

# Advanced Dressings now a Legal Right - Italy **UPDATE**

## Reform in Jan 2017 of the Essential Level of Care Law made the provision of advanced wound dressings a legal right in Italy.

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### In Summary

- **The Gov't decree of January 2017 on the new "Essential Level of Care" provided by the health service expanded the definitions of which wound care dressings and technologies could be prescribed in the community to include the most common types of "advanced dressings" ...**

✓ Alginates	✓ Hydrogels	✓ Non-Adherent Wound Contact Layers
✓ Hydrocolloids	✓ Silver Dressings	
✓ Foams	✓ Cavity Dressings	

- **Prescriptions have to be written by a qualified specialist and must be accompanied by a clinical diagnosis justifying the care plan including the choice of dressing.**
- **The choice of procurement systems for these products remains delegated to Regional and District level.**
- **An increase in the use of these dressings in the community is expected.**
- **Some well accepted technologies north of the Alps such as superabsorbents are as yet not specifically defined on the list.**

### A little more detail...

The decree (DPCM) of 12 January 2017 on the new "Essential Levels of Care" – (LEA) for Italy was published on March 18<sup>th</sup>, 2017 in the Gazzetta Ufficiale no. 65.

The Essential Levels of Care (LEA) are the benefits and services that the National Health Service (SSN) is required to provide to every citizen, either free of charge or with a co-payment, using public resources financed through general taxation.

The decree describes, in more detail and with greater precision than before, the performance and activities already included in the essential levels of care to date. It redefines and updates the lists of rare, chronic and disabling diseases that are entitled to exemption from co-payment (the “ticket” in Italian); updates the specifications of the category lists of outpatient specialist and prosthetic care, and introduces technologically advanced products and services, deleting the obsolete. The decree defines the three major areas of health care provision as Public Health, covering prevention and health maintenance for communities as well as individuals, District or Territorial Care covering community health and social care provision including medicines and aids to living and Hospital care. The Commission reviewing and updating the Essential Levels of Care was chaired by the Minister of Health.

**The most important feature of the new law for the Wound Care industry is that Advanced wound dressings as disposable medical devices now fall under the definition of products and services that can be provided as essential levels of care (LEA).**

Article 11.2 of the decree stipulates that *the provision of disposable medical devices referred to in the Register Annex 2 to this decree shall be paid when the devices are prescribed by the specialist physician using the standard form of the National Health Service*. All the Regions and autonomous provinces are free to identify the ways in which general practitioners, paediatricians and community doctors are allowed to prescribe. The doctor who prescribes the treatment is directly responsible for ensuring the treatment plan is carried out.

In the new disposable medical device register, advanced dressings fall under **category 04.49**, “products for treating ulcers” of Annex 2. Codes for specialist therapies for the treatment of skin lesions are defined in Annex 4.

Most importantly for wound care, when defining the therapies to which the patient should have a legal right the new law takes into account the degree of efficacy of a therapy including the efficacy of the modern products to be used as well as the severity of the wound.

Annex 4 introduces the following new categories:

- Simple advanced dressings
- Complex dressings
- Advanced complicated wound dressings
- Advanced complicated wound dressings involving other technology (such as negative pressure wound therapy, ultrasound, dermal substitutes, growth factors, inhibitors of matrix metalloproteases)

Each of these categories specifies the type of wound, its features, its size and any further treatment needed (e.g. resolution of infection, cleansing, surgical debridement, vacuum therapy, revascularization, etc.)

## Impact of the Law

The reform clarified the eligibility of the most common advanced wound dressings to be prescribed for use in the community and so widened the access to modern dressings even though the choice and design of procurement and financing mechanisms to support prescription remain delegated to Regional Authorities. We should see an increased use of foams, alginates and hydrocolloids in the community but price levels and the number of brands per dressing type will be controlled by the ever-wider use of price-reference tenders.

Some dressing types, such as superabsorbents, have been omitted from the new categories so we can expect pressure from industry to add categories to the new register over the next few years.

**Wound Market Consulting (WMC) – your local and global partner for insights and access to the wound care markets.**

- ✓ **Understand what opportunities the new law offers – contact WMC for full review of the implementation and explanation of the reimbursement categories**
- ✓ **Italy – a complex wound care market but a growing opportunity – talk to WMC on how best to access it for your products and services**
- ✓ **Want to try the market before committing fully? Talk to WMC about its Market Access Team in Italy:- clinical evaluations, pilot sales, reimbursement applications.**