HAUTE AUTORITÉ DE SANTÉ

REVIEW OF HOMOGENEOUS CATEGORIES OF MEDICAL DEVICES

Tracheal vacuum suctioning systems

Weekly fee

Summary

July 2017

The full report supporting this assessment can be downloaded from
www.has-sante.fr

Haute Autorité de Santé
Documentation and Public Information Department
5, avenue du Stade de France – F 93218 Saint-Denis La Plaine Cedex, France
Tel.: + 33 (0)1 55 93 70 00 – Fax: + 33 (0)1 55 93 74 00

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Contents

Summary

Background

The Medical Device and Health Technology Evaluation Committee (CNEDiMTS), a specialised committee of the Haute Autorité de Santé (HAS), is responsible for the medical assessment of applications for inclusion, inclusion renewal, or change of the conditions for inclusion of products and services on the list of products and services qualifying for reimbursement (LPPR).

This assessment concerns medical devices for tracheal suction included on the LPPR.

Medical devices and services associated with tracheal suction pumps are listed in Title I, Chapter 1, section 1, subsection 2/ paragraph 3 and subsection 3/ paragraph 1 of the LPPR. They may also be combined with other weekly fees listed in Title I, Chapter 1, section 1, subsection 2, paragraph 5 of the LPPR.

Respiratory filters and tracheal protectors listed in Chapter 1, section 1, subsection 3/ paragraph 5 of the LPPR have also been reviewed during this assessment.

Objectives – Working Method

The objective is to assess the benefit of tracheal vacuum suctioning systems listed on the LPPR, in view of reimbursement by the National Health Insurance Fund.

The specific objectives of this assessment are:

- To specify the indications for tracheal vacuum suctioning systems;
- To specify their conditions for prescription and use (provision of supplies, quantities or frequency);
- To define the content of associated services;
- To define the minimum technical specifications for tracheal vacuum suctioning systems;
- To define precisely the generic descriptions for respiratory filters and tracheal protectors for laryngectomy patients.

The working method involved a systematic review of the literature, analysis of the data provided by manufacturers, and opinions from healthcare professionals who met in a multidisciplinary working group dedicated to the topic. The members of the working group declared any conflicts of interest at the start of and throughout the project.

Assessment – Analysis of Data from the Literature

In the absence of data provided by manufacturers, the data mainly come from the literature search conducted.

An analysis of the literature identified 198 references, from which 18 were selected. These are 15 clinical practice recommendations and 3 observational studies. Each article selected was analysed using the principles of critical assessment of the literature, with criteria drawn up in advance and assessment grids.

The available literature primarily comes from resuscitation and intensive care units, which makes it difficult to extrapolate to home use.

The clinical efficacy of supraglottic and endotracheal vacuum suctioning systems, notably in terms of hospitalisation rates or duration of hospital stay, has not been the subject of specific studies.

Clinical practice recommendations mention the adverse events that can be related to suction, especially endotracheal suction. However, no specific study permitting evaluating the frequency and severity of adverse events related to suction was found.

The literature report was sent to the working group before the first meeting.

Opinion of healthcare professionnals

The working group's proposals are based primarily on expert opinion, due to the limited literature and the low level of evidence on the specific benefit of each type of suction, endotracheal and supraglottic.

The main working group proposals involve:

- The definition of a specific indication for endotracheal suction and a specific indication for supraglottic suction;
- The review of the specific features of endotracheal suction;
- The contents of the prescription according to the type of suction;
- The provision of supplies and accessories according to the type of suction;
- The definition of the minimum technical specifications for tracheal vacuum suctioning systems;
- The description of all services related to the home use of tracheal tracheal vacuum suctioning systems according to the type of suction;
- Specifications on generic descriptions for respiratory filters and tracheal protectors for laryngectomy patients.

Conclusion of the Medical Device and Health Technology Evaluation Committee (CNEDiMTS)

In view of the literature data, deemed limited by the Committee, and the proposals of the working group, the CNEDiMTS confirms the benefit of tracheal vacuum suctioning systems and approves the listing under generic description of two categories of suction devices:

1. Devices for endotracheal suction indicated in patients with risk of tracheal obstruction having percutaneous tracheal access;
2. Devices for supraglottic suction indicated in patients with excessive stagnation in secretions in the upper airways.

The actual benefit of these two categories of suction devices is deemed sufficient.

In particular, the CNEDiMTS recommends:

- The provision of a battery-operated electric tracheal vacuum suctioning system and a back-up tracheal vacuum suctioning system. The backup system may be manual or battery-operated electric. The provider will comply with the medical prescription.

  The manual system has the advantage of being smaller and able to mitigate any power outages.

The backup battery-operated electric tracheal vacuum suctioning systemshould be used regularly to ensure it is working properly in the event of an emergency;

- The provision of cannulas and accessories *via* the supply of endotracheal vacuum suctioning system.
- A technical installation service at the patient's home for supraglottic vacuum suctioning system. For follow-up visits, the choice is left to the patient to go to the service provider's premises.

  This choice should be discussed with the prescriber.

The Committee has defined the minimum technical specifications for tracheal tracheal vacuum suctioning systems. They are described in the health technology assessment report. The Committee has also specified the content of services.

Working group

The working group was composed of the following professionals:

- **Mr. Philippe BAUDOUIN**, Nursing Care, LA-ROCHE-SUR-YON (85)
- **Mr. Guillaume BUIRET**, ENT Surgery, VALENCE (26)
- **Mr. Jacques DE MONTBLANC**, Anaesthesia / Resuscitation, LE KREMLIN-BICETRE (94)
- **Mr. Michel ENJALBERT**, Physical Medicine and Rehabilitation, CERBERE (66)
- **Ms. Anne FREYNET**, Physical Therapy, PESSAC (33)
- **Ms. Agnès GONZALEZ**, Nursing Care, MONTPELLIER (34)
- **Mr. Jesus GONZALEZ**, Respiratory Medicine, PARIS (75)
- **Mr. André LABBE**, Respiratory Medicine/Paediatrics, CLERMONT-FERRAND (63)
- **Ms. Marilène GUILLET**, Nursing Care, VILLEJUIF (94)
- **Ms. Cécile MAURI**, Physical Medicine and Rehabilitation, MONTPELLIER (34)
- **Ms. Sophie SIEGRIST**, General Medicine, LE BAN-SAINT-MARTIN (57)
- **Mr. André STAGNARA**, Physical Therapy, FRANCHEVILLE (69)

The opinion of the working group presented in this report was validated by each of its members.

The members of the working group were appointed by the CNEDiMTS board from among the experts proposed by the relevant associations or learned societies, experts who responded to an appeal for candidates and experts known to HAS.

In accordance with decree No. 2004-1139 of 26 October 2004 (Article R. 161-84 to R.161-86 of the Social Security Code), all members of the working group have completed a public declaration of interest, mentioning direct or indirect links with any company or body involved in the field covered by the missions of HAS.

The analysis of the declarations of interests was carried out in accordance with the criteria of the HAS "Guide des déclarations d'intérêts et de gestion des conflits d'intérêts" [Guide to declarations of interest and the management of conflicts of interest] (adopted by the HAS Board on July 2013[1]).

This analysis of the working group members' interests did not reveal any interests that were likely to lead to a significant conflict. The makeup of the working group and declarations of interest were published on the HAS website (http://www.has-sante.fr) before the group's first meeting. These were also restated at the start of the group meeting and when presenting the working group's position to the CNEDiMTS.

These experts' declarations of interest are published on the HAS website (http://www.has-sante.fr).

[1]Haute Autorité de Santé – Guide des déclarations d'intérêts et de gestion des conflits d'intérêts [Guide to declarations of interest and the management of conflicts of interest] – July 2013 [link].

Fact sheet

Heading	TITLE
Working method	Literature analysis, multidisciplinary working group.
Posting date	September 2017
Objective(s)	To define the conditions for reimbursement for tracheal vacuum suctioning systems.
Professional(s) concerned	Respiratory medicine specialists, nursing care specialists, anaesthesiologists/resuscitation specialists, paediatricians, physical therapists, physical medicine and rehabilitation specialists, general practitioners.
Requester	Ministry.
Sponsor	Haute Autorité de Santé.
Project Management	Catherine AUGER, Project Manager, Medical Devices Assessment Department (SED) (Head of SED: Gregory EMERY; Deputy: Hubert GALMICHE). Secretary: Hélène DE TURCKHEIM and Yakaré TOUNKARA, assistants. The target population was estimated by Emmanuelle SCHAPIRO-DUFOUR, Project Manager, Medical Devices Assessment Department.
Participants	Philippe BAUDOUIN, Nursing Care, LA-ROCHE-SUR-YON (85), Guillaume BUIRET, ENT Surgery, VALENCE (26), Jacques DE MONTBLANC, Anaesthesia/Resuscitation, LE KREMLIN-BICETRE (94), Michel ENJALBERT, Physical Medicine and Rehabilitation, CERBERE (66), Ms. Anne FREYNET, Physical Therapy, PESSAC (33), Agnès GONZALEZ, Nursing Care, MONTPELLIER (34), Jesus GONZALEZ, Respiratory Medicine, PARIS (75), André LABBE, Respiratory Medicine/Paediatrics, CLERMONT-FERRAND (63), Ms. Marilène GUILLET, Nursing Care, VILLEJUIF (94), Cécile MAURI, Physical Medicine and Rehabilitation, MONTPELLIER (34), Sophie SIEGRIST, General Medicine, LE BAN-SAINT-MARTIN (57), André STAGNARA, Physical Therapy, FRANCHEVILLE (69).
Literature search	Conducted by Sylvie DESPEYROUX, documentalist, with the assistance of Juliette CHAZARENG, assistant documentalist, under the supervision of Frédérique PAGES, Head of Documentation and Public Information, and Christine DEVAUD, Assistant Department Head.
Authors of the rationale	Catherine AUGER, Project Manager, Medical Devices Assessment Department, under the supervision of Gregory EMERY (Head of SED) and Hubert GALMICHE (Deputy Head of SED).
Validation	Examination by the Medical Device and Health Technology Evaluation Committee (CNEDiMTS): July 2017.
Other formats	No format other than the electronic format available at www.has-sante.fr
Related documents	Summary of the technological assessment report and opinion of the CNEDiMTS on the medical devices concerned at www.has-sante.fr