Swiss Cell- and Gene Therapy

Different P&R process for product & medical procedure

This newsletter deals with the pricing and reimbursement of cell and gene therapies (CGTs) with a special focus on Switzerland which, like Germany, can assess an ATMP either as a drug or as a medical procedure. The differences between these two processes are described.

P&R for Medicinal Products or as Medical Procedure

In Europe (top 5), ATMPs are evaluated as medicinal products according to the traditional procedure, except in Germany where ATMPs can also be evaluated as a medical procedure. European P&R decisions are quite heterogeneous across European countries, apart from CAR-T, which are reimbursed in all top 5 [1]. The assessments are similar to the approach for orphan drugs and the existing framework conditions are mostly applicable [2]. HTA authorities are reluctant to change existing frameworks for CGTs [3]. Pricing as a drug is based either on the domestic assessment of the added clinical benefit together with international price comparison or on a health economic assessment. Both methods use pricing models to manage clinical and economic uncertainties and accelerate patient access. In contrast, medical procedures in hospitals are covered by DRG-based reimbursements, with medication costs usually included[i]. The product price is the result of purchasing negotiations with the risk that the hospital will not be reimbursed for all costs (risk shift to the providers).

[i] To absorb very high medication costs within a DRG, add-on payment can be granted upon successful application.

Swiss Cell- and Gene Therapy (May 2022)

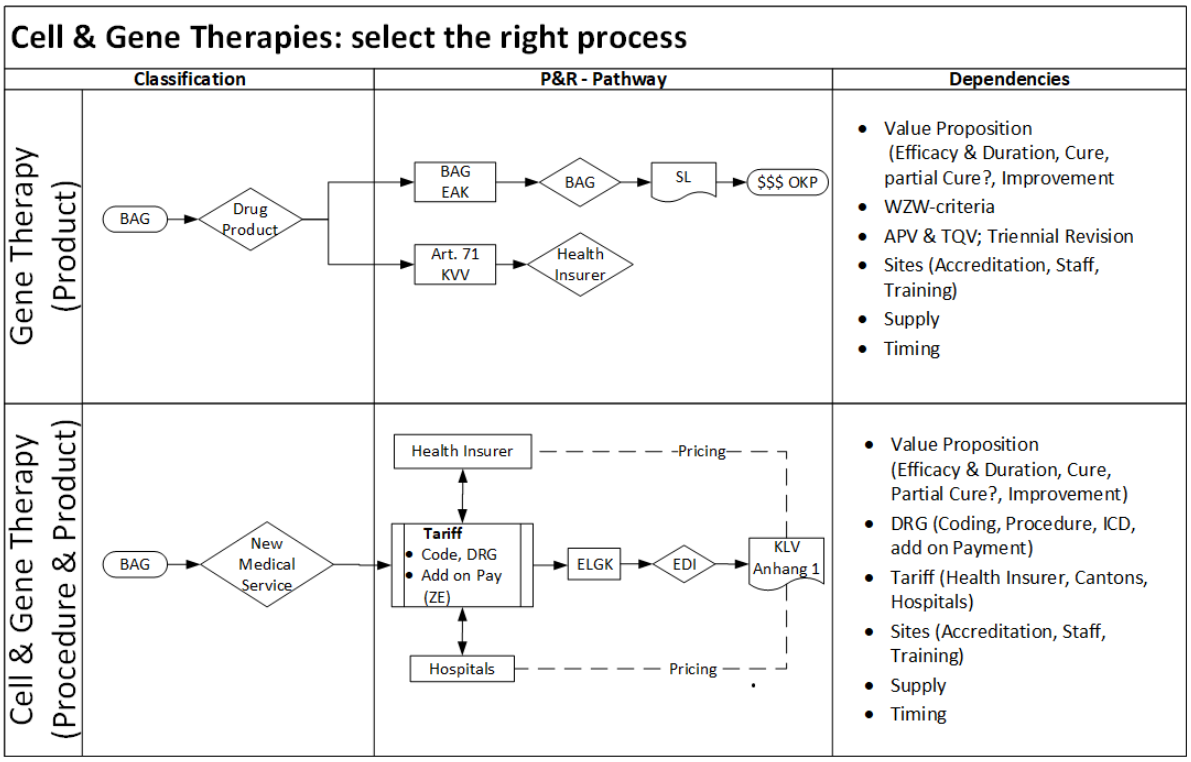
Brand	DCI	Company	Indication	Vector	Mechanism	Classification	Dose	Swissmedic	Coverage Type & Path	Reimbursement
Spinraza	Nusinersen	Biogen	SMA		ASO Antisense Oligonuc.	AOS based GT Legally a chemical not an ATMP	Multiple	Yes 2017	Product Drug List	SL temporary reimbursement
IMLYGIC	Talimogen laherparepvec	Amgen	Melanoma	HSV-1	HSV-1 editing to GM-CSF Suicide Gene	GTMP	Multiple	yes 2017	Product Drug List	SL temporary reimbursement Registry FMH
Alofisel	Darvadstrocel	Takeda	Crohn's Disease, Fistula	-	Adipose Stem Cell	CTMP	Single	yes 2018	Product Drug List	Not SL 2 Swiss Centers (USZ; CHUV) Individual coverage and reimbursement decision based on health insurer KVV Art. 71
Kymriah	Tisagenlecleucel	Novartis	ALL	CAR-T	CAR-T	GTMP cell based	Single	yes 2018	Procedure & Product Medical Service	KLV Anhang 1 CAR-T in Eval
Spherox	Chondrocytes	Co.Don	Cartilage repair femur and patella	-	Cell implant autologous	TEP	Single	yes 2019	Product & Procedure?	KLV Anhang 1 Autologous chondrocyte transplantation
Yescarta	Axicabtagene ciloleucel	Gilead	B-Cell-Lymphoma	CAR-T	CAR-T	GTMP cell based	Single	yes 2019	Procedure & Product Medical Service	KLV Anhang 1 CAR-T in Eval
Luxturna	Voretigenum neparvovecum	Spark Novartis	Inherited eye disease	AAV9	Deliver missing gene; RPE65-Mutationen Gene Replacement	GTMP	Single	yes 2020	Product Drug List	SL temporary reimbursement
Onpattro	Patisiran	Alnylam	hATTR amyloidosis		RNAi	RNAi based GT Legally a chemical not an ATMP	Multiple	yes 2020	Product Drug List	SL temporary reimbursement 2 center USZ/CHUV Registry
Abecma	Idecabtagen Vicleucel	Celgene, BMS	Myelom	LVV	CAR-T	GTMP cell based	Single	yes 2021	Procedure & Product Medical Service	Not yet? Listed in KLV Anhang 1
Tecartus	Autologous Anti-CD19-transducede CD3+ cells	Gilead Science	Mantle Cell Lymphoma	Retrovirus	CAR-T	GTMP cell based	Single	yes 2021	Procedure & Product Medical Service	Not yet? Listed in KLV Anhang 1
Zolgensma	Onasemnogene Abeparvovec-xioi	Novartis	Spinal Muscular Atrophy (SMA)	AAV9	SMN1 Gen	GTMP	Single	yes 2021	Product Drug List	GGL (SL) IV

Compiled by pharmaLevers GmbH in April/May 2022. No claim to completeness and correctness. Any additional and corrective notifications are welcome.

In Switzerland, 11 cell and gene therapies have been approved by Swissmedic (as of May 2022) and 9 CGTs are reimbursed by health insurance companies. 2 are limited to specific centers or are still being evaluated. 5[ii] or nearly half of CGTs are reimbursed as medical procedures, underscoring the importance of distinguishing between product and process reimbursement. The focus on CAR-T continues in more than 500 clinical trials [4].
2 Products are CGTs without being legally an ATMP [5]. 3 CGTs require multiple dosing, which affects price evaluation. The temporary reimbursement applies to the product reimbursement, while the reimbursement of medical procedures is legally binding (KLV Annex 1) without fixing a price.

[ii] As in the European and US markets [4]

Swiss Cell- and Gene Therapy P&R Processes



The figure above shows the two different reimbursement processes as CGT product or as CGT medical procedure.

The pricing and reimbursement pathway for a GCT-Product follows the principle of a conventional drug: assessment of efficacy, appropriateness and economics whereby external and internal reference pricing are considered. At the end, the product is listed on the positive drug list (SL) with maximal prices. In addition, off label coverage may be possible on a case-by-case basis (Art. 71). In the case of birth defects, the route is identical, except that for patients under 20 years of age, payment is made from disability insurance and not from health insurance.

The P&R path for a CGT-Medial Procedure corresponds to a tariff procedure between hospitals and health insurance companies with DRG-based reimbursements. Coverage obligation is laid down in KLV Annex 1 by the Federal Department of Home Affairs (EDI/FDHA). The price is negotiated between the hospital, health insurance company and manufacturer, whereby an analogous DRG tariff together with a possible add on payment can serve as a basis.

Swiss Cell- and Gene Therapy P&R Processes

Most Cell-& Gene Therapies are approved and reimbursed in Switzerland. The main differences between the Product and the Procedure P&R paths are as follows:

- Product prices are uniform across the country, with a reimbursement rate of 90%, while procedural prices depend on tariffs negotiated between providers and health insurers and may vary between cantons and hospitals.
- A legal challenge is possible for a BAG/FOPH decision for a Product but not for EDI/FDHA decision on a medical procedure
- Health insurers have limited influence over Product pricing. For a medical Procedure, however, they can have a significant impact on pricing in collective bargaining.
- The pricing process for a medical Procedure usually takes longer and requires wider stakeholder involvement but offers more flexibility in pricing. However, there is a risk of a coverage gap, whereby the risk can shift to the providers.

Further Information visit:

- Swiss CGT on SlideShare for download
- Swiss CGT on YouTube for audio presentation

Limitation

This newsletter focuses on the pricing and reimbursement of cell and gene therapies (CGTs) with a special focus on Switzerland. The aim of this newsletter is to outline the two different P&R processes for CGTs. It is a snapshot of April/May 2022. Completeness and correctness are not claimed; Additions, corrections and comments are welcome.

References

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5. Iglesias-López C, Agustí A, Obach M, Vallano A. Regulatory framework for advanced therapy medicinal products in Europe and United States. Front Pharmacol. 2019;10(JULY):1–14.