HAUTE AUTORITÉ DE SANTÉ

ASSESS
HEALTH TECHNOLOGIES

GUIDE

LPPR: Dossier submission to the Medical Device and Health Technology Evaluation Committee

(CNEDiMTS)

8 September 2020

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This document is available to download at www.has-sante.fr
Haute Autorité de santé – Communication and Information Department
5 avenue du Stade de France – 93218 Saint-Denis la Plaine Cedex. Tel.: +33 (0)1 55 93 70 00

Introduction

Inclusion on the list of products and services qualifying for reimbursement (LPPR) envisaged in article L.165-1 of the French Social Security Code is a decision of the Minister for Social Security and the Minister for Health following a review by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS), the French National Authority for Health's special committee responsible for the evaluation of these product categories.

Therefore, this guide is intended for manufacturers, distributors or service providers seeking to submit an application dossier for inclusion by brand name, or changes in the conditions of inclusion/renewal of inclusion of a product or service on the LPPR.

It details the elements to be provided to enable the examination of the dossier and its review by the CNEDiMTS regardless of the product type falling within the remit of the LPPR.

These products falling within the remit of the LPPR include connected medical devices (CMDs). Up to now, two submission guides were available: a general one for any type of MD, and another CMD-specific document produced by HAS in 2018 in view of their specific features.

As medical device connectivity is now featured in many dossiers submitted to the CNEDiMTS for evaluation, this updated version of the submission guide includes specific questions inherent to CMDs. As such, this single guide providing an overview of the requisite elements of your dossier replaces the guide for the submission of a CMD-specific dossier issued in 2018.

This evaluation is defined by articles R. 165-11 and R. 165-11-1 of the French Social Security Code. The CNEDiMTS review particularly assesses the actual clinical benefit (ACB) and, if deemed sufficient, the clinical added value (CAV).

The dossier will therefore include elements suitable for:

- demonstrating the clinical benefit of the MD product, as well as its place in the therapeutic, diagnostic or disability compensation strategy.
- providing the information required to evaluate the procedure if the use of the MD requires the creation or amendment of a procedure in the General nomenclature of medical procedures (NGAP) or the Joint classification of medical procedures (CCAM).

The operating procedure of the CNEDiMTS is defined in its regulations and its evaluation principles.

Prior to submitting a dossier, if you so wish, you can contact the medical device assessment department for the purposes of dialogue. Two types of dialogue are available, according to the progress status of your dossier:

• early dialogue: the primary aim of these meetings is to dialogue on any queries you may have in relation to the methodology of the clinical study that you are envisaging;

• pre-submission meetings: these meetings are arranged specifically for medical devices with a view to providing manufacturers with guidance on technical and regulatory aspects in the composition or in the finalisation phase of their dossier (remit of LPPR, content of dossier in particular).

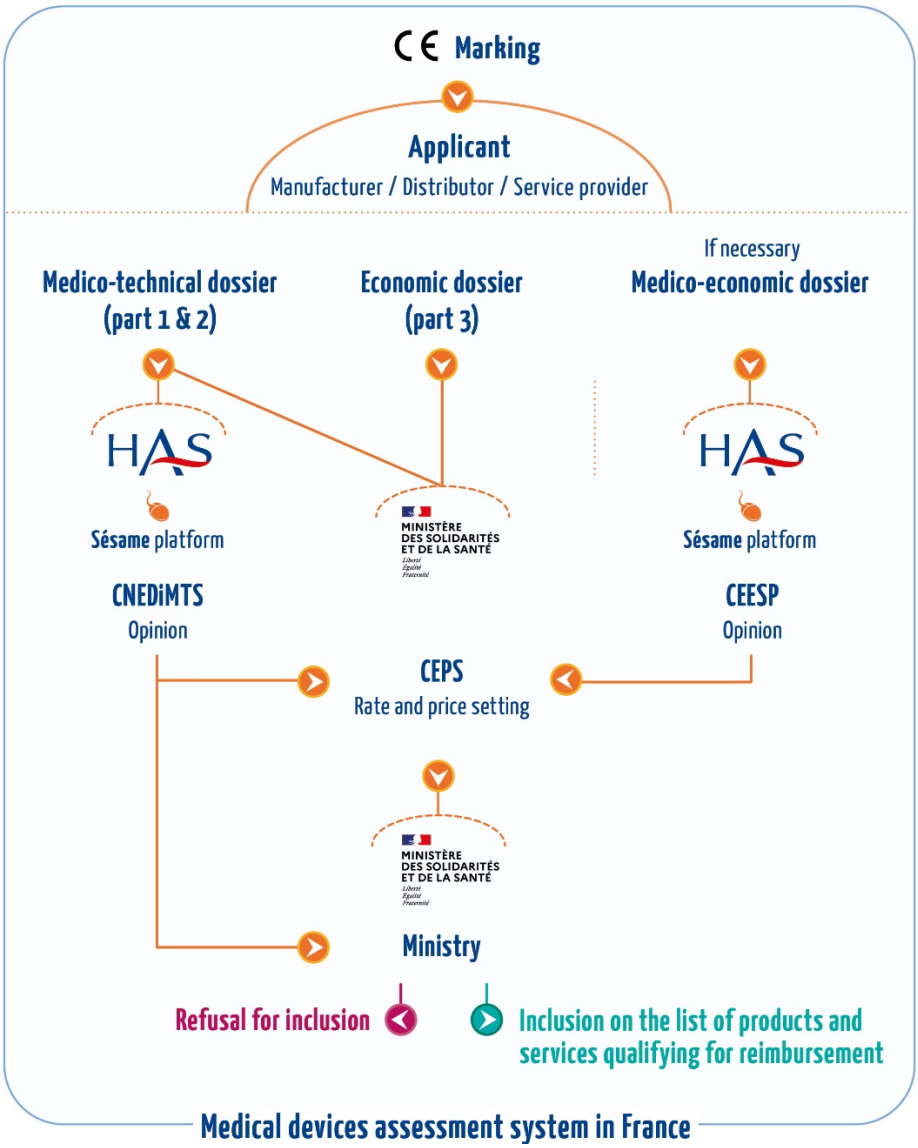
No CNEDiMTS members are present for these two types of dialogue.

General instructions for dossier submission

The application is made up of three parts:

- Part 1: summary and identification of the application;
- Part 2: medico-technical dossier;
- Part 3: economic dossier.

Where and how do you submit your application?



The full dossier (parts 1, 2 and 3) must be submitted to the French Healthcare Products Pricing Committee (CEPS).

Simultaneously, parts 1 and 2 should be submitted electronically to the CNEDiMTS, via the HAS SESAME platform (see further information on accessing the SESAME platform on page 8).

You should specify **a single designated contact** who will be the sole recipient and point of contact with HAS throughout the dossier examination phase.

For any claimed CAV I, II, or III with a significant impact on French health insurance fund expenditure[1], please also consult the specific dossier submission procedure to obtain an efficiency opinion from the Commission for Economic and Public Health Evaluation (CEESP) using the following link: Efficiency opinion dossier submission.

In the case of a price adjustment or maximum sale price request, the procedure only applies to the CEPS. [for more details, see the Practical guide of procedures to follow in the context of the inclusion of medical devices on the list of products and services qualifying for reimbursement (LPP)]

Dossier structure

➔ Format

The full dossier (including the instructions for use, tables and figures of the tabulated abstracts) is written in French, with the exception of the appended reports, protocols, and publications which may be in English. The dossier is composed of three documents

- which must include page numbering;
- as per the dossier template plan and the formats described (see page 10)
- and complies with the rules relating to electronic documents (see page 54).

➔ Content

Your **dossier must contain a justification**.

You are required to furnish **all requisite information and data** to the CNEDiMTS on the various sections of its evaluation (clinical, epidemiological, etc.) (copies of publications or study reports appended).

A systematic documentary search must be conducted to identify the main clinical data (see page 23).

This justification **is not based** on:

- abstracts, poster or conference presentations;
- theses;
- general articles of the narrative, editorial or opinion piece type;
- documents and publications written in a language other than English or French;
- expert letters of recommendation;
- preclinical studies.

These items will **not be taken into consideration**.

If some data are not published, only the following types will be taken into consideration:

- clinical studies under publication: text accepted for publication (please provide proof).
- the final version of the full study report with the study protocol, both dated, signed, and clearly identifiable.

[1] As per article R. 165-71-3 of the French social security code.

Examples of useful reference documents and sites are proposed (see page 36). Relevant studies must be summarised in tabulated abstract form as per the template on page 38.

Bibliographic references must adhere to the recommendations adopted by the International Committee of Medical Journal Editors (Vancouver guidelines), namely: Authors*. Title. Subtitle. Title of journal; Year of publication; volume (issue or supplement): start page-end page.

*For up to six authors, the authors' names must be given; from seven, the first six should be cited, followed by a comma and the words "et al.".

Once the evaluation has been completed, HAS deems all the information disclosed by the manufacturer to be suitable for disclosure on request or publication in compliance with business confidentiality in particular. Otherwise, you must notify HAS and specify, giving reasons for your request, the information that you deem to fall within the remit of industrial and commercial confidentiality. Based on the information provided, HAS will issue its opinion as to the confidential nature of this information.

- On receipt by HAS and verification of the presence and validity of the administrative documents, to be included with the submission (see page 8), the dossier will be assigned a HAS project manager for appraisal/examination. As such, the HAS project manager will be the applicant's point of contact during the dossier examination process. Members of the CNEDiMTS will not respond to any dossier-related requests from applicants.
- The examination period commences at the time of registration of the dossier by the CEPS. The CNEDiMTS will suspend the time limit stipulated in article R.165-8 of the French social security code should the dossier be incomplete. This time limit will be suspended until the date of receipt of the information requested by HAS.

To save time in the LPPR inclusion process, take care to ensure that the dossier submitted is complete. An analysis of the dossiers submitted over a 6-month period (June to December 2018) has been conducted by the SED (HAS medical device assessment department). This analysis showed that 44% of the dossiers submitted during the period were suspended. In over 60% of cases, there were at least 2 grounds for suspension (mostly failure to supply clinical data and regulatory prerequisites). The other common grounds for suspension were linked with the justification sections of the dossier, the description of the device or the comparator / CAV. **These different grounds for suspension would appear to be easily avoided.**

Submission procedure

Dossiers are submitted to the CNEDiMTS online only via the SESAME platform.

Dossier submission via the SESAME platform does not exempt the applicant from making a submission to the CEPS according to the specific procedure involved. [see also Practical guide of procedures to follow in the context of the inclusion of medical devices on the list of products and services qualifying for reimbursement defined in article L. 165 1 of the French social security code (LPP)]

SESAME platform access procedure

To be able to submit a dossier via the SESAME platform, the applicant (company or national professional council) must have previously requested to **set up an account for access**. This account set-up request is also made via the SESAME platform using the relevant form. HAS creates a dedicated account, with authorised access for no more than two individuals designated by the company. These individuals become their company's account managers. They can then set up **contributors**, who will be able to access/submit/track dossiers via the SESAME platform on behalf of the company in question. Each contributor will have their own ID and password, which will be their responsibility.

You will only have to enter most of the personal details once; they will subsequently be automatically pre-populated for each new application.

To set up an account for access, you will need the company's or professional council's SIRET number and a statement stamped and signed by the legal representative authorising the individuals mentioned to act as "account manager".

The company can also commission a consultant to submit/track a dossier on its behalf. In this case, HAS sets up access for the individual designated by the company's legal representative. This user will only be able to submit and track dossiers that they have created.

For more information, a dedicated FAQ section and a dossier submission guidance procedure are available in the dossier submission section of the HAS website.

You can consult the status of a dossier on the platform at any time, allowing you to track its progress in real time. Each time the status changes, you will be sent an email notification (if you have enabled this option).

A fee is due for each application for inclusion, renewal of inclusion or changes in the conditions of inclusion in respect of a medical device for individual use [article 1635 bis AH (LPP) and article 1635 bis AG (within-DRG) of the French general tax code)][2]:

Inclusion in list[3]	€3,200
Changes in the conditions of inclusion	€644
Renewal of inclusion	€644

[2] This fee is only due for reimbursement applications pertaining to medical devices. This fee does not apply to DFSMPs, grafts, and services. The fee amount was amended by decree No. 2012-698 of 7 May 2012

[3] These terms are defined in the Practical guide of procedures to follow in the context of the inclusion of medical devices on the list of products and services qualifying for reimbursement defined in article L. 165 1 of the French social security code (LPP)

The fee payment is only made after forwarding the acknowledgement of receipt sent by the SED department via the platform and by bank transfer to the Direction des Créances Spéciales du Trésor (DCST):

22 boulevard Blossac, BP 40648 - 86106 CHATELLERAULT CEDEX

Tel +33 (0)5 49 05 53 92 – email: dcst.rg@dgfip@finances.gouv.fr

DCST bank account
Bank details: 30001 00639 0000S055158 88
IBAN: FR8030001006390000S05515888
BIC: BDFEFRPPCCT

After your dossier has been submitted via the platform and registered by our department:

1. You must pay the relevant fee to the DCST including, both in the transfer reference and in the order:
   - the ID provided by the SED,
   - the name of the product and,
   - if possible, that of the applicant.

2. The applicant receives an acknowledgement of receipt by email from the DCST as proof of fee payment.

No exceptions to this rule are allowed. An acknowledgement of receipt is associated with an application.

Template plan and format of dossier to be submitted to the CNEDiMTS

Dossier template plan

Part 1 – Summary and identification of the application

This part also includes the regulatory prerequisites and administrative documents to be included with the application:

- Letter of application to the ministers for social security and health forwarded to the CEPS.
- Letter of application to the HAS medical device assessment department (SED).
- Declaration of CE conformity and certification:

CE declaration of conformity to Directive 93/42 for medical devices or 90/385 for AIMDs.

Declaration of conformity to Directive 98/79 for in vitro medical devices.

EU declaration of conformity as per Regulation 2017/745.

- CE certificate(s) issued by a notified body – with, if available, the basic UDI-DI4.
- For connected medical devices, other regulatory requirements:

for personal data processing, the declaration of conformity to the requirements of the General Data Protection Regulation (GDPR);

where the data processing gives rise to hosting of health data as per Article L.1111-8 of the French Public Health Code, the certificate of conformity of the host.

- For products other than medical devices, other regulatory prerequisites:

for dietary foods for special medical purposes: notification to the DGCCRF and, if applicable, the ANSES review.

For allografts: single authorisation issued by the ANSM.

- Instructions for use in French bearing the CE mark[5].

Where applicable, proof of conformity with a view to reimbursement through inclusion on the LPPR to guidelines, standards, specifications, tests or analyses (+ full reports or specifications, proof of conformity to the technical specifications set out in the LPPR).

All of these elements should be submitted in the form of a single document, with page numbering, in usable PDF format.

Part 2 – Medico-technical dossier

- Besides the medico-technical dossier per se, Part 2 must particularly include:
- The tabulated abstracts, in French, of the scientific data provided in Appendix I;
- The materiovigilance data summary table.

The medico-technical dossier must be submitted in the form of a single document, including page numbers, in Word format.

Appendix 1 – Scientific data

This appendix compiles all of the clinical data forming the basis of the justifications detailed in the medico-technical dossier and the contents of Appendix 2, according to the following framework:

- Contents
- Specific studies section in support of the justification

For each study:

[4] In accordance with Regulation 2017/45, from 26 May 2020

[5] In accordance with Article 20 of Regulation 2017/745

- tabulated abstract;
- publication or, for unpublished studies, study protocol & report.

– **NON**-specific studies section in support of the justification

  For each study:
  - tabulated abstract;
  - publication, or for unpublished studies, study protocol & report.

– List and references of general documents included in the application in Appendix II (i.e. the contents of Appendix II)

Appendix 1 must be submitted in the form of a single document, with page numbering, if possible in PDF format.

Appendix 2 – General documents included in the application

This section relates to any other data that you wish to add in support of your application, such as professional guidelines or other reports or publications cited in the dossier (not the subject of a tabulated abstract), any prior CNEDiMTS opinions or orders published in the French Official Journal in relation to the application, letters of application for removal from list, etc.

Appendix 2 must be submitted in the form of a single document, with page numbering, in PDF format.

Part I: Summary of the application

Trade name of the product:			
Product type:			
Type of application	☐Inclusion	☐Change	☐Renewal
Type of dossier submitted	☐ Full	☐ Simplified	
Function of the device	☐Therapeutic ☐Diagnostic	☐Disability compensation ☐Other	
Models / references / software version / basic UDI-DI, if available:			
Applicant:			
Claimed indications:			
Claimed CAV ratings and comparators ***(not required for within-DRG indication):***			
Terms of prescription and use (detailed description of associated services):			
Procedure-related MD	☐Yes	☐No	☐Not applicable
	If yes, procedure included in the CCAM/NGAP ☐ Yes ☐ No Code and name of relevant procedure		
Target population:			

Part I: Identification of the application

Trade name of the product or service	
Commercial models and references subject to the application	
Applicable discipline	

1. Applicant

Applicant (specify whether the applicant is a manufacturer, agent, importer distributor or service provider)	Company name: Address: Tel. / Fax / email: SIREN No.: And/or SIRET:
Single contact **(Only one contact per dossier)**[6]	Name, capacity and contact details: Address: Tel. / fax / email:
Signatory of any agreement with the CEPS	Name, capacity and contact details: Address: Tel. / fax / email:
Manufacturer/agent (If different from applicant)	Company name: Address: Tel. / fax / email: SIREN No.: Name and capacity of contact:

[6] If the contact belongs to a different legal entity than the applicant, please furnish a mandate.

2. Administrative details

- CE mark classification
  - Specify the indication of the CE mark

Class (I, I sterile, IIa, IIb, III, AIMD, IVDMD)	Name, code and country of notified body (with the exception of class I: declaration of conformity by the manufacturer)	Date of initial notification and expiry date of the current certificate, by reference

3. Type of application

This section must be used to identify the precise nature of the application.

List links to orders and prior opinions published in the French Official Journal justifying the history of the reimbursement application.

Does the application concern:

- a product: ☐ yes ☐no
- a service: ☐ yes ☐no

Is the application for:

Inclusion in list	☐yes	☐no
Changes in inclusion – Date of Official Journal of first inclusion on the LPPR – Date of Official Journal of latest changes in the conditions of inclusion ➔ Purpose of the change:	☐yes	☐ no
Renewal of inclusion – Date of publication of first inclusion on LPPR in Official Journal – Date of end of inclusion	☐yes	☐no
Price adjustment – Date of Official Journal of first inclusion on the LPPR – Date of Official Journal of latest adjustment	☐yes	☐no

4. Product or service concerned

The application may pertain to a product, a service, or a product associated with a service.

4.1. If the application pertains to a product:

- Trade name and references of current product version:
  - in France,
  - in other countries of the European Union,
  - in other countries in the world.

- Packaging:
  - precise and full description of contents: number of units, sterile/non-sterile, does it contain accessories, ancillary materials, etc.
  - types of packaging (number of units of product per packaging unit) particularly in France, Europe, and the United States of America.

- Development history:

  State of the art in the development field, successive incremental upgrades and origins thereof. You should particularly note any market withdrawals.

- International marketing history and any market withdrawals: complete the relevant columns for each country

Country	Full NAME and MODELS and VERSIONS under which the product was marketed[7]	Marketing			
		Authorisation type[8]	Date of authorisation	Special indications and condition(s)	Date of introduction on the market

- Number of devices sold or implanted in the last 5 years (if available) in France and internationally.
- Pre-existing supply in France through trial including public funding: potential clinical research programmes (MIG, PHRC, PRME, SANTINEL), telemedicine rollout trials (Article 91 of Social Security Finance Act (LFSS) for 2017), etc.

[7] Specify internal codes or references

[8] e.g.: CE mark, FDA approval procedure (Premarket approval (PMA), 510(k)), etc.

- Reimbursement under Article L.165-1-1 of the French Social Security Code.
- Any existing lines of the LPPR (codes) enabling product reimbursement.
- Other reimbursable products of the same category.
- Prior dossier submissions and previous CNEDiMTS opinions

- Simultaneous application for early reimbursement under Article L.165-1-5 of the French Social Security Code: ☐Yes ☐No

4.2. If the application pertains to a service:

- Description of the different components (general, administrative, and miscellaneous: on-call service, potential delivery, etc.).

4.3. If the application pertains to a product associated with a service:

Parts 4.1 and 4.2 must be completed.

Part II: Medico-technical dossier

1. Dossier contents

Depending on the context of the application, the applicant will be required to submit a “full” or “simplified” dossier, where the type of dossier to be submitted – “full” or “simplified” – is not linked with the reason for the application (inclusion on the LPPR, renewal of inclusion, or changes in the conditions of inclusion).

In the “full” dossier, all sections should be completed in respect of the descriptive information for the product and/or service, the identification and selection of the clinical data available, evidence of the claimed actual clinical benefit, proposals in relation to the terms of prescription and use, evidence of the claimed clinical added value, and the target population.

In the “simplified” dossier, all sections could be completed, but the details required will be limited due to the type of application. The requirements for these details are specified in specific inserts.

The scenarios in which a “full” dossier or a “simplified” dossier are required are described below:

1.1. Full dossier

A “full” dossier is required for all scenarios not falling within the scope of section 1.2.

1.2. Simplified dossier

In each of the following four scenarios, a “simplified” dossier can be envisaged if all the conditions detailed in the table below are met.

Scenarios	Conditions
Inclusion of a product on the list by brand name as per the requirements set out in the LPPR (technical specifications) Examples: energy storage and return prosthetic feet, so-called “memory foam” viscoelastic foam cushions,long-term therapeutic footwear, anatomical hydrocolloidal dressings, anatomic hydrocellular dressings (cavity or non-standard geometric shape), etc.	No new indication is claimed with respect to other previously assessed products of the same category; No clinical added value is claimed, as the comparator is the category to which the product in question belongs.

Inclusion of a range extension, addition of new references (for a product already listed on the LPPR)	The extensions made (new diameter, size, colour, packaging, etc.) do not modify the mode of action and are not liable to modify the clinical effect of the previously assessed product; No new indication is claimed with respect to the other products of the same range; The claimed comparator and CAV rating for each indication are restricted to those taken into consideration by the CNEDiMTS for the previously evaluated product; The CNEDiMTS has previously ruled on one or products of the range and no new data are liable to modify the place of these products in the strategy.
Range upgrade (incremental upgrade of a product previously listed on the LPPR)	The changes made are incremental and do not modify either the mode of action or the nature and quantity of the clinical effect of the previously assessed product; No new indication is claimed with respect to other previously assessed products; No clinical added value is claimed, as the comparator is the product of the prior range; No new data are liable to modify the place of the product in the strategy.
Renewal of inclusion	No modification of the findings of the previous review is claimed; No clinical and materiovigilance data are liable to modify the findings of the previous review; No new data are liable to modify the place of the product in the strategy; No request for a post-inclusion study has been made.

However, the medical device assessment department reserves the right to request that a "full" or supplemented dossier be furnished if deemed necessary during the examination process.

The examination method is not determined by the type of dossier submitted.

2. Descriptive product information

2.1. Product description (technical characteristics)

This section is intended to specifically describe the technology under consideration in the application: composition, technologies involved and technical characteristics (weight, size, diameter, materials, origin of materials (particularly in the case of constituents of biological origin), shape, battery or cell service life under the various conditions of MD use, warranty period, shelf-life, etc.).

In view of the broad range of products liable to be assessed by the CNEDiMTS, you will need to adapt the required descriptive information in order to convey:

- the composition of the product under assessment;
- its technical characteristics;
- if applicable, the devices or technologies liable to be used alongside the product or required for its operation.

The exact product description may be supplemented by drawings, diagrams, photos.

Where applicable, conformity to guidelines, standards, specifications, tests, or analyses (attach specifications document if applicable) or proof of conformity to the technical specifications set out in the LPPR may be documented or attached.

If the application concerns connected technology, as some or all of the device is digital, a specific description is required according to the recommendations on page 40, in addition to the hardware description of the product.

2.2. Description of functions based on machine learning processes (technologies falling within the scope of artificial intelligence), where applicable

For medical devices embedding decision-making systems based on machine learning processes, it is required to provide a description of the functions built or subject to change using these technologies.

For this purpose, you must use the specific descriptive grid appended from page 41. This will provide you with a base to particularly describe the role of each function concerned, the characteristics of the data processes, the results obtained, and the algorithm operating procedure.

2.3. MRI compatibility, if applicable

For implantable MDs liable to give rise to artifacts, the potential impact of these artifacts on MRI interpretation and the associated recommendations for use must be documented.

For AIMDs specifically, you should specify the limits of compatibility with MRI procedures and the main precautions to be taken. Where applicable, the AIMD deactivation measures, required to conduct the test, must be specified.

2.4. Supplementary descriptive information for products arising from the upgrade of a product previously assessed by the CNEDiMTS

You should provide details of:

- All of the successive upgrades applied to the product since it was first introduced onto the market (for example in the form of a table comparing the technical characteristics).
- The expected objectives (or measured effect if it has been assessed) of these changes should be described to gain an understanding of the impact for the patient and/or users.

2.5. Description of end-of-life or end-of-use disposal measures.

In this section, you should describe the measures for the end-of-life or end-of-use disposal of the MD, its accessories or its consumables. This section particularly must be documented for AIMDs or for non-implantable technologies including electrical or electronic components.

In the case of a simplified dossier

- **Inclusion of a product in accordance with the requirements set out in the LPPR (technical specifications):** provide information to support product conformity with respect to the requirements set out in the LPPR.
- **Inclusion of a range extension or addition of new references:** specify the reasoning behind the supply of the new reference or range extension (new diameter, size, colour, packaging, etc.).
- **Range upgrade:** explain and justify the incremental changes made using a comparative table.
- **Renewal of inclusion:** briefly summarise the product description, specifying that there have been no changes since the previous CNEDiMTS assessment.

3. Mode of action of the product

- Description of the mode of action on the pathology or disability.

In the case of a simplified dossier

- Specify any changes. Otherwise, specify that the mode of action has not changed compared to that indicated in the CNEDiMTS opinion of “date, month, year”.

4. Description of procedures, services and organisational aspects associated with MD use (where applicable)

Specify whether a procedure performed by a healthcare professional or a service is required to implant the implantable device or produce/fit/dispense the device.

Reimbursement of the device is subject to reimbursement of the associated procedure.

4.1. Description of procedures

- If the procedure required is already listed in the NGAP or CCAM

Specify the relevant procedure (code and description of the associated procedure) according to the nomenclature in force (date and version) and the pricing.

- If the required procedure is not listed in the NGAP or CCAM or if use of the product requires the amendment of a previously listed procedure

The procedure must be assessed by HAS. You may link your application for inclusion on the LPPR with the professionals involved in the assessment or concerned by the device implantation or use procedure, for which they submit, via their professional organisation, an application for inclusion of the procedure to HAS, with a copy to the UNCAM. The CNEDiMTS may also decide to take it upon itself to assess such a procedure.

In any case, if the procedure required for the use of the product covered by your application is not listed in the NGAP or the CCAM or if its use requires the amendment of a previously listed procedure, you should provide the information described on page 51, essential for its assessment alongside that of the medical device.

If the use of the medical device requires a telecommunication function-related procedure, specify the procedure required:

☐ remote medical monitoring;

☐ remote consultation;

☐ other:

This section should contain descriptions of:

- the requisite tasks to be performed by various healthcare professionals (data/alert configuration, patient training, aptitude and follow-up; care protocol specifying the procedure to follow in the event of an alert: additional interventions and procedures for therapeutic patient support; etc.);
- the qualification of these healthcare professionals required to perform these tasks.

In the case of a simplified dossier

Specify any changes. Otherwise, specify that the procedure(s) has/have not been changed with respect to that/those mentioned in the opinion of “date, month, year”, simply recalling the descriptions of the procedure(s) concerned.

4.2. Non-medical services (technical services)

If MD installation or use requires specific technical services other than those carried out by caregivers, you should describe them, specifying the capacity of the service provider, the exact nature of the service, its frequency and methods. This service-related section particularly applies to:

- installation services;
- user training services;
- technical support (service opening hours, maximum connection time, cost of connection);
- maintenance (preventive or corrective).

4.3. Organisational aspects

Should the MD have impacts on the general organisation of care for patients (ranging from a change in their care to a change in their care pathway), for healthcare professionals and for the healthcare system, we recommend providing an accurate and exhaustive description of the care currently in place and the new organisation following the introduction of the MD. In this section, you should describe the proposed changes between the two organisations. You may illustrate the proposed organisation using a diagram.

Linking this section of the dossier with section 4.1 relating to the associated professional procedures and section 4.2 relating to non-medical services, if the new care organisation involves cooperation with or between professions, it will be necessary to describe:

- the different interactions between professions liable to arise between the different stakeholders (interprofessional meetings, patient file review, etc.);
- the coordination measures between the prescriber and the professionals responsible for patient follow-up, if they are different; possible task delegations (specifying the existence of cooperation protocols within and between professions).

For CMDs, the role of each of the professionals, if they are different for certain functions. For example, in the case of CMD-generated alerts, the alert processing and handling procedure should be explained (call to patient; call to a third party; referral of patient to a treatment or emergency unit; treatment adjustment; dose adaptation; patient invitation for face-to-face consultation; remote consultation; etc.).

For this section, you may be supported by documents containing the matrix definition, for example:

- remote medicine efficiency medico-economic assessment report;
- specifications in respect of trial remote medicine programmes for chronic and/or complex wound management.

5. Identification and selection of clinical data available

5.1. Systematic documentary search

You are required to conduct a systematic documentary search to justify your application.

The purpose of the systematic documentary search is to identify the clinical data on the MD and/or service available in the literature. According to the applicant's strategy, this search will focus on the specific data in respect of the MD covered by the reimbursement application or extended to technologies of the same type. You must justify your search strategy. It should be explicitly described: search period, sources consulted, terms used.

If the product is a CMD, your documentary search should take the different functions of the CMD into consideration:

CMD capable of fulfilling a separate therapeutic or diagnostic function from the telecommunication function;

CMD having solely a health data telecommunication function linked with the therapeutic or diagnostic purpose.

Your documentary search must include queries of international bibliographic databases and consultation of the websites of health technology assessment agencies and learned societies with expertise in the field studied.

The search concerns the following clinical data:

- best practice guidelines;
- health technology assessment reports;
- systematic reviews and meta-analyses;
- clinical studies

in which the objective is linked with the application.

Based on this systematic search, you should then select the relevant documents in respect of the theme of your application. Your selection method must be explicitly described (selection criteria used). The results of your search should be presented in diagram form (number of references identified by data type, number of references selected based on title and abstract, number of references retained based on full text). In your selection, and subsequently in the analysis, you should differentiate between specific data in respect of the MD covered by your reimbursement application and non-specific data. The studies ultimately included should be listed in a table specifying: name of author, date, study type, population included, number of subjects, duration of follow-up, primary endpoint.

A copy of each relevant report included along with the protocol, as well as each publication, must be appended.

The documents obtained following this selection (based on full text) must be appended.

Example:

- Medline: National Library of Medicine, United States. The systematic search is run on Medline via the free interface, PubMed.
- The search strategy consists of combining the name of the product and/or product category and/or service with the following study type descriptor terms:

French and international guidelines	(Guidelines as Topic[MeSH] OR Practice Guidelines as Topic[MeSH] OR Health Planning Guidelines[MeSH] OR Consensus Development Conferences as Topic[MeSH] OR Consen- sus Development Conferences, NIH as Topic[MeSH] OR Practice Guideline[Publication Type] OR Guideline[Publication Type] OR Consensus Development Conference[Publication Type] OR Consensus Development Conference, NIH[Publication Type] OR recommendation*[Title] OR guideline*[Title])
Meta-analyses and systematic reviews	(Meta-Analysis as Topic[MeSH] OR Meta-Analysis[Publication Type] OR meta-analysis[Title] OR metaanalysis[Title] OR systematic review[Title])
Randomised controlled trials	(Controlled Clinical Trials as Topic[MeSH] OR Randomized Controlled Trials as Topic[MeSH] OR Single-Blind Method[MeSH] OR Double-Blind Method[MeSH] OR Random Alloca- tion[MeSH] OR Cross-Over Studies[MeSH] OR Controlled Clinical Trial[Publication Type] OR random*[Title])

The applicant can copy and paste these filters into the search window in *Pubmed.*

The websites of national and international health technology assessment agencies and learned societies can be used to find guidelines, health technology assessments, and systematic reviews.

A non-exhaustive list of links that can be consulted for the systematic documentary search is available on page 36.

The list of sites visited should be used for drafting the documentary search methodology.

Failure to provide an explicit description of the documentary search and/or selection in the dossier will give rise to a request for supplementary information by HAS resulting in a suspension of the time limit for examination.

Negative clinical data in respect of the product and/or service must be selected according to the same criteria as other data. Otherwise, your dossier is liable to have its time limit for examination suspended and not qualify for CNEDiMTS review.

5.2. Post-inclusion study (for inclusion renewal applications only)

Post-inclusion study requested by the committee: ☐Yes ☐No ☐Not applicable

If yes: Wording of post-inclusion study request

- Date of protocol: Click here to enter a date.
- Date of study report: Click here to enter a date.

5.3. Other identified data

Besides the systematic documentary search, other data may be relevant (unpublished data in particular).

You must justify your choice of data. They must be described and appended.

In the case of a study in progress, you must provide the protocol and, where applicable, the intermediate findings.

In the case of unpublished studies, the applicant must provide depending on the case,

- clinical studies under publication: text accepted for publication (providing proof);
- the final version of the full study report with the study protocol, both dated, signed, and clearly identifiable.

If applicable, you can include the approval rationale from the notified body, in French or in English, pertaining to the evidence of equivalence of the product with those for which the manufacturer is claiming use of the data.

In the case of a simplified dossier

Apart from the case of inclusion of a product on the list by brand name as per the requirements set out in the LPPR (technical specifications), the clinical data available must be identified and selected in the same way as the full file. They must nonetheless concentrate on new data according to the type of application:

- **Inclusion of a range extension, addition of new references, range upgrade:** focus the search on the upgrade or incremental change.
- **Renewal of inclusion:** focus the search on the new clinical data not provided in the previous dossier submission (initial inclusion or renewal(s) concerned).

6. Evidence of Actual Clinical Benefit (ACB) claimed by the applicant

At the beginning of this section, enter the claimed indication(s)[9] and compare them with the CE mark indications, if applicable.

The assessment of the actual clinical benefit of an MD and/or a service is based on the analysis of the following criteria[10]:

[9] Reminder: the claimed indications must be strictly identical to those mentioned in the summary of the application.

[10] Article R165-2 of the French Social Security Code

- **product benefit:**
  - its place in the therapeutic, diagnostic or disability compensation strategy, given all the other available therapies or diagnostic or compensation methods,
  - its therapeutic, diagnostic or disability compensation effect, as well as undesirable effects or risks associated with its use;

- **its public health impact:**
  - its impact on the health of the population, in terms of mortality, morbidity and quality of life,
  - its capacity to meet a therapeutic, diagnostic or disability compensation need that is not covered, in view of the severity of the pathology or of the disability,
  - its impact on the healthcare system,
  - its impact on public health policies and programmes.

In the case where the product is a CMD, and the CMD fulfils a separate therapeutic or diagnostic function from the telecommunication function, the applicant can, if necessary, separate the different claimed indications for the therapeutic or diagnostic function and for the telecommunication function. Separate justifications will also be provided in this case.

Moreover, insofar as CMD use can impact the general organisation of care for patients, for healthcare professionals, and for the healthcare system, besides the requisite clinical data to demonstrate the impact of the telecommunication function on the patient's clinical condition, data for assessing the impact on quality of life, and patient satisfaction are also expected.

6.1. Product benefit

You should develop the justification separately for each claimed indication, if applicable by population group.

- initial inclusion: the justification relates to the actual clinical benefit.
- In the case of a renewal:
  - the justification relates to the actual clinical benefit, under actual conditions of use;
  - presentation of any supplementary studies requested during the inclusion process
  - update of data relating to the pathology and its care
- In the case of an application for changes in the conditions of inclusion: assessment of the actual clinical benefit of the requested change (e.g. the new indication(s), the new reference, the new condition(s) of use).

In the case of a simplified dossier

Evidence of the actual clinical benefit provided in your application is limited to confirming, for each indication, that the claimed actual clinical benefit is that taken into consideration by the CNEDiMTS in its opinion of "date, month, year". You should simply note it in this section. If applicable, you may provide supplementary data.

6.2. Pathology concerned

In this section, you should describe:

- The nature and severity of the pathology in terms of morbidity and mortality (life-threatening, acute/chronic, etc.), disability (severity, duration, temporary or permanent), quality of life, health state perceived by the patient, and medico-social consequences.

If this description refers to severity stages, we recommend preferential use of the quantitative and qualitative measurement scales or validated classifications in the pathology where available (for example: International Classification of Functioning, Disability and Health = ICF).

- Characteristics of patients concerned by the product and/or service in the French population in the indication claimed for reimbursement: age, sex, stage of severity of the pathology, etc.

In the case of a simplified dossier

The claimed pathology concerned is limited to that taken into consideration by the CNEDiMTS in its opinion of “date, month, year”. You should simply note it in this section.

6.3. Current therapeutic, diagnostic or disability compensation alternatives

This section is devoted to identifying and describing the alternatives available for care in **routine practice**.

You should thus describe the existing/available arsenal in the indications of the MD proposed for reimbursement, specifying the risk-benefit ratio and the endpoints used.

The alternatives may be:

- one or more other MDs, a medicinal product, a surgical procedure, or another form of care provided by healthcare workers (e.g. rehabilitation session provided by a physiotherapist)
- **authorised for reimbursement, or not.**

In this arsenal, you should justify the gold standard based on literature data (systematic reviews, reports by French or international health technology assessment agencies, meta-analyses, randomised controlled trials) or existing professional guidelines. Failing scientific evidence, the gold standard will be defined as the strategy used in routine practice.

This gold standard should be the strategy that, in the absence of the new MD, is expected to yield the best results in patients having the pathology concerned.

In some cases, there is no therapeutic alternative – the need is then unmet.

The place of the MD in the therapeutic, diagnostic or disability compensation strategy should be determined after assessing the risk-benefit ratio. (see section on Place of the product and/or service in the therapeutic, diagnostic or disability compensation strategy).

In the case of a simplified dossier

The alternatives claimed by the applicant may be limited to those taken into consideration by the CNEDiMTS in its opinion of "date, month, year", noting them in this section.

6.4. Therapeutic / diagnostic / disability compensation effect / adverse events / risks associated with use: analysis of data available and quality of evidence

You should specify for the product or service:

- the therapeutic, diagnostic or disability compensation effect which is based on the clinical trial data;
- the risks associated with the product for the patient and for operators.

Two types of risks may be reported:

- those associated directly with the product or the service including the risks associated with poor patient compliance or misuse,
- and those inherent to the operating technique (particularly experience of the team, technical platform, and training required, etc.)

You should supply the analysis of the adverse events arising from clinical trials and materiovigilance (by reference and by indication as well as the data relating to previous products from the range where relevant).

If the product is a CMD, you should also provide the analysis of incidents having had an impact on the availability and proper operation of the constituent components of the CMD.

Your justification of the risk-benefit ratio should be based on the clinical data identified (see section on 5. Identification and selection of clinical data available). You should differentiate:

- the specific clinical data relating to the product subject to the application for inclusion on the LPPR,
- the non-specific clinical data relating to previous products or versions from the range or competitor products. Their use must be scientifically justified (characteristics of the product under study compared to those of the product subject to the application, evidence of equivalence, etc.).

The choice of studies taken into consideration and their methodological quality should be discussed in your dossier. The extrapolation of the clinical trial data to the population liable to be treated with this product should be justified.

The absence of specific clinical data should be justified.

You should provide an analysis of the study findings: this analysis should be based on the assessment of the primary endpoint, whether it consists of a clinical or quality-of-life endpoint. You should justify its relevance with regard to those recommended by the state of the art. Otherwise, you should base your justification on the items that you consider relevant.

The use of intermediate endpoints requires that these endpoints also be scientifically validated as corresponding to an effect on morbidity and mortality or quality of life. As a reminder, an intermediate endpoint is validated if the literature provides evidence of the close correlation between the latter and a robust clinical endpoint.

You should take care to systematically provide the publication or, failing that, the protocols and study report of any relevant study for the justification of the risk-benefit ratio of the MD. These items should be appended in their entirety to the dossier with a specific tabulated abstract according to the template plan on page 38.

In the case of an application for renewal of inclusion, you should merely describe new data. If a post-inclusion study has been requested, the findings of this study will be key for the reassessment of the MD by the CNEDiMTS. If you are relying on the updated data from a study previously examined by the CNEDiMTS, you should repeat the protocol of the original study.

In the case of a simplified dossier

- **Inclusion of a range extension, addition of new references or range upgrade:** for each indication, detail the specific data obtained from the documentary search, if applicable. In the case of a claim of equivalence or in the absence of specific data, provide any element helping explain the approval rationale of the notified body, as well as the technical and clinical equivalence data. The extrapolation of the data available on the previous range must be duly justified.

- **Renewal of inclusion:** for each indication, provide details of the new clinical data not provided in the previous dossier submission (initial inclusion or renewal).

6.5. Ongoing studies

You should describe ongoing or planned studies in this section. If available, the protocols should be included with your application.

6.6. Place of the product and/or service in the therapeutic, diagnostic or disability compensation strategy

In this section, it is necessary to place the MD with respect to the therapeutic arsenal available described in section Current therapeutic, diagnostic or disability compensation alternatives.

In view of the current care of the pathology and the clinical data provided, you should provide a justified description (with bibliographic references) of the place of the MD and/or service in the therapeutic, diagnostic, or disability compensation strategy (1st, 2nd or nth -line, preventive treatment, etc.).

You should also specify whether this MD is intended to replace or be added to the existing arsenal.

In the case of a simplified dossier

The place of the product in the therapeutic, diagnostic or disability compensation strategy claimed by the applicant may be limited to that taken into consideration by the CNEDiMTS in its opinion of "date, month, year". You should simply note it in this section.

7. Public health impact

7.1. Transposability of study findings to practice

You should discuss the transposability of clinical trial findings to the population likely to be treated in routine use scenarios, in particular:

- the comparison between the study population and the target population (patients involved);
- the medico-technical environment available (care team, multidisciplinary coordination, etc.);
- risks of misuse: over-prescriptions (outside indications recognised by the LPPR) or under-prescription or incorrect use of the product (patient compliance or incorrect use by users) and the proposed measures to prevent these risks;
- ability to identify patients who will benefit from the product and/or service (tool availability and reliability);
- reproducibility of practice (quality of execution of the associated procedure or service, training, learning curve, critical mass);
- dependency of the risk-benefit ratio with respect to the environment, particularly care organisation (technical platform, multidisciplinary coordination, etc.) and any need to modify care organisation to enable product use.

7.2. Potential population health impact:

If an estimation is possible, you should express it in terms of morbidity, mortality, disability / sequelae, quality of life and health state perceived by the patient.

7.3. Capacity to meet a therapeutic, diagnostic or disability compensation need, in view of the severity of the pathology or the disability.

With regard to available alternatives, you should explain the need addressed by the product subject to the application.

7.4. Anticipated impact on care organisation

In this section, you should specify any effects (positive or negative) on care organisation, on individual or collective health expenditure, or giving rise to changes in practices.

In this section, describe any potential repercussions of the introduction of the CMD on care organisation, on access to care provision, or on changes in work practices (e.g. remote consultations instead of face-to-face consultations). These repercussions may be expressed in terms of the number of GP or specialist consultations, number of hospital admissions associated with pathology complications, hospitalisation time, emergency department attendance rate, number of remote medicine procedures, healthcare product consumption, care team time, healthcare transport, etc.

7.5. Anticipated impact on public health policies and programmes

In this section, you should specify whether product reimbursement is in keeping with the public health objectives and programmes set out by law or by other guidelines from relevant bodies.

In the case of a simplified dossier

The public health benefit claimed by the applicant may be limited to that taken into consideration by the CNEDiMTS in its opinion of “date, month, year”. You should merely note it in this section, without any further information.

8. Applicant’s proposals on terms of prescription and use

You should specify the following information, whenever it applies to the MD subject to the application:

- details on product use: number of units used, administration dose and frequency, envisaged duration of use, etc.;
- qualification of prescriber or operator, need for special training on the technique, technical resources and environment required, etc.;
- recommended duration of initial prescription and renewal frequency;
- prescription renewal procedure;
- if applicable, all practical measures, including the need to train the patient or their close family, equipment supply and return procedure, etc.;
- any other element affecting the actual clinical benefit (minimum frequency of use, other, etc.).

In the case of a simplified dossier

The terms of prescription and use claimed by the applicant are those taken into consideration by the CNEDiMTS in its opinion of “date, month, year”. You should merely note them in this section, without any further information.

9. Evidence of Clinical Added Value (CAV) claimed by the applicant

In this section, you should explain your claims in terms of:

9.1. The proposed comparator

The relevant comparator is based on the gold standard, or the strategy used in routine practice in the absence of scientific evidence, or the absence of treatment if the need is unmet. It may consist of another medical device, listed on the LPPR or not, a product, a medicinal product, a service, or a professional procedure qualifying for reimbursement or not.

If the product is a CMD:

- for a CMD in which the telecommunication function is remote monitoring, the most relevant comparator will in principle be conventional monitoring if it is the gold standard. The question of another comparator will arise if other remote monitoring CMDs are already used in routine practice;
- if the device carries out a separate therapeutic or diagnostic function from the telecommunication function, the choice of comparator(s) should be justified according to the ultimate medical purpose.

9.2. Endpoints on which added value is based

The relevant endpoints are dependent on the clinical context in which the MD is used. They must be valid endpoints:

- clinical endpoints: mortality, morbidity, disability compensation, reductions of adverse effects, validated substitution criteria;
- quality of life: validated quality-of-life scales;
- patient satisfaction: validated satisfaction questionnaires.

9.3. Claimed CAV rating

The clinical added value rating should be selected based on the following grid containing five ratings:

I	Major added value
II	Significant added value
III	Moderate added value
IV	Minor added value
V	No added value

To assess the CAV rating, a randomised controlled trial designed and conducted in double-blind (or at least with an independent observer) is the study offering the highest level of evidence. However, in

some scenarios, this type of study is not possible or not relevant. This scenario must be justified and the selected study should also be justified.

In brief, the claim must account for:

- the end purpose of the product;
- its place in the therapeutic strategy: besides the treatment line, the applicant should account for the fact that the product is used as an alternative to the selected comparator or in addition to this comparator;
- data available to support its claim.

For example, if the product only has a telecommunication function and if the CMD is intended to be added to the existing arsenal, the applicant should adjust the mode of evidence (superiority or non-inferiority) to its claims.

In the case of a simplified dossier

- **Inclusion of a product meeting the requirements set out in the LPPR:** the claimed comparator is the category to which the product in question belongs and, by definition, no CAV is claimed with respect to this category.
- **Inclusion of a range extension, addition of new references:** the claimed comparator and the CAV rating claimed for each indication are limited to those taken into consideration by the CNEDiMTS in its opinion of “date, month, year”. Note these.
- **Range upgrade:** the claimed comparator relates to the device of the previous range. By definition, no CAV is claimed for each indication.
- **Renewal of inclusion:** the claimed comparator, the endpoints on which the added value is based, and the CAV rating claimed for each indication are limited to those previously taken into consideration by the CNEDiMTS.

10. Target population

The target population consists of the population likely to benefit from the product and/or service in France in each indication claimed for reimbursement. A quantitative estimation should be made for each indication and justified.

For each indication, you should:

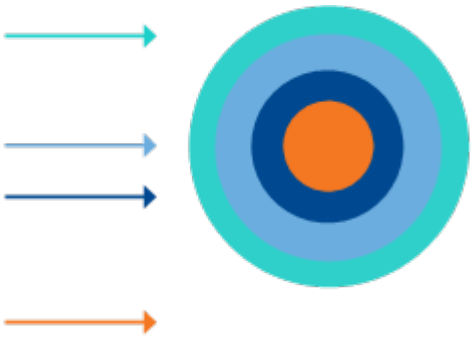
10.1. Describe the sources used

The most recent French or, failing that, international data.

10.2. Justify choices

The rationale, to be included on a step-by-step basis, is required to gain a clear understanding of the estimation. The purpose of the justification is to be able to define and quantify, insofar as possible:

- population corresponding to the overall pathology/pathologies targeted;
- proportion of diagnosed patients;
- proportion of patients liable to receive care (treatment, diagnosis, disability compensation);
- proportion of patients liable to be concerned by the device and/or service.



The following should be mentioned in the justification:

- type of data: epidemiological study, survey or observational study, cohort follow-up, database, clinical studies, etc.;
- dates on which these data were compiled and published, and their geographic origin (countries concerned);
- bibliographic references (documents to be appended).

In some cases, there are no epidemiological data suitable for estimating the target population. In these cases, you can use your own sales projection data to propose an estimation of the target population or use a beneficiary population approach. This approach makes it possible to estimate the population actually treated (independently of market shares when several devices of the same category are covered in France). You may use this approach, particularly when products with the same indication are covered or in the case of an application for renewal of inclusion insofar as the French health insurance system or the national health data system (SNDS) databases make it possible to tally the number of patients using or wearing the product in question or products for the same purpose. Note that this estimation based on the beneficiary population may be less than the population that is liable to benefit in scenarios where there is significant under-diagnosis or under-treatment.

By way of indication, a list of epidemiological data websites is proposed on page 36.

10.3. Conclude with the quantitative estimation of the target population.

In the case of a simplified dossier

The target population claimed for each indication may be limited to that taken into consideration by the CNEDiMTS in its opinion of “date, month, year”. In the absence of any new data liable to change this situation, you should merely note it. You will be required to make an update in the event of the existence of new epidemiological data. Failing new data, you should specify that there are no new data available liable to change the previous estimation based on the results of your documentary search.

Table of appendices

Appendix 1. Non-exhaustive list of links that can be consulted for the systematic documentary search and the epidemiological data search

French data sources

ANSM

ANSES

French national health insurance system

French national health insurance system/Open Data

ASIP Santé

FNMF

FNORS

HAS

HCSP

INCa

INED

Epidemiology portal

Santé publique France

INSEE

INSERM

IRDES

IRSN

French ministry of health

Observatoire de médecine générale

ORPHANET

French Sentinelles Network

ScanSanté (ATIH)

SNDS/Open Data

International data sources

AHRQ

AHRQ/Guidelines and measures

CADTH

CDC

CMA Infobase

Cochrane

CRD databases (HTA database)

DIMDI

ECRI INSTITUTE

EUROSTAT

Eunethta

FDA

Finotha

HIQA

HPA

IARC

INAHTA

INESSS

IQWIG

ISC

KCE

MSAC

NICE

OECD

OEAW

WHO

RIVM

SBU

Databases

Public health database

BML

CHU Rouen

ENCEPP

Medline

Examples of documents and sites to consult:

- HAS
- CNEDiMTS reviews and assessment reports
- MD assessment - Guidebook (version in French and English)
- Guide to the specific features of clinical evaluation of a CMD in view of its application for reimbursement (version in French and English)
- Assessment principles established by CNEDiMTS to determine the reimbursement eligibility of medical devices for individual use
- Methodological choices for the clinical development of medical devices
- Methodological guidance on cooperation protocol between healthcare professionals
- Regulation of the CNEDiMTS

- ANSM
- Alerts, regulatory prerequisites, etc.
- Mobile health software and apps

- CEPS

- French national health insurance fund
- LPPR nomenclature

- Europa website
- Guidance MEDDEV, directives, regulation, etc.

- CNIL website
- Quelles formalités pour les traitements de données de santé à caractère personnel ? (What are the formalities for personal data processing?)

- French ministry for solidarity and health: information on remote medical monitoring trials (ETAPES programme): the terms of use of remote monitoring trials are set out by specifications documents. They apply to five pathologies: heart failure, kidney failure, respiratory failure, diabetes, and implantable cardiac prostheses.

Appendix 2. Template of tabulated abstract to be completed

The relevant studies provided in the dossier are summarised in table format, separated into two separate sections:

- studies pertaining to the device examined by the CNEDiMTS;
- studies pertaining to devices other than that examined by the CNEDiMTS.

Reference	
Type of study	
Study date and duration	
Objective of study	
METHOD	
Selection criteria	
Study framework and location	
Products studied	
Primary endpoint	
Secondary endpoints	
Sample size calculation method	
Randomisation method	
Results analysis method	
RESULTS	
Number of subjects analysed	
Follow-up period	
Patient characteristics and group comparability	
Results for primary endpoint	
Results for secondary endpoints	
Adverse events	

Please note:

- "Not applicable" when an item does not need to be entered (depending on study type);
- "Not described" when an item is to be entered but no information is provided.

Appendix 3. Template of materiovigilance data summary data to be provided

You should report the French and international materiovigilance data for each of the zones in a separate summary table over a 5-year period.

Geographic zone (to be specified)	**Period 1 (year 20xx)**	**Period 2 (year 20xx)**	**Period 3 (year 20xx)**	**Period 4 (year 20xx)**	**Period 5 (year 20xx)**	**TOTAL**
Number of units sold						
Total number of units sold						
Materiovigilance data summary						
Total number of reported events						
Number of events in relation to number of units sold (%)						
Total number of events						
Total number of events in relation to number of units sold (%)						
Reported event types						
Number of level 1 events						
Number of level 2 events						
Number of level 3 events						
…						
Death						

Appendix 4. Specific descriptive data required for the characterisation of connected medical devices (CMDs)

This section describes the supplementary technical data to be provided for CMDs. This CMD-specific descriptive section should be included in part 2. Descriptive product information (see page 19). According to the type of MD and according to its ultimate medical purpose(s), the applicant should identify the appropriate descriptive information in the sections listed below.

The description of the different product data should make it possible to define the hardware or software technical specifications of the MD. As regards the specific section relating to software or connectivity, the following information is particularly expected:

- description of the different functions:
  - user interfaces (patients and healthcare professionals);
  - components (e.g. a messaging module, data import and export modules).

The functions for which any modification (with the exception of corrections associated with functional defects) or deletion would be liable to result in a substantial modification of the CMD during app updates must be identified.

- Description of any data specifically collected by the solution and the purpose of the collection of each item.
- Concerning the data:
  - collection and transfer procedures (frequency, human intervention or not);
  - access procedures according to user profiles;
  - processing procedures (time limit, data circuit) and data consultation, rectification and/or deletion procedures;
  - storage period.
- Description of the technical environment required for installation (installation and update procedures, compatible operating system) and for data transfer (characteristics of network used). Requisite conditions for interoperability with other solutions, where possible, must be described.
- The description of service characteristics (maximum number of simultaneous logins, guaranteed range of service, guaranteed restoration time, availability rate, description of restoration procedures, etc.).
- Description of update and maintenance procedures (upgrade and corrective).

In order to gain an understanding of the software architecture, a general diagram mentioning the different components and their relationships is requested.

For electronic services, apps or software, the descriptive data provided can be supplemented with access provided to the tool in simulation mode, using fictitious profiles enabling access to the different functions, included in the dossier, with a view to shedding more light for the committee on its characteristics or on its use.

For an application for renewal of inclusion pertaining to medical device software, the new software version (version and revision numbers, date of revision), the list of major updates (upgrades and corrections) applied since inclusion should be entered. It will also be necessary to provide a comparison of the different functions impacted by the new version.

Appendix 5. Specific descriptive information to be provided for medical device functions relying on machine learning processes (technologies falling within the scope of artificial intelligence)

Preliminary observations

If your MD is based on at least one machine learning process, you should complete this grid to provide the committee members with the information needed in this area of your MD. Included in the submission guide in September 2020, it should be amended as needed in line with technological upgrades.

Depending on the case, you should construct one or more grids, the principle being that you complete one grid for each "smart" function of the device:

- where there is only one function relying on machine learning processes: you should complete a single grid. This particularly applies when the interlinking, or succession, of several processes can justify their grouping in the same grid when they contribute to the same "smart" function.
- in the case of an MD including several functions of this type, you should complete one grid per function.

Depending on the type of technology, some items may not be adapted. In these cases, you should specify this, providing a justification. Conversely, you can also supplement the descriptive information listed with any information deemed useful.

Descriptive grid

		Information to help you complete the grid
Purpose		
1	Note the claimed use and the envisaged scope of the medical device (MD) including one or more machine learning algorithms	Is it used for example to: – help the patient adjust the dosage of their treatment? – predict or provide early detection of the occurrence of a clinical event? You should specify the pathologies or clinical scenarios addressed, or the multidisciplinary nature of the MD, where applicable. You should also systematically specify the user (patient or professional).
2	Specify the benefit of the information provided or decisions made by machine learning processes	In this section, specify the "smart" function in which machine learning has played a direct role. For example: – Determining a severity score? – Calculating a dose for treatment adaptation?
3	Note the characteristics of the target population and, where applicable, the	These may be: – Demographic (age groups, sex, etc.)

	characteristics for which use of the MD is unsuitable, due to non-indication, contraindication, or factors influencing the product result	– Physiopathological (pregnancy, diabetics or asthmatics, etc.) or morphological (lower limb amputees, etc.) – Clinical or biological (disease stage, etc.)
4	Describe the operating environment of the smart system	Particularly specify the environmental conditions (meteorological, brightness, temperature, ground conditions, etc.) used to characterise the operating range.

Data		
Description of samples used for initial model learning or relearning		
5	Specify the characteristics of the population on which the initial model learning or relearning data are based	These may be: Demographic (age groups, sex, etc.) Physiopathological (pregnancy, diabetics or asthmatics, etc.) or morphological (lower limb amputees, etc.) Clinical or biological (disease stage, etc.) Differentiate the population on which the initial learning data are based (training, validation, and testing) from that used during the relearning phase (retraining, validation, and testing of updated system), where applicable.
6	Specify the characteristics of each sample used for the initial model learning or relearning data .	Expected: their function, size and composition. Included variables must be cited. The manner in which rare events are taken into account must be described. Differentiate the databases of the initial learning phases (training, validation, and testing) and in the relearning phase (retraining, validation, and testing of updated system), where applicable
7	Specify the methodology for separating or segmenting samples	For example, specify the procedures for separating (methods used and proportions) and segmenting (random, by date, by subject, etc.) the training, validation, and test data sets Differentiate the databases in the learning and relearning phases, where applicable.
Description of input data involved in initial model learning or relearning		
8	Specify the characteristics of the variables (variable type, distribution, etc.)	Differentiate the training, validation and test corpus where applicable.

9	Indicate the method of acquisition of the variables and their origin during the learning process	For example, was a variable entered by a patient? Does it come from a sensor? Was it generated from virtual patient models? Specify whether the variables were extracted from corpora of open or purchased data, and indicate which, where applicable, as well as whether they are long-term or not. Specify the types of sensors used during variable acquisition, where applicable.
10	Describe the pre-processing applied to the data.	For example, tasks to clean, transform, reduce, increase data (additions of artificial noise, artificial interference simulating weather variations or sensor faults, etc.) Specify the data concerned and the proportion of data modified by these pre-processing operations
11	Indicate the proportion of missing data, among the raw data, and describe their management.	Specify the types of missing data (random or anticipated).
12	Explain the procedures in place to detect and manage outliers, where applicable	In particular, specify how outliers (e.g. physiologically impossible data) are distinguished from atypical values (e.g. rare events)
13	Justify the representativeness of the samples used for the initial learning (training, validation, and testing) of the algorithm in relation to the data to which this algorithm will be exposed once deployed	A justification of the representativeness criteria is expected. Particularly specify the tools and methods used to verify the representativeness of the samples and detect potential bias. In the case of incremental or continuous learning, indicate the potential impact of updates on all learning data.
Description of input data involved in decision-making (once the medical device has been deployed)		
14	Specify the characteristics of the variables (type, distribution, etc.)	Indicate the main sources of difference between the training, validation and test data, and the data involved in decision-making, once the system has been deployed (different sensors, different environmental conditions, etc.).
15	Indicate the method of acquisition of the variables and their origin	For example, was a variable entered by a patient? Does it come from a sensor? Indicate the measurement range and sensitivity settings of the measuring devices, where applicable.

16	Describe the pre-processing applied to the data used for decision-making	For example, tasks to clean, transform, reduce data, etc.
17	List the output variables (model prediction objects) and their characteristics (type, unit, etc.)	Specify the variables that will be processed in relation to the objective. Specify whether they are processed by another component of the MD or whether they are communicated to the user (if so, how)

Model: description of training, validation, and testing, before and after MD deployment		
18	Describe the type of learning used	Is this machine learning process: – supervised, – semi-supervised, – unsupervised, – by reinforcement, – federated, – centralised, – other? These suggestions are not mutually exclusive.
19	Describe the type of task automated by the algorithm	supervised classification (determine the ranking criteria), unsupervised classification (define classes), ranking (rank in classes), regression (quantitative projection), segmentation, other?
20	Specify the update frequency	Is learning: – continuous (system learning autonomously after deployment)? – initial (algorithm designed based on learning then fixed after MD deployment)? – or incremental (algorithm for which updating of the structure and/or settings after MD deployment is supervised by a human and involves prospective and/or retrospective validation)?
21	Describe the model selection criteria	For example, the error rate, computing time, the number and nature of the data available, explainability or embeddability, etc.

		Do not go into detail on the system input data (covered in questions 5 to 17), or the test methods used (covered in questions 26 to 32)
22	Describe the various training, validation, and test phases, prior to MD deployment	Indicate the various training, validation, and test phases, particularly specifying whether they are based on individual or collective data. Do not go into detail on the test methods in place (covered by questions 26 to 32).
23	Describe the training, validation and test strategies for updates, if applicable	Indicate the various training, validation, and test phases applied once the MD is deployed, particularly specifying whether they are based on individual or collective data. Specify in particular the retraining frequency, the variables involved and the data inclusion period, the retraining computation location (locally on the MD or on server). Do not go into detail on monitoring and/or human intervention in these phases (already covered in questions 24 and 25), or the update test methods (already covered in questions 26 to 32).
24	Describe how parties involved in system development are referenced	Specify whether the human managers or legal entities involved at each stage of the life-cycle of the smart MD (data collection, development, qualification, use and feedback for MDs with AI capability) can be identified.
25	Where applicable, state in which cases a human being is involved in the retraining process	For example, in the case of active learning, specify the frequency and qualification of the person involved. In the case of operator annotation, specify the operator's qualification and role.

Functional characteristics		
Performance and qualification		
26	Describe and justify the choice of metrics used to measure performance …	For example: Root-mean-square deviation, Area Under Curve, F1-score, ZoneMap, Jaccard
27	Describe the processing operations applied which have had a substantial impact on performance	For example, in the case of class imbalances in the context of supervised classification, indicate whether class rebalancing has been carried out, as well as the method used.
28	Describe the identified risks of over- and under-learning and the methods in place to remedy this	A link may particularly be established with the responses to question 7 on data separation/segmentation.

29	Specify whether the system returns a confidence rating for each of its decisions	This could for example indicate, for an image classifier, whether it returns the probabilities of the input image to belong to each of the classes
30	Describe the qualification methods of the machine learning system	Particularly specify the test protocol in place and the procedures used to ensure performance measurement repeatability and test reproducibility. If using formal methods to qualify the machine learning system, justify the choice of methods used and how the ranges on which the formal methods were applied were defined.
31	Indicate the performance measurement results on the different data sets	For example, the error rates supplied by the metrics on the training, validation, and test databases, according to the distribution applied. Specify whether a separate database from the training, validation, and test databases was used to qualify the model. Specify, in the case of formal proof analysis, the results obtained and the validity range of these results.
32	Specify the performance thresholds selected (limit values, maximum error rate, etc.) and explain the choice of these thresholds	
System robustness		
33	Specify the tools in place to generate antagonistic examples in the performance evaluation and qualification phase	
34	Specify the tools in place to monitor the performances of the smart system after its deployment	Particularly specify the mechanisms in place to measure model degradation and/or concept drift (regular evaluation campaigns, etc.), as well as performance degradation logging, archival and analysis
35	Specify the thresholds selected (limit values, maximum error rate, etc.) for tracking model degradation and/or concept drift and explain the choice of these thresholds	
36	Specify the measures in place in the case of automatic or user detection of model degradation or concept drift	For example: information sent to the user, substitution of the learning algorithm by an expert system, retraining, etc.

System resilience		
37	Describe the system in place for input data anomaly detection in operational use	This could for example concern the detection of data outside the nominal operating range of the smart system
38	Describe the potential clinical and technical impacts induced by anomalies on the input data of the machine learning system	For example, what will happen: In the event of non-correction of outliers? In the event of a declarative value input error by the patient? Due to the level of uncertainty associated with the input data (physiological, environmental data, etc.)? In the event of data unavailability? In the event of data integrity loss?
39	Specify the measures in place in the case of automatic or user error detection (e.g. malfunction damaging the input data)	For example: information sent to the user, degraded mode, substitution of the learning algorithm by an expert system, clinician or technician intervention, etc.
Explainability and interpretability		
40	Indicate the explainability elements provided by the smart device	Specify, where applicable, the explainability technique(s) in place to help understand the main factors leading to the decision taken or proposed by the machine learning algorithm. Specify the recipient of these explanations: user (caregiver or patient), developer, etc. Also indicate whether the explanations are recorded for retrospective analysis by experts (users and/or developers).
41	Indicate the interpretability elements, i.e. the parameters (input variables, weightings, etc.) influencing decision-making, as well as the method used to identify them	For algorithms with initial or incremental learning, are these parameters identified (e.g. by means of influence functions)?
42	Specify whether the decisions and actions of the smart device are compared to professional guidelines	Particularly indicate whether the machine learning algorithm outputs are compared to professional guidelines in real time or retrospectively. Specify whether these comparisons are made accessible to users. For example, are the machine learning algorithm outputs compared to those of an expert system modelling care guidelines?

Glossary

This glossary is solely intended for use alongside this descriptive grid of machine learning algorithms in the context of CNEDiMTS medical device evaluation.

Term	Definition	Source
Machine learning	Process whereby an algorithm evaluates and improves its performances without programmer intervention, by repeating its execution on data sets, until appropriate results are regularly obtained.	11
Unsupervised learning	Machine learning in which the algorithm uses a raw data set and obtains a result based on the detection of similarity between some of these data items.	11
Supervised learning	Machine learning in which the algorithm practises a defined task using a data set each accompanied by an annotation indicating the expected result	11
Ranking	Action of ranking objects, persons in a certain order.	12
Supervised classification	Technique consisting of categorising data according to their proximity thus making it possible to differentiate among two or more discrete classes.	13
Concept drift	A machine learning algorithm in which the parameters are fixed becomes inconsistent with its environment if the latter has been updated.	14
Range of use	Description of the environment and target population, for which the algorithm or program is designed.	-
Data	Representation of the observation of a variable on an element, individual, or instance of a population, intended to facilitate its processing.	-
Raw data	Data having undergone no transformation since the initial observation.	-
Input data	Data used for model learning or decision-making.	-
Output data	Value representing all or part of the decision made by the algorithm based on the input data.	-

[11] Official Journal of 09/12/2018

[12] https://www.larousse.fr/dictionnaires/francais/classement/16405

[13] Based on ISO definition (drafting in progress)

[14] Tsymbal, A. (2004). The problem of concept drift: definitions and related work. Computer Science Department, Trinity College Dublin, 106(2), 58.

Sample	Representative fraction of a population or a statistical universe	15
Training	Machine learning process through which the artificial intelligence system builds a model from data.	13, 16
Antagonistic example	Borderline case placing the system under evaluation in difficulty.	-
Explainability	Ability to link and explain the elements taken into account by the algorithm, for example the input variables, and their consequences, for example, on the prediction of a score, and thus on the decision. The explanations must be adapted to the comprehension level of the person for whom they are intended.	-
Hyperparameter	Parameters tweaked during successive runs of training of a model in order to check under- and over-learning in particular.	17
Information	Knowledge element expressed by a data set according to a defined code, with a view to being stored, processed, or communicated. An item of information is obtained from the interpretation of one or more pooled data items.	18
Interpretability	Ability to render the operation of an artificial intelligence system comprehensible. An algorithm is “interpretable” when its operation is accurately understood, for example, when an expert system models a decision tree.	13
Data set	Collection of data	-
Model	Mathematical construction generating an inference or a prediction from input data.	13
Parameter	Coefficient of a model that the machine learning system estimates or trains on its own and which impacts the output data.	17
Resilience	Ability of the system to maintain its conformity with performance and/or security requirements in the presence of input data outside its range of use (e.g. due to a sensor fault).	-
Robustness	Ability of a system to maintain its performance level whatever the circumstances.	13

[15] Centre National de Ressources Textuelles et Lexicales www.cntrl.fr
[16] From the Montreal Declaration for a Responsible Development of Artificial Intelligence
[17] https://developers.google.com/machine-learning/glossary
[18] https://www.dictionnaire-academie.fr/article/A9I1218

Segmentation “Data segmentation” “Automatic segmentation task”	Data segmentation: division of a corpus of data into several bases (e.g. training, validation, and testing) either based on objective criteria (date, age, etc.), or at random. Automatic segmentation task: extraction and automatic recognition of zones of interest from input data (e.g. an image).	19
Test	Process consisting of detecting errors associated with running an algorithm or a program based on input data sets not used during the training phase.	-
Validation	Process consisting of testing, observing and optimising (hyperparameters) system behaviour during running so as to ensure, in the range of use, that the output data are in line with the expected results.	13
Variable	Observable characteristics (qualitative or quantitative) of an element.	-

[19] Rakoto–Ravalontsalama, M. (1990). Méthodes de segmentation automatique d'image. Analyse quantitative des formes, Télédétection, pp251-260.

Appendix 6. Information to be provided to enable the evaluation of the procedure associated with that of the medical device

- Application
  - creation of a procedure;
  - amendment of an existing procedure.
- Description of the procedure(s) (with the proposed title of the procedure(s)).
- For each indication concerned by the application:
  - specify the number and types of procedures, indicating the type of application (creation/amendment/pricing) each time;
  - indicate, where applicable, the other procedures associated with the MD, which are already included in the CCAM.

Technical description of each procedure concerned by the application

- Proposed name of the procedure.
- Organs concerned by the procedure and, where applicable, extent of lesions.
- Type of procedure: diagnostic, therapeutic or disability compensation.
- Type of care: day case, full hospitalisation (specify duration), hospital consultation, community medicine, etc.
- Are there any other MDs for the same purpose likely to be used for this procedure?
- Is the proposed procedure specific to the proposed MD?
- Is the technique well standardised?
- Can the procedure be carried out in an emergency situation?
- Can the procedure be carried out on children? If yes, specify the age limit for carrying out this procedure.
- If the procedure relates to paired organs, can it be carried out bilaterally during the same intervention?
- If the procedure relates to extensive or multiple lesions, is it possible to treat the entire lesion/all the lesions during the same intervention?
- For all cases in which the procedure needs to be repeated to achieve a full treatment, specify the usual number of times that it needs to be repeated, and the optimal time interval between 2 interventions.
- Specify whether an anaesthetic is needed or not with details in particular on the mode of administration (general, local, locoregional, sedation, analgesia, description, etc.).
- Description of the technique, specifying the approach (direct, transcutaneous, vascular, endoscopic, etc.), specifying whether guidance is needed or not (ultrasound, doppler ultrasound, X-ray, etc.), as well for each of the steps, their duration, number, type and role of each caregiver (physician conducting the procedure, anaesthetists, nurses, etc.).
- Description of the technical platform (equipment of room where procedure is carried out, etc.) and the environment needed to perform this procedure: particularly specify whether the procedure needs to be performed in an operating theatre or not: otherwise, whether a pre-existing specific technical platform is required; otherwise, description of the environment required to carry out the procedure with a financial evaluation.

- Specify whether associated pre- and perioperative procedures are needed (diagnostic tests, pre-implantation reviews or tests, therapeutic procedures, surgical debridement, etc.).
- Specify whether extemporaneous anatomopathological examination during the procedure is needed or not.
- Specify the need to check that the procedure has been completed properly at the end or remotely or not.
- Specify the need to envisage ablation or replacement procedures or not.
- Description of immediate postoperative period: resuscitation, intensive care, etc.
- Routine post-procedure patient follow-up regimen.
- Specify the need for specific post-procedure rehabilitation or not.
- Procedure conditions.
- Contraindications associated with the procedure.
- Any requirements in respect of training, level of expertise, activity threshold for caregivers.
- Indicate whether the procedure relates to activities subject to authorisation (interventional cardiology, neurosurgery, etc.).
- Name and contact details of practitioners carrying out the procedure in France.
- Indicate the countries in which the procedure is covered by national health insurance and particularly specify the conditions (technical platform and environment, requirements, etc.), the economic data (pricing, etc.) associated with this cover and the wording of the listing.

Description of similar procedures

- Are there any similar procedures, in terms of ranking?
- If yes, show the similarities/differences in terms of technicity, duration of the procedure, technical platform, etc. in the form of a comparative table.
- Specify the pricing of similar procedures as well as that of associated DRGs.

The specific information in respect of the procedure to define the place in the gold standard strategy, evidence of the actual clinical benefit and the clinical added value should be described in chapter 3.

In the presentation of the data, specify where applicable any specific features associated with the procedure, such as for example the risks (including adverse effects) induced by the procedure, differentiating where applicable those associated with the operator (experience of team, technical platform, training, learning, etc.) and those inherent to the product.

Requisite medico-economic data for ranking and pricing

- Estimation of the impact of the procedure on health insurance expenditure and on healthcare facility expenditure:
  - Estimation of all direct medical costs generated and avoided by the procedure for the national health insurance system and where applicable for healthcare facilities (particularly if investments are required).
  - Estimation of the indirect costs generated/avoided associated with sick leave (for the national health insurance system).
  - This detailed analysis which must, at least in part, be based on the technical description of the procedure, should particularly highlight when this is relevant.

- In the case of substitution for an existing procedure: the substitution rate and the volume of procedures replaced.
- If the procedure evaluated gives rise to existing associated procedures: the complementarity rate and the volume of associated procedures.
- Post-interventional care and its impact on community medicine.
- Where applicable, the pricing of the DRGs that the procedure is liable to fall under and/or those associated with similar procedures.
- Any costs generated by the set-up of a specific technical platform or adaptations of the existing technical platform.

– Results of the medico-economic studies relating to the associated procedure
  - Present the medico-economic studies conducted on the topic, differentiating those conducted in France (particularly those of the STIC and PRME programmes) from those conducted internationally.

Appendix 7. Rules in relation to the electronic documents associated with applications for inclusion, changes in the conditions of inclusion, or renewal of inclusion of medical devices

Electronic document characteristics

File type

The source files drafted by the applicant should also be provided in a text format compatible with Microsoft Word 2007. All files submitted in PDF format must be compatible with Acrobat Reader 9.0 and later.

Files containing figures in Excel format, if they are compatible with version 2007 of the program, may be accepted, as well as those in ASCII format (use the extension *.txt).

For other files, the following formats are accepted:

- images: *.jpg, *.gif, *.tip, *.bmp
- video: *.avi, *.mpg, *.mpeg, *.wmv, *.flv
- bibliography: *.ris

For any other format, approval from the department responsible for dossier examination is required.

For file compression or grouping, *.zip format is accepted.

Character font

The character fonts must all be included in PDF type files.

It is recommended to limit the number of fonts used when creating documents. If the PDF includes images from a digitised source, the image resolution must be the lowest possible without compromising adequate display or print quality.

Protection options

The files must not include protection.

File size

The maximum size of each file submitted in SESAME is dependent on its type, between 100 and 300 MB. Size reduction options must systematically be used for these documents. The naming rules listed below must then allow logical reading of the documents submitted.

For videos, the applicable limit is 150 MB.

File and directory naming rule

Directory and file names must be explicit.

The file names must not exceed 70 characters and must only contain non-accented upper and lower case letters and numbers. Spaces, apostrophes, or special characters must not be used (e.g. “~”, “*”, “|”, “‘”, etc.); however, it is recommended to use the underscore character (_) to separate words in file or directory names.

The file or directory names must be preceded by a sequence of two characters and an underscore character (_) in order to retain the logical reading order.

Example:

01_NOM_DU_DM_Partie_I_Synthèse_identification_demande

02_NOM_DU_DM_Partie_II_Dossier_medico_technique

03_NOM_DU_DM_Annexe_I_Donnees_scientifiques

04_NOM_DU_DM_Annexe_II_Documents_generaux

Etc.

Abbreviations and acronyms

ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health & Safety)
ANSM	Agence nationale de sécurité du médicament et des produits de santé (French National Agency for Medicines and Health Products) (formerly AFSSAPS)
CAV	Clinical added value
CCAM	Classification commune des actes médicaux (Joint classification of medical procedures)
CEPS	Comité économique des produits de santé (French Healthcare Products Pricing Committee)
CNEDiMTS	Commission nationale d'évaluation des dispositifs médicaux et des technologies de santé (Medical Device and Health Technology Evaluation Committee)
CNIL	Commission nationale de l'informatique et des libertés (French Data Protection Authority)
CSS	Code de la sécurité sociale (French Social Security Code)
MD	Medical Device
CMD	Connected Medical Device
IVDMD	In vitro diagnostic medical device
AIMD	Active implantable medical device
DGCCRF	Direction générale de la concurrence et de la consommation et de la répression des fraudes (French Directorate-General for Competition, Consumer Affairs and Prevention of Fraud)
HAS	Haute Autorité de santé (French National Authority for Health)
UDI	Device identification system
UDI-ID	Unique device ID
JO	Journal officiel (French Official Journal)
LPPR	Liste des produits et prestations remboursables (List of products and services qualifying for reimbursement)
MIG	Mission d'intérêt général (General Interest Mission)
NGAP	Nomenclature générale des actes professionnels (General Nomenclature of Medical Procedures)
PHRC	Programme hospitalier de recherche clinique (Hospital Clinical Research Programme)
PMSI	Programme de médicalisation des systèmes d'information (French programme for the medicalisation of information systems)
PRME	Programme de recherche médico-économique (Medico-economic Research Programme)
PSDM	Prestataire de services et distributeur de matériels (Service provider and distributor of equipment)
ACB	Actual clinical benefit
SED	Service évaluation des dispositifs (HAS medical device assessment department)
HIS	Health information system
SNDS	Système national des données de santé (French National health data system)

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