La posizione associativa
In tema di

Supplementary
and
Prosthetic Health Care Provision
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The Viewpoint of Assobiomedica

The Prostheses Pricing Nomenclature

Prosthetic health care provision is, to this day, regulated by Decreto ministeriale (ministerial decree) no. 332 of 27 August 1999, "Regulations with provisions concerning prosthetic health care provided within the ambit of the National Health Service: manners of health care provision and prices".

The Pricing Nomenclature is made up of 3 parts*:

- Annex 1, made up, in turn, of three lists:

  List 1: Articles for therapeutic treatment of hernias, spinal orthopaedic appliances, appliances for the upper limb, splints for the lower limb, upper limb prostheses, lower limb prostheses, devices for mobility, sight aids, hearing aids etc.

  These articles are constructed specifically for the patient or are mass produced, or current, products; when applied, they are modified by a qualified technician, on the basis of indications prescribed by a specialist physician, who then tests the product. List no. 1 also includes continuous production articles or articles produced as limited series, which, for use by a given patient, must be endowed with specific features and prepared by a qualified technician on the basis of indications prescribed by a specialist physician. The articles in list no. 1 are only for the patients for whom they have been prescribed.

  List 2: Devices for personal mobility, prostheses for laryngectomy patients, anti-decubitus articles, articles for ostomy patients, articles for prevention and treatment of skin lesions, articles for incontinence, articles for sight impairments etc.

  List 3: Articles for respiratory therapy and for eating and drinking, lifting equipment etc.;

- Annex 2: this annex specifies the instances of care provision involving the disposable articles specified in lists 1, 2, and 3 of the pricing nomenclature, with specifications as to manner of provision.

Decree 332 foresaw that the decree would be updated. Since the update has not yet taken place, a number of regional government authorities have attempted to overcome the rigidity of the current Nomenclature and current regulations by arranging for manners of provision which, while not contemplated in the lists of annex 1, can, in consideration of functions, be linked to the said list.

However, the manners in which these products are selected and provided still do not ensure appropriateness or quality in regard to the care provided, as a result of which care provision may be unsatisfactory and wasteful, and access to technological innovations may be impeded. Lawmakers have acknowledged the existence of such problem areas. In the Finanziaria (budget act) of 2006, they decided that such products should be included among those covering essential assistance levels (livelli essenziali dell'assistenza; LEA). The Health Ministry therefore stipulated an agreement for collaboration with Assobiomedica (national association for biomedical, diagnostic, and medical equipment, services and telemedicine technologies) for the purposes of revising and updating the Nomenclature.
The fundamental role of the clinician

A fundamental aspect of the revised version, as hypothesized by ourselves, is that the clinician should follow up the patient. The clinician must be able to select the most appropriate article in view of the needs of each patient. The fact that the Nomenclature has, as yet, not been updated has greatly limited freedom in selecting products, as attested by the discontent frequently expressed by health care providers and patients.

Health care provision must be ‘calibrated’ to the patient’s needs, while the burdens placed upon physicians, paramedical staff and health units must be minimised. Drawing up prescriptions is to be considered a task requiring considerable proficiency on the part of the specialist, since prescription-making must be based on extremely precise, detailed indications in regard to the characteristics of the articles to be used for each patient as an individual. In regard to prescription, individuals and/or their care provider/s must therefore select products from among those which, while meeting the indicated requisites, are also the most appropriate in view of the needs of the said individuals.

Furthermore, for cases of skin ulceration, prevention and prompt treatment are both fundamental if complications (even serious complications such as gangrene and amputation) are to be avoided. The considerable impact of chronic skin lesions on the national health service should be borne in mind, since such lesions are mainly managed by public structures, entailing costly treatment by physicians and paramedical staff. These costs can be curbed in part by promptly adopting remedies known as advanced medication.

In regard to patients undergoing ostomy, a fundamental consideration is that the collection appliances must be appropriate. Such devices are crucial to the patient’s conditions and quality of life. Likewise, prescription of articles for patients displaying incontinence and/or urinary retention must go beyond merely indicating a product. Prescription must be based on a careful assessment of the dysfunctional condition and the needs arising out of that condition.

Customized health care provision: freedom of choice, adequacy, access to innovation

It must be borne in mind that all diseases for which supplementary and prosthetic health care provision are required induce physical and social disabilities and derive from various conditions (malnutrition, vascular diseases and hypotension, diabetes, local or systemic infections, neurological or mental disorders, tumours, congenital malformations, or birth defects, inflammatory diseases, trauma, bowel obstruction, chronic degenerative diseases, rare diseases, spina bifida, osteoporosis etc.).

The priority consideration must be the needs expressed by the patient, who must receive the most appropriate solution.

Behind each need there is a person (in this case, a particularly vulnerable person). Medical devices exist for all, to enable not just independence of movement, but also the patient’s continued presence in the workplace and maintenance of normal social relations. Since these articles are ‘worn’ by the patient, only the patient knows which article he/she shall ‘feel at ease with’.

The results of recent research conducted by the organisation, Cittadinanza Attiva, in collaboration with Assobiomedica are not encouraging. The public at large has little access to the right information, and patients frequently have to adopt articles which are unsatisfactory in view of their needs, and which are technologically outdated, or in any case inappropriate.

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1 There are 45,000 ostomy patients in Italy – Source A.I.S.TOM.
2 Incontinence affects approx. 3 million patients in Italy – Source FINCO
3 Il Rapporto Assistenza Integrativa e Protesica – Source Cittadinanza Attiva
The costs taken on by users and by households/families providing assistance, in efforts to ensure acceptable quality of life, are to be ascribed to long waiting times for issue of authorisations, the low quality of the articles provided, and the need to supplement quantities received (since insufficient quantities are provided).

For years now, access to innovation has not been assured, since, according to current regulations, the patient must take on the costs of purchase of articles which are technologically superior to those included in the Nomenclature (which has not been updated since 1999).

If a person chooses a type of article or article model which is not included in the Nomenclature, but which, in terms of functional homogeneity, is analogous to the prescribed article, the pertaining authority must permit provision of the said type of article or article model (authorisation being based, of course, on the conclusions of the specialist responsible for prescription). It is therefore a question of authorising provision of products which are not specified in the Nomenclature, the functions of which, however, are the same. Authorities cover the cost of the selected product up to the level of the price set for the article included in the Nomenclature which corresponds to the article actually provided.

### The role of the industry

Employment of medical technologies for prevention and treatment of various forms of disability is becoming more and more widespread, and the industry, thanks to its Research and Development investments, provides increasingly sophisticated medical devices.

The ambit of clinical practice includes a crucially important area, given the number of persons involved and the adverse effects upon their quality of life. It is an area in which innovation of the first order has been attained for conditions such as surgical ostomy, incontinence and urinary retention, and chronic skin lesions. For these conditions, medical devices and articles are commercially available which improve the patient’s quality of life or which, in the case of sores, prevent onset of, or provide a cure for, such conditions. These articles consist in bags, catheters and absorbents, and advanced medication.

Races to the bottom and centralised purchasing must both be avoided if optimal health care provision is to be ensured. Races to the bottom induce decision-makers to overlook the quality of products, while centralised purchasing, since it leads to standardisation of products, overlooks patients’ needs.

### Proposals

To ensure that the needs expressed by patients figure as the priority consideration, and to avoid transfer to the patient of the burden of compensating for the shortcomings of the current Nomenclature and regulations, Assobiomedica proposes the following:

updating the Nomenclature within the context of a more general revision of essential assistance
levels (livelli essenziali dell’assistenza; LEA), in regard to prosthetic and supplementary health care provision, and ensuring access to technological innovations.

February 2012