Schweizerische Eidgenossenschaft
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Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Health and Accident Insurance Directorate

Operationalisation of the criteria “effectiveness, appropriateness and economic efficiency”

according to Article 32 of the Federal Act on Health Insurance (HIA)

Foundational document

Version dated 31 March 2022
Valid as of 1 September 2022

Disclaimer: This document only pertains to the situation in Switzerland. Only the German, French, and Italian versions of this document are binding.

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Introduction

The criteria of effectiveness, appropriateness and economic efficiency (EAE criteria) set out in Article 32 paragraph 1 of the Federal Act on Health Insurance (HIA; SR 832.10) comprise the fundamental requirements to be fulfilled in their totality by services covered by compulsory health insurance (CHI). They are regarded as eligibility requirements at two levels: firstly as general requirements for designating the services reimbursed under the compulsory health insurance scheme, and secondly as a condition of reimbursement in individual cases (EUGSTER, Art. 32 N 1; GÄCHTER/RÜTSCHE, 274).

This paper is the conceptual foundational document and has been produced for the purpose of operationalising the EAE criteria for assessing and designating all services covered by compulsory health insurance. It is also intended to provide guidance on assessing medical measures under the invalidity insurance scheme. Following the revision of the Federal Act on Invalidity Insurance (InvIA; SR 831.20) approved by Parliament on 19 June 2020, Article 14 paragraph 2 InvIA now cites the EAE criteria as a requirement for coverage. One of the aims of the revision was to ensure harmonised coverage when coverage of costs is transferred from invalidity insurance to health insurance.

This paper represents a refinement of the 2011 working paper and supersedes it in its entirety. The present foundational document is based on internationally applied health technology assessment (HTA) methods. The main changes in content compared to the 2011 version are as follows:

- Safety and comparison with alternative services have been moved from the appropriateness criterion to the effectiveness criterion. This is because any service simultaneously has potential for harm as well as benefit, and the effectiveness of a service must always be assessed by comparing its benefit-harm profile with those of alternative services. The previous categorisation was derived from judicial rulings on individual cases, which are distinct from the general EAE appraisal of a service (see section 1.1).
- The term “reasonableness” is no longer used in the appropriateness criterion. This aspect is already included under suitability in terms of benefit and harm compared to alternative services.
- In-depth consideration of ethical aspects under the appropriateness criterion.
- Novel structure for the assessment of compliance with each EAE criterion.

In addition to the general principles described in the present document, further documents will discuss specific requirements and appraisal principles for specific services in greater detail (e.g. the manual on the list of specialities (SL)[1]). Some of these are still in preparation or will be prepared at a later date. Furthermore, separate documents address procedural principles for assessing the assumption of costs for different services and test procedures.

From a legal perspective, the present document is an administrative ordinance. It contains general instructions intended to ensure a uniform administrative practice and to guarantee equitable treatment of the affected subjects. Administrative ordinances cannot go beyond the applicable legal framework; instead they substantiate it (FSC decision 141 V 175, E. 4.1; FSC decision 142 II 182, E. 2.3.2). They are not actual legal provisions, but contain general, abstract information on how to interpret and apply non-specified legal terms in the relevant legislation (FSC decision 141 III 401, E. 4.2.2).

With regards to the service designation process, this document firstly provides a basis for preparing assessments and secondly provides the Federal Commissions[2] responsible for the services in question with guidance for appraising the extent to which services fulfil the EAE criteria and issuing a recommendation on insurers’ obligation to provide reimbursement.

[1] The document is available in German at: www.bag.admin.ch > Versicherungen > Krankenversicherung > Bezeichnung der Leistungen > Antragsprozesse > Antragsprozesse Arzneimittel

[2] Federal Medical Services Commission (FMSC), Federal Commission for Analyses, Aids and Devices (FCAAD), Federal Medicines Commission (FMC)

The first part provides a general definition of the EAE criteria. The second part uses questions to describe the content to be assessed. The third part deals with the appraisal of compliance with the EAE criteria by means of key questions, while the fourth part builds on this to derive recommendations on insurers' obligation to reimburse a given service.

1 Definitions of EAE

1.1 Effectiveness

A service is effective if:

- it makes an objectively suitable contribution to achieving the desired diagnostic, therapeutic, nursing or preventive outcomes,
- it has been proven by scientific methods to provide a favourable balance of benefit and harm compared with alternative services, and
- the study results can be assumed to be applicable to the Swiss clinical practice setting.

The term effectiveness was introduced in the Federal Act of 18 March 1994 on Health Insurance (HIA), replacing the previous legal concept of "scientific recognition". The intention was to accommodate complementary medicine as well (Art. 118a Cst.)

Effectiveness refers to the causal relationship between a cause (medical service) and its effect (medical success). The deciding element in assessing the effectiveness criterion is whether the service makes an objectively suitable contribution to achieving the desired outcome (diagnostic, therapeutic, preventive, nursing) (FSC decision 133 V 115 E. 3.1; FSC, 3.4. 2008, 9C_824/2007, E. 3.3.2; GÄCHTER/RÜTSCHE, 274). This includes not only curative outcomes but also outcomes that have a stabilising, palliative or preventive effect on the course of the disease.

The assessment of effectiveness is guided by the patient's perspective. Proof of the effectiveness of a service must be obtained using scientific methods (Art. 32 para. 1 HIA). Different scientific methods may be employed depending on the nature of the service. The method used to demonstrate effectiveness must firstly provide objective evidence as to whether the desired benefit has a causal relationship to the service, is reproducible and not solely the result of the body's natural healing powers or the suggestiveness of the treatment (placebo effect). Secondly, the method must be able to provide evidence with regards to harm. The deciding element is a favourable balance of benefit and harm that must be compared to that of alternative interventions ("doing nothing" may also be an evaluable alternative).

In judicial rulings to date, the comparative assessment of alternative measures and the associated selection of the appropriate method have been assigned to the criterion of appropriateness. This is justified in individual cases in which the specific measure to be employed must be selected from a range of different services which are generally thought to be effective. Conversely, in a general appraisal of the effectiveness of a service it is necessary to assess benefit and harm in comparison to alternative measures, as is the scientific standard in medicine.

When assessing the effectiveness criterion, it must be borne in mind that different scientific methods also differ in their reliability and informative value. Not all methods are applicable to all services. For example, surgical interventions cannot be performed in such a way that they are blinded for patient and surgeon (double blind), and the low number of cases must be taken into consideration when assessing effectiveness in rare diseases. This results in differences in the level of evidence regarding the demonstration of effectiveness. Randomised, controlled double-blind trials have the highest level of evidence; case studies with expert consensus have a low level of evidence.

Since specific study conditions are usually required, for example to demonstrate effectiveness in order to exclude confounding factors (e.g. multimorbidity), or if studies are performed within a health system that differs from the conditions prevailing in Switzerland, the applicability of the study results to the setting in Switzerland must be assessed.

Effectiveness is deemed to be present if an assessment of the balance of benefit and harm prior to the intervention is positive (ex-ante approach) and not as a function of whether the intended outcome is in fact achieved to the desired extent after the intervention.

1.2 Appropriateness

A service is appropriate if:

- it is relevant to and suitable for patient care in comparison with alternative procedures,
- it is consistent with legal requirements, ethical and social aspects or values of society, and
- its quality and appropriate use are ensured in practice.

The general appraisal of appropriateness prior to the designation of services covered by compulsory health insurance takes into account the relevance of a service (in particular the medical need for it) and its suitability within the treatment pathway. Additionally, and in line with the internationally applied principles for appraisal of health technologies (health technology assessment, HTA), conformity with organisational, legal, ethical and social or societal aspects is examined. Economic impact may be included in the assessment of appropriateness. Likewise, the necessary quality and appropriate use of the services must be ensured in the practical setting.

1.3 Economic efficiency

A service is economically efficient if:

- its tariffs and prices are plausible,
- it has a favourable cost-benefit balance with respect to direct healthcare costs in comparison with alternative procedures, or
- the additional costs are associated with a corresponding additional benefit, and
- the impact of the costs on compulsory health insurance is acceptable.

According to Article 43 paragraphs 4 and 6 HIA, the tariff agreements reached between providers and insurers, as well as the tariffs and prices set by the competent authorities must be calculated economically and have an appropriate structure. Furthermore, attention should be paid to achieving a high quality of care at as low a cost as possible. The way in which tariffs and prices are calculated may comprise different aspects depending on the type of service involved. The corresponding principles will be described in other service-specific documents. Thus, the tariffs and prices must be plausible when economic efficiency is assessed.

If effectiveness and appropriateness are comparable, the least expensive alternative is always considered to be economically efficient (FSC, 22 June 2016, 9C_572/2015; FSC decision 137 V 295 E. 6.3; FSC decision 130 V 532 E. 2.2; 127 V 138 E. 5). A better benefit-harm ratio and greater appropriateness, on the other hand, justify higher costs and their reimbursement under the compulsory health insurance scheme (FCS decision 127 V 138 E. 5). No upper limits for cost-benefit ratio have been determined in Switzerland, and they do not constitute an absolute standard for appraisal (FSC decision 136 V 395 and FSC decision 142 V 144 E. 4.2, E. 5.4). Although no such limits have been defined, the principle of proportionality still applies, as does the question of the limits of affordability of healthcare. If there is a great discrepancy between cost and benefit, or if the burden on the solidarity-based community is deemed too great, the criterion of economic efficiency can no longer be considered to be met. New, very expensive services may push the limits of affordability, and therefore provision is made for more in-depth and more specific approaches when working with health economic models and health economic appraisal methods.

When comparing the costs of alternative services, only the tariffs or maximum reimbursement amounts applicable to or planned under the compulsory health insurance scheme are relevant, and only the costs that the health insurer must actually bear will be compared (FSC decision 126 V 334 E.

2c). When comparing out-patient and in-patient services for which the cantons bear part of the cost, the total costs borne by both payers must be considered. The appraisal of economic efficiency thus takes into account all the effects on the direct costs borne by the payers. Wider economic costs are not included in the assessment of economic efficiency (FSC decision 126 V 334 E. 2e; FSC 9C/2011 E. 3.4). The wider economic costs are assessed as part of the appropriateness criterion.

2 Operationalisation of the EAE assessment

In this section the term “technology”, as used internationally in health technology assessments (HTA), is used to refer to the services covered by compulsory health insurance that are to be assessed. Not all the aspects mentioned are of equal importance to every technology. The specific documents for each technology (e.g. medicinal products, laboratory analyses, services provided by doctors, preventive services) provide details on the extent to which these aspects must be taken into account or do not have to be taken into account.

2.1 Medical background / Description of the technology

2.1.1 Questions relating to the medical background

a. For which health problem and target group (risk of contracting the disease, disease-related situation) is the technology used/intended to be used (indication) and is the cost (to be) borne by compulsory health insurance?
b. What are the incidence and/or prevalence rates of the health problem under consideration?
c. What are the natural course and burden of disease in Switzerland?
d. What is the current standard of care in Switzerland for the health problem in the target group? How great is the level of unmet medical need?
e. What other alternative or competing technologies are being developed?

2.1.2 Questions relating to the description of the technology

f. How does the technology work and how is it used/implemented?
g. What are the indications for using the technology?
h. Which indications are intended for reimbursement under the compulsory health insurance scheme?
i. Have contraindications been defined? If so, which ones?
j. What are the patient-relevant critical and important outcomes for this technology within the indication foreseen for compulsory health insurance?*

* Outcomes are stratified according to GRADE (Grading of Recommendations, Assessment, Development and Evaluation). The health outcomes that are typically critical and important include mortality, morbidity, clinical events (e.g. stroke or myocardial infarction), patient-reported outcomes (e.g. symptoms, quality of life) and adverse events.

2.1.3 Questions relating to regulatory status

k. Does the technology require regulatory approval or marketing authorisation?
If so: what is the approval/authorisation status of the technology in Switzerland and other countries?*
l. Has the technology already been reimbursed under the compulsory health insurance or another social insurance scheme?
m. Is the technology reimbursed under the compulsory health insurance or another social insurance scheme in other countries (particularly EU/EFTA)?
n. Are decisions involving compulsory health insurance or state-provided healthcare pending in other

countries?

* Information about the regulatory status must be provided in accordance with the legal requirements applicable to the respective technology (e.g. medicinal products, medical devices, foods for special medical purposes [FSMP]).

2.1.4 Questions relating to providers

o. Which professions/medical disciplines are involved in using the technology?

2.1.5 Questions relating to current use

p. Is the technology used in an out-patient and/or in-patient setting?

q. Where (region and/or type of provider) and how often is the technology currently used in Switzerland?

2.1.6 Questions relating to future development of the technology

r. What are the main driving forces/influencing variables impacting the further development of the technology?

s. What are the expectations regarding the future development of this technology in terms of technology, indications and the providers who will use the technology?

t. How will the further development of the technology affect the future need for it, the need for preceding and/or subsequent services and the corresponding volume development (per indication)?

2.2 Effectiveness criterion

Appraisal of the effectiveness of a medical technology comprises the following three aspects: **efficacy** (efficacy under study conditions), **effectiveness** (efficacy under everyday conditions in routine care) and Safety. Since there are no distinct German equivalents of the English terms "efficacy" and "effectiveness", the English terms are also used in the German text to ensure that the meaning is unambiguous in the scientific context.

2.2.1 Questions relating to efficacy

a. Is the technology effective in the described patient populations and indications under study conditions (particularly in terms of the critical and important health outcomes as defined in section 2.1.2 letter j)?*

b. How effective is the technology compared with alternative technologies?*

c. What is the quality of the available evidence?**

* If no direct comparative studies (head-to-head) are available for two technologies being compared (comparators), indirect comparisons can be drawn on the basis of individual studies. The limitations on the reliability of indirect comparisons which result from the differences between the studies must be discussed in depth. Similarities and differences/deviations between study designs and health outcomes must be discussed, as must the question of missing data.

** Various systems of classifying the quality of evidence (validity) exist, such as the Canadian Task Force Levels of Evidence and the more recent Oxford Centre for Evidence-Based Medicine (CEBM) and GRADE (Grading, Recommendations, Assessment, Development and Evaluation). In the context of compulsory health insurance, evidence should be classified using GRADE. The quality of evidence should be stated in terms of the respective critical and important outcomes.

2.2.2 Questions relating to effectiveness

d. Has effectiveness (efficacy under everyday conditions in routine care) been studied; if so, what are the results? To what extent can these results from effectiveness studies be applied to clinical practice in Switzerland?

e. How do the patient populations and everyday conditions in clinical practice in Switzerland differ from the clinical studies (efficacy) and to what extent can the study results concerning the critical and important health outcomes described in section 2.1.2 letter j be applied to clinical practice in Switzerland?*

* taking into account differences in terms of patient populations, care structures, provider qualification, place of the service in the treatment pathway, for example.

2.2.3 Questions relating to safety

f. How does the safety profile of the technology compare to alternative technologies?

g. What is the quality of the available evidence in terms of the risk of harm/safety risks?*

h. How likely is it that the risk of harm/safety risks described are applicable to clinical practice in Switzerland?**

* Various systems of classifying the quality of evidence exist, such as the Canadian Task Force Levels of Evidence and the more recent Oxford Centre for Evidence-Based Medicine (CEBM) and GRADE (Grading, Recommendations, Assessment, Development and Evaluation). In the context of compulsory health insurance, evidence should be classified using GRADE.

** The overall rates and specific rates of adverse events and side effects should be described on the basis of the information in the literature. Relevant side effects are those that occur most commonly (highest rate) and/or are serious. Not all possible side effects need to be described.

2.2.4 Questions relating to evidence gaps / ongoing studies

i. Does the level of evidence* that can be expected for the technology in question exist, or are there critical evidence gaps?

j. Are there ongoing studies or data surveys that could fill the evidence gaps, or are any planned?

* The expected level of evidence relates primarily to the best possible study design, taking into account the nature, frequency, setting or the need (unmet medical need) or relevance of a technology. The possibilities offered by data-based evidence from clinical practice or specific aspects such as affordability may also be taken into account.

2.3 Appropriateness criterion

2.3.1 Questions relating to the place of the technology in patient care

a. What is the current status of the technology in the diagnostic/treatment pathway according to policy statements, expert statements or (inter)national clinical practice guidelines?**

b. What changes in the diagnostic/treatment pathway and care situation (providers, alternative technologies) are expected as a result of the new inclusion or further development of the technology or restriction of its reimbursement status?

** Additional opinions from individual experts and/or professional societies/associations/organisations can also be presented.

2.3.2 Questions relating to quality assurance

c. Are there any specific quality assurance requirements with respect to the technology; if so, which?

d. Are specific qualifications, interdisciplinary skills, accreditations/certificates required to use the technology; if so, which?

e. Do quality assurance processes/programmes exist; if so, which?*

* Quality assurance processes/programmes include, for example, periodic certification procedures, monitoring of quality indicators, peer reviews, interdisciplinary boards for therapeutic decisions.

2.3.3 Questions relating to appropriate care

f. To what extent is the nature or assembly of the technology suitable for ensuring appropriate care?

g. Are there risk factors concerning patient adherence (compliance) to the technology?

h. Are there risk factors for overuse, underuse or misuse of the technology?

2.3.4 Questions concerning legal aspects

i. Are there relevant legal aspects associated with the implementation, non-implementation, limitation or withdrawal of the technology that need to be taken into account or resolved?

Legal aspects include, for example, patients' rights, data protection, intellectual property rights (e.g. patents) and licensing, legal conditions/limitations in providers' regulations. Examples of this include the Federal Act on Human Genetic Testing (HGTA), the Intercantonal Agreement on Highly Specialised Medicine (IVHSM) and licensing regulations according to the Radiological Protection Act (RPA).

2.3.5 Questions concerning ethical aspects

j. Are there relevant ethical issues associated with the implementation, non-implementation, limitation or withdrawal of the technology that affect patients, healthcare professionals or society?***

*** The relevant ethical issues should be identified for the appraisal of a specific technology. There are four well-established areas of concern relating to ethical aspects in healthcare: patient autonomy, patient welfare, prevention of harm and social justice.[3] The list of questions below is an excerpt from the checklist developed by Hofmann et al.[4] which has been adapted slightly in line with the structure of EAE operationalisation in Switzerland. It provides guidance in assessing the ethical aspects of a health technology. Questions relevant to the technology in question can be selected in each case. It should be noted that the list is neither exhaustive nor final, and that the questions may be interrelated in some cases.

Table 4: Ethical questions relevant for health technology

1.	Does the widespread use of this technology change the patient role? (Does it change the prestige or status of the disease, the conceptions, prejudice or status of persons with certain diseases?)
2.	Does the implementation, use or withdrawal of the technology challenge patient autonomy, integrity, privacy, dignity or interfere with basic human rights?
3.	Does the technology challenge social or cultural values, institutions or arrangements, or does it affect religious convictions?
4.	What are the morally relevant consequences (benefits and harms) of the implementation, use or withdrawal of the technology (in particular from a patient perspective)? How should the harms be balanced against the benefits? Are there alternatives?

[3] Avoiding the unintended consequences of growth in medical care. Fischer ES, Welch HG. JAMA. 281:446-453 (1999).

The normative basis of (health) technology assessment and the role of ethical expertise. Grundwald A. Poiesis Prax. 2:175-195 (2004).

[4] Toward a procedure for integrating moral issues in health technology assessment. Hofmann, Bjørn. International journal of technology assessment in health care. 21 (3), S. 312–318 (2005).

Harmonization of ethics in health technology assessment: a revision of the socratic approach. Hofmann B, Drostle S, Oortwijn W et al. Int. Journal of health Technology Assessment in Health Care, 30:1; 3-9 (2014).

5. Will there be a moral obligation related to the implementation, use or withdrawal of the technology? (E.g. are there special difficulties with informing patients, with privacy or confidentiality?)
6. Does the technology in any way challenge or change the relationship between patients and healthcare professionals or between healthcare professionals?
7. Are there morally relevant aspects with respect to the level of generalisation?
8. Is the symbolic value of the technology of any moral relevance? (Prestige, status?) May this change as a result of the health technology?
9. Are there moral challenges related to components of a technology that are relevant to the technology as such?
10. Are there any related technologies that have turned out to be morally challenging? (Are the same challenges relevant for this technology?)
11. How does the technology contribute to, challenge or alter healthcare professionals' autonomy?
12. Are there morally relevant issues related to the choice of end points, cut-off values and outcome measures in the assessment?
13. What morally relevant challenges follow from knowledge gaps?

2.3.6 Questions concerning societal aspects

k. Are there any technology-related harm or safety risks for healthcare professionals, the public and/or the environment?

l. Is there equitable access to the technology within Switzerland, or have geographical or socio-economic differences been reported?

m. Are there reported patient acceptance or preference issues concerning the technology or the alternatives?

n. Will the technology have any effects on the cost to the economy? If so, how do these differ from those caused by the alternative technologies?

2.4 Economic efficiency criterion

Appraisal of the economic efficiency of a technology is based on the direct costs to the compulsory health insurance scheme and the related financial consequences.

2.4.1 Questions concerning the cost of the technology

a. What are the prices or tariffs for the technology, and how are they calculated?*

b. If the technology involves a medicinal product or medical device: How does the price in Switzerland compare to the price in other countries?**

c. How are prices likely to develop in the future?

d. What are the costs of the technology and the alternative technologies per treated case?

* Depending on the technology, research and development costs may be considered in addition to the cost of providing or producing the technology, or other pricing methods may be used.

** In particular, comparisons with countries which are comparable to Switzerland in the service area under consideration (baskets of countries will be defined in separate service-specific documents).

2.4.2 Questions relating to costs versus health outcomes

e. What is the relationship between the costs of the technology to the health outcomes in comparison

with the alternative technologies?

f. How reliable is the information? Do any uncertainties exist, how great are they, and is the information applicable to the everyday setting in Switzerland?

Various analytical methods are available to assess economic efficiency which compare two or more treatments with each other. They include cost-effectiveness analysis (CEA), cost-benefit analysis (CBA) and cost-utility analysis (CUA). All these methods set the differential costs (incremental costs) against the differential effects (incremental outcomes, benefit). Some authorities in other countries apply cost-utility thresholds as an expression of how much a given society is willing to pay for one quality-adjusted life-year (QALY) gained. No thresholds of this kind have been determined in Switzerland. The specifics of using such methods to assess economic efficiency are still being developed and will be added at a later date.

Internal reference pricing (IRP) is a special method used for medicinal products. More information on this can be found in the manual for the list of specialities (SL).

2.4.3 Questions concerning cost impact

g. What is the financial impact of the technology on compulsory health insurance costs at the level of the insurers and/or cantons?

The cost impact (budget impact) on direct costs when a technology is included for the first time or withdrawn must be demonstrated, taking into account the impact on the treatment pathway, i.e. the expected change in overall compulsory health insurance expenditure in the short, medium and long term. The adoption of a new technology must be compared with the standard of care and any alternative technologies. The extent to which the diagnostic or treatment pathway is included in the calculation is determined by the nature and complexity of the technology and by its place within the diagnostic and treatment pathway. A budget impact analysis (BIA) can be performed (guidance on designing, conducting and reporting a BIA in accordance with internationally accepted principles is provided by ISPOR[5], for example). Further details of the presentation of budget impacts are detailed in the processes and documents for specific types of services.

3 Operationalisation of the EAE appraisal

Introduction

Decision-making is a two-stage process. In the first stage, the information about a technology generated by the assessment is used to appraise fulfilment of the EAE criteria. In the second stage, a recommendation in favour of or against reimbursement and any conditions is made on the basis of the outcome of the first stage (see section 4).

If the appraisal of the individual points shows major differences for different areas in which the technology is used or for subpopulations of patients, it may be appropriate to perform a separate appraisal for each area or population.

Depending on the type of technology, the stage of assessment and the process used, it is not always necessary to perform a full appraisal of all criteria. The first criterion to be appraised is always effectiveness, followed by appropriateness and finally economic efficiency. If a criterion is appraised as not being fulfilled, there is no need for detailed evaluation of the subsequent criteria. The competent commission is responsible for deciding how to proceed.

There is admittedly some leeway in assessing the degree to which the individual criteria are fulfilled. The appraisal must be justified in each case. More in-depth work will be carried out to provide guidance for the commissions and decision-makers and to standardise the way fulfilment of the EAE criteria is appraised. It should also be borne in mind that these criteria must be considered specifically for

[5] https://www.ispor.org/home

the service in some areas.

The appraisal questions shown in Figures 3.1 to 3.3 illustrate one possible appraisal method as guidance for the competent commissions. Methods adapted to specific services may be used, and these are defined in greater detail in separate documents.

3.1 Appraisal of the effectiveness criterion

3.1.1 Appraisal questions concerning effectiveness (E1)

Question E1a: Is the technology suitable to achieve the desired diagnostic, therapeutic, nursing or preventive outcomes?

❑ No	❑ Partially	❑ Yes

Justification E1a

Question E1b: How does the technology affect (benefit) the course of the disease concerned under study conditions compared with alternative technologies?

❑ Unknown	❑ Less positive	❑ Equally positive	❑ More positive

Justification E1b

Question E1c: Are the study results applicable to clinical practice in Switzerland?

☐ Unknown	❑ Not applicable	❑ Partially applicable	❑ Fully applicable

Justification E1c

3.1.2 Appraisal question concerning safety (E2)

Question E2: What is the safety profile of the technology compared with alternative technologies?

❑ Unknown	❑ Less safe	❑ Equally safe	❑ Safer

Justification E2

3.1.3 Appraisal questions concerning quality of evidence and evidence gaps (E3)

Question E3a: What is the overall quality of the reported evidence on efficacy and effectiveness?

❑ Very low	❑ Low	❑ Moderate	❑ High

Justification E3a

Question E3b: What is the overall quality of the reported evidence on safety?

❑ Very low	❑ Low	❑ Moderate	❑ High

Justification E3b

Question E3c: Is the reported evidence consistent with the expected evidence in terms of the nature, frequency, setting and need for (unmet medical need) or relevance of the technology and the practicability and affordability of studies?

❑ No	❑ Partially	❑ Yes

Justification E3c

3.1.4 Summary appraisal of the effectiveness criterion (E4)

Question E4: Does the technology fulfil the effectiveness criterion?

Note: Fulfilment of the effectiveness criterion does not necessarily assume that the technology is more effective than alternative technologies. Technologies with a smaller benefit may nonetheless make a suitable contribution to achieving the desired medical benefit and thus fulfil the effectiveness criterion at least partially.

❑ Unclear	❑ No	❑ Partially	❑ Yes

Justification E4

3.2 Appraisal of the appropriateness criterion

3.2.1 Appraisal question concerning relevance of the technology (A1)

Question A1: What is the relevance of the technology in terms of its status in patient care or addressing an unmet medical need?

❑ Not relevant	❑ Little relevance	❑ Moderately relevant	❑ Highly relevant

Justification A1

3.2.2 Appraisal question concerning acceptability of the technology (A2)

Question A2: Is the technology considered acceptable for patients (including in terms of adherence), providers/healthcare professionals and carers in comparison with alternative technologies?

❑ Not acceptable	❑ Less acceptable	❑ Equally acceptable	❑ More acceptable

Justification A2

3.2.3 Appraisal question concerning quality requirements (A3)

Question A3: Is the quality of the technology likely to be good when provided in the clinical practice setting?

❑ No	❑ Partially	❑ Yes

Justification A3

3.2.4 Appraisal question concerning appropriate use (A4)

Question A4a: Is the nature or assembly of the technology suitable for ensuring appropriate care?

❑ No	❑ Partially	❑ Yes

Justification A4a

Question A4b: Is there a risk of the technology being used inappropriately, excessively or in the wrong indication under the foreseen conditions?

❑ Unknown	❑ High risk	❑ Low risk	❑ No risk

Justification A4b

3.2.5 Appraisal question concerning legal requirements (A5)

Question A5: Is the technology consistent with the legal requirements?

❑ Not consistent	❑ Partially consistent	❑ Consistent

Justification A5

3.2.6 Appraisal question concerning ethical and social aspects (A6)

Question A6: Is the technology consistent with the existing social and ethical norms or values and in terms of equitable access for all insured persons?

❑ Not consistent	❑ Partially consistent	❑ Consistent

Justification A6

3.2.7 Appraisal question concerning benefit for society (A7)

Question A7: What is the benefit of the technology for society, in particular in terms of reducing the transmission of diseases and economic costs compared with alternative technologies?

❑ No benefit	❑ Little benefit	❑ Equal benefit	❑ Greater benefit

Justification A7

3.2.8 Summary appraisal of the appropriateness criterion (A8)

Question A8: Does the technology fulfil the appropriateness criterion?

❑ Unclear	❑ No	❑ Partially	❑ Yes

Justification A8

3.3 Appraisal of the economic efficiency criterion

3.3.1 Appraisal question concerning cost plausibility (EE1)

Question EE1: Are the nature and level of the prices, tariffs and costs calculated plausibly?

❑ Unclear	❑ Not plausible	❑ Plausible

Justification EE1

3.3.2 Appraisal question concerning costs versus health outcomes (EE2)

Question EE2: Is the relationship between the costs and the health outcomes associated with the technology acceptable in comparison with alternative technologies?*

** Evaluation of the acceptability is at the discretion of the commission issuing the recommendation and the decision-making body. More in-depth operationalisation is planned in order to make this aspect easier to substantiate and to promote uniform application.*

❑ Unclear	❑ Not acceptable	❑ Acceptable

Justification EE2

3.3.3 Appraisal question concerning budget impact (EE3)

Question EE3: Is the impact of mandatory reimbursement on the overall costs incurred by the compulsory health insurance scheme acceptable?

❑ Unclear	❑ Not acceptable	❑ Acceptable

Justification EE3

3.3.4 Summary appraisal of the economic efficiency criterion (EE4)

Question EE4: Does the technology fulfil the economic efficiency criterion?

❑ Unclear	❑ No	❑ Partially	❑ Yes

Justification EE4

4 Operationalisation of the coverage recommendation

The coverage recommendation is based on the appraisals of the individual EAE criteria. The possible recommendation categories for coverage under the compulsory health insurance scheme (or mandatory reimbursement) are shown in the table below.

Table of possible recommendation categories:

EAE appraisal	**Coverage recommendation**
One or more criteria are considered to be not fulfilled	No coverage
One or more criteria are considered to be partially fulfilled or unclear	Temporary coverage / under evaluation (coverage according to Art. 33 para. 3 HIA; coverage with evidence development, CED[6]), with or without specific requirements / limitations
All three criteria are only considered to be fulfilled by means of regulatory requirements / limitations	Indefinite coverage with specific requirements / limitations
All three criteria are considered to be fulfilled	Indefinite coverage without specific requirements / limitations

If certain criteria are considered to be partially fulfilled, the overall assessment and coverage recommendation are determined by the **overall appraisal of all three criteria**. For instance, a service may be less effective than another service but may be more appropriate than the more effective service because it is easier to use, or may be similarly appropriate but less expensive, giving it an advantage in terms of economic effectiveness and thus making it suitable for coverage. Justifications for the coverage recommendation must be given in each case.

Coverage may be granted under the following conditions, for example, in order to ensure that the EAE criteria are fulfilled:

- Restriction to specific indications
- Restriction to second-line treatment/test
- Coverage only for defined providers/institutions to ensure quality or appropriate use
- Coverage after prior authorisation by the physician appointed by the insurer (in German "*Vertrauensarzt*", in French "*médecins-conseils et médecins d'assurances*") and approval of costs by the insurer

[6] For suitability for CED see checklists (therapy or diagnosis) Application processes for general services (admin.ch)