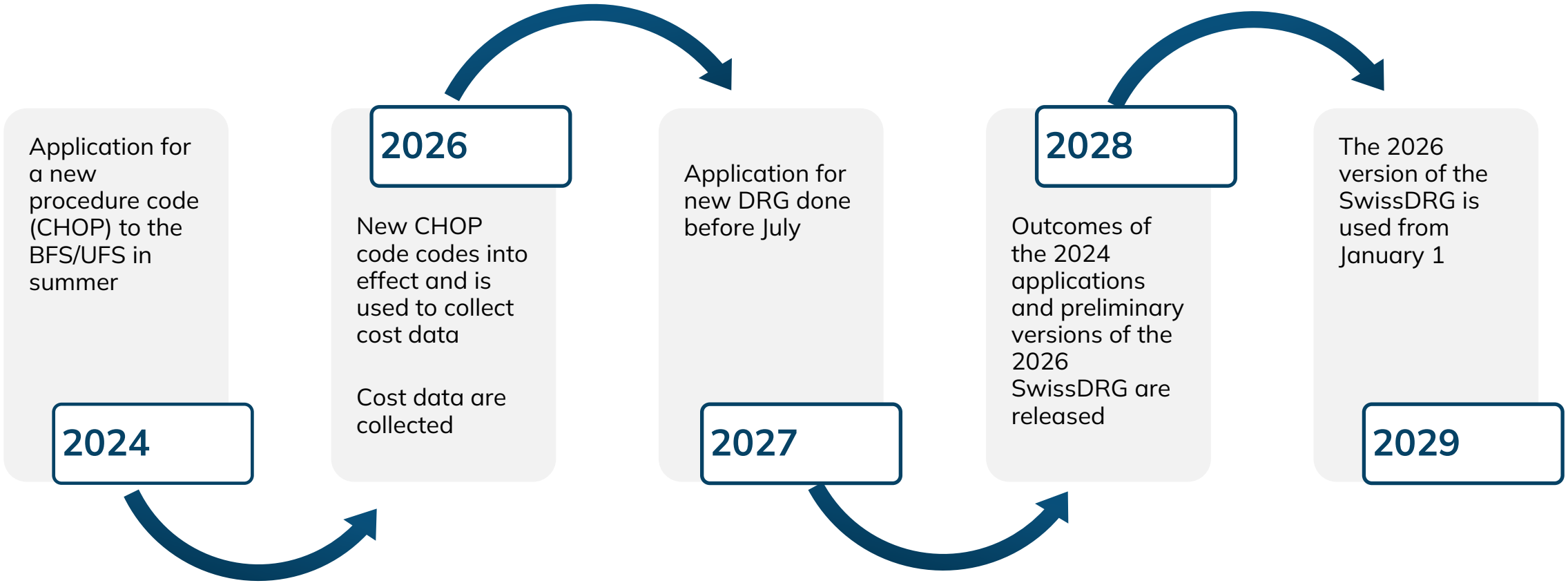
New Procedure Integration Requires Coding, Data Collection, DRG Review, and Federal Approval

- It takes 1.5 years to introduce a new procedure code in the system
  - For example, the CHOP 2023 version was based on the 2021-2022 update cycle, meaning that the requests made in summer 2021 were assessed in winter 2021/2022, and the new CHOP codes were implemented in 2023

- It also takes 1.5 years to process the request for the DRG change
  - For example, the application is made by July of 2022, a preliminary version of the system is announced in the middle of 2023, and the system becomes effective in 2024
  - Applications for the 2024 SwissDRG system are based on the 2023 grouper version and 2021 CHOP and ICD-10-GM codes



SwissDRG Change Typically Takes Five Years in the Best-Case Scenario



Conclusions

- The integration of a novel procedure into the SwissDRG system five years, in the best-case scenario
- It can often take longer if the new procedure is not coded enough and if there is not enough data generated

Analog Coding Provides an Interim Route When Dedicated CHOP Codes Are Absent

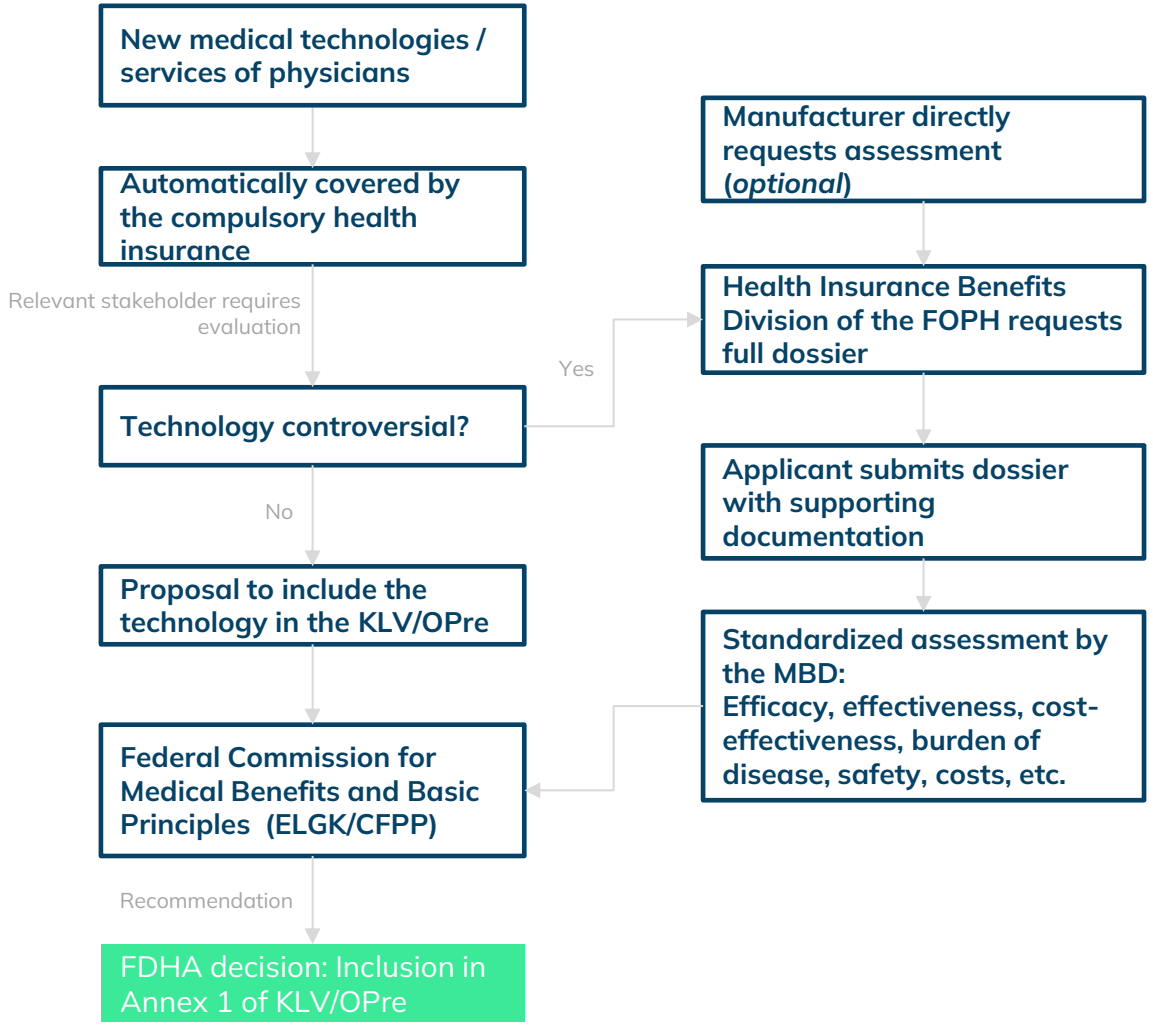
- While waiting for the definition of new, uniform, and binding differentiated codes for an innovative method (through a regular application procedure), analog codes must be applied
- These analog codes are valid starting from the publication and are relevant for any revision of the codes

- Historical examples of analog codes are provided below:
  - Microvascular flap grafting from muscle or band to the hand (valid from the 31st of August 2018; CHOP 2018)
    - It is encoded with the CHOP codes 83.82.47 “Graft with microvascular anastomosis from muscle or band, other localization” and 82.58 “Other hand transfer or transplantation of muscles“
  - Removal of cytokines by adsorbents - valid from the 5th of April 2018 (CHOP 2018)
    - The use of a CytoSorb® adsorbent cartridge for the removal of hydrophobic substances (e.g., cytokines) from the blood is encoded with the CHOP code 99.76.99 “Extracorporeal immunoadsorption, other“
  - Flow Diverter – valid from the 1st of January 2018 (CHOP 2018)
    - The flow deviators used for the selective embolization of intracranial vessels (also concerning, e.g., Medina Embolization Device and intra-aneurysmal Flow Diverter) are codified with the CHOP code 39.72.13 “Selective embolization of intracranial vessels by flow-diverter”

A 'Trust-Based' Funding Model with Selective HTA Review Underpins Market Access in Switzerland

- Acceptance by decision-makers is an essential element of market access for medical technologies in Switzerland
- Under the statutory health insurance system, medical technologies are generally presumed to meet the statutory WZW criteria (Efficacy, Appropriateness, and Economic efficiency) and are therefore covered according to the "principle of trust" (Vertrauensprinzip)
- Evaluations are typically initiated when insurers or other stakeholders question the technology's compliance with the statutory WZW criteria, though manufacturers may also proactively apply for a coverage determination. The Federal Office of Public Health (FOPH), part of the Federal Department of Home Affairs (FDHA/EDI), conducts the evaluation based on clinical and economic evidence submitted by the manufacturer. Both cost-effectiveness and budget impact analyses are required
- The Federal Commission for General Services and Principles (ELGK/CFPP), part of the FOPH, manages the assessment process. Their recommendations are based on the HTA reports about the safety and benefits of a method/device developed by the Health Insurance Benefits Division of the FOPH
- The entire process lasts approximately one year
- Final decisions are made by the FDHA and are listed in Annex 1 of the Healthcare Benefits Ordinance (Krankenpflege-Leistungsverordnung, KLV), which serves as the official register for medical services that have undergone a formal national evaluation for coverage within statutory health insurance. It explicitly lists these services and defines their coverage status, which can be:
  - "Yes" (continue coverage)
  - "No" (excluded from coverage)
  - "Yes, in evaluation" (provisional coverage)
  - Before 2014, the fourth option (No, in evaluation) existed
- **NB!** Annex 1 of the KLV/OPre regularly undergoes revision, and some services that have previously been listed there (positive or negative coverage) may be removed for the sake of keeping the document tidy

Inclusion in Mandatory Insurance Requires FOPH Assessment and FDHA Decision



Leistungen in Evaluation Enables Coverage With Evidence Development for Contested Technologies

- The objective of the scheme is to provide temporary reimbursement coverage for medical services where existing evidence is insufficient to decide whether or not coverage unlimited in time is warranted. The scheme applies to novel, promising, and contested medical technologies. During this defined period, further evidence is collected. The scheme is classified as a coverage with evidence development (CED) scheme

- The provisional reimbursement of medical procedures (Leistungen in Evaluation) scheme was introduced in Switzerland in 1996

- According to the principle of trust, medical services, including devices and in-vivo diagnostics, are covered by the Swiss compulsory health insurance scheme without formal health technology assessments. However, in cases where there is doubt regarding the efficacy, appropriateness, and efficiency of a medical service, the service can be challenged by anyone with a legitimate interest

- Typically, the insurance companies challenge the coverage of already reimbursed procedures, but other stakeholders, including the manufacturer, hospitals, clinical societies, patient organizations, or even the Federal Office for Public Health (FOPH), can request the evaluation of a medical (new or already covered) service

CED Eligibility Depends on Evidence Gaps, National Relevance, Feasibility, and Expected Decision Impact

- For a technology to be eligible for provisional reimbursement, all the following questions besides number 3 must be answered positively:
  1. Is there a critical evidence gap? Most relevant in relation to effectiveness, safety, economic data, and conditions of use;
  2. Is there interest in the technology/test from a national healthcare perspective? I.e., it regards a severe or high-incidence disease, improves care and patient outcomes, or has a significant economic impact;
  3. Is there ongoing national or international research that can fill the evidence gap? I.e., independent studies, post-marketing trials, or registries that are applicable to Switzerland and available within a reasonable timeframe;
  4. Can a research question be defined? A research question should contain information on the patient/population, intervention/test, comparator (if available), and clinical outcome;
  5. Is CED feasible? In relation to timeframe, study design, finances, availability of a competent and willing investigator, market and/or ethical regulations, and alternative research;
  6. Is the estimated balance between the value and costs of conducting CED favorable?
  7. Will the new evidence justify a potential change in the coverage decision?
- More details about the requirements are provided in checklists for medical devices and diagnostic tests by the Federal Office for Public Health (FOPH)

Coverage With Evidence Development Is Used Across Diverse Procedures and Indications

Procedure name	Evaluation period
Lymphovenous anastomosis and vascularized lymph node transplantation for the treatment of lymphedema	1.7.2021 until 31.12.2026
Liposuction to treat pain associated with lipedema	1.7.2021 until 31.12.2025
Metabolic surgery (patient with type 2 diabetes mellitus, which is difficult to control and body mass index (BMI) of 30 – 35)	1.1.2021 / 1.7.2021 until 31.12.2025
Autologous chondrocyte transplantation for the treatment of post-traumatic lesions of knee joint cartilage and cartilage lesions in osteochondritis dissecans in the knee joint	1.1.2002 / 1.1.2004 / 1.1.2017 / 1.1.2020 / 1/1/2021 until 31/12/2024
Autologous fat transplantation for postoperative reconstruction of the breast	1.7.2018 until 30.6.2023
Extracorporeal photopheresis in obliterating bronchitis syndrome following lung transplantation	1.1.2009 / 1.8.2016 / 1.1.2020 / 1.1.2022 until 31.12.2024
Endovascular therapy of vascular erectile dysfunction: endovascular revascularization of the arteries supplying the penis; endovascular embolization therapy of the veins draining the penis	1.1.2022 / 1.7.2022 until 31.12.2025
Focused ultrasound therapy in the pallidum, thalamus, and subthalamus for the treatment of severe, chronic, therapy-resistant neuropathic pain	15.7.2015 / 1.7.2020 / 1.1.2021 until 31.12.2025
Multigene expression test in breast cancer. Examination of tumour tissue of a primary, invasive breast cancer	1.1.2011 / 1.1.2015 / 1.1.2019 until 31.12.2023
Hematopoietic stem cell transplantation - autologous - in cases of Ewing sarcoma, soft tissue sarcomas, Wilms tumour	1.1.2002 / 1.1.2008 / 1.1.2013 / 1.1.2018 until 31.12.2022

Coverage With Evidence Development Is Used Across Diverse Procedures and Indications

Procedure name	Evaluation period
Hematopoietic stem cell transplantation - autologous - in cases of autoimmune diseases with the exception of systemic sclerosis, multiple sclerosis, Crohn's disease, and diabetes mellitus	1.1.2002 / 1.1.2008 / 1.1.2013 / 1.1.2018 until 31.12.2022
Hematopoietic stem cell transplantation - autologous - in multiple sclerosis	1.7.2018 until 30.6.2024
Hematopoietic stem cell transplantation - allogenic - in cases of autoimmune diseases	1.1.2002 / 1.1.2008 / 1.1.2013 / 1.1.2018 until 31.12.2022
CAR-T-cell therapy (CAR = chimeric antigen receptor) with Tisagenlecleucel: in the case of relapsed or treatment-refractory diffuse large B-cell lymphoma	1.1.2020 until 31.12.2022
CAR-T-cell therapy (CAR = chimeric antigen receptor) with Axicabtagen-Ciloleucel: in relapsed or refractory diffuse large-cell B-cell lymphoma	1.1.2020 until 31.12.2022
CAR-T-cell therapy (CAR = chimeric antigen receptor) with Brexucabtagene Autoleucel in adults with refractory or relapsed mantle cell lymphoma	1.7.2022 until 1.7.2027
Embolization of the prostate arteries in symptomatic benign prostatic hyperplasia in patients with moderate to severe obstructive symptoms (IPSS >8, QoL >3) with prostatic hyperplasia > 30-50 ml	1.7.2022 until 31.12.2024
Proton therapy for non-small cell lung cancer (NSCLC) UICC stages IIB and IIIA / B, as part of the randomised controlled study RTOG 1308	1.4.2020 until 31.12.2025
Proton therapy in locally advanced esophageal carcinoma (≥ T2 or N+, M0), as part of the randomised controlled PROTECT study	1.1.2022 until 31.12.2026
Transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis who have a medium surgical risk	1.7.2020 until 30.6.2023
Regional deep hyperthermia for tumour therapy in combination with external radiation therapy or brachytherapy for the following indications: - Soft tissue sarcoma (maintenance of function) if chemotherapy is contraindicated - Local tumour recurrences with compression symptoms in a palliative situation, focal depth > 5 cm	1.1.2017 / 1.1.2019 / 1.7.2021 until 30.6.2023

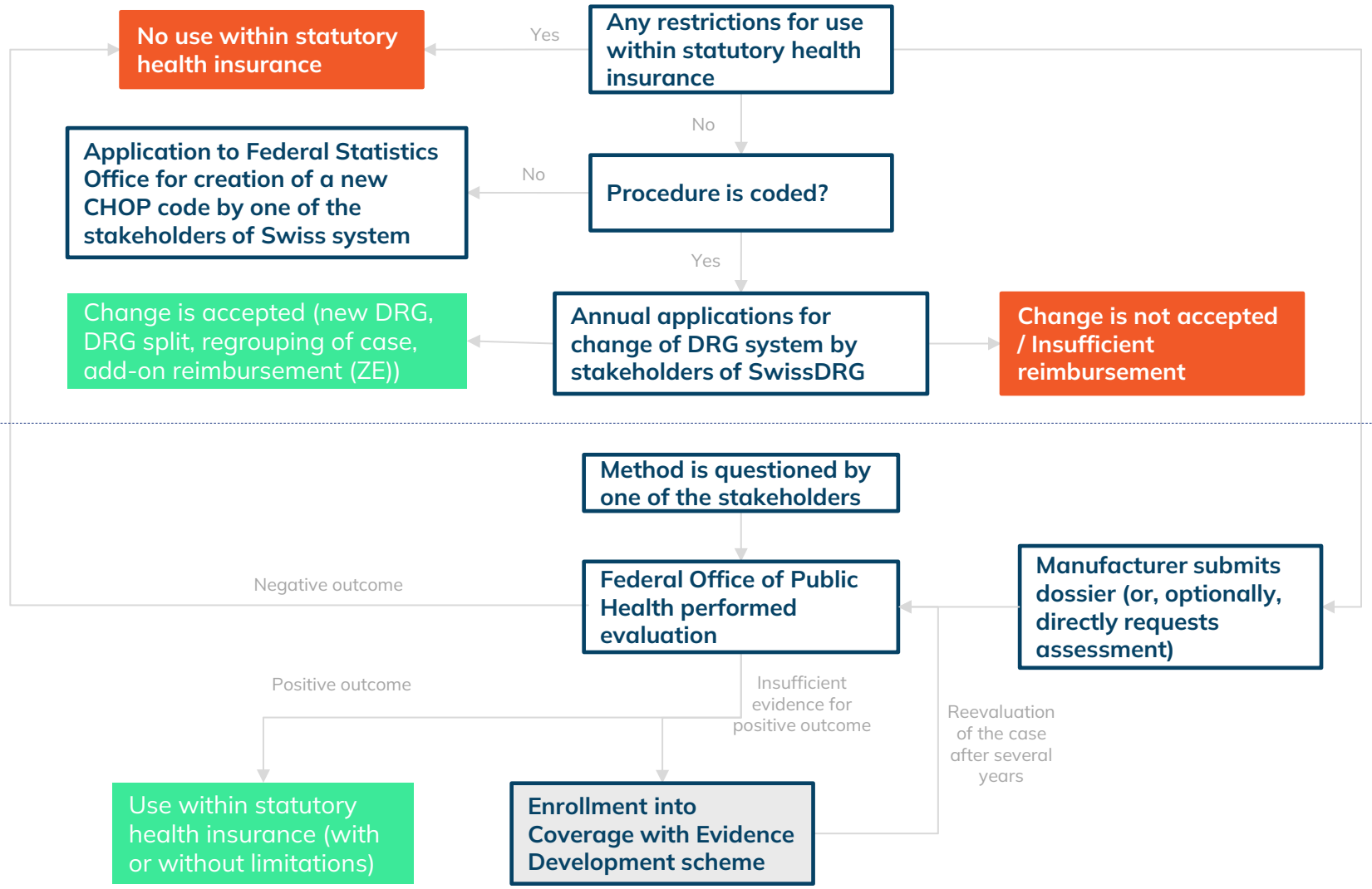
HTA Is Integrated Into Funding Decisions Rather Than a Stand-Alone Access Barrier

- Health technology assessment (HTA) supports reimbursement and coverage decisions under Swiss compulsory health insurance by assessing whether medical services and technologies meet the statutory criteria of effectiveness, appropriateness, and economic efficiency
- The Health Insurance Benefits Division defines the catalog of benefits paid under compulsory health insurance, including services, devices, laboratory tests, and medical aids
  - The assessment is usually based on the documentation provided by the applicants and usually lasts 4-6 months
  - The reports are used by the relevant Federal Commissions (Federal Commission for Medical Benefits and Basic Principles (ELGK/CFPP); Federal Commission for Analyses, Products, and Devices (EAMGK/CFAMA); Federal Drugs Commission (EAK/CFM)), which then make final recommendations to the Federal Department of Home Affairs (DFI) whether to cover the assessed benefits or not
- In 2015, the Federal Office for Public Health (FOPH) launched the HTA programme with the goal of reassessing the benefits already reimbursed by statutory health insurance that may no longer meet the relevant criteria. It is managed by the Health Technology Assessment Section of the Health Insurance Benefits Division

Swiss Market Access Requires Parallel Management of Reimbursement and Coverage Risk

Reimbursement pathway

Funding (coverage) pathway



MTRC

www.mtrconsult.com

info@mtrconsult.com

Market access consulting

Avenida Perfecto Palacio de la Fuente, 1, 03003, Alicante, Spain

HEOR consulting

Building 3, City West Business Park, Gelderd Road, Leeds, West Yorkshire LS12 6LN, the United Kingdom

Billing/contracting

10 Stefan Karadzha Street, floor 3-4, Sredets District, Sofia, 1000, Bulgaria