TUBULAR ORTHOSES and BANDAGES
Use in ORTHOPAEDICS/RHEUMATOLOGY/TRAUMATOLOGY

Assessment report

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

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Management project team

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Summary

Limb bracing is a method that has been used since ancient times to limit the movement of one or more joints or part of a limb. Many clinical conditions may be candidates for treatment by bracing, whether they relate to the musculoskeletal system or to vascular medicine. Treatment with bracing requires the use of textile articles of varying degrees of elasticity, which can either be worn together with “tubular” orthoses, or can be used for bandages. These medical devices have been funded in France for over 20 years. In 2010, 20 million bandage articles were reimbursed to beneficiaries under the general National Health Insurance fund, but this figure does not reveal the proportion of bandage articles used in orthopaedics/rheumatology/traumatology. In 2010 the data available from records of funded medical treatment showed something of the order of 200,000 instances of strapping by bandage, without indicating the precise medical use made of this. With respect to the data on tubular orthoses, they supplied a figure of 800,000 knee and ankle orthoses sold in pharmacies in 2010. The market is actually larger than this because these products are also distributed in outlets other than pharmacies.

To be funded by National Health Insurance, tubular orthoses and bandages have to be included in the list of products and services qualifying for reimbursement (Liste des Produits et Prestations Remboursables, LPPR) under a common heading covering a category of products (generic description). The generic descriptions for these reimbursed products were prepared from a product specification based on manufacturing processes drawn up in collaboration with manufacturers, then included in the regulation (type of yarn, knitting method and in vitro tests that the products have to pass in order to be funded). There are no European standards. The funded indications included in the LPPR are vague and refer to ligament disorders, signs and symptoms of inflammation and postoperative protection in the case of tubular orthoses, with no more precise medical details. No indications for bandages are mentioned. In fact, the clinical conditions in orthopaedics/rheumatology/traumatology for which the use of tubular orthoses or bandages may be considered fall into the following four groups of pathology:

- ligament (sprains of the thumb, elbow, acromioclavicular joint, knee, ankle, talocrural region and mid-foot);
- joint (dislocation of the glenohumeral joint, osteoarthritis of the tibiofemoral joint);
- tendon (lateral epicondylitis, patellofemoral syndrome, tendinitis);
- other (fractures of the ribs or clavicle, patellar dislocation, isolated types of congenital deformation, accidents involving the muscles).

Objectives, field of assessment and methodology

The objective of this assessment is to assess the Actual Benefit of tubular orthoses and bandages on the basis of their therapeutic benefit and any conditions to be placed on them (technical specifications, procedures for prescription and use), with the aim of recommending indications for reimbursement.

This assessment covers all tubular orthoses with or without adjunctions. When additional parts are involved, only “non-articulated” ones are considered, i.e. guides, cushioning, stays, patellar ring or adjustment straps. This assessment does not cover slings, or orthoses with semi-rigid or rigid supports (including articulated orthoses in particular). The assessment also covers bandages, whether adhesive, cohesive or dry, and its use for the purposes of compression in vascular disorders having been reviewed in 2010 by HAS. This study is limited to the area of clinical conditions managed by non-hospital doctors.

The methodology for reassessing generic descriptions is based on an analysis of data from the scientific literature and the opinions of healthcare professionals. Two distinct groups of professionals were appointed for this work (a steering group and a rating group composed of 6 and 12 healthcare professionals respectively; by means of the rating group, a formal consensus could be reached).

Critical analysis of data from the literature

An exhaustive review of the literature was carried out, covering the period 2000-2012, by searching bibliographic databases, web sites publishing guidelines and technological assessment reports, as well as the sites of learned societies relevant to the field of study (in English or French).
The studies selected were those assessing devices on the basis of a clinical criterion (quality of life, function, pain, return to work, recurrence, oedema, undesirable effects) in the clinical conditions identified. In all, out of 447 references identified, 44 publications were selected (37 being literature reviews and 7 being trials in addition to the reviews). Data from manufacturers’ dossiers were also analysed and no additional studies were selected.

The data from the literature relating to efficacy/safety/place in therapeutic strategy chiefly concerned disorders such as talocrural sprains, osteoarthritis of the knee, patellofemoral syndrome or lateral epicondylitis. Irrespective of the clinical condition, the conclusion of the literature reviews is that functional treatment is of limited benefit owing to the lack of evidence. Overall, these reviews use high-quality methodology (clear objectives, exhaustive research, little selection bias, limited analysis bias, information on interests). However, they rarely specify the type of devices assessed (particularly when orthoses solely in the field of assessment are involved).

The source studies cited in the literature reviews and specific to the devices being assessed were therefore researched. Analysing them revealed literature that was ill-suited to the devices in the field of assessment (large number of devices, imprecise terms used to define the devices assessed, including brand names, details of composition rarely given). In all, 69 source studies (randomised or crossover), together with 7 non-randomised studies, were identified as dealing with devices being assessed, with an additional 7 clinical trials resulting from updates to the literature reviews. Irrespective of clinical condition, the same source trials were included among the various literature reviews.

The results from the trials selected did not lead to any conclusion as to the efficacy of the devices to be assessed, either alone or combined, compared with other available options (no treatment, medical treatment, other conservative treatment). The results do not reveal the influence of using any one type of device rather than another. The major methodological limitations underlying these conclusions relate to the study itself (randomised trial where randomisation is not guaranteed or crossover trial), associated bias (subjects lost to follow-up, concomitant procedures not described, missing information on the procedures assessed), low subject numbers and very old studies. The data with the best level of evidence do not show any difference between tubular orthoses or bandages and the other available options, apart from cutaneous complications found when adhesive bandages was applied. No data on minimum technical specifications or procedures for prescription and use were found in the literature.

In conclusion, the inadequate clinical data available, the absence of any professional guidelines on tubular orthoses and bandages, and the multiplicity of clinical conditions involved, mean that it is essential to involve healthcare professionals formally in the matter. The method of formal consensus of experts (consensus formalisé d’experts, CFE), based on rigorous and explicit modelling, allows the positions of a representative panel of prescribers to be quantified.

**Position of healthcare professionals**

The steering group drew up a list of 305 proposals based on the literature and professional practice. This list, which was submitted to the rating group, involved the therapeutic benefit of tubular orthoses and bandages in each of the clinical conditions identified. Using the rating results, it was possible to measure the level of agreement and disagreement among the experts in the group.

Based on the agreement among the professionals, the steering group recommends that the devices to be reassessed should be included in normal medical or rehabilitation funding, chiefly in acute conditions for certain orthopaedics/rheumatology/traumatology disorders. The following are covered:

- for ankle tubular orthoses with or without non-articulated adjunctions: talocrural sprains in both acute and chronic conditions, and painful sequelae with no significant residual laxity;
- for open-patella knee tubular orthoses: dislocation of the patella in the acute phase;
- for thigh, calf and armbands tubular orthoses: recent accidents involving the muscles in the acute phase;
- for bandages, the indications are the same as for tubular orthoses, with the addition of acromioclavicular and mid-foot sprains in the acute phase, together with varus/equinus club foot in
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non-walking infants and malpositioned feet in the first six months of life. Of particular note is the case of elastic bandage for chest bracing with hook-and-loop fastening, which is reserved for rib fractures in the acute phase.

There are two possible objectives of treatment: the effect sought can either to prevent oedema and provide pain relief, or limit movement, which also has an analgesic role. These two effects may sometimes be sought simultaneously, depending on the stage in the course of the pathology concerned, using a suitable bandage technique or with adjunctions in the case of tubular orthoses.

The number of units proposed in the case of funding tubular orthoses is a maximum of two orthoses per injury per prescription (including recurrences), whereas for bandages there is no limit to the number because of the great variability associated with the characteristics of the injury to be treated, the pathology concerned or the patient him/herself.

Since no agreement was reached among the professionals, the steering group did not recommend funding for open-patella knee tubular orthoses, with or without non-articulated adjunctions, or for elbow tubular orthoses. Finally, according to the steering group, dry bandages should not be used in orthopaedics/degenerative rheumatology/traumatology in view of the consensus against such use.

In conclusion, the healthcare professionals consulted propose that nomenclature recommended in 2010 by HAS be used for medical devices used for vascular disorders, with an added section for tubular orthoses, a section on bandage for chest bracing and additions to the section on vascular bandages. The principle of listing by generic description may be retained, because it is not possible to distinguish between the various devices on the basis of the information provided to HAS. In view of the functions performed, the minimum technical specifications selected for tubular orthoses cover: 

- in vitro measurement of pressure on the area concerned, the presence or absence of adjunctions, the requirement for morphological adaptation, tests and compliance with technical specifications, a minimum range of products, supervised dispensing and a tolerability standard. For adhesive and cohesive bandages, the minimum technical specifications are identical to those recommended by HAS in the 2010 nomenclature project for vascular bandages, with the addition – in the case of adhesive bandage – of the need to use a skin protection material, which must ensure adhesion when a strapping effect is sought. With regard to devices that cannot be funded through generic descriptions, the steering group recommends that a relevant, carefully conducted clinical study should be carried out.

- **Target populations**

There is a large population concerned by the use of ankle tubular orthoses and bandages, mainly because of the population suffering from non-severe talocrural sprains. This is thought to amount annually to 1,500,000 acute cases with painful sequelae not involving laxity, in 300,000 patients. In 2010, there were 46,235 procedures involving strapping of the lower limb, from which the population treated by bandage can be estimated. The population concerned by use of open-patella knee tubular orthoses in France is thought to be of order of 20,000 patients each year. In the case of arm, calf and thigh tubular orthoses the figure cannot be estimated but is sizeable according to the professionals consulted, who state that these products are not exclusive to sporting activities.

- **General conclusion of the HAS Committee (National Committee for the Evaluation of Medical Devices and Health Technologies – CNEDiMTS)**

In its opinion adopted on 10 July 2012, the CNEDiMTS based its conclusion on proposals from the healthcare professionals appointed for the study, and recommended that the reimbursement of tubular orthoses and bandages used in orthopaedics/rheumatology/traumatology be renewed. The amendment of the current nomenclature involved simplifying the product specifications and stating the procedures for prescription, dispensation and use. It mentioned the indications for each type of tubular orthoses and bandages.