CAU-08 version 4 Requirements on the structure of technical documentation to be submitted along with applications and on the structure of opinions of other parties in the submission of evidence in procedures concerning determination of or change to the amount and conditions of reimbursement of medicinal products and foods for special medical purposes

This guideline supersedes guideline CAU-08 version 3 as of 16th January 2026.

The guideline has been drafted by the State Institute for Drug Control (hereinafter referred to as the "Institute") in order to:

- establish uniform standards for typical situations, in the effort to reduce the number of shortcomings and missing data, facilitating the assessment process;
- facilitate communication between parties to the procedure and the Institute;
- simplify the process of the preparation of documentation on the part of the applicant;
- provide straightforward key documentation for the Institute's decision-making,

The guideline is issued in compliance with the provisions of Sections 39b to 39f of the Act No 48/1997 Coll., on Public Health Insurance, as amended, and Decree No 376/2011 Coll., implementing some provisions of the Act on Public Health Insurance, as amended.

The Guideline is of the nature of a recommendation.

A uniform structure for submission is recommended for all individual administrative procedures upon request or in-depth revisions, where a complete assessment of the clinical benefit or cost-benefit or budgetary impact evaluation are conducted due to a proposed change to the amount or conditions of reimbursement in compliance with effective legislation. The uniform structure does not apply to applications for abbreviated procedures for the launch of similar medicinal products into the reimbursement system, etc.

The changes effective from 1 January 2022 concern, in particular, a new type of administrative procedure according to section 39da of the Act No 48/1997 Coll., on Public Health Insurance, as amended, and Decree No 376/2011 Coll., implementing some provisions of the Act on Public Health Insurance, as amended), related to orphan medicinal products. New forms for submission of structured opinions from individual participants in the procedure (except for the applicant) are also designated for this type of procedure with a larger number of parties; these forms are provided as annexes hereto.

The Institute expects that all of the entities concerned by the aforementioned type of administrative procedures will benefit from the implementation of the uniform structure for the submission of technical documentation. The following, in particular, is expected:

- implementation of uniform standards for typical situations, reducing the number of shortcomings and missing data, thus facilitating the assessment process;
- easier communication between the parties to the procedure and the Institute;
- easier preparation of documentation on the part of the applicant;
- a more straightforward documentation for decision-making, allowing the Institute to better navigate in the documentation, as well as a more straightforward course of the procedures conducted by the Institute.

In the preparation of these forms, the representatives of all stakeholders concerned by the process of determination or change of the amount and conditions of reimbursement were addressed. The representatives of these entities had the opportunity to provide their opinions and comment on the documents in the course of the preparation. The entities addressed were (in alphabetical order):

- Association of Innovative Pharmaceutical Industry
- Association of Clinical Nutrition Manufacturers
- Czech Association of Pharmaceutical Companies
- Czech Medical Society of Jan Evangelista Purkyně

- Czech Society for Pharmacoeconomics and Health Technology Assessment
- General Health Insurance Company of the Czech Republic
- Institute for Health Economics and Technology Assessment
- Ministry of Health of the Czech Republic
- Patient Council at the Ministry of Health
- Union of Health Insurance Companies of the Czech Republic

Annexes:

Annex No 1: Structured submission template A for marketing authorisation holders

Annex No 2: Structured opinion template B for health insurance companies

Annex No 3: Structured opinion template C for professional societies

Annex No 4: Structured opinion template D for patient organisations

Annex No 5: Structured submission template A for marketing authorisation holders – immunization

Annex No 6: Structured opinion template B for National Institute of Public Health - immunization