HAUTE AUTORITÉ DE SANTÉ

ASSESSMENT OF MEDICAL DEVICES FOR HOME INFUSION

REVISION OF CATEGORIES INCLUDED ON THE LIST OF PRODUCTS AND SERVICES QUALIFYING FOR REIMBURSEMENT: « MEDICAL DEVICES FOR HOME INFUSION »

SEPTEMBER 2010

Medical Devices Assessment Department

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THE TEAM

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WORKING GROUP

The Working Group consisted of the following professionals:

- Pierre-Yves CHAMBRIN, pharmacist, Paris
- Dr Karine CHAMPION, specialist in internal medicine, Paris
- Cécile COLLONGE, nurse coordinator, Dardilly
- Chantal FIORAMONTI, health executive specialising in home-based care, Colombes
- Anne GRUMBLAT, member of the National Committee for the Assessment of Devices and Health Technologies and pharmacist, Besançon
- Maryse GUILLAUME, private practice nurse, Castres
- Catherine LACROIX-LAURIOL, health executive at an expert centre for home-based artificial nutrition, Montpellier
- Michel LAUTREY, nurse technician, Dardilly
- Blandine MAIGNAN, nurse, Chevilly Larrue
- Danièle MARANDE, nurse for home-based care, Paris
- Dr Isabelle NEGRE, anaesthetist and resuscitation specialist, le Kremlin-Bicêtre
- Christelle PAULIN, private practice nurse, Bordeaux
- Dr Anne PETIT, general practitioner, Boulogne Billancourt
- Maria PERES, private practice nurse, Saint Aygulf Freyjus
- Pascal RABIER, nurse, paediatric home-based care, Nice
- Julia REMOND, nurse for home-based care, Montreuil
- Valérie TALON, pharmacist, Paris

The Working Group was set up at the suggestion of the learned societies in the specialities concerned.

Also involved in the implementation of this project: Anne Josseran.

In accordance with Decree No. 2004-1139 of 26 October 2004 (art. R. 161-84 to R. 161-86 of the Social Security Code), all the members of the group completed a public declaration of interests (déclaration publique d'intérêts, DPI), the aim of which was to inform HAS of any potential conflicts of interest that some members of the group could have had with respect to a manufacturer.

These DPI were analysed before the group was established. Each expert was requested to update them for the purposes of presenting the conclusions to CNEDiMTS.

Two experts who had been contacted personally declared that they worked for commercial companies. Another declared having received a one-off invitation from a manufacturer. No

other member of the working group had a conflict of interests according to the criteria of the *Guide on the declaration of interests and the prevention of conflicts* of the HAS.

It was considered that these declarations did not form a major conflict of interest which would prevent participation in the assessment of devices for home-based infusion.

In fact, the professionals were invited on account of their competence. They brought their professional expertise to this group, but they did not represent their respective professional trade unions, which were consulted independently.

The opinion of the working group presented in this dossier was ratified by each of the group members.

SHORT TEXT

Background

For medical devices to be covered by the health insurance system, they need to be included on the list of products and services qualifying for reimbursement (LPPR). Products are included either under a common description covering a class of products (generic description) having the same indications or in the form of an individual entry with the product's commercial name (brand name). The National Committee for Evaluation of Medical Devices and Health Technologies (CNEDiMTS) of the HAS is responsible for the medical assessment of these products. In particular, it periodically reassesses these generic descriptions.

The review of the generic descriptions “Medical devices for home infusion” is the topic of this document; the services associated with the devices were also reassessed.
On the occasion of this review, CNEDiMTS did not consider it appropriate to reassess external, portable and programmable insulin pumps on account of their recent entry (order of 17 July 2006) into the LPPR.
Likewise, medical devices used for home parenteral nutrition were not included in this report because of their recent assessment by another working group (opinion of the HAS on home parental nutrition - current situation and methods of management, May 2008).

Working method

CNEDiMTS performed an assessment of the actual benefit of these medical devices for home-based infusion. The method used in this document is based on the analysis of the data from the scientific literature and on the opinions of healthcare professionals brought together in a multi-disciplinary working group. The members of the group declared any conflicts of interest they might have at the start and end of the project.
A literature search was performed by interrogating the main medical bibliographic databases (*Medline, the Cochrane Library, National Guideline Clearing House and* HTA database). Data from dossiers submitted by manufacturers was also analysed.
Based on the critical review of the literature and the dossiers submitted by the manufacturers, the working group was able to give its opinion on the benefit of the products, their indications, the methods of prescription and use, as well as on the methods of inclusion on the LPPR so that the cost can be covered by the health insurance system.

A framework meeting took place with the Directorate-General for Health (Direction générale de la santé, DGS), the Social Security Directorate (Direction de la sécurité sociale, DSS) and the health insurance funds in order to define problems specific to the management of medical devices for home-based infusion. Meetings were organised with the manufacturers, SNITEM (National Union for the Medical Technology Industry), UFAT (Union of Manufacturers of Assistive Products) and the service providers (SYNALAM: National Union for Services and Technologies in Home-based Healthcare, SNADOM: National Union of Associations for Help in the Home and UNPDM: National Union of Service Providers for Medical Devices). Meetings also took place with INCa (National Cancer Institute).

Critical analysis of the data

The literature search, conducted for the period from January 1999 to April 2010, identified 138 references, of which 34 were selected. In total, 7 publications were considered.

The data analysed were of low to moderate methodological quality: articles with a low level of evidence, methodology of recommendations not detailed, etc. Most of the recommendations are founded exclusively on the opinion of experts.
Most of these recommendations concern infusion in a hospital setting; they cannot be transposed to home-based care. In fact, these two situations cannot be superimposed on one another and they require infusion to be managed and organised in different ways. The specific management of home infusion was not discussed in any of the recommendations.

Despite the methodological limitations of the literature, it did provide elements of an answer relating to the prevention of infections through conditions of hygiene and the specific uses of infusion devices, in particular the frequency with which these devices (catheters and other infusion line devices) should be changed. In contrast, the data from the literature did not enable a decision to be made regarding the respective benefits of rinsing with a heparinised solution or with physiological saline.

Working group opinion

The benefits of home infusion are acknowledged in certain clinical situations, because with it the moving and hospitalisation of a patient in order to administer injectable medicinal products or labile blood products can be avoided; when the patient is already in hospital, home infusion can be an alternative to prolongation of the hospital stay.

Nevertheless, not all hospital care can be transferred to the home; the patient's state of health, environment and family circle, as well as the constraints of carers or service providers influence the organisation of care and its feasibility.
Furthermore, taking into account the preservation of the patient's independence at his/her place of residence can also impact on the choice of devices.

The working group examined the different situations that involve home-based infusion. It suggested a manner of organisation and defined the indications, methods of prescription and content of service provision which must be implemented.

Opinion of CNEDiMTS

Home-based infusion is an alternative to hospitalisation. This practice must nevertheless be strictly supervised in view of the risks of infection or of misuse.

In particular, CNEDiMTS notes the importance of the application of standard precautions and rules of hygiene on account of the risk of infection associated with the routes of access used, regardless of whether these are peripheral or central.

On the basis of the working group's opinion, CNEDiMTS recommends in particular:

- to consider medical devices for home-based infusion as carriers for medicinal products and labile blood products and thus to make their coverage come under that for the products or medicinal products that have been prescribed,
- the use of devices secured by healthcare professionals,
- washing of hands by healthcare professionals before providing care, this practice being an elementary hygienic measure.

The proposed nomenclature includes all devices considered by CNEDiMTS to be necessary for home-based infusion regardless of the different methods of management.

In the absence of medico-technical arguments, CNEDiMTS has not pronounced on the following points:

- listing for purchase or renting of medical devices for home-based infusion on the LPPR,
- the supply of devices individually or as sets,
- the sterile or non-sterile nature of the gloves used during care associated with the peripheral route,
- the criteria for the assignment of different types of infusion pumps. The assignment of the pump should respond to the specific needs of the prescribed therapy; in order to respond to this need, the various types of pumps need to be made available.