REIMBURSEMENT SYSTEMS

FOR WOUND CARE PRODUCTS IN SELECTED EUROPEAN COUNTRIES

SECOND EDITION 2026

EWMA Innovation Alliance

The European Wound Management Association EWMA

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Published by the European Wound Management Association and EWMA Innovation Alliance,
Nordre Fasanvej 113, 2, 2000 Frederiksberg, Denmark
Web: www.ewma.org. Email: ewma@ewma.org and innovation@ewma.org

1. Introduction

In March 2025, the European Wound Management Association (EWMA) published the first European overview of reimbursement mechanisms for wound care products, addressing a key barrier to equitable access to evidence-based wound care. This initiative directly supports EWMA's Strategic Priorities 2025–2027 by promoting transparency, strengthening system-level understanding, and enabling informed decision-making across Europe. The data were collected and validated through close collaboration with EWMA's national member associations and societies, reflecting a shared commitment to quality, credibility, and collective ownership.

The same rigorous methodology has been applied to the 2026 edition. In addition, University Hospital Düsseldorf made a substantial and highly valuable contribution by providing an in-depth analysis of the German reimbursement system. EWMA sincerely thanks all contributors for their expertise, time, and sustained engagement, which are essential to advancing EWMA's strategic objectives.

Reimbursement for wound care products across Europe remains highly heterogeneous, driven by differences in healthcare organisation, regulatory frameworks, and coverage criteria. Improving transparency within this complex landscape is therefore a strategic, long-term endeavor. In line with EWMA's 2025–2027 strategy, this work represents an incremental but purposeful approach, developed through close partnership with national wound management associations, academic institutions, and other relevant stakeholders.

This second edition expands both the geographical and practical scope of the initiative, with new contributions from Germany, Ireland, and Lithuania. Several countries have also strengthened their input by clarifying procedures for companies seeking reimbursement, while others have updated previously published information. These developments align with EWMA's aim to foster structured dialogue between clinical practice, research, policy, and industry.

EWMA intends for this evolving resource to support clinicians, policymakers, researchers, and industry partners in navigating the European wound care market, and to contribute to more consistent, evidence-based, and patient-centred access to wound care products across Europe.

Prof. Dimitri Beeckman
President, European Wound Management Association (EWMA)
April 2026

2. Belgium

The Belgian national healthcare system is generally privately organized but publicly funded. The state ensures partial (the major part) reimbursement of healthcare for all citizens residing in Belgium and abroad, as long as they pay their social security contributions, or for foreign citizens living outside Belgium but working in Belgium and paying their social security contributions in Belgium. Citizens may also purchase additional private health insurance at their own expense, enabling them to receive a higher reimbursement.

Hospitals, nursing homes, home care, and community care:

Reimbursement for active dressings for chronic wounds

If one suffers from chronic wounds, the compulsory insurance for medical care will cover the cost of active dressings, upon prescription and after authorization from the health insurance fund.

Who is entitled to a reimbursement: A patient is entitled to reimbursement if suffering from chronic wounds (wounds that do not heal sufficiently after adequate treatment for 6 weeks) AND from at least one of the following conditions:

- Arterial ulcer
- Venous ulcer
- Diabetic ulcer
- Stage II, III or IV pressure ulcer
- Neuropathic ulcer (in non-diabetics)
- Ulcers due to vasculitis
- Hidradenitis suppurativa
- Oncological wounds
- Post-surgical wounds
- Burns
- Chronic ulcer other than the above conditions for which active dressings are the only therapeutic alternative, confirmed after diagnostic examination by a doctor specialist in dermatovenereology
- Junctional or dystrophic epidermolysis bullosa.

What amount will be refunded:

- 20% of the public price of a box of bandages.
- The portion of the cost that a patient must pay (the co-payment) is eligible for reimbursement up to the maximum invoice.

Which active dressings are reimbursed: There is financial assistance for active dressings registered on the List of Reimbursable Active Dressings.

How to obtain reimbursement for active dressings?

Initial application:

- The treating physician, or the physician specialist in dermato-venereology, or possibly a physician specialist in pediatrics (only in the case of junctional or dystrophic epidermolysis bullosa) must complete the first part of the application for authorization for the reimbursement of active dressings.
- This application must be transferred to the advising physician of their health insurance fund.

Authorization validity: If approved, the advising doctor will provide authorization, which is valid for a maximum of 3 months.

Extension of authorization:

- The reimbursement authorization can be extended to a maximum of 3 times. Each for a period of up to 3 months.
- For extensions, the treating physician or the physician specialist in dermato-venereology or possibly (or in the case of junctional or dystrophic epidermolysis bullosa the physician specialist in pediatrics) must complete the second part of the application of the authorization for the reimbursement of active dressings.
- The application must be submitted to the advising physician of the health insurance fund.

Dispensing of dressings:

- The pharmacist will provide the dressings based on the prescription and authorization.
- The reimbursement amount will be automatically deducted from the public price through the compulsory insurance for medical care from the public price (third-party payer scheme).

Extension after 1 year of treatment:

For all indications (except for junctional or dystrophic epidermolysis bullosa), the reimbursement authorization may be extended for new periods of up to 3 months if:

- The doctor specialist in dermato-venereology, endocrino-diabetologists, orthopedics, plastic surgery or surgery re-evaluates the clinical condition and draws up a recent report stating, among other things, the reasons for the extension.
- The doctor specialist in dermato-venereology, endocrino-diabetologists, orthopedics, plastic surgery, or surgery completes the third part of the application for authorization for reimbursement of active dressings, which must be transferred to the advising physician of the health insurance fund.

If one suffers from junctional or dystrophic epidermolysis bullosa, the reimbursement authorization can be renewed annually under two conditions:

- The doctor specialist in dermato-venereology or the doctor specialist in pediatrics draws up a detailed treatment plan that justifies the choice and number of active dressings required each month.
- The doctor specialist in dermato-venereology or the doctor specialist in pediatrics completes the third part of the application for authorization for the reimbursement of active dressings, which must be submitted to the advising physician of the health insurance fund.

Reimbursement for specific products

Compression therapy:

- Compression Bandages: No reimbursement
- Compression Stockings (Therapeutic Elastic Support Stockings)

  What is reimbursed?
  - Support stockings used for lymphedema or chronic venous disorders, both ready-made and custom-made.

  Indications:
  - Lymphedema: after lymph node removal or radiation in the groin/pelvis, primary hereditary lymphedema, congenital abnormalities.
  - Chronic venous disorders: recurrent venous ulcers, deep vein thrombosis, post-thrombotic syndrome.

  Compression class:
  - For lymphedema: class II (≤15 years old) or III/IV; for adults: class III/IV.

  For chronic venous disorders: always class III/IV.

  Annual allowance:
  - Lymphedema: maximum of 4 stockings per treated leg per calendar year.

- Venous disorders: maximum of 2 stockings per leg per calendar year.

Who can prescribe?

- First prescription for lymphedema: specialist physician (surgery, internal medicine, rehabilitation, etc.); renewals can be done by any treating physician.
- For venous disorders: any treating physician can prescribe both initial and renewal.

Procedure:

- Medical prescription with form 94A completed by the physician.
- Purchase from an accredited orthotist/ bandagist; obtain delivery certificate (form 13).
- Submit documents to the health insurance fund (by mail or via e-health if available).

Reimbursement:

- If purchased from a contracted supplier: the health insurance fund reimburses according to RIZIV/INAMI tariffs, with little or no out-of-pocket cost.
- Non-contracted supplier: possible surcharge, lower reimbursement.
- Children (<15 years): eligible for classes II, III, IV.

Additional benefits:

Some health insurance funds (e.g., Helan) offer extra discounts on top of statutory reimbursement (e.g., €25 discount).

Disinfectants:

- Wound disinfectants, if registered as pharmacological products, are reimbursed in hospital and nursing home settings
- Wound disinfectants are not reimbursed in community care situations.
- The portion of the cost paid by the patient (co-payment) is eligible for reimbursement, up to the maximum invoice amount.

Negative Pressure Wound Therapy (NPWT) supplies:

- The systems and associated consumables are reimbursed only in hospital settings.

Essential wound care products:

- Basic dressings (gauze) and bandages are often partially reimbursed by health insurance.
- The co-payment amount varies, typically ranging from 10% to 50% of the product's cost.

Pharmacy dispensation

Process: Wound care products are dispensed through pharmacies. Patients present their prescription at a pharmacy, where the pharmacist provides the necessary items.

Pharmacist's role: Pharmacists ensure that patients receive the correct wound care products and offer advice on their proper use.

Patient co-payments

Standard co-payments: While health insurance covers most healthcare costs, patients often need to make co-payments for certain wound care products.

Reduced costs: Specific patient groups, such as those with chronic conditions, disabilities, or low-income status, may be eligible for reduced costs or exemptions from co-payments.

Supplementary health insurance

Additional coverage: Many Belgians opt for supplementary health insurance to cover additional costs not covered by the compulsory system.

Benefits: Supplementary insurance may cover extra costs for wound care products, reducing the financial burden on patients.

Home care services

Chronic wounds: For patients with chronic wounds or those needing long-term wound management, home care services are available.

Coverage: Home care services, including wound care provided by healthcare professionals, are typically covered by health insurance.

Quality control and approval

Regulatory oversight: INAMI/RIZIV and the Federal Agency for Medicines and Health Products (FAMHP) oversee the quality and safety of wound care products in Belgium.

Approval process: Products must meet regulatory standards and undergo approval processes to be eligible for reimbursement.

Special patient groups

Support: Certain patient groups, such as those with severe financial difficulties or chronic conditions, may receive additional support to ensure access to necessary wound care products.

Summary

Belgium's reimbursement system for wound care products ensures that essential treatments are accessible through a well-regulated health insurance framework. The system aims to provide equitable access to high-quality wound care products while managing costs. Patients benefit from both compulsory and supplementary health insurance options, ensuring comprehensive coverage for their wound care needs.

For the most current and detailed information, patients and healthcare providers can consult INAMI/RIZIV's resources or their healthcare insurance provider.

The information provided on Belgium is collected by www.wondzorg.net

3.
Bosnia & Herzegovina

In Bosnia and Herzegovina, the reimbursement for wound care products is managed through the public healthcare system, which includes the Health Insurance Fund (HIF). However, the healthcare system in Bosnia and Herzegovina is complex due to the country's administrative structure, which consists of two entities: the Federation of Bosnia and Herzegovina (FBiH) and the Republika Srpska (RS) as well as the Brčko District. Each entity has its own health insurance system and policies.

Overview of healthcare system structure

Federation of Bosnia and Herzegovina (FBiH):
- Consists of 10 cantons, each with its health insurance fund.
- Health policies and reimbursement procedures can vary between cantons.

Republika Srpska (RS): Has a centralized health insurance system under the Health Insurance Fund of Republika Srpska.

Brčko District: Operates its health insurance system independently of FBiH and RS.

Reimbursement process for wound care products

Prescription and authorization:
- Wound care products must be prescribed by a healthcare professional, doctor specialist.
- The prescription needs to be justified based on the patient's medical condition and the type of wound.

Approval and reimbursement:
Federation of Bosnia and Herzegovina (FBiH)
- Each canton's health insurance fund has its own list of reimbursable products.
- Reimbursement rates and eligibility criteria can differ from one canton to another.

Republika Srpska (RS):
- The Health Insurance Fund of RS maintains a list of reimbursable medical products, including wound care items.
- The approval process involves evaluating the necessity and cost-effectiveness of the prescribed products.

Coverage levels

Basic wound care products:
- Generally, it includes items like bandages, gauze, and basic dressings.
- Often fully or partially reimbursed depending on the specific health insurance fund's policies.

Advanced wound care products:
- Include items such as hydrocolloids, alginates, hydrogels, and foam dressings.
- Reimbursement may be more restrictive and often requires additional justification.

Specialized wound care products:
- Products like negative pressure wound therapy (NPWT) devices and advanced biological dressings.
- Typically requires a detailed clinical justification and may undergo a more rigorous approval process.

Patient co-payment

- Patients may be required to pay a portion of the cost, depending on the type of product and the specific health insurance fund's policies.
- Co-payment amounts and coverage percentages vary between entities and cantons.

Exceptional cases

- For products not listed on the standard reimbursement lists, healthcare providers can apply for exceptional funding.
- This involves submitting detailed clinical documentation to justify the need for the specific product.

Challenges and considerations

- **Variability in coverage:** Due to the decentralized nature of the healthcare system, there is significant variability in the coverage and reimbursement rates across different regions.
- **Access to advanced products:** Access to more advanced and specialized wound care products can be limited, and obtaining reimbursement for these often involves navigating a complex approval process.
- **Economic constraints:** The overall economic situation and healthcare budget constraints can impact on the availability and reimbursement of certain wound care products.

Examples of wound care products reimbursement rates in Bosnia & Herzegovina

Federation of Bosnia and Herzegovina (FBiH)

Basic wound care products:
- Generally, these are well-covered across various cantonal health insurance funds.
- Reimbursement rates can cover 70-100% of the cost, with variations depending on the canton.

Advanced wound care products:
- Hydrocolloid dressings, foam dressings, and similar products typically require a detailed prescription.
- Reimbursement rates may cover 50-90% of the cost.
- Some cantons may have stricter controls and require additional approval for reimbursement.

Specialized wound care products:
- Products like NPWT devices and silver dressings usually need prior authorization.
- Reimbursement rates can vary significantly, often covering 50-80% of the cost, subject to clinical justification.

Republika Srpska (RS)

Basic wound care products:
- These are generally covered by the Health Insurance Fund of RS.
- Reimbursement rates typically cover 80-100% of the cost, depending on the product and necessity.

Advanced wound care products:
- Similar to FBiH, advanced products require a detailed prescription and sometimes additional approval.
- Reimbursement rates generally cover 60-90% of the cost.

Specialized wound care products:
- Specialized products like NPWT devices often require rigorous clinical justification.
- Reimbursement rates can cover 50-75% of the cost, contingent on the approval process.

Brčko District

Basic wound care products:

- Coverage is generally high, with reimbursement rates around 80-100% for essential products.

Advanced wound care products:

- Coverage and reimbursement practices are similar to those in other entities, typically covering 60-90% of the cost.

Specialized wound care products:

- Approval of specialized products often requires detailed clinical documentation.
- Reimbursement rates may cover 50-80% of the cost, depending on the specific product and clinical need.

Summary

Reimbursement for wound care products in Bosnia and Herzegovina is managed through a fragmented system, with policies varying significantly between dregions. Healthcare professionals play a crucial role in navigating the reimbursement process, ensuring that patients receive the necessary wound care products based on their clinical needs. Patients may face co-payments, and obtaining advanced wound care products often requires thorough justification and adherence to specific approval procedures.

The information on Bosnia & Herzegovina is provided by the Association for Wound Management in Bosnia and Herzegovina (AWMinB&H).

4. Finland

In Finland, reimbursement for wound care products is managed through the national health insurance system. Here are the key aspects of the reimbursement process:

National health insurance system

- Finland has a publicly funded healthcare system, providing universal healthcare coverage to all residents.
- The system is primarily funded through taxation and ensures access to essential medical treatments and products. Wound care supplies are based on certain criteria and are generally restricted for chronic wounds lasting more than 3 months. This is based on Health Care Act No. 1326/2010.

Prescription requirement

- Wound care products are prescribed by a doctor or a nurse if private health care insurance, accident insurance or occupational accident insurance requires a prescription for products.
- A prescription is also required to obtain wound care products for free if a person is receiving a supplementary benefit from the Social Insurance Institution of Finland,
- Wound care products must be prescribed by a doctor.

Reimbursement process

- Wellbeing service counties have their own treatment supply for wound care products, and a referral or prescription (each county has its own referral formulas and criteria) is needed to obtain wound care products from treatment supply by a nurse or wound care specialist.
- The prescription should specify the type of wound, the required treatment, and the specific products needed. This is needed only when the patient is receiving wound care products for the treatment of chronic wounds, which means the patient receives them for free.
- If the wound care products are for the treatment of acute wounds, then the prescription only needs to list the specific products required, not the type of wound.

Reimbursement rates

- Reimbursement rates for wound care products vary by wellbeing county in Finland.
- In general, the criteria are restricted to chronic wounds which have lasted for 3 three months. Acute wounds and post-operative wounds are excluded.
- There are several exceptions to the 3-month rule, depending on the wellbeing service county.
- Some counties provide wound care products for free from the first evaluation by a wound care professional (e.g., the counties of Kainuu and Lapland)
- Some counties provide wound care products based on diagnosis (listed, including common chronic wound etiologies) (e.g., the counties of Pirkanmaa, Päijät-Häme, Keusote, Pihlajalinna, Pohde and Varha)
- Some counties provide free wound care products based on the evaluation of a wound care professional (nurse or doctor) if there

is a risk of the wound becoming chronic (e.g., counties of Kuopio, Siun Sote, Kymenlaakso, Keski-Suomi)

Approved product list

- Each wellbeing service county separately establishes, through competitive tendering, lists of reimbursable medicines and medical products, including wound care items.
- Only products included in these lists are eligible for reimbursement.

Pharmacy dispensation

- Wound care products are dispensed through pharmacies only if the insurance company is paying (private health care insurance and accident or occupational accident insurance) or if a patient qualifies for social services according to legislation.
- Patients present their prescription at a pharmacy, where the pharmacist provides the necessary items.
- Pharmacists play a role in ensuring that patients receive the correct wound care products and can offer advice on their proper use.

Patient co-payments

- In general, the patient is responsible for paying for medication, creams, painkillers, local anesthetics and any wound care product not included in the county's reimbursement list.
- Patients often pay client fees for wound care, especially for home care, and health centers may also charge fees dependent on the area.
- Wound care products are included in the daily hospital charge. Wellbeing service counties can independently decide which wound care products are included in the care of patients with chronic wounds.

Exemptions and reduced costs

- Some groups of patients may be exempt from co-payments or eligible for reduced costs. This includes individuals with chronic illnesses, low-income individuals, and those with specific medical conditions.
- Patients with long-term illnesses may receive full coverage for necessary wound care products.
- The Social Insurance Institution of Finland provides this supplementary benefit based on certain criteria. To qualify, a doctor's evaluation and specified certification are required.

Home care services

- For patients with chronic wounds or requiring long-term wound management, home care services are available. These services ensure that patients receive the necessary wound care at home.
- Wound care is included in home care services, but the fees may increase due to longer and more frequent appointments.
- Home care services vary by wellbeing service county, while wound care products are provided on the same principles as primary care health services

Quality control and approval

- Fimea oversees the quality and safety of wound care products available in Finland.
- Products must meet regulatory standards and undergo an approval process to be eligible for reimbursement.

Summary

Finland´s reimbursement system varies geographically as wellbeing counties have control over the criteria and distribution of wound care products.

The national health care system provides only the overarching principles for equal access to health care. The reimbursement of wound care products in Finland still needs further development.

The information on Finland has been completed with the cooperation of the Finnish Special Competence Committee of Wound Management (by the Finnish Medical Association, www.laakariliitto.fi/en/) and the Finnish Wound Care Society, www.shhy.fi.

Lääkäriliitto
Läkarförbundet

Suomen Haavanhoitoyhdistys ry

Authors: Kirsti Ahmajärvi, Leena Berg and Heli Kallio.

5. Germany

Health System Overview

Brief description

Germany has a social health insurance (SHI)-based system with a dual structure of statutory health insurance ("Gesetzliche Krankenversicherung" - GKV) and substitutive private health insurance ("Private Krankenversicherung" - PKV). Health insurance is mandatory for all residents and around 90 % of the population is covered by SHI, with the remainder insured privately. There are 94 different Statutory Health Insurance Funds and over 40 Private Health Insurance Funds currently in Germany. They are organized in governing structures called the National Association of Statutory Health Insurance Funds and the Association of Private Health Insurance.

The SHI system is organized on the principles of solidarity (contributions linked to income, benefits linked to need) and benefits in kind. Patients usually do not pay providers directly; services are reimbursed by sickness funds. It covers virtually the full continuum of care (primary, specialist, hospital, pharmaceuticals, medical devices and aids, prevention and rehabilitation), including the treatment of patients with acute and chronic wounds.

Funding model

The system is primarily insurance-based. SHI is funded by income-related contributions shared between employers and employees, plus federal tax transfers to support non-contributory insured groups e.g. unemployed and certain family members). PKV is funded by risk-related premiums paid by individuals and in some cases supported by employer or civil service.

People with income above the compulsory insurance threshold (ca. 73,800 € per year in 2025) and certain groups (e.g. self-employed, civil servants) can opt out of SHI (GKV) and take substitutive private cover (PKV) instead.

For **inpatient care**, hospitals are reimbursed under **diagnosis-related groups (G-DRG/aG-DRG)** for SHI patients, which typically bundle medical services, nursing and most wound care products into the case payment. The base amount per case is based on diagnosis, complexity, severity and necessity for intervention of the given disease treated. Depending on necessity and duration of in-hospital stay, certain additional surcharges can be reimbursed. DRGs are re-evaluated and reimbursement sums re-negotiated yearly between the National Association of Statutory Health Insurance Funds and the German Hospital Federation ("Deutsche Krankenhausgesellschaft" - DKG).

For **ambulatory (outpatient) care**, physicians are paid mainly via a **uniform assessment standard** ("Einheitlicher Bewertungsmaßstab" – **EBM) fee schedule**. Wound care products may be reimbursed as either dressings ("Verbandmittel") and 'other wound treatment products' ("sonstige Produkte zur Wundbehandlung") under the Medicinal Products Directive ("Arzneimittel-Richtlinie" - AM-RL) or medical aids (e.g. certain compression systems or NPWT devices) via the curated Medical Aids Directory ("Hilfsmittelverzeichnis") of the National Association of Statutory Health Insurance Funds. The EBM is also re-evaluated regularly and newly negotiated between the National Association of Statutory Health Insurance Funds and the National Association of Statutory Health Insurance Physicians ("Kassenärztliche Bundesvereinigung" - KBV).

In the **private insurance sector**, the **German Medical Fee Index** ("Gebührenordnung für Ärzte"

- GOÄ) represents the legal basis that specifies how physicians may bill for their services privately or to self-paying patients.

Role of national/regional authorities in healthcare delivery and reimbursement

At the **national level**, the Federal Ministry of Health (BMG) sets the legal framework (notably Book V of the Social Code - SGB V), within which the SHI operates. The Federal Joint Committee ("Gemeinsamer Bundesausschuss" - G-BA) is the highest decision-making body of joint self-governance (physicians, dentists, hospitals and health insurance funds) in Germany. It defines the SHI benefit package, adopts binding guidelines and assesses new methods and products.

For wound care, the G-BA regulates dressings and 'other wound treatment products' in Section P and Annex Va/V of the Medicinal Products Directive (AM-RL), including the criteria for what counts as a reimbursable dressing and the procedure for 'other wound treatment products' to become prescribable.

Wound care products are thereby categorized under Section P of the Medicinal Products Directive (AM-RL) and the associated Annex Va in Part 1 ('dressings without additional properties'), Part 2 ('dressings with additional properties') or Part 3 ('other wound treatment products'). Products which are listed in Part 1 and Part 2 may be regularly reimbursed by the SHI in ambulatory/outpatient care, while products listed in Part 3 of the Annex Va may only be reimbursed after a positive review of its medical benefits by the G-BA.

The Medical Aids Directory, which lists reimbursable medical aids and sets framework conditions for their provision, including some wound-related products such as compression therapy and certain devices, is maintained by the National Association of Statutory Health Insurance Funds representing all SHI funds.

At the **regional level**, federal states are responsible for hospital planning and investment funding, deciding which hospitals and specialized centers are included in regional plans, which indirectly shapes where advanced wound care can be delivered.

They do not define different SHI benefit packages, so reimbursement rules for wound products are nationally uniform, but local implementation can vary. Selective reimbursement plans and contracts such as integrated care (IV) contracts between a health insurance fund and individual service providers (doctors, clinics, wound centers, networks, etc.) or specific care pathways can be established on a regional level.

The Associations of Statutory Health Insurance Physicians ("Kassenärztliche Vereinigungen" - KVs) and its national umbrella organization, the National Association of Statutory Health Insurance Physicians ("Kassenärztliche Bundesvereinigung" - KBV) negotiate and implement outpatient contracts, fee schedules and practical prescribing rules, including information for physicians on the prescribability of wound care products and any transitional arrangements.

Overall, reimbursement of wound care products in Germany is determined centrally via SHI legislation and G-BA guidelines, with a differentiation between inpatient (DRG-bundled) and outpatient (product-specific reimbursement as medicinal product, medical device or medical aid) care sectors. Implementation and contracting is thereby handled by self-governance bodies at national as well as regional level.

Reimbursement Pathway for Wound Care Products

General Legal Frame

Coverage of wound care products in SHI is governed by:

- **German Social Code (SGB)** V (esp. §12, §27, §31, §31(1a), §139) under the principle, that care must be sufficient, appropriate and economical.

- **Medicinal Products Directive (AM-RL)**
  - **Section P & Annex Va** defining dressings and 'other wound treatment products', including clinical and technical requirements.
  - **Annex V** listing the prescribable medical products and devices incl. wound products.
- **Medical Aids Directory** (§ 139 SGB V) defining indications, quality criteria and supply conditions for medical aids (e.g. compression therapy).

These rules apply nationwide and are complemented by guideline-based clinical standards.

General Principles

In the **outpatient sector**, reimbursement follows SHI rules with 'benefits-in-kind'. Once a product is prescribed by an SHI-contract physician, the SHI fund covers costs according to the applicable framework (Medicinal Products Directive or Medical Aids Directory). Standard co-payment applies, which is 10 % of the product price with a minimum of 5 €, but a maximum co-payment of 10 € with some exemptions.

In the **inpatient sector**, wound care products are included in the aG-DRG case payment and are not billed separately. Only a limited number of advanced technologies (e.g., specific NPWT components) may qualify for extra reimbursement rules (New methods of examination and treatment – NUB or additional fees - ZE) if nationally negotiated and accepted.

Differentiation by Product Category

General dressings (listed in Part 1 and 2 of the Section P of the Medicinal Products Directive (AM-RL) and the associated Annex Va) are fully reimbursable when prescribed on a 'Muster 16' standard prescription form without specific prior authorization. This includes basic and advanced dressings if their mode of action meets the specified criteria.

The categorization is defined nationally by G-BA criteria. Thereby, primary characteristics of Part 1 dressings are covering, absorption, stabilization or compression. Part 2 dressings exhibit additional features such as moisture balance, cleansing, anti-adhesion or antimicrobial, however without a pharmacological, immunological or metabolic mode of action.

The *'other wound treatment products'*, as listed in Part 3 of the Annex Va, are products that do not meet the definition for general dressings but potentially provide clinically relevant wound-healing functions. Thus, their primary mode of action is pharmacological, immunological or metabolic and directly influencing the wound healing process.

Before outpatient prescribing is allowed for Part 3 products, a prior positive G-BA evaluation and listing is required. Application for listing needs to be initiated by the products company and evaluation is based on medical study evidence. After listing, standard SHI reimbursement applies. Until a listing has been realized, patient self-payment or a case-by-case SHI approval upon individual application can be tried.

These reimbursement regulations only apply for the outpatient sector. Within the inpatient sector, all products are included in the flat-rate remuneration system (aG-DRG case system) for inpatient hospital services.

Medical aids, such as compression therapy systems, certain NPWT devices or components, and specialized support systems are reimbursable when listed in the Medical Aids Directory curated by the National Association of Statutory Health Insurance Funds. These are commonly provisioned via contracted suppliers, however prior approval by the responsible SHI fund may apply, depending on the product and local contract.

Clinical Indications and Patient Groups

SHI-insured patients have a general entitlement to dressings (Annex Va, Part 1 and 2) when medically indicated. There is no formal restriction to 'chronic' wounds or specific diagnoses.

Coverage for 'other wound treatment products' (Annex Va, Part 3) however is restricted to the

indications defined for each product group in Annex Va and Annex V (e.g. specific wound types). Only products with a positive benefit assessment by G-BA and inclusion in Annex V/Va are regularly reimbursable. Others may currently fall under a time-limited transitional rule if they were reimbursed before 02. December 2020, however this transitional rule is currently under debate and re-evaluation by the federal government.

Indications for medical aids are narrowly defined in the Medical Aids Directory ("Hilfsmittelverzeichnis", e.g. chronic venous disease, lymphoedema, etc.). The wound itself is often not the primary indication, but the underlying pathology (e.g. chronic venous insufficiency (CVI)).

In practice, chronic wounds are the main area where advanced products and compression systems are used, however the legal entitlement is not limited to chronicity as such, but to medically justified indication.

Prescription and Authorization Requirements

Prescribers and Care Settings

Outpatient setting: SHI-accredited physicians (general practicioners, dermatologists, surgeons, etc.) can prescribe medication and medicinal products. Home-care nursing services, nurses, wound managers or podiatrists in general perform application or treatment and can recommend products, but cannot prescribe medicinal products. Prescription is exclusively limited to physicians.

Inpatient setting: hospital physicians may use products provided within their institution without individual billing under the aG-DRG system. Discharge prescriptions at intersectoral boundaries follow outpatient rules, however hospital physicians are only allowed to a certain amount of prescriptions and for a limited period of time after discharge (generally a maximum of 7 days after discharge) and this option can be subject to internal institutional regulations and policies.

Authorization, Contracts, Procurement

Prior authorization by SHI funds: generally not required for listed dressings and medical aids, however may be required for certain medical aids and specific advanced systems or therapies if newly introduced into the market.

Contracts: SHI funds may conclude selective reimbursement contracts (e.g. integrated care (IV) contracts) with doctors, clinics, home-care providers or distributors for supply and training. However, these do not change clinical prescribing rights but may affect supplier choice and logistics. Tendering occurs in certain segments of medical aids supply, which can lead to preferred suppliers and defined price levels.

Co-Payments, Exemptions and Exclusions

Details on **co-payment caps and exemptions** (e.g. 1–2 % income thresholds, chronic disease regulation) will be elaborated in **the section Patient Co-payments and Exemptions**.

Products which **do not meet the legal definition of dressings**, are **not listed as 'other wound treatment products' in Annex V/Va** and are **not covered as medical aids** are, as a rule not reimbursed under the SHI and therefore **self-pay**. Typical examples include 'comfort' or lifestyle products (e.g. cosmetics or wellness items around wound care), non-listed topical agents (e.g. certain OTC (over the counter) gels, sprays or alternative preparations) and products whose main effect is cosmetic or not essential to treatment.

Intersectoral Issues / Transitional Situations

At hospital-to-home transition, advanced dressings used in the inpatient setting may not automatically qualify under the outpatient reimbursement rules. Therefore, physicians in the outpatient setting, but also hospital physicians prescribing in the transitional situation must adhere to outpatient

regulations and prescribe according to outpatient eligibility.

Wound centers or specialized outpatient clinics often coordinate continuity of care and product selection but must adhere strictly to outpatient reimbursement eligibility.

Product-Specific Limitations

(as per publication date – can be subject to regulatory changes)

Transitional regulation for 'other wound treatment products':
The current transitional rule allows the prescription of certain 'other wound treatment products', even if not yet listed, provided they were already reimbursable before 02. December 2020. This has been extended until 02. December 2025 and is currently under re-evaluation by the federal government regarding another extension. After the transitional rule ends, non-listed products are in principle no longer reimbursable in the outpatient sector. The inpatient sector is not affected by this ruling as reimbursement is performed under the DRG system on a case-base.

Dressings vs. non-form-stable preparations:
The G-BA clarified that liquid to semi-solid preparations ('non-solid dosage forms', e.g. hydrogels and sprays) for wound treatment do not fall under the definition of dressings as per Part 1 and 2 of the Section P & Annex Va. Such products can only be SHI-reimbursed as 'other wound treatment products' after benefit assessment and listing in Annex V/Va. Until then, they are not standard SHI benefits (apart from the current transitional arrangements).

Restrictions for particular substances / technologies:
Some product groups (e.g. silver-containing dressings and honey preparations) were assessed by the G-BA and categorized in Part 3 of the Annex V due to immunological, metabolic or pharmacological influence on the wound. The reimbursement of such products currently falls under the transitional rule. In the futurte Annex Va/AM-RL may define specific indications, time limits or prerequisites (e.g. only for infected wounds) that allow reimbursement of such products for specific indications. However, this is subject to prior evaluation by the G-BA based on adequate clinical studies. Generally, products that primarily act pharmacologically (e.g. antiseptics) are classified as pharmaceuticals/medicinal products, which means their use is subject to the usual prescribing limitations or exclusions as in other AM-RL annexes (OTC, exclusion lists, etc.).

Quantity, Duration and Economic Efficiency
There are no **fixed national maximum numbers** of dressings per week, however several qualitative layers of limitation.

The **principle of economic efficiency** (§ 12 SGB V) states, that physicians must prescribe only what is necessary in type, quantity and duration. Overuse can trigger a regress. A **regress** is a financial audit of an outpatient institution (e.g. a physicians practice) performed by the responsible Association of Statutory Health Insurance Physicians (KV) on behalf of the health insurance funds.

Wound- and disease-specific guidelines (e.g. venous leg ulcer, diabetic foot) indirectly define reasonable use (frequency of dressing change, duration for special antimicrobials, etc.) and are used in **economic audits** in terms of **guideline orientation**.

The Medical Aids Directory sets minimum and maximum supply intervals, renewal criteria and requirements for compression garments, bandages, and devices. Exceeding this usually requires **individual justification and approval** by the responsible SHI fund.

In practice, **complex or expensive products** (e.g. some advanced dressings, NPWT and specialised devices) are more closely scrutinised by SHI funds in economic reviews than standard dressings.

Product Categories and Reimbursement Rates

Basic Wound Care Products

In the outpatient SHI system, **basic wound care products** are reimbursed as dressings if they meet the G-BA criteria for 'dressings without additional features' **(AM-RL, Section P / Annex Va Part 1).** These typically include:

- Gauze and cotton pads (simple absorbent dressings)
- Non-adherent wound contact layers (simple wound contact nets without active agents)
- Simple absorbent dressings (e.g. cellulose pads, sterile wound pads)
- Fixation materials (bandages, fixation tapes, cohesive bandages)
- Simple wound plasters

If such products are coded and dispensed as dressings, they are directly prescribable on SHI prescription (Muster 16) and reimbursed as a benefit-in-kind.

Advanced Wound Care Products

Many **advanced dressings** are also reimbursed as 'dressings with additional features' under the G-BA criteria of the **AM-RL, Section P / Annex Va Part 2**, provided their primary mode of action is not pharmacological, immunological, or metabolic. These typically include:

- Foam dressings (incl. with varying absorption capacities, bordered/non-bordered)
- Hydrofiber and alginate dressings
- Hydrocolloid dressings
- Hydrogel dressings (form-stable sheets)
- Superabsorbent dressings
- Soft silicone contact layer dressings
- Advanced absorbent multi-layer dressings

If an advanced product meets the 'dressing with additional features' definition, it is prescribable.

Products whose primary effect is beyond classical dressing functions, and involves targeted active influence on wound healing processes, fall under 'other wound treatment products' and require G-BA assessment and listing in AM-RL Annex Va Part 3 to be regularly reimbursable (beyond the current transitional rule).

NPWT, Compression Therapy and Antimicrobial Dressings

Negative Pressure Wound Therapy (NPWT):

- *Inpatient:* reimbursed within aG-DRG and recognized as a standard method (obtained procedural code within OPS).
- *Outpatient:* NPWT has been explicitly included as a method in SHI after G-BA decision and is now an established, reimbursable benefit in both hospital and ambulatory care. However, specific qualification and documentation requirements are necessary for reimbursement. The **materials/devices** are treated as part of the reimbursed method or, depending on the contractual setup, as medical aid with prior approval in individual cases.

Compression therapy

- Medical compression stockings, adaptive compression systems and compression band age systems are reimbursed as medical aids in the Medical Aids Directory product group 17 - "medical aids for compression therapy".

Antimicrobial / antiseptic dressings and solutions

- Some antimicrobial dressings (e.g. silver-containing or similar) can be reimbursed if:
  - they meet the 'dressing with additional features' criteria (Part 2), whereby an antimicrobial agent (such as silver) can be embedded within the dressing, however may not be in direct contact with the wound bed and may not be released from the dressing into the wound.
  - they are classified and positively assessed as 'other wound care products' and are accordingly listed in Annex V.

- **Antimicrobial irrigation solutions** and **antiseptics** (e.g. polyhexanide (PHMB) and octenidine) are also categorized as 'other wound care products', as they do not meet the definition criteria for dressings (liquid and not form-stable). Therefore, after the after the transitional arrangement has expired, they need to be positively assessed and listed in Annex V to be regularly reimbursable. Currently, only neutral irrigation solutions (e.g., 0.9 % NaCl or Ringer solution) are prescribable for wound irrigation. Also, certain antiseptics can be prescribed for limited indications (e.g., PVP--Iodine for pressure and leg ulcers).
- The use is often **indication-bound** (e.g. infected wounds) and can be subject to guide line-based and economic scrutiny.

Official Reimbursement Lists and Registers

- Medicinal Products Directive (AM-RL)
  - Annex Va: defines dressings and 'other wound treatment products' and their classification criteria.
  - Annex V: the official list of reimbursable medical devices, including 'other wound treatment products' that have undergone a positive G-BA benefit assessment.
- Medical Aids Directory
  - Central directory of reimbursable medical aids, including wound-relevant aids/devices.

Prices for dressings and products are handled via pharmacy price systems and contracts, but reimbursement eligibility is governed by the G-BA rules above, not by a stand-alone wound-dressing reimbursement catalogue. Therefore, there is no separate "national price list" for dressing materials.

Reimbursement Application Process for Manufacturers

For wound-care products, there are **two main reimbursement routes:**

1. Medicinal Product Directive (AM-RL)

– Annex V

- relevant for 'other wound treatment products' (including antiseptic/irrigation solutions, active wound dressings, etc.).

2. Medical aids supply / Medical Aids Directory

- relevant for aids such as compression systems or NPWT devices.

Responsible Authorities

- G-BA (Federal Joint Committee)

Responsible for

- definitions of product categories in the AM-RL.
- benefit assessment and decisions on listing of prescription-eligible medical devices, including 'other wound treatment products', in Annex V AM-RL.
- issuing methods decisions (e.g. NPWT) and restrictions on indications or requirements of specific documentation/quality standards.

- **National Association of Statutory Health Insurance Funds**

Responsible for

- maintaining the Medical Aids Directory and setting quality, functionality and indication re quirements for medical aids.
- evaluation and listing of medical aids in the Medical Aids Directory.

Both act at federal level. There is no regional decision-making on inclusion or exclusion of specific wound products.

Procedure to obtain national reimbursement eligibility

Dressings:
General dressings (as defined in AM-RL Section P/Annex Va Part 1 and 2) that meet the legal definition and are CE-marked are immediately reimbursable. No additional G-BA listing procedure is needed for reimbursement status.

'Other wound treatment products':
For products which fall under the category 'other

wound treatment products' (as defined in AM-RL Section P/Annex Va Part 3), manufacturers must submit an application to the G-BA to have the product included as a prescription-eligible, reimbursable medical device in Annex V of the AM-RL.

The G-BA procedural rules (chapter 4) and the specific application package for Annex V specify pre-requisites that must be fulfilled.

Manufacturers must submit:

- Administrative and product information
  - Detailed product description and classification as 'other wound treatment product'.
  - Regulatory status (e.g. CE-marking, risk class, intended purpose, instructions for use).
- Clinical evidence / therapeutic benefit
  - Structured clinical study data demonstrating therapeutic benefit vs. appropriate comparator (e.g. standard wound care or best practice dressing).
  - Typically randomized or at least high-quality comparative clinical studies. The G-BA provides templates for study extraction and bias assessment (tabular evidence, extraction sheets).
  - Systematic literature searches and summaries following G-BA methods (search strategies, documentation of hits, risk of bias, etc.).
- Safety data
  - Adverse events, contraindications, interaction issues and post-market experience where available.
- Economic / resource use information
  - Not a full pharmacoeconomic dossier as in AMNOG ("Arzneimittelmarkt-Neuordnungsgesetz"), but data on resource use, treatment duration, dressing change frequency, etc., may be relevant for the economic efficiency assessment.

Applications are filed via the AM-RL portal (online) or in defined electronic formats. The G-BA offers pre-submission scientific advice specifically for 'other wound treatment products', focusing on required evidence and study design (fee-based).

If the application is successful, the product is added to Annex V, and becomes nationally reimbursable as part of SHI outpatient care.

Medical aids (e.g. compression and certain devices):
Manufacturers apply to the National Association of Statutory Health Insurance Funds for inclusion in the curated Medical Aids Directory (§ 139 SGB V). Applications of new product or change applications are submitted via the GKV online portal.

Manufacturers must submit documentation on:

- Functionality and performance of the device
- Safety (CE-marking, conformity assessment)
- Fulfilment of defined quality requirements in the relevant product group
- Medical or nursing benefit, if applicable (clinical data, guidelines, expert consensus)
- Complete labelling and instructions in German use information

A positive decision leads to listing under a product type and allocation of a 10-digit product number, and the aid becomes reimbursable nationwide for indications defined in the respective product group. There are no separate regional reimbursement lists for these products.

Timelines, Fees, Submission Windows

'Other wound treatment products':
After complete documentation has been submitted, the G-BA must decide on the application within **90 days**. Before that, manufacturers often use **optional advisory meetings**, typically scheduled within about three months after request. These are **subject to fees** as laid down in the G-BA procedural rules and its fee schedule.

There are **no fixed submission windows**, applications can be submitted continuously, they are not limited to specific 'calls' and the procedure is generally fee-based.

Medical aids:
The National Association of Statutory Health Insurance Funds decides **within three months** after all required documents have been submitted. If documentation is incomplete, a **grace period up to six months** is granted for missing documents. If the submission is still incomplete after that period, the application is rejected.

The process is governed by a set of procedural rules and the listing can be updated or withdrawn if later requirements are not met. There are no **fixed submission windows** for medical aids as well, manufacturers may apply at any time and the procedure is also **fee-based**, with fees set in the respective regulations.

Dispensation and Access

Access to wound care products

Outpatient sector:
Community pharmacies are the main dispensing point for wound care products in general (dressings and 'other wound treatment products'). Material can be purchased as self-payment or be prescribed on Muster 16 recipe forms. Pharmacies use the usual pharmacy pricing system (Lauer-Taxe). If material was prescribed on Muster 16, the patient pays only the SHI co-payment, if applicable.

Medical supply stores (Homecare providers) are the primary channel for medical aids (e.g. compression stockings/systems) and work under contracts with SHI funds. They handle measurement, fitting, training and follow-up and sometimes also supply dressings and wound care products as part of integrated homecare contracts.

For patients with chronic or complex wounds, SHI funds often contract homecare providers who deliver dressings, compression materials and devices directly to patients and coordinate with the treating physician and community nursing services providing the actual wound treatment.

Inpatient sector:
In **hospitals**, wound dressings, irrigation solutions, NPWT materials and most devices are supplied via the **hospital's internal pharmacy or logistics.** Patients do **not** receive individual prescriptions for in-hospital use as everything is covered by the **aG-DRG case payment.**

At **discharge**, physicians may issue prescriptions for continued outpatient wound care within a limited amount and time-frame. From then on, dispensation follows the outpatient rules and logistics (pharmacy, medical supply stores and homecare).

Role of Pharmacists and Suppliers

Pharmacists:
- Check formal prescription validity (product, pack size, dosage, indication wording if needed).
- May substitute within the same reimbursement category if allowed (e.g. contracted products, discount contracts), but must ensure medical equivalence.
- Provide basic counselling on use, storage and combination with other products.

Medical supply stores /
Homecare providers:
- Have an important role in **practical implementation** of wound therapy and compression: measurement, fitting, patient education, sometimes documentation for SHI.
- Often act as an **interface** between physician and community nursing services, helping to ensure that **prescribed products match reimbursable items** under existing contracts.
- For medical aids, they are usually responsible for **applying SHI framework agreements**, including any prior approval and renewal routines.

Access Considerations

In urban areas, access to dressings via pharmacies and medical supply stores is generally good, while in rural regions, access can depend more on homecare providers and delivery services, especially for patients with mobility limitations.

However, the **main access barriers** are usually not availability, but **reimbursement status** (e.g. products not (yet) listed in Annex V or the Medical Aids Directory), **fund-specific contracts** (preferred suppliers, required product lines) and the **need for formal prescriptions** by SHI-contract physicians.

Patient Co-payments and Exemptions

Standard Co-payment Rules (SHI)

At the **outpatient level** the statutory co-payment applies for all SHI-covered products prescribed, which is 10 % of the reimbursed price with a minimum of 5 € and maximum 10 € per prescription item, however never more than the actual price.

For medical aids (e.g. compression) co-payment typically comprises 10 % of the price, with a maximum of 10 € per item, for consumable medical aids, 10 % per pack, with a maximum of 10 € per monthly requirement.

This covers standard and advanced dressings, 'other wound treatment products' listed in Annex V or still covered under the transitional rule as well as medical aids (e.g. compression systems).

At the **Inpatient level** no product-specific co-payments exist.

Exemptions

Patients can be fully exempt from co-payments if they reach the annual burden limit which is 2 % of the gross household income or 1 % for those with certified chronic disease status. An additional full exemption exists for children and adolescents under the age of 18 (no co-payment for prescription items except dental services).

Once the threshold is reached (documentation via receipts or SHI confirmation), all further co-payments within that calendar year are waived.
To qualify for the reduced 1 % co-payment limit, the patient must have:

- A chronic condition requiring continuous medical treatment for at least 1 year, and
- Physician certification that regular treatment adherence reduces risk of progression (e.g., diabetic foot, severe CVI, PAD, chronic ulcer).

Patients with chronic wounds often meet this criterion if underlying pathology (e.g. diabetes with neuropathy, CVI stage C6, PAD Fontaine III/IV) is documented. For chronically ill wound patients, most reach their 1 % threshold relatively early, **after which supplies become co-payment free,** substantially reducing the financial burden.

Home and Community Care Services

Availability of Home / Community Wound Care

Home/Community nursing services (based on HKP / SGB V § 37) can be prescribed when wound care cannot be performed independently by the patient. This includes dressing changes, monitoring, compression application, documentation and coordination with physicians.

Outpatient specialist wound clinics (wound centres) are often interdisciplinary (dermatology, surgery, diabetology, vascular medicine) centres providing assessment, plan development, debridement, NPWT follow-up, and escalation triage.

Homecare supplier networks provide logistics (delivery of dressings, NPWT materials, compression) and interface with SHI fund requirements.

Reimbursement of Home and Community Wound Care

Reimbursement for treatment and wound care (as performed by physicians and nursing services) and for product supply need to be distinct. Nursing care and product reimbursement are separate. A wound nurse may **apply** dressings but **cannot prescribe** them. Prescriptions for products (using Form/Muster 16) as well as services under the

Comparison of reimbursement components:

Component	Legal basis	Reimbursed by	Notes
Nursing service performing wound care	SGB V, § 37 HKP	SHI	Must be prescribed by physician; frequency & duration specified
Dressings & wound care products	AM-RL - Annex V	SHI	Via pharmacy/homecare suppliers; co-payment rules apply
Compression systems	Medical Aids Directory	SHI	Co-payment applies unless exempt
NPWT outpatient use	G-BA methods decision	SHI	Professional qualification and documentation required

HKP (using Form/Muster 12) can only be issued by a physician.

A HKP service prescription (Form/Muster 12) issued by a physician covers:

- Dressing change frequency and recommended products
- Specific measures (e.g. compression application)
- Duration (initial period usually 2-4 weeks, with extension if medically justified)

The SHI fund then checks plausibility and may request clarification but generally does not limit wound-care frequency if clinically justified. A hospital physician can issue a HKP service prescription for transition into the outpatient sector, however limited for a duration of 7 days post-discharge. After that period, if necessary, a prescription extension needs to be issued by a SHI-certified physician in the outpatient sector to continue reimbursement. A HKP service prescription only covers the actual care and performance of wound treatment, not the prescription of products or materials, which need to be prescribed separately.

HKP teams must only use products that are prescribable under SHI rules, substitution to cheaper but inappropriate products may breach medical and economic compliance. Homecare suppliers sometimes provide product packages under SHI contracts, but the prescribing physician remains medically responsible.

Limitations & Practical Challenges

Regional availability of specialized wound nurses or specialized nursing services varies and reimbursement amounts remain at a sub-optimal level, leaving an inadequate remuneration for performed or necessary care services. Especially, rural areas often depend more on homecare delivery partners. The inadequate remuneration for actual wound care and time spent with patients, combined with poorly controlled reimbursement for prescribed wound care products, promotes an imbalance that places the focus on refinancing through high and expensive product expenditure rather than on medical care and adequate treatment time for patients. This situation has encouraged the emergence of profit-oriented care structures based on the profit margin of products sold/prescribed.

Additionally, there is a fragmentation risk based on the partially isolated sectors which act as separated silos (physician, hospital , nursing service, homecare supplier, pharmacy) with often poor intersectoral communication at the expense of the patient passing through the system. Adequate treatment and care continuity depends largely on

good regional and local coordination.

Lastly, product coverage changes (especially after the transitional period ending December 2025) may impact home- and outpatient-care workflows, as products that are no longer reimbursable cannot be prescribed and delivered.

Product Approval and Quality Control

Regulatory Approval (Market Access)
Before reimbursement is even considered, wound care products must be **legally placed on the market in the EU/Germany.**

Medical devices (most dressings, 'other wound treatment products', NPWT systems, compression systems) require **CE-marking** under the **EU Medical Device Regulation** (MDR, Regulation (EU) 2017/745) and must demonstrate **safety, performance and clinical benefit** through a conformity assessment (involving a **Notified Body**) and post-market surveillance.

Medicinal products (e.g. some antiseptic solutions) require **marketing authorisation** from either the **Federal Institute for Drugs and Medical Devices (BfArM), Paul-Ehrlich-Institut (PEI),** or via **EMA procedures.**

Only once regulatory approval / CE-marking is in place can a product enter reimbursement processes in Germany.

Reimbursement Eligibility
Details about the Reimbursement Application Process are outlined in **Chapter 5** including responsible authorities, eligibility criteria and process.

Ongoing Quality Control and Monitoring
- **Post-market surveillance** (manufacturer obligation under MDR)
  - Continuous collection of safety and performance data, periodic safety update reports.
- **Vigilance systems**
  - Reporting of serious incidents to authorities; possible f**ield safety corrective actions** or product withdrawal.
- **G-BA / GKV reviews**
  - Re-assessment is possible if new evidence emerges (e.g. safety concerns, lack of benefit).
  - Products can be **removed from Annex V** or **reclassified**, and medical aids entries may be amended or revoked.
- **SHI economic audits**
  - Use of expensive products can be scrutinised, indirectly shaping **practice patterns** and favouring guideline-conform, evidence-based products.

Summary

Germany operates a **statutory health insurance (SHI) mode**l with nationwide reimbursement rules for wound care. Coverage is centralised through G-BA (AM-RL) and the **National Association of Statutory Health Insurance Funds** (Medical Aids Directory), ensuring uniform access but subject to strict definitions and cost-effectiveness requirements.

Product reimbursement framework:
- **Dressings** (basic and many advanced) are **immediately reimbursable** once they fit the legal definition, **no listing process** required.
- Dressings or wound-treatment agents that exceed passive dressing functions are classified as **'other wound treatment products'** and require **G-BA benefit assessment and Annex V listing** for long-term reimbursement.
- **Transitional clause for 'other wound treatment products' remains valid until 02. December 2025,** after which unlisted products may lose SHI coverage if not included in Annex V.
- **Compression therapy (PG17)** and certain devices (e.g., parts of NPWT) are reimbursed via the **Medical Aids Directory.**

Care delivery structure:

- Wound care is delivered across **outpatient practices, specialised wound centers, homecare providers and community nurses**, with **inpatient treatment bundled into DRG tariffs.**
- **Home nursing care (HKP)** is widely used for chronic wound management and is separately reimbursed, distinct from product reimbursement.
- NPWT is fully integrated into SHI after a **G-BA methods decision**, including outpatient use with qualification and documentation requirements.

Dispensation and access:

- Products are dispensed through **pharmacies, medical supply stores** or **homecare logistics** depending on classification.
- Access is generally good but can be affected by **SHI selective contracts**, preferred suppliers, regional variability in home-care availability and product transitions under Annex V.

Co-payments and financial protection:

- Standard SHI co-payment: **10 %, min. 5 € / max. 10 €** per prescription item/product.
- **Chronic patients** often qualify for the **1 % hardship exemption threshold**, significantly reducing out-of-pocket burden.
- No product co-payments during hospitalization (covered by DRG).

Quality and regulatory oversight:

- CE-marking under **MDR** is obligatory but insufficient for SHI reimbursement.
- SHI coverage requires **evidence-based therapeutic benefit and economic justification.**
- Ongoing monitoring and potential **delisting** help control cost and maintain quality standards.

System strengths and opportunities:

- Clear national infrastructure with **uniform rules** across federal states.
- High availability of **advanced dressings and NPWT** under SHI in inpatient as well as outpatient care, nationally and regional.
- Strong **guideline frameworks** (S3 guidelines, medical professional associations guidelines such as ICW e.V.) provide a basis to align reimbursement with evidence-based care.
- Growing use of **digital documentation** offers potential for better continuity, especially across sectors and in rural regions.

System challenges:

- **Annex V transition in reimbursement** represents the largest upcoming shift, potentially affecting reimbursement of longstanding antiseptic agents and some specialty dressings creating uncertainty.
- Future reimbursement eligibility processes in Germany may be comparably complex, lengthy and still unclear regarding the specific design which could **limit innovation capabilities and options** in the wound care product sector.
- Fragmentation risks at the **intersectoral interfaces.**
- Contracting mechanisms can create **regional variability in product choice** despite national eligibility rules.
- Low remuneration for skilled wound care and time, contrasted with easier product-based refinancing, encourages a **reimbursement imbalance between care giving and product reimbursement** supporting profit-driven supply models undermining access to qualified wound nursing, especially in rural areas.

Overall conclusion

Germany currently offers broad and robust reimbursement for wound care products, but the system is entering a **critical consolidation phase** with the full implementation of **Annex V listing requirements.** Efficient navigation of classification routes, benefit proof, and documentation will determine future market access, especially for antiseptics, irrigation solutions and high-innovation wound technologies. The system remains highly structured, quality-controlled and guideline-driven,

positioning Germany as a mature but increasingly selective wound care reimbursement landscape.

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Contributing expert:

Dr. med. Julian-Dario Rembe, PhD
Department for Vascular and Endovascular Surgery, University Hospital Düsseldorf (UKD)
Heinrich-Heine-University Düsseldorf (HHU).

Executive Board Member German Professional Medical Association ‘Initiative Chronische Wunden e.V

6. Greece

In Greece, reimbursement for wound care products is managed through the National Organization for Health Care Services (EOPYY), which is responsible for providing healthcare coverage to the population. EOPYY is the country's largest public health provider, offering health services to over 95% of the population. Here's an overview of how the reimbursement process works for wound care products in Greece:

Health insurance system overview

Public health system: Greece has a public health system where nearly all residents are covered by national health insurance, primarily managed by EOPPY.

Funding: The system is funded through contributions from employers, employees, the self-employed, and the government.

Prescription requirement

Healthcare professionals: Wound care products can only be prescribed by licensed medical doctors with specific medical specialties. The physicians entitled to prescribe wound care products include:

- General Surgeons
- Vascular Surgeons
- Plastic Surgeons
- Radiation Therapists for actinic dermatitis lesions
- Pathologists-Diabetologists for diabetic foot
- Orthopedists for chronic pressure ulcers resulting from orthopedic injury
- General Practitioners for repeat prescriptions and continuation of treatment
- Dermatologists and pediatricians for epidermolysis.

The prescription should specify:
- The type of wound.
- The required treatment.
- The specific products needed.

Prescription validity:
- Typically, valid for 1 month.
- May be valid for up to 2 months in cases where the patient suffers from certain chronic diseases.

Wounds or ulcers are categorized by EOPYY into 7 categories:
- Category I: Partial-thickness ulcers without clinical signs of infection.
- Category II: Partial-thickness ulcers with clinical signs of infection.
- Category III: Full-thickness ulcers without clinical signs of infection.
- Category IV: Full-thickness ulcers with clinical signs of infection.
- Category V: Partial-thickness burns.
- Category VI: Full-thickness burns.
- Category VII: Epidermolysis.

Reimbursement rates

Reimbursement rates for advanced wound care products in Greece depend on the type of wound and the classification of the product.

Partial thickness wounds:
- Reimbursement typically covers 10 wound dressings per month.
- Maximum reimbursement amount: 200 euros.

Full thickness wounds:
- Reimbursement typically covers:
  - 30 secondary wound dressings per month.
  - 20 primary wound dressings per month.
- Maximum reimbursement amount: 400 euros.

Basic wound care products

Full reimbursement:
- Basic wound care products, such as standard dressings, bandages, and gauze, are generally not reimbursed.

Exceptions:
- Reimbursement is possible for specific medical conditions, such as peritoneal dialysis.
- Products must be prescribed by a physician to qualify for reimbursement.

Co-payment: Patients typically need to pay for these basic items.

Advanced wound care products

Reimbursement types: Advanced wound care products are either fully or partially reimbursed. Product categories: Includes hydrocolloid dressings, alginate dressings, foam dressings, and antimicrobial dressings. Categorized into 23 groups (Y.1 to Y.23). Examples:

- Adhesive foam dressing: Y.1
- Non-adhesive foam dressing: Y.2
- Hydrocolloid dressing: Y.9
- Others follow the same categorization.

Prescription requirements: Products must be prescribed by physicians authorized to prescribe wound care products.

Eligible diagnostic codes:
- Reimbursement is valid only for 33 ICD10 diagnostic codes that justify wound creation.
- Diagnostic codes are specified in decisions by the Board of Directors of the EOPPY.

Reimbursement levels:
- Dressing fully reimbursed (100%) for chronic diseases classified as medical conditions.
- Dressings are partially reimbursed (90% or 75%) for beneficiaries with other specified diseases.

System integration: Reimbursement details and decisions are incorporated into the electronic consultation system.

Co-payment requirement:
- Patients may be required to pay a portion of the cost for advanced wound care products.
- Co-payment amounts are typically 10% or 25% of the product's cost.
- Applies to patients with conditions not classified as chronic diseases.
- Based on specific decisions made by the EOPPY Board.

Reimbursement codes: Advanced wound care products must have specific reimbursement codes assigned by EOPYY to qualify for full or partial reimbursement. These codes are listed in EOPPY's electronic Register of Reimbursed Products.

Approved product list

EOPYY List:
- EOPYY maintains a list of reimbursable medical products, including wound care items.
- The list is regularly updated to include new products and remove outdated products.
- Accessible in electronic form.
- The list is known as the Register of Reimbursed Products of the Hellenic Health Insurance Fund.

Eligibility: Only products included in the approved list are eligible for reimbursement. Reimbursement is not provided for:

- Wound care products used for medical conditions not listed in the relevant Annex.
- Products not included in the Register of Reimbursed Products of the Hellenic Health Insurance Fund.

Provider dispensation

Process: Patients obtain their prescribed wound care products from providers contracted with EOPYY. The providers process the reimbursement based on the product's classification and reimbursement rate.

Provider's Role: Providers ensure that patients receive the correct products and offer guidance on their proper use.

Patient co-payments

Standard co-payments: Co-payments for advanced wound care products are mandatory and depend on the specific product and its cost.

Reduced costs:
- Fully reimbursed (100%) for medical conditions classified as chronic diseases.
- Partially reimbursed (90% or 75%) for beneficiaries with other diseases.
- Reimbursement levels are specified by a decision of the EOPPY Board of Directors.

Supplementary health insurance

Additional coverage: Many individuals opt for supplementary health insurance to cover additional costs not included in the public system.

Benefits: Supplementary insurance may cover the co-payment required for advanced wound care products, reducing the financial burden on patients.

Home care services

Chronic and long-term care: For patients with chronic wounds or those requiring long-term wound management, home care services are not covered by EOPPY.

Comprehensive coverage: Services, including wound care provided by healthcare professionals, are not covered by the national health insurance system.

Quality control and approval

Regulatory standards: The National Organization for Medicines (EOF) oversees the quality and safety of wound care products available in Greece.

Approval process: Products must meet regulatory standards and undergo approval processes to be eligible for reimbursement.

Annual reimbursement list updates

The list of reimbursable products and their rates is updated annually or twice a year by EOPYY to reflect new medical advancements and cost considerations.

Examples of wound care products and their reimbursement rates

Basic dressings, gauze swabs, and pads:
- Generally not reimbursed.
- Exceptions apply for specific medical conditions, such as peritoneal dialysis.
- Reimbursement is only possible if prescribed by a physician.

Advanced dressings:
- Hydrocolloid dressings reimbursed at 100%, 90%, or 75%.

- Alginate dressings reimbursed at 100%, 90%, or 75%.
- Foam Dressings reimbursed at 100%, 90%, or 75%

Antimicrobial dressings:

- Silver-impregnated dressings reimbursed at 100%, 90%, or 75%.
- Honey dressings reimbursed at 100%, 90%, or 75%.

Negative Pressure Wound Therapy (NPWT) Supplies: These advanced systems and their consumables are not reimbursed in Greece.

Compression therapy:

- Compression bandages are not reimbursed by EOPPY.
- Compression Stockings are not reimbursed by EOPPY.

Debridement agents: Enzyme-based debridements are listed as drugs and follow the rules of drug prescription.

Summary

In Greece, reimbursement for wound care products is managed by EOPYY under the national health insurance system. Basic wound care products are not reimbursed. Advanced wound care products are fully reimbursed (100%) for medical conditions classified as chronic diseases, or partially reimbursed (90% or 75%) for beneficiaries suffering from other diseases according to the decisions of EOPYY. The process involves prescriptions, provider dispensation, and an approved list of products maintained by EOPYY. Supplementary private health insurance may help cover additional costs. For the most accurate and up-to-date information, patients and healthcare providers should consult EOPYY directly.

References

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The information provided about Greece was collected by the Hellenic Society of Wound Healing and Chronic Ulcers,

Ελληνική Εταιρεία Επούλωσης Τραυμάτων και Ελκών
www.hswh.gr

Author:
Georgios Vasilopoulos, Associate Professor in Surgical Nursing and Wound Management, Department of Nursing, University of West Attica, Greece

Contributors:
Ourania Castana MD, PhD, Plastic Surgeon, Director of the Center for Prevention and Treatment of Melanoma at Athens Euroclinic, Greece

Maria Charcharidou, RN, MSc, PhD. Head of Nursing Sector, General State Hospital of Athens "G.Gennimatas", Greece

Evangelos Dimakakos MD, PhD, Angiologist, Lemphologist, Assistant Professor in Human Anatomy-Physiology, Department of Nursing, University of West Attica, Greece

Ioannis Kalemikerakis, Associate Professor in Community Nursing with emphasis on the Prevention and Care of Chronic Ulcers, Department of Nursing, University of West Attica, Greece

Georgia Koulermou, MD, PhD, Plastic Surgeon, Professor of Plastic Surgery (Hon) at the University of Nicosia Medical School, Cyprus

Emmanuel Papadopoulos, Associate Professor in Physiotherapy, Frederick University of Cyprus, Cyprus.

Varvara Zacharioudaki, RN, MSc. Public Eye Hospital of Athens, Greece

7. Hungary

In Hungary, the reimbursement for wound care products is managed by the National Health Insurance Fund (NEAK). The system aims to provide access to necessary medical supplies while maintaining cost-effectiveness. Below is an overview of how the reimbursement process works for wound care products in Hungary:

Health insurance system overview

Public health insurance: All residents in Hungary are covered by the national health insurance system, managed by NEAK.

Funding: The system is funded through contributions from employers, employees, and the government.

Prescription requirement

Healthcare professional: Wound care products must be prescribed by a licensed healthcare professional, such as a doctor.

Prescription details: The prescription must include specific information about the type of wound, the treatment required, and the exact products needed

Duration:

- Prescriptions for wound care can cover treatment for up to four months.
- If the treatment exceeds four months the doctor may continue the treatment.
- Requires the countersignature of the chief medical examiner of the National Health Insurance Fund (NEAK).

Reimbursement rates

- Reimbursement rates are set at 80% of the cost of the cheapest dressing in each group.
- The amount of support can thus be 80% or FIX.

Basic wound care products

Partial reimbursement: Basic wound care products, such as standard dressings, bandages, and gauze, are typically partially reimbursed (80% or FIX) when prescribed by a healthcare professional.

Co-payment requirement:

- Patients are required to pay a portion of the cost for these basic items.
- The co-payment varies but is usually 20% of the product's cost.

Advanced wound care products

Partial reimbursement: Advanced wound care products, including hydrocolloid dressings, alginate dressings, foam dressings, and antimicrobial dressings, are typically partially reimbursed (80% or FIX) when prescribed by a healthcare professional.

Co-payment requirement:

- Patients are required to pay a portion of the cost for advanced products.
- The co-payment varies but is typically 20% of the product's cost.

Reimbursement codes: Advanced wound care products must have specific reimbursement

codes assigned by NEAK to qualify for partial reimbursement.

Approved product list

NEAK list: NEAK maintains a list of reimbursable medical products, including wound care items. This list is regularly reviewed and updated to include new products and remove outdated ones.

Eligibility: Only products included in this approved list are eligible for reimbursement.
Pharmacy or medical devices shop dispensation

Process:
- Patients can obtain prescribed wound care products from pharmacies or medical devices shops contracted with NEAK.
- Pharmacists or shop assistants process the reimbursement claims based on the product's classification and applicable reimbursement rate.

Pharmacist role: Pharmacists or medical devices shop assistants ensure correct dispensation and guide the proper use of the products.

Patient co-payments

Standard co-payments:
- Both for basic and advanced wound care products co-payments are mandatory.
- The exact amount depends on the product's classification and cost.

Reduced costs:
- Vulnerable groups such as low-income individuals, those with chronic conditions and people with disabilities may be eligible for reduced co-payments or exemptions.
- These are evaluated on a case-by-case basis by NEAK.

Supplementary health insurance

Additional coverage: Many individuals choose supplementary health insurance to cover costs not included in the public healthcare system.

Benefits: Supplementary insurance can help cover co-payments for advanced wound care products, reducing the financial burden on patients.

Home care services

Chronic and long-term care: Home care services may be available for patients with chronic wounds or those requiring long-term wound management.

Comprehensive coverage:
- Provided by healthcare professionals
- Covered by the national health insurance system
- Varying reimbursement rates depending on the patient's condition and insurance plan.

Quality control and approval

Regulatory oversight: The National Institute of Pharmacy and Nutrition (OGYÉI) oversees the quality and safety of wound care products available in Hungary.

Approval process: Products must meet regulatory standards and undergo approval processes to be eligible for reimbursement.

Reimbursement Application Process for Manufacturers

The system of support for dressings and wound care materials by the National Health Insurance is currently transparent and well-organized. In case of acceptance of a new product, the distributor must submit an application, professional opinions, the product itself, and pay the procedure fee.

During the assessment process, cost-effectiveness and medical-professional aspects are taken into account, and the duration is 2-3 months. The decision is made by the professional managers and medical experts of the National Health Insurance.

An application to establish a new category takes longer than this, and only in strongly justified cases is a positive support granted after careful consideration. The support list is renewed and published monthly. The support system operates at the national level.

Annual updates

NEAK regularly updates the list of reimbursable products and their reimbursement rates to account for new medical advancements and cost considerations.

The information provided on Hungary is collected by the Hungarian Wound Care Society, www.etalon95.hu

8. Ireland

Health System Overview

Ireland has a mixed public-private healthcare system. The public system, managed by the Health Service Executive (HSE), provides services funded through taxation, with some services offered free or subsidized based on eligibility.

The private sector offers options for those who prefer or need to pay for private health insurance or directly for service.

Brief description of the national healthcare system

The public healthcare system is managed by the Health Service Executive (HSE), which is funded through general taxation. It provides a wide range of services, including hospital care, GP services, and community health services (either free of charge or at a subsidised rate, depending on eligibility criteria such as income, age, or medical need). Ireland's private healthcare sector enables individuals to opt for private health insurance to access private hospitals and clinics.

Funding model (public, private, insurance-based, etc.).

To qualify for a medical card, your weekly income must be below a certain figure for your family size. Cash income, savings, investments and property (except for your own home) are taken into account in the means test. If your income is above the limit, you may still be able to get a medical card if your circumstances would result in financial hardship without one. This is sometimes called a discretionary medical card.

Role of national/regional authorities in healthcare delivery and reimbursement

The Department of Health have responsibility for the planning of health services. Overview of this Government Department. Public health services are provided by the Health Service Executive (HSE)

Reimbursement Pathway for Wound Care Products

This section has been divided in community based and hospital based as they differ in what services are available.

How wound care products are reimbursed: national fund, regional systems, insurance, etc.

Community

- General Medical services (GMS) holders living at home are entitled to all their dressing, bandages and basic wound care products (products listed on the HSE national wound care contract) from the public health nursing service
- GMS holders living in a private nursing home are entitled to their dressing and bandages through discretionary hardship arrangements. The nursing home and community pharmacist complete the form and submit it to the Local Health Authority HSE for authorization. Once authorized the pharmacist will be able to provide that dressing or bandage for 6 months. Basic wound care products such as gauze, conforming or tubular bandages are not included.
- Non-GMS holders are entitled to their dressing, bandages and basic wound care products through the Drugs Payment Scheme Cards (must be products listed by Primary Care Reimbursement Scheme). A prescription is required for these, they are dispensed by the pharmacist. With a minimal payment of a capped fee.

Hospital
Public: While you are an inpatient all dressing requirements are provided.

Private: Is at the discretion degression of the local agreements in the hospital. However, in most private hospitals you are billed for each product required.

Who is eligible for reimbursement (insured persons, certain patient groups, etc.)?
To qualify for a medical card, your weekly income must be below a certain figure for your family size. Cash income, savings, investments and property (except for your own home) are taken into account in the means test.

Anyone who does not meet the criteria for a GMS card is entitled to a Drug payment scheme (DPS) card. The dispensary fees are capped, each year depending on the yearly budget set by the government.

Prescription and Authorization Requirements

Who can prescribe wound care products?

- Most wound management products are not classified as prescription only medications and therefore do not require prescribing.
- Prescriptions for wound care products are only needed for reimbursement. If a prescription is needed a medical doctor, nurse prescriber or dentist can write the prescription.

Is prior approval required?

- Only for GMS holders living in private nursing homes

Are there any restrictions on prescriptions (e.g., duration, product types)?

- For GMS holders living in nursing homes.
- Local arrangements depending on the skill set of the practitioner and the clinical need of the patient. For example, advanced wound management therapies e.g., topical Negative dressings and larval therapy

Reimbursement Application Process for Manufacturers

What is the procedure for a company to have a wound care product included on the national or regional reimbursement list?

For the Primary Care Reimbursement Scheme (PCRS): PCRS list companies apply to the PCRS. There are set criteria that the products must meet. The expert panel meets twice a year to review all new applications, if the product meets the requirements and the price is agreed the product is listed on the PCRS list.

The HSE national contract is a National Multi-Supplier Direct Drawdown Framework appointing qualified and competent companies to supply Wound Management Products to the HSE across 188 sub-lots. This National Drawdown Framework ensures that service users have access to the same wound care products both in acute hospitals and in the community to ensure continuity of care. This National Drawdown Framework provides uniformity of products and service provision, standard 'fair' price for acute and community, transparency to services required and contract compliance. The scope of the contract is for the supply of Wound Management Products which includes all Bandages, Tapes, Dressings and Anti Embolic Stockings to the HSE.

Private hospitals are independent of the national system.

Which authority or agency is responsible for evaluating and approving products for reimbursement?

PCRS and expert panel (consists of wound care experts) evaluate and approve the products.

HSE Procurement are represented on the expert panel and they assist in the evaluation and approval of the products.

Private hospitals are independent of the national system.

What documentation or clinical evidence is required?

Published in e-tender

Are there any timelines, fees, or submission windows to consider?

There are no specific time lines, the details are published in e tender.

Are decisions made at national or regional level?

National level, but locally formulary can be produced based on the national lists.

Dispensation and Access

- **Where can patients obtain wound care products (e.g., pharmacies, hospitals, medical supply shops)?**

Patients living at home with GMS obtain their wound care products from their public health nursing team

GMS patients living in private nursing homes obtain their dressing from the pharmacy

Drugs payments scheme patient obtain their dressing from the pharmacy

Hospital - at point of care.

Role of pharmacists or suppliers;

- To supply and dispense the dressings.

Patient Co-payments and Exemptions

What out-of-pocket costs do patients face?

Non-GMS patients pay a capped fee per family per month, this covers all prescribed drugs for the household too.

Are there exemptions for specific groups (e.g., low-income, chronic illness)?

Low-income families would be eligible for the GMS card.

Certain long-term illnesses are covered under a long-term Illness card; however, this only gives them access to products directly related to their illness.

Are there maximum co-payment limits?

Non-GMS patients face a maximum capped payment per family per month, this covers all prescribed drugs for the household too.

Home and Community Care Services

Availability and coverage of wound care in home or community settings

All dressing and bandages listed on the national wound care and dressing contract is available to all GMS patients through the public health nursing team to patient living in the community setting.

Reimbursement for products used in these contexts

These products are provided by the HSE to all GMS patients

Patients who are non-GMS patients are at the desecration of the available services and patient's needs.

Product Approval and Quality Control

Regulatory bodies involved in product approval

The HPRA-Health products regulations authority.

Requirements for a product to be eligible for reimbursement

Be listed on the HSE Primary Care Reimbursement Service (PCRS) Non-Drug Reimbursement List.

There are national programmes, guidelines, and initiatives within the Health Service Executive that provide the **clinical framework and strategic support** underpinning how wound care and indirectly wound care product use and reimbursement is standardised and governed nationwide. ".

Summary

The Irish health system is a mixture of public and private and wound care is not free at the point of care. In certain circumstances the provision of wound care is provided although this is based on a means test. Different services and interventions are provided based on the geographical region and the type of care required which is difficult for patients, their family and healthcare staff to navigate. To support the provision of up-to-date wound care, the Irish health service (HSE) provides health care staff with evidence-based guidelines which are applicable across all health care settings. In addition to the means-tested free wound care (GMS), citizens are able to access wound care products and services via one of a number of schemes where they are eligible e.g., PCRS, DPS, LTI. In overall summary there are a number of challenges with the provision of wound care which can be confusing for patients and health care staff to understand.
Health care services in Ireland can be challenging to navigate due to the complexity of the different systems, public, private and insurance based:

- There are challenges around the provision of wound management between primary and secondary care which can be difficult to understand in relation to both products and services
- The different schemes, PCRS, Model of Care, can be difficult to interpret for the non-specialist although they reduce the cost on individuals
- While there is no national wound care programme there are guidelines provided on wound care which were developed via a combination of best evidence and clinical expertise
- The provision of products is supplied based on a combination of cost and clinical need which is positive as this allows for patients to receive products based more than price alone

The information provided on Ireland is collected by HSE, www.hse.ie;
University of Galway, College of Nursing, Medicine and Health Sciences, www.universityofgalway.ie/medicine-nursing-and-health-sciences;
and RCSI University of Medicine and Health Sciences, Faculty of Nursing & Midwifery, www.rcsi.com/dublin/About/faculty-of-medicine-and-health-sciences/school-of-nursing-and-midwifery

Authors:
Niamh McLain, Healthcare Executive (HSE)

Pauline Wilson, University of Galway, College of Nursing, Medicine and Health Sciences

Helen Strapp, RCSI University of Medicine and Health Sciences, Faculty of Nursing & Midwifery, President of the Wound Management Association of Ireland.

9. Italy

In Italy, the reimbursement for wound care products is managed through the national health system (Servizio Sanitario Nazionale, SSN). The SSN operates under a regional organizational framework, which creates differences in access and reimbursement between patients and regions. Below are the key aspects of the process:

National health system (SSN)

- The SSN provides comprehensive healthcare coverage, including wound care products, to all residents.
- Healthcare services are funded through taxation, ensuring that essential medical treatments and products are accessible to everyone.

Prescription pathway and requirement

Prescription pathways:

- Basic wound care products (e.g., gauze, plasters, iodopovidone, and liquid antiseptics in selected cases) can be prescribed directly by a general practitioner (GP).
- Advanced or more complex wound care products require a specialist's prescription and an assessment of the patient's degree of dependency or disability.

Prescription details: The prescription must specify:

- Type of wound,
- Required treatment
- Specific products needed
- Duration for which they are to be used.

Regional differences: Only certain regions, such as Piedmont, Sicily, and Trentino, provide reimbursement for wound care products. In other regions, PDTA (diagnostic and therapeutic care pathways)—if present—guide the process of requesting materials. This creates a confusing and inconsistent situation across the country.

Approved product list

Reimbursable products: A list of reimbursable medical products is derived from Annex 2 of the Essential Levels of Assistance (LEA) law. This list is based on literature evaluations and is reserved for individuals with disabilities.

Regional evaluation:

- The evaluation of dressing products falls under the responsibility of the regional health system through a "regional tender" process.
- The evaluation assigns for example 40% of the points to quality and for example 60% to price.
- These regional tenders are designed to supply dressing materials for use by doctors and nurses, not directly for patients.

Reimbursement rates

Delivery variations: The mode of delivery for wound care products varies depending on the region and the specific product.

Coverage: Essential wound care products are generally fully covered by the SSN, but the modalities create a complex and inconsistent system:

- NHS and Annex 2 of the LEA: Basic and advanced dressings are covered by the NHS under Annex 2 of the Essential Levels of Assistance (LEA) law, but only for individuals with disabilities. The issue is that this law is not uniformly applied across all regions of Italy. The application of the law is expected to take effect across the entire national territory starting in April 2025.
- **Regional reimbursement:** In regions with reimbursement systems, different types of dressings are available depending on regional policies.
- **Regional tenders:** The types of dressings are determined through regional tenders, which allocate materials primarily for use by healthcare professionals. As a result, patients can access these materials in hospitals, health system outpatient clinics, or if the patient is assigned to home care, but not directly for personal use.

Regional healthcare autonomy

Decentralized system: Italy's healthcare system is decentralized, granting regions significant autonomy in managing healthcare services and budgets.

Regional differences: This decentralization leads to variations in the availability and reimbursement of wound care products, with some regions providing more comprehensive coverage than others.

Pharmacy dispensation

Regional reimbursement: Wound care products are typically dispensed through pharmacies, but only in regions where reimbursement is provided.

Patient expenses: In most regions, patients must cover the full cost of wound care products themselves.

Pharmacist's role: Pharmacists can offer advice on the proper use of wound care products and ensure that patients receive the necessary care.

Patient co-payments

Not Applicable in Italy.

Exemptions and reduced costs

Long-term illnesses: Patients with long-term illnesses (esenzioni per patologia) are eligible for full coverage of necessary wound care products if they meet the criteria outlined in the LEA and live in regions where the law is applied.

Home care services

Chronic wounds and long-term care: Available for patients with chronic wounds or those requiring long-term wound management, ensuring that they receive appropriate wound care at home.

Coverage: Home care services and the associated wound care products are typically covered by the SSN, alleviating the financial burden on patients.

Quality control and approval

Product list definition: The NHS defines a list of approved products; however, the application and updates are delegated to regional and control organizations.

Quality and control: The quality and control of dressing and devices is not overseen by AIFA (Italian Medicines Agency). Instead, in regional tenders, product accessibility is determined based on local protocols, with for example 40% of the evaluation focused on quality and 60% on price.

Specialized programs

Chronic wound management: Some regions offer specialized programs for chronic wound management, providing comprehensive care plans that include regular monitoring, specialized wound care products, and coordinated care.

Program goals: These programs aim to improve patient outcomes and reduce the overall healthcare burden associated with chronic wounds.

Examples of wound care products and their reimbursement rates

Basic dressings - Gauze swabs and pads:

- Basic gauze swabs and pads are typically covered under standard reimbursement rates, which vary but generally cover a significant portion of the cost.
- *Example:* Gauze swabs might be reimbursed at 100% of their cost.

Advanced dressings:

- Hydrocolloid dressings reimbursement is available only to individuals with disabilities in regions that apply the Essential Levels of Assistance (LEA) law.
- Alginate dressings reimbursement is available only to individuals with disabilities in regions that apply the LEA law.
- Foam dressings reimbursement is available only to individuals with disabilities in regions that apply the LEA law.

Antimicrobial dressings:

- Silver-impregnated dressings reimbursement is available only to individuals with disabilities in regions that apply the LEA law.
- Honey dressings reimbursement is not covered by the LEA law.

Negative Pressure Wound Therapy (NPWT) supplies: NPWT Systems reimbursement is available only for use in hospitals or for patients receiving home care.

Compression therapy:

- Compression bandages reimbursement is available only to individuals with disabilities in the few regions that apply the LEA law.
- Compression stockings reimbursement is available for different classes of compression stockings based on the severity of the condition but is only available in a few regions.

Debridement agents: Enzyme-based debridement is not reimbursed.

Summary

In summary, Italy does not have a national reimbursement system for wound care products managed by the SSN. The system's decentralization allows for regional flexibility in managing healthcare services, but it also results in variability in the availability and reimbursement of wound care products across different regions.

The information provided on Italy is collected by the *Associazione Infermieristica per lo Studio delle Lesioni Cutanee* (AISLeC), www.aislec.it and Associazione Italiana Ulcere Cutanee (AIUC) www.aiuc.it

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10. Lithuania

Health System Overview

- **National Healthcare System:** Lithuania operates a universal healthcare system primarily funded through compulsory health insurance (Compulsory Health Insurance Fund – CHIF (or PSD)). The Ministry of Health oversees national health policy and regulation, while the National Health Insurance Fund (NHIF (or VLK)) manages the financing and reimbursement of healthcare services.
- **Funding Model:** The system is predominantly public, with funding sourced from payroll contributions (6.98% of the minimum monthly wage) and state budget allocations for specific groups such as children, pensioners, and the unemployed
- **Role of Authorities:** The Ministry of Health formulates health policies, while the NHIF administers healthcare financing. Municipalities are responsible for organizing primary and social care services.

Reimbursement Pathway for Wound Care Products

- **Reimbursement Mechanism:** Wound care products are reimbursed through the NHIF, which allocates funds for medical aids, including wound care supplies, as part of the compulsory health insurance scheme.
- **Eligibility:** All insured individuals under the CHIF are eligible for reimbursement of wound care products, provided the items are included in the NHIF's approved list.

Prescription and Authorization Requirements

- **Prescribers:** Wound care products can be prescribed by licensed healthcare professionals, including general practitioners and specialists.
- **Prior Approval:** Generally, prior approval is not required for standard wound care products. However, for advanced or specialized products, prior authorization may be necessary.
- **Prescription Restrictions:** Prescriptions are subject to clinical guidelines and the NHIF's approved product list. Duration and product types are determined based on medical necessity and NHIF policies.

Product Categories and Reimbursement Rates

- **Basic Wound Care Products:** Items such as gauze and bandages are typically reimbursed under the NHIF's medical aids scheme.
- **Advanced Wound Care Products:** Products like foam, alginate, and hydrocolloid dressings may be reimbursed if included in the NHIF's approved list and deemed medically necessary.
- **Specialized Therapies:** Negative Pressure Wound Therapy (NPWT), compression therapy, and antimicrobial dressings are subject to specific reimbursement criteria and require prior authorization.
- **Reimbursement Rates:** The NHIF sets reimbursement rates for each product category. Co-payments may apply, depending on the product.
- **Official Reimbursement List:** The NHIF maintains an approved list of reimbursed medical aids, including wound care products.

Healthcare providers and patients can access this list to determine eligibility.

Reimbursement Application Process for Manufacturers

- Procedure: Manufacturers seeking reimbursement for wound care products must submit an application to the NHIF, including product specifications and clinical evidence supporting efficacy and safety.
- **Evaluating Authority:** The NHIF evaluates applications based on clinical data, cost-effectiveness, and alignment with national health priorities.
- **Documentation Required:** Applications should include clinical studies, regulatory approvals, and evidence of product safety and effectiveness.
- **Timelines and Fees:** Specific timelines and fees for the application process are determined by the NHIF. Manufacturers are advised to consult the NHIF for detailed information.
- **Decision-Making:** Reimbursement decisions are made at the national level by the NHIF.

Dispensation and Access

- **Access Points:** Patients can obtain wound care products through pharmacies, hospitals, and medical supply shops contracted with the NHIF.
- **Role of Pharmacists and Suppliers:** Pharmacists and suppliers are responsible for dispensing approved products and ensuring they meet NHIF standards.

Patient Co-payments and Exemptions

- **Out-of-Pocket Costs:** Patients may be required to make co-payments for certain wound care products, depending on the product's classification.
- **Exemptions:** Specific groups, such as pensioners and individuals with chronic illnesses, may be eligible for exemptions or reduced co-payments.
- **Co-payment Limits:** The NHIF sets maximum co-payment limits to protect patients from excessive out-of-pocket expenses.

Home and Community Care Services

- **Availability:** Wound care services are available in home and community settings, with reimbursement provided for medical aids used in these contexts.
- **Coverage:** The NHIF covers wound care products used in home and community care, subject to the same reimbursement criteria as those used in clinical settings.

Product Approval and Quality Control

- **Regulatory Bodies:** The State Medicines Control Agency of Lithuania is responsible for evaluating and supervising medicines and medical devices, including wound care products.
- **Eligibility for Reimbursement:** Products must be approved by the State Medicines Control Agency and included in the NHIF's approved list to be eligible for reimbursement.

Special Considerations or National Programs

- Chronic Wound Care Programs: The Lithuanian healthcare system includes programs aimed at managing chronic wounds, focusing on prevention, treatment, and rehabilitation

- **Innovations:** The government supports innovations in wound care delivery, including digital health initiatives and pilot projects aimed at improving access and efficiency.

Summary

- **Key Points:** Lithuania's healthcare system provides comprehensive coverage for wound care products through the NHIF, with a focus on accessibility and equity.
- **Challenges:** Challenges include ensuring timely access to advanced wound care products and managing the financial sustainability of the reimbursement system.
- **Opportunities**: Opportunities exist in enhancing digital health infrastructure and expanding access to home and community--based wound care services.

References and Source Acknowledgments

- National Health Insurance Fund (NHIF or VLK): https://ligoniukasa.lrv.lt/en/
- Ministry of Health of the Republic of Lithuania: https://sam.lrv.lt/en/
- State Medicines Control Agency of Lithuania: https://www.vvkt.lt/

The information provided on Lithuania is collected by the Lithuanian Wound Management Association www.lzga.lt

11. Netherlands

Here's an overview of the reimbursement mechanisms in the Netherlands (as of September 2025):

In the Netherlands, reimbursement for wound care products is managed through the national health insurance system. Below are the key aspects of the reimbursement process:

Health insurance coverage

Basic health insurance: All residents in the Netherlands are required to have basic health insurance (basisverzekering), which covers a wide range of healthcare services, including wound care products.

All resident from the age of 18 years are required to pay a deductible when using healthcare services included in the basic package. The deductible amount constitutes a mandatory amount to be paid, after which the health insurer will assume responsibility for covering the costs.

Insurance providers: Health insurance companies (zorgverzekeraars) provide this coverage, which is regulated by the government.

Prescription requirement

Healthcare professional: A healthcare professional, such as a general practitioner (GP), a medical specialist, a nurse specialist (verpleegkundig specialist) or a physician assistant (PA) must issue the authorization for wound care materials. With this authorization wound care nurses can decide which specific materials are ordered.

Prescription details: The prescription must specify:

- Type of wound
- Required treatment
- Specific products needed.

Reimbursement rates

Basic products: Basic wound care products are typically fully covered by health insurance in cases of a complex wound or a high risk thereof, in the presence of severe scarring, or in the case of chronic skin conditions. Topical aids are generally not reimbursed in the absence of evidence demonstrating their effectiveness.

Specialized products: More specialized or advanced products may have partial reimbursement, requiring patients to cover a portion of the cost. NPWT falls under specialist medical care and is considered hospital-substituting care. The health insurer reimburses the costs directly to the hospital.

Approved product list

Assessment by Zorginstituut Nederland: The National Health Care Institute (Zorginstituut Nederland) evaluates the effectiveness and cost- effectiveness of medical treatments and products, including wound care items.

Eligibility for reimbursement: Only products included in the G-Standaard (the standard list of reimbursable medicines and medical aids) are eligible for reimbursement.

Reimbursement Application Process for Manufacturers

The Z-index is an organization responsible for managing the G-Standaard, a Dutch database containing comprehensive information on all healthcare products used within pharmacies and healthcare institutions, including medicinal products and medical devices. The core activities of Z-index include the collection, structuring, integration, verification, and continuous updating of data within the G-Standaard.

Obtaining a Z-index number is a prerequisite for the reimbursement of wound care products.
To have a wound care product listed on Z-index.nl, healthcare providers are required to submit an application to the Dutch Healthcare Authority (NZa) for inclusion of the product in the G-Standaard.

Procedure for obtaining a Z-index number:

1. Verify whether the wound care product is already included in the G-Standaard, which is maintained by Z-index.
2. If the product is not listed, submit an application to the NZa to request its registration.
3. The application process involves completing the online application form and attaching a duly signed declaration form.
4. Upon assessment of the application, the NZa will contact the applicant once the product has been included in the G-Standaard, after which a Z-index number will be assigned.

The reimbursement of wound care products is subject to the policy of individual health insurers and the applicable regulations set forth by the National Health Care Institute (Zorginstituut Nederland).

More information: https://www.z-index.nl/help/GStandaardInvoerloket/handleiding/Quick%20start%20guide%20G-Standaard%20data%20entry%20web%20portal%20v4.1.pdf

Dispensation and Access

Assessment by Zorginstituut Nederland: The National Health Care Institute (Zorginstituut Nederland) evaluates the effectiveness and cost-effectiveness of medical treatments and products, including wound care items.

Eligibility for reimbursement: Only products included in the G-Standaard (the standard list of reimbursable medicines and medical aids) are eligible for reimbursement.

Pharmacy dispensation

Access to products: Wound care products are dispensed through pharmacies. Patients present their prescription at a pharmacy, where the pharmacist provides the necessary items.

Pharmacists' role: Pharmacists play a role in ensuring that patients receive the correct wound care products and can offer advice on their proper use.

Patient co-payments

Coverage limitations: While basic health insurance covers most healthcare costs, patients may still need to make co-payments for certain wound care products.

Co-payment variability: The amount of co-payment varies depending on the insurance policy and the specific product.

Exemptions and reduced costs

Eligibility for exemptions: Certain patient groups may be exempt from co-payments or qualify for reduced costs including:

- Individuals with chronic illnesses
- Low-income individuals

- Those with specific medical conditions.

Full coverage: Patients with long-term illnesses may receive full coverage for necessary wound care products.

Home care services

Chronic and long-term wound management: Home care services are available for patients with chronic wounds or those requiring long-term wound management. These services ensure that patients receive the necessary wound care at home.
Insurance coverage: Home care services and the associated products are typically covered by health insurance to reduce the financial burden on patients.

Quality control and approval:

Assessment by Zorginstituut Nederland: Zorginstituut Nederland evaluates the effectiveness and safety of wound care products before they are included on the reimbursable list.

Eligibility standards: Products must meet stringent quality and safety criteria to be eligible for reimbursement.

Summary

The Netherlands' reimbursement system for wound care products ensures that essential treatments are accessible to all residents through basic health insurance coverage. The system strives to provide equitable access to high-quality wound care products while managing costs effectively.

The information provided on the Netherlands has been collected by *V&VN Wondexpertise* www.venvn.nl/afdelingen/wondexpertise/

12. Norway

Norway has a publicly funded healthcare system, that provides universal healthcare coverage to all residents, including immigrants and refugees.

Prescription requirements

Medical doctor: To be eligible for reimbursement, wound care products must be prescribed by a medical doctor. The doctor must fill out a form according to § 5-22 of the Norwegian Health Care Act.

Prescription details: The doctor needs to:

- Specify the type of wound
- Confirm that the wound has lasted, or is expected to last, more than three months.
- Applications for reimbursement can be submitted, and reimbursement can begin, even before the wound has exceeded the three-month duration, provided it is expected to last longer.

Types of wounds: The following types of wounds are covered:

- Chronic wounds,
- Chronic fistulas, sinuses, epidermolysis bullosa, and other skin conditions with open wounds
- Postoperative wound complications where the treatment is expected to exceed three months.

Wound care products: The doctor does not need to specify which wound care products are to be used for the treatment. It is sufficient to write "wound care products" on the application. This allows for the flexibility often needed in wound care where treatment regimens frequently change over the course of treatment.

Eligibility: To be eligible for reimbursement:

- The patients must either perform the dressing changes themselves or have them done at the general practitioner's office.
- If a homecare provider performs the dressing changes, the municipality must cover the full costs of the wound care materials.
- However, a hybrid solution is possible: if the patient sometimes performs dressing changes alone and, at other times, they are done by a homecare nurse, the patient can still be reimbursed for the materials used when they manage the dressing changes independently.

Approved product list

The Norwegian Health Authority HELFO maintains an updated list of wound care products established through competitive tendering. This list is extensive, including products from all major European suppliers.

Reimbursement rates

Treshold: To be eligible for reimbursement the patient must show expenditures related to wound care products exceeding 190 euros (2024). The amount of 190 euros serves as the patient's co-payment and is not reimbursed. However, after this threshold, the patient is reimbursed for 90% of all subsequent wound care product expenses.

Wound care products: All types of wound care

dressings and ointments are reimbursed by § 5-22. This also includes NPWT dressings.

Compression therapy: Since January 2023 also compression therapy products are reimbursed as wound care products. This includes:

- Compression bandages
- Medical grade compression stockings
- Velcro compression.

To be eligible for reimbursement for compression devices, the patient has to have a chronic ulcer > 3months duration. Like other wound care products, compression devices are reimbursed for one calendar year, and a doctor has to send a new application the following year if the ulcer persists.

Prophylactic compression devices: Compression devices for prophylactic purposes are not reimbursed.

Reimbursement of orthopedic shoes and other orthopedic devices used in wound care

Eligibility: Patients with diabetes, arterial disease, rheumatism, paraplegia, severe malformations, or similar conditions who have existing ulcers or are at high risk of developing ulcers are eligible for reimbursement for these devices.

Hospital doctor: The application for reimbursement must be written by a hospital doctor specializing in orthopedics, vascular surgery, or neurology.

Standard orthopedic shoes: These are covered up to 150 Euros per pair, prices exceeding this limit must be covered by the patient.

Custom-Made Orthopedic Shoes: For custom-made shoes, there is a patient co-payment of approximately 60 euros per pair. Patients are entitled to four pairs of shoes in the first year, and two new pairs each subsequent year.

Additional Pairs: Patients may be reimbursed for additional pairs of shoes if they wear them faster than expected due to an underlying medical condition.

Exemptions and reduced costs

Some groups of patients may be exempt from co-payments or eligible for reduced costs. This includes individuals with chronic illnesses, low-income individuals, and those with specific medical conditions.

Transport costs

- Reimbursement is provided for the cheapest mode of public transport to and from wound care providers
- Transportation by taxi is reimbursed for patients with significantly impaired health conditions.
- Patients who are driving themselves are reimbursed by a standard rate per kilometer.

Wound care in specialist health care (hospitals)

- Patients pay 34 euros per visit to an ambulatory wound clinic. Once the patient has paid a total of 266 euros for ambulatory visits, the patient receives a “free card” and all subsequent visits for the remainder of the year are free of charge.
- Additionally, patients pay 5,5 euros for wound care dressing materials, regardless of the actual costs of the dressings. This includes all NPWT (Negative Pressure Wound Therapy) treatments.
- Public wound care clinics are not permitted to sell wound care dressings to the patients. If the wound care providers need to send extra materials home with the patient, these must be provided free of charge.

Wound care in nursing homes, home care and community care

- Patients are not required to pay for wound care when treated by home care nurses or in these institutions.
- All personnel and product costs are fully covered by the municipality.
- However, this often leads to situations where home care nurses cannot use the same products as recommended by specialist wound clinics, as the municipality may deem these products too expensive.

Wound care at the general practitioner's practice

- Patients pay between 15 and 19 euros per treatment at their general practitioner's (GP) office, depending on whether the GP has a specialty in internal medicine.
- Once the patient has spent a total of 266 euros on GP visits within a calendar year, they automatically receive a "free-card" making all subsequent visits within that year free of charge.
- However, patients must pay the full cost of all wound care dressings used at the GP's office. The prices for these dressings can vary significantly between GP practices.
- This can make it more expensive for a patient to get the wound treated at the GP practice, than at the wound clinic of a public hospital. For instance, advanced wound care treatments like Negative Pressure Wound Therapy (NPWT) are oftenm not feasible at GP offices since patients would need to cover the full costs themselves. As a result, NPWT has not been widely implemented in the primary Norway's health care sector.
- To reduce costs, many patients prefer to purchase reimbursed dressing materials (e.g., from a pharmacy) and bring them to the GP`s office for use during treatment.
- It is important to note that while patients may qualify for reimbursement for wound care products, this does not apply to wound care products purchased directly at the GP`s office.

This information was collected for EWMA by Bodo Günther on behalf of the Norwegian Wound Management Association (NIFS), www.nifs-saar.no

13. Portugal

Health System Overview

Portugal operates a public health service, Serviço Nacional de Saúde (SNS), which provides comprehensive healthcare coverage to its residents. The system is primarily funded by the government, ensuring access to essential medical treatments and products, including wound care supplies.
The healthcare system also incorporates private insurance mechanisms. If private insurance coverage is incomplete, patients maintain the ability to return to the public system. The SNS maintains agreements with the private sector for certain services, such as diagnostic exams, dialysis, and surgeries, especially when the public sector cannot provide these services within the expected time frame.

Reimbursement Pathway for Wound Care Products

Wound care coverage in Portugal is overseen by the SNS and follows a structured process. The use of a wide range of wound care products is covered by the NHS when provided within NHS institutions (hospitals and primary care settings).
Wound care products are generally not reimbursed in outpatient settings (e.g., community pharmacies), except for ostomy products, which are reimbursed at 100% of the price.

Prescription and Authorization Requirements

Wound care products must be prescribed by a healthcare professional, such as a doctor. While nurses typically possess the autonomy to select wound care products based on the patient's condition and wound assessment, nurse prescribing is not yet regulated in Portugal.

The prescription must include detailed information regarding the wound type, size, location, the specific products required for treatment, and the frequency of dressing changes. There are no national criteria in Portugal that limit the duration of coverage or delay the onset of treatment coverage by the public system.

Product Categories and Reimbursement Rates

In NHS hospitals and primary care settings, products are purchased by the respective institution. Wound care treatment is provided free of charge. A wide array of products are covered and provided free of charge in NHS institutions, including:

- Basic Wound Care Products: Gauze, bandages, and antiseptics.
- Advanced Wound Care Products: Hydrocolloids, hydrogels, alginates, foams.
- Specialized Products: More advanced products like Negative Pressure Wound Therapy (NPWT) are covered within the NHS institutions.

For inpatients, the hospital team provides treatment using available dressings in stock. Upon discharge, outpatient departments or community settings continue care and bear the associated costs.

Reimbursement Application Process for Manufacturers

The National Authority of Medicines and Health Products (Infarmed) is the agency responsible for evaluating and approving medical products, including wound care items.

The CE marking is mandatory for medical devices to be marketed and circulated freely. Medical devices must be approved and listed by Infarmed to qualify for reimbursement in the outpatient setting, such as for ostomy supplies. Each NHS institution selects products from a nationally approved list.

Dispensation and Access

Wound care products are dispensed by the public health service through NHS hospitals and primary care settings.

If an NHS institution does not have a specific product but its use is clinically justified, the product can be obtained at no cost to the patient. However, if a patient wishes to be treated with a specific product that is not available in the public institution, they must purchase it independently.

Specialized suppliers or medical equipment companies may provide advanced wound care products, often collaborating directly with healthcare providers, particularly for complex or chronic wounds.

Patient Co-payments and Exemptions

In the public sector (NHS), wound care treatment in hospitals and primary care is free of charge.

Patients with specific healthcare plans (e.g., ADSE plan, or plans for law enforcement or military personnel) may have nursing or doctor appointments partially or fully reimbursed, but the wound care products themselves are not reimbursed.

Home and Community Care Services

For patients suffering from chronic wounds or requiring long-term wound management, care is available to ensure they receive necessary wound treatment either at home or in long-term care units. When patients are discharged from inpatient care, outpatient departments or community settings continue care and cover the associated costs.

Product Approval and Quality Control

The National Authority of Medicines and Health Products (Infarmed) serves as the regulatory body involved in the evaluation and approval of medical products.

The requirements for a product to be legally marketed include obtaining the CE marking. To be eligible for reimbursement in the outpatient setting (e.g., ostomy products), medical devices must be approved and listed by Infarmed.

Special Considerations or National Programs

There are no criteria in Portugal limiting the duration of coverage or delaying the onset of coverage for treatment by the public system.

Private insurance plans may impose restrictions on treatment options; for example, if a patient experiences a surgical complication, the insurance plan might not cover Negative Pressure Wound Therapy (NPWT).

Summary

Portugal's wound care reimbursement system is characterized by the comprehensive coverage provided by the public National Health Service (SNS). Wound care products used within NHS

institutions (hospitals and primary care) are supplied free of charge to the patient. The system ensures accessibility to advanced therapies like NPWT within the public sector.

A key challenge is that medical supplies for wound care are generally not reimbursed in outpatient settings (pharmacies), except for ostomy products and more recently nutrition supplements. Regulatory oversight falls under Infarmed.

References and Source Acknowledgments

The information provided on Portugal was collected by:

Associação Portuguesa de Tratamento de Feridas (APTFeridas)

- Web: www.aptferidas.com
- Author for review: Paulo Ramos

Sociedade Portuguesa de Feridas – ELCOS

- Web: www.sociedadeferidas.pt
- Authors for review: Kátia Furtado, Tânia Santos

The National Authority of Medicines and Health Products (Infarmed) is the regulatory body for product approval.

14. Spain

In Spain, reimbursement for wound care products is managed through the 17 Autonomous Health Agencies that constitute the National Health System (NHS) (Figure 1). Additionally, one agency is managed directly by the Ministry of Health, the National Institute of Health Management (INGESA), and oversees reimbursement for the autonomous cities of Ceuta and Melilla. These are the key aspects of the reimbursement process:

Autonomous Health Agency

- Provides universal and free healthcare coverage to all residents in Spain, who are registered with Social Security (SS). SS is responsible for collecting the contributions of workers and employers.
- It is funded through taxation and ensures that essential clinical treatments and products are accessible to everyone.

Prescription requirement

- Wound care products must be prescribed by a healthcare professional, such as a physician, dentist, nurse, or podiatrist.
- The prescription or indication should preferably be issued as an electronic prescription and must specify diagnosis, product, dosage, posology, and duration.
- There may be limitations on the duration for which the product can be prescribed, with the option of a temporary extension of the prescription if necessary.

Contribution and/or reimbursement rates

- To access reimbursement for a wound care product under the NHS, it must be authorised for marketing and included for financing with public funds, a process exclusively managed by the State.

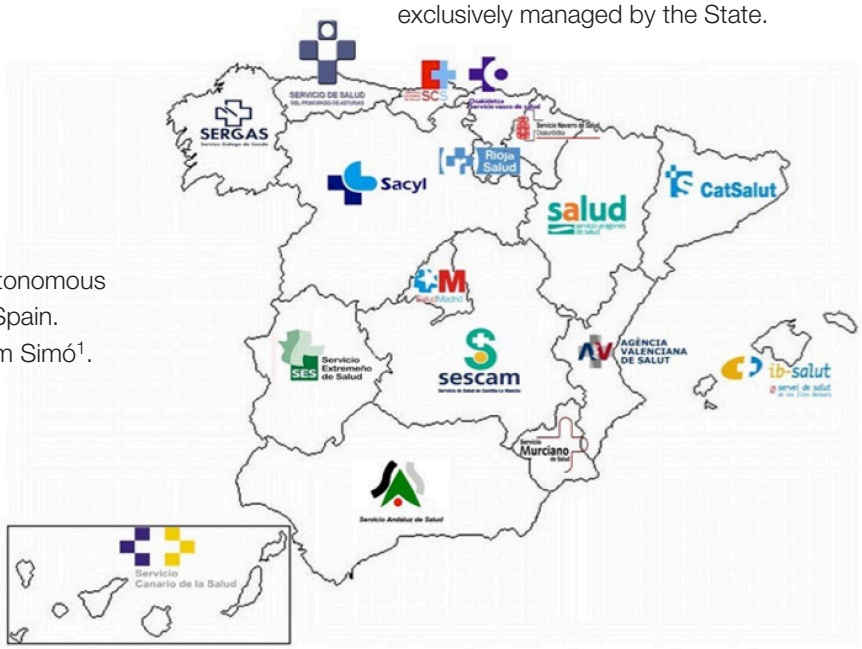

Figure 1. The 17 Autonomous Health Agencies in Spain. Figure extracted from Simó[1].

- Wound care products used by health care professionals in NHS centers (hospitals, primary care centers, etc.) and included in the standard catalog of each center are exempt from patient contribution.
- Reimbursement rates for wound care products may vary depending on the product and the region, as each region is governed by a specific Autonomous Health Agency.
- A significant proportion of essential and specialised wound care products is generally fully or partially covered by the Autonomous Health Agency.
- A co-payment is required based on the established rates only when the product needs a prescription and is classified as a special dressing not included in the standard catalog of the center. This is more common in the primary care setting (Table 1. Patient co-payments[2]).
- There are no limits on the reimbursement period for wound care products.
- For individuals with private health insurance, the reimbursement and/or co-payment conditions depend on the terms of the contracted insurance.

A distinction must be made between:

- Medicines and medical devices that are prescribed and available in the healthcare center where the individual is treated (Primary Care, Hospital, or Sociosanitary Center), which incur no cost to the patient.
- Medicines or medical devices prescribed but obtained from a pharmacy, for which the patient pays according to their work-economic situation (refer to “Exemptions and Reduced Costs”).

List of funded products

- The Spanish Agency for Medicines and Health Products (AEMPS) is responsible for evaluating, authorizing, quality control, and continuously monitoring the efficacy and safety of medicines and health products, including wound care products.
- The AEMPS maintains a list of medical products approved for marketing with a national code. The Ministry of Health determines whether these products are subsidized by public funding.
- The list of funded wound care products is updated monthly to ensure the inclusion of safe and effective options.

Pharmacy dispensing

- Wound care products are normally dispensed through pharmacies. Patients present the prescription issued by a healthcare professional at any pharmacy in Spain, where the pharmacist provides the prescribed or indicated product(s). The patient makes the appropriate co-payment based on their specific situation (see “Contribution and/or reimbursement rates”).
- Pharmacists play a key role in ensuring that patients receive the correct wound care products and providing guidance on their proper use.

Patient co-payments

- While the Autonomous Health Agencies cover most healthcare costs, patients may still be responsible for co-payments for certain wound care products. This depends on whether the product has been prescribed and is available at the health care facility or must be purchased from a pharmacy by prescription.
- Patients may either be treated at the facility with a product provided by the center itself (in which case no co-payment is required) or must obtain the product from a pharmacy where they will make the co-payment based on their employment status.

- The method of co-payment varies depending on the product and the regional policies of each Autonomous Health Agency.
- The percentage of contribution for prescription medicines and medical products under the NHS is determined based on income, status (active or pensioner), and degree of illness. For pensioners, maximum monthly contribution limits are established based on income.
- Patients with chronic treatments benefit from a reduced contribution of 10% on these medicines and medical products, with a maximum monthly limit.
- Individuals who belong to the Army, Judiciary, and certain State Administration positions generally have a fixed contribution rate of 30%.

Exceptions and reduced costs

Users and their beneficiaries who belong to one of the following categories are exempt from contributions (RD Leg 1/2015 Art.102):

a) Individuals affected by toxic syndrome and individuals with disabilities, as specified in their respective regulations.
b) Individuals receiving social integration income.
c) Individuals receiving non-contributory pensions.
d) Unemployed individuals who have lost the right to receive unemployment benefits, as long as this situation persists.
e) Individuals undergoing treatments related to work accidents or occupational diseases.
f) Individuals receiving the minimum vital income.
g) Minors with a recognised degree of disability equal to or greater than 33%.
h) Individuals receiving economic benefits from Social Security for a child or dependent minor.
i) Social Security pensioners with annual incomes of less than 11,200 euros.

Home care services

- The home care service and the medical products used are part of the NHS service portfolio. With some exceptions, the wound care products required are exempt from contributions.
- For patients with chronic wounds who are unable to travel to their referral health center, home care services are available, typically provided by primary care teams. These services ensure that patients receive the necessary wound care at home.

Quality control and approval

- The AEMPS ensures that all reimbursable wound care products meet strict quality and safety standards.
- At the national level, an Alert Network, comprising the AEMPS and the regional surveillance points, operates to communicate information, recommendations, and measures to healthcare professionals and centers in the event of the event of adverse incidents.

Income	Active	Pensioner	Maximum limit
Income < 18,000 €	40%	10%	8,23 € / month
Income 18,000 € – 100,000 €	50%	10%	18,52 € / month
Income > 100,000 €	60%	60%	61,75 € / month
Chronic treatments reduced contribution	10%	4,24 € / month	
Mutualist (Army, Judiciary)	30%		

Table 1. Patient co-payments (Gobierno de España[2]).

- If necessary, AEMPS can take action to cease marketing or withdraw products from the market that may pose risks.
- Products are evaluated for efficacy and safety before being approved for reimbursement.

In summary, the Spanish reimbursement system ensures that essential wound care products are accessible to all residents, regardless of their financial situation.

Reimbursement Application Process for Manufacturers

What is the procedure for a company to have a wound care product included on the national or regional reimbursement list?

Procedure for Inclusion on the Reimbursement List:

The manufacturer must submit an application for public funding of the product to the Ministry of Health, specifically to the Dirección General de Cartera Común de Servicios y Farmacia (DGCYF).

The application is usually first reviewed to ensure the product meets European and national requirements, and then the evaluation for inclusion in the Sistema Nacional de Salud (SNS) benefits portfolio begins. The process begins with the marketing authorization of a medicine by the Spanish Agency for Medicines and Health Products (AEMPS), which assigns a National Code to the product. Subsequently, the Ministry of Health, through the DGCYF, conducts a study and evaluation to determine whether the medicine will be publicly funded and sets its price. This evaluation is rigorous and based on therapeutic and economic criteria.

Not all medicines or products automatically receive this authorization and National Code for public funding; there is an evaluation and selection procedure. Inclusion in the pharmaceutical benefits of the National Health System is formalized through an express resolution that establishes the financing conditions and price. Therefore, national codes and public funding are limited and are only granted to products that meet established criteria, thus ensuring equity and efficiency in access to treatments.

There are products and medications that, although approved by the Ministry of Health, are not funded by Social Security for prescription dispensing, and therefore the patient would normally have to pay for them.

However, the Comunidades Autónomas (regions) have the authority to manage certain healthcare services provided in primary or hospital care. These communities may include in their catalogs of healthcare products and medications those that are not funded in the national list for use in public hospitals or health centers, thus ensuring that the patient does not have to pay for them in those healthcare settings.

This means that:

A medication or product may not be funded for public prescription services (not included in the national funding nomenclature).

However, it may be available at no cost to the patient if used within a public hospital or primary care center, at the regional level, through a catalog approved by the Autonomous Community.

These products can be prescribed and dispensed in these specific settings, and the patient does not make any direct payment.

Which authority or agency is responsible for evaluating and approving products for reimbursement?

National: La Dirección General de Cartera Común de Servicios del SNS y Farmacia del Ministerio de Sanidad is the primary entity responsible for the evaluation and approval of products for reimbursement.

Technical and Clinical Regulation: The Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) oversees the authorization and control of medical devices, issues guidelines, and ensures regulatory compliance and conformity (CE marking, MDR legislation).

Regional: The autonomous communities have pharmacy committees or services that can decide on the financing and procurement of certain wound care medical devices, especially advanced and hospital-grade ones.

What documentation or clinical evidence is required?

Certification: CE marking, certified by the Centro Nacional de Certificación de Productos Sanitarios (CNCps), and EU declaration of conformity in accordance with Regulation (EU) 2022/2346, are mandatory.

Clinical Evidence: Clinical evaluation and data demonstrating safety, efficacy, and clinical benefit in relation to cost must be provided. This includes published studies, research results, and comparisons with available alternatives.

Economic Evaluation: Cost-effectiveness analysis or information on added therapeutic value is required, especially for advanced products processed as hospital innovations.

Additional Documentation: Detailed technical information, instructions for use, risk management, and justification for the choice of conformity assessment procedure.

For advanced therapies (negative pressure therapy, special dressings), robust clinical evidence and real-world testing are usually requested, sometimes with clinical experience in Spain or in reference hospitals.

Are there any timelines, fees, or submission windows to consider?

Timeframes and Windows: Calls for inclusion of products in the NHS portfolio and regional catalogs are published in the Boletín Oficial del Estado (BOE) and regional bulletins; they are typically established as annual or multi-year windows.

Deadlines for hospitals and autonomous communities: The deadlines depend on internal processes, such as framework agreements and specific public tenders for wound care products (BOCM, ISFAS, etc.).

Fees: There are administrative fees associated with the registration and evaluation process depending on the type of product, as set out in the AEMPS regulations.

Are decisions made at national or regional level?

The decision on inclusion and reimbursement may be made nationally (SNS) when the product is funded throughout Spain, especially if it is included in the common service portfolio.

In the case of advanced materials, negative pressure devices, and high-cost products, the decision is usually made regionally or even at the hospital level, where each autonomous community and healthcare center may conduct additional evaluation processes and issue specific inclusion agreements.

It is always essential to have national approval and sufficient clinical evidence before initiating any regional or local process.

Additional information

Relevant information to consider-
We are awaiting the publication of:

- The new Royal Decree on the rational use of medicines and medical devices. This is expected to be published in the coming months.
- The draft Royal Decree regulating the financing procedure for medical devices for non-hospitalized patients.

This could affect the information provided in this report.

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The information provided about Spain is collected by GNEAUPP (Grupo Nacional para el Estudio y Asesoramiento en Úlceras por Presión y Heridas Crónicas) www.gneaupp.info and SEHER (Sociedad Española de Heridas) www.seheridas.org.

GNEAUPP authors for the review:

- Carmen Blasco García: Nurse, Hospital Germans Trias i Pujol, Badalona, Instituto Catalán de la Salud, Spain. Council Member of GNEAUPP.
- Hector Gonzalez de La Torre: Nurse, Lecturer at the University of Las Palmas de Gran Canaria (ULPGC), Spain. Council Member of GNEAUPP.
- Angel Romero Collado: Nurse, Universitat de Girona, Spain. Council Member of GNEAUPP.
- J.Javier Soldevilla Agreda: Nurse, Servicio Riojano de Salud, Spain. Director

SEHER authors for the review:

- Miren Arantzazu García Colinas: Pharmacist, Servicio Aragonés de Salud. Farmacia de Atención Primaria. Hospital de Alcañiz, Teruel, Spain. SEHER collaborator.
- Silvia Blasco Gil: Nurse, Servicio Aragonés de Salud Hospital de Alcañiz, Teruel, Spain. Council member of SEHER.
- Daniel Chaverri Fierro: Orthopaedic surgeon, Hospital MAZ, Zaragoza, Spain. President of SEHER.

15. Switzerland

In Switzerland, reimbursement for wound care products is managed through a combination of the national health insurance system and private health insurance. Here are the key aspects of the reimbursement process:

Swiss health insurance system

- Switzerland has a mandatory health insurance system, requiring every resident to have basic health insurance coverage.
- Basic health insurance is provided by private insurance companies but regulated by the Swiss Federal Office of Public Health (FOPH, or Bundesamt für Gesundheit).
- The basic health insurance covers essential medical treatments and products, including wound care supplies.

Prescription requirement

- Wound care products must be prescribed by a healthcare professional, such as a doctor or a wound care specialist. The wound care specialist must be a medical doctor; neither nurses nor wound care nurses are authorized to prescribe wound care products.
- The prescription must specify the type of wound, the required treatment, and the specific products needed.

Reimbursement rates

- The reimbursement rates for wound care products vary depending on the specific product and whether the product is included in the list of equipment and appliances (LiMA in French, MiGeL in German). This applies when the product is used by the insured person themselves, with the assistance of a non-professional involved in treatment, or by long-term care institutions, community care organisations or independent nurses, as part of care provided under the Healthcare Law and covered by compulsory health insurance.
- Essential wound care products may be fully covered by health insurance, while more specialized or advanced products may be partially reimbursed, requiring patients to pay a portion of the cost.
- Cost overruns are borne by patients as the purchase price of products can be adjusted by pharmacists under competition law. Patients have no tariff protection if the costs exceed those reimbursed by the insurance company.

Approved product list

- The FOPH regulates the approval and reimbursement of medical products, including wound care items.
- Only products included in the approved list are eligible for reimbursement.

Pharmacy dispensation

- Wound care products are dispensed through pharmacies. Patients present their prescription at a pharmacy, where the pharmacist provides the necessary items.
- Pharmacists play a key role in ensuring that patients receive the correct wound care

products and can offer advice on their proper use.
- Patients may choose to collaborate with medical device suppliers and service providers to obtain their wound care products. These suppliers offer comprehensive support by providing the necessary medical devices and managing interactions with insurance companies.

Patient co-payments

- While basic health insurance covers the majority of healthcare costs, patients may still be responsible for co-payments on certain wound care products.
- The amount of co-payment varies depending on the insurance policy, the specific product, and where the product is purchased.

Supplementary insurance

- In addition to basic health insurance, individuals can purchase supplementary health insurance plans from private insurers.
- Supplementary insurance may offer additional coverage for wound care products, including coverage for more specialized or high-cost items.

Home care services

- For patients with chronic wounds or those requiring long-term wound management, home care services are available to ensure they receive necessary wound care at home.
- Home care services and associated products may be covered by basic health insurance or supplementary insurance, depending on the policy.

Quality control and approval

- The FOPH is responsible for overseeing the quality and safety of wound care products available in Switzerland.
- Products must comply with regulatory standards and undergo approval processes to be qualify for reimbursement.

Summary

Switzerland's reimbursement system for wound care products ensures that essential treatments are accessible to all residents through the mandatory health insurance system. The system strives to provide equitable access to high-quality wound care products while offering additional coverage options through supplementary insurance.

This information on Switzerland is provided by the Swiss Association for Wound Care, including the French and German sections
www.safw-romande.ch

www.safw-romande.ch

Authors: Lucie Charbonneau, Maria Iakova, Doris von Siebenthal, Hubert Vuagnat

16. Türkiye

The reimbursement system for wound care products in Türkiye is primarily managed by the Social Security Institution (SGK - Sosyal Güvenlik Kurumu), which oversees the country's health insurance system. Below is an overview of how the system works:

Eligibility and coverage

Insured individuals: The reimbursement system is available to individuals covered under Türkiye's public health insurance scheme, which includes employees, retirees, and their dependents. Some private health insurance plans may also provide additional coverage, but SGK remains the primary provider.

Covered products: SGK maintains a list of reimbursable wound care products, including various types of dressings, bandages, and other medical supplies essential for wound management. This list is periodically updated based on new medical evidence and cost considerations.

Prescription requirement

- To qualify for reimbursement, patients must obtain a prescription from a licensed physician. The prescription must specify the exact wound care products required, such as types of dressings, ointments, or other supplies.
- For certain high-cost or specialized products, additional medical documentation or prior approval from SGK may be necessary.

Procurement process

- Patients can obtain prescribed wound care products from pharmacies or medical supply stores. These suppliers must be approved by the SGK to participate in the reimbursement system.
- In some cases, particularly for expensive or specialized products, the procurement may be managed directly by the healthcare provider or hospital, which then supplies the products to the patient.

Reimbursement claim submission

After purchasing the products, patients (or the pharmacy on their behalf) submit a reimbursement claim to the SGK. This claim should include:

- The original prescription.
- The receipt or invoice from the pharmacy or medical supply store.
- Any additional required documentation, such as a detailed medical report or prior approval if applicable.

The reimbursement claim must be submitted within a specific time frame, typically within a few months of the purchase date.

Reimbursement processing

- The SGK reviews the claim to ensure it meets all the requirements. This includes verifying the medical necessity of the products, checking that they are on the approved list, and confirming that the claim was submitted correctly.

- If the claim is approved, the SGK reimburses either the patient or the pharmacy directly. The reimbursement amount is typically based on a fixed rate set by the SGK, which may not cover the full cost of the product.
- Patients may need to pay out-of-pocket for any portion of the cost that exceeds the SGK's reimbursement rate.

Out-of-pocket costs and co-payments

- Patients may be responsible for a portion of the cost, known as co-payment. This co-payment varies depending on the type of product and the patient's insurance coverage.
- Some products may not be covered at all, requiring the patient to bear the full cost.

Repeat prescriptions and long-term care

- For chronic wounds or long-term care needs, patients may be required to obtain repeat prescriptions and submit multiple reimbursement claims over time.
- Ongoing care often involves periodic reassessment by a physician to justify continued use of wound care products.

Reimbursement rates

Fixed reimbursement rates:

- The SGK establishes fixed reimbursement rates for each product on the approved list. These rates are determined based on factors such as the average market price, clinical effectiveness, and budgetary considerations.
- The reimbursement rate may only cover a portion of the actual product cost. Patients are responsible for paying the difference if the market price exceeds the reimbursement rate.

Percentage-based reimbursement:

- For certain products, the SGK may reimburse a percentage of the total cost. For example, the SGK might cover 80% of the cost, leaving the patient responsible for the remaining 20%.
- The percentage of reimbursement can vary depending on the type of product, the patient's insurance plan, and whether the product is classified as essential or optional.

Co-payments:

- Patients are often required to make a co-payment, which represents the portion of the cost not covered by the SGK. The co-payment amount can vary depending on the product and its classification within SGK's reimbursement system.
- For certain low-cost or essential products, the co-payment may be minimal, while for more expensive or less essential items, the co-payment could be substantial.

Special considerations

Price limits: The SGK may impose maximum price limits for certain wound care products. If the market price exceeds this limit, the patient may need to pay the difference.

Annual or monthly limits: There may be restrictions on the number of certain wound care products eligible for reimbursement within a specific time frame (e.g., monthly or annually).

Re-evaluation: For ongoing wound care needs, the SGK may require periodic reevaluations to continue reimbursement. This ensures that the use of the products remains medically necessary.

Appeals and disputes

- If a reimbursement claim is denied, patients have the right to appeal the decision. This process typically involves providing additional documentation or undergoing a further medical evaluation.
- This system is designed to balance the provision of necessary wound care products for patients with the need to manage overall costs within Türkiye's healthcare system.

Examples of wound care products and their reimbursement rates

Absorbent wound care products

Foam/sponge wound dressings:

- Coverage applies if used on superficial, slightly transudative and non-infected wounds, with a minimum change interval of at least once every 3 days (50%).
- Silver products are covered if used on superficial, exudative and infected wounds, with the same change interval (50%).

Hydrocolloid dressings: Coverage applies if used on superficial, non-exudating and non-infected wounds, with a minimum change interval of once every 3 days (50%).

Alginate/Fiber/Aquafibre wound dressings: Coverage applies if used on superficial, slightly transudative and non-infected wounds, with a minimum change interval of once every 3 days (50%). Silver products are covered if used on superficial, exudative and infected wounds and with the change interval requirement.

Composite wound dressings containing at least 3 layers, absorbent and impermeable outer, in contact with the tissue: Coverage applies if used on superficial, slightly transudative and non-infected wounds, with a minimum change interval of once every 3 days. Silver products are covered if used on superficial, exudative and infected wounds and with the same change interval requirement.

Hydrofiber fibrin fixing wound dressings: Coverage applies if used on superficial, slightly transudative and non-infected wounds, with a minimum change interval of once every 3 days. Silver products are covered if used on superficial, exudative, and infected wounds, with the same change interval requirement.

Wound dressings capable of controlled silver release: Coverage applies if used on superficial or deep, exuding and infected wounds, with a change interval of at least once every 7 days and at most three times a year.

Barrier wound dressings: Coverage applies if used on superficial, non-exudating and non-infected wounds, with a minimum of 1 piece every 3 days.

Compression products: Coverage applies only for venous ulcers with a replacement interval of at least 1 piece every 4 days.

Wound care products containing extracellular matrix elements

Collagen-containing wound dressings: Coverage applies if used on superficial and non-infected wounds, with a required usage interval of once every 3 days and a maximum of 5 applications per year.

Debridement systems

Hydrocurgical debridement system hand tool, all forms: Coverage applies for deep second-degree burns involving the face, neck, hands, feet, perineum and areas in accessible with a dermatome. The coverage is limited to a maximum of 1 item per burn case.

Skin imitations

Dermis skeleton and skin analogs are reimbursed only when used for burn treatment.

Topical negative pressure

Coverage applies under the following conditions:

- Initial applications: At least 48 hours for the first 3 applications,
- Subsequent applications: At least every 72 hours after the initial 3 applications,
- Extended use: After 15 days of use, continued treatment must be documented by a report from a medical board including the specialist physician performing the follow-up and treatment, as well as at least a specialist in general surgery, orthopedics and traumatology, or plastic and reconstructive surgery. Coverage applies if used for cavitary and/or exudative chronic wounds, provided the systems is changed at least every three days.
- Vacuum Assisted Collection Set: If used with the Negative Pressure Open Abdomen Management System, the cost of a maximum of 2 sets per day for the first 5 days. A maximum of 1 set per day is covered for subsequent days.
- Reimbursement rates: Range from 90-100%.

Negative pressure open abdomen management system

Criteria: The cost of a maximum of 5 sets will be covered if the following criteria are met during the same hospitalization period:

- Treatment is provided by tertiary official health
  service providers.
- The system is used for the management of abdominal wall openings where primary closure is not possible, and/or repeated abdominal intervention is required, in abdominal compartment syndrome or for open abdominal wounds with visible viscera.
- At least one printed photograph or digital copy documenting the patient's condition (showing the open abdomen and the applied product) must be kept in the file.

Change interval:

- Maximum of 1 set per day for the first 3 days,
- Maximum of 1 set every 3 days after the initial 3 applications.

The information provided on Türkiye was collected by the Wound Management Association of Türkiye,
www.yarabakimidernegi.org.tr

17. United Kingdom

In the United Kingdom, the reimbursement for wound care products is managed through the National Health Service (NHS). Here are the key aspects of the process:

NHS coverage

- The NHS provides comprehensive coverage for wound care products. These include a wide range of items such as dressings, bandages, antiseptics, compression hosiery, and advanced wound care products.
- The NHS covers the cost of these products for most patients, ensuring access to necessary wound care supplies without direct charges. The only exception is when prescription charges apply (see below).

Formulary and approved products

- The NHS operates formularies (approved lists of medicines and medical products) that include wound care products.
- The Drug Tariff, which lists reimbursable products and their prices, serves as a key reference for what is covered. Only products listed in the Drug Tariff are eligible for NHS reimbursement.
- Formularies vary between different NHS trusts but generally follow national guidelines.

Prescriptions and other supply routes

- Wound care products may be prescribed by a healthcare professional, such as a general practitioner (GP), nurse, or specialist.
- Prescriptions are based on the clinical assessment of the wound and the specific needs of the patient.
- Some clinical areas obtain wound care products through distributors, where large amounts of stock are purchased and then used on a patient-by-patient basis. The cost of this is still covered by the NHS.

Dispensing

- If prescribed, wound care products can be obtained from community pharmacies. Patients present their prescription, and the pharmacist provides the required items.

Reimbursement process

- Prescription charges in England are set at a standard rate per item, but many patients are exempt from these charges. Exemptions apply (see exemptions below).
- Residents of the devolved nations - Wales, Scotland and Northern Ireland - do not pay prescription charges.

Patient exemptions

A significant number of patients are exempt from prescription charges, meaning they receive wound care products at no cost. Exempt groups include:

- People under 16 or over 60 years of age.
- Pregnant women and those who have given birth in the past 12 months.
- Individuals with specific medical conditions, such as diabetes or cancer.

- Individuals receiving income support, income-based jobseeker's allowance, or certain other benefits.

Home care and specialised services

- For housebound patients, community nursing services provide wound care at home.
- These services ensure that patients receive the necessary wound care products and treatment, which are also covered by the NHS.

NHS Trusts and ICBs

- NHS Trusts and Integrated Care Boards (ICBs) oversee the provision of wound care products in their respective areas. They ensure that products are available and that prescribing practices align with local and national guidelines.
- ICBs may have specific formularies and guidelines tailored to their local population needs.

Quality and safety:

- The NHS emphasizes the quality and safety of wound care products. Products must meet regulatory standards and be approved for use within the NHS.
- Regular reviews and updates to formularies ensure that patients have access to the latest and most effective wound care treatments.

Summary

The reimbursement system for wound care products in the UK, managed by the NHS, ensures that patients have access to necessary treatments at minimal or no direct cost. The system is designed to provide equitable access to high-quality wound care products, supported by a comprehensive network of healthcare providers and services.

The information provided on the UK is collected by the Society of Tissue Viability, www.societyoftissueviability.org

Society of Tissue Viability

Author: Kate Williams

18. THE CHANGING LANDSCAPE OF EU HEALTHCARE REIMBURSEMENT

Edwin den Braber MD PhD, EWMA Innovation Alliance

Where first the regulation of medicinal products became pan-European with the introduction of the Mutual Recognition Procedure (MRP), followed later by European medical device legislation, there the reimbursement of therapies has remained an adamantly national undertaking [1]. Listening carefully though, one can hear that there might be new winds blowing. A clear and very public example of things to come was the pan-European procurement of vaccines during the SARS-2-CoV-2 pandemic in 2020. That joint approach was not new or unique to the SARS-2-CoV-2 pandemic though, since the underlying European Joint Procurement Agreement was already introduced in 2014 [2–7].

HTA LEGISLATION FOR EUROPEAN PRICING AND REIMBURSEMENT

Since this joint procurement initiative in 2014, various additional European regulations have been introduced to reshape new therapy evaluation, approval, and indeed, reimbursement. One of these is Regulation (EU) 2021/2282, the Health Technology Assessment Regulation (HTAR), which came into force in January 2025 [8]. With HTAR, the European Commission expects to not only improve the availability of innovative health technologies for EU patients, but perhaps more prominently, to ensure an efficient use of resources, and reduce duplication of efforts across the various Members States of the Union. It does so by the establishment of a Coordination Group of national and regional HTA authorities, a stakeholder network, and rules on the involvement of joint clinical assessments, scientific consultations of patients, clinical experts and other relevant experts [9]. Regulation (EU) 2021/2282 itself summarises the main objective of the European Commission for this clearly: "The outcome of HTA is used to inform decisions concerning the allocation of budgetary resources in the field of health, for example in relation to establishing the pricing or reimbursement levels of health technologies. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems, and stimulate innovation that delivers better outcomes for patients" [8].

EUROPEAN PROCUREMENT, JOINT PRICING AND REIMBURSEMENT NEGOTIATIONS

Another pan-European initiative can be found in the "Best Practices in the Public Procurement of Medicines" report, which was commissioned in 2022 by The Directorate-General for Health and Food of the European Commission [10]. In it, a large inventory of different European financial healthcare practices, models, procedures, and real-life experiences are discussed. Based on this detailed review, the consulted stakeholders formulate policy recommendations for a general, more unified healthcare procurement and reimbursement system for all of the investigated 32 European countries, i.e. EU-27 plus EEA/ EFTA countries and the UK. The recommendations corroborate the earlier 2020 multi-year vision document by the European Commission, "Pharmaceutical Strategy for Europe", where it wrote: "To complement existing cross-country collaborative approaches in public procurement, joint pricing and reimbursement negotiations, new ways of information sharing, such as horizon scanning, should be considered. [...] The Commission will step up co-operation with and among Member States on the affordability and cost-effectiveness of medicines and will launch a

group to steer cooperation between national pricing and reimbursement authorities and healthcare payers" [11].

SO IS THE REIMBURSEMENT POINT OF CALL STILL NATIONAL?

Although the report underlines specifically that "Decisions on the pricing and reimbursement of medicines are the purview of Member States", a condition stipulated by Directive 89/105/EEC [12], the European Commission stresses that there is a mutual beneficial goal to consider:

"The affordability of medicines has implications for both public and household finances. It poses a growing challenge for the majority of Member States. [...] There is a lack of transparency (in particular in R&D costs) and consensus on costing principles. Better understanding and greater clarity are fundamental as a basis for policy debates on the pricing of niche medicines and 'fair return' on research contributions. Changing business models (e.g. high value acquisitions of promising pipeline products) and novel payment approaches, such as risk-sharing arrangements and deferred payment schemes, may have long-term implications, and thus affect affordability of new medicines. The Commission will foster transparency of price information to help Member States take better pricing and reimbursement decisions, also considering possible knock-on effects for innovation" [11].

That the European Commission is not just suggesting, but really committed to healthcare reimbursement changes, can be deduced from the (new) legislation it considers to motivate the National Competent Authorities on Pricing and Reimbursement and Public Healthcare Payers (NCAPR) to comply:

"Legislative measures could include stronger obligations on industry to ensure the supply of medicines, earlier notification of shortages and withdrawals, enhanced transparency of stocks across the supply chain, and a stronger coordinating role for the EMA in monitoring and managing shortages. Such measures will be complemented by enhanced cooperation between Member States, for example improved procurement approaches and strategies, joint procurement for critical medicines and EU-level cooperation on tools and instruments for national policy making on prices and reimbursement" [11,13].

TO BE OR NOT TO BE AVAILABLE, THAT MIGHT BE THE QUESTION

Although many will agree that assuring access to affordable medicines through EU level cooperation on pricing and reimbursement might be good, one can also ask oneself whether such legislation would also include the obligation for manufacturers to make their products available in the Member States. After all, without such an (unlikely) obligation, manufacturers remain free to follow their preferred business strategy, and for example not make their products available within the Union [14,15]. Multiple reports are available of products not being submitted for regulatory approval in the EU, not being distributed although approved, or being withdrawn completely from the European market due to pricing and reimbursement disputes [16–19]. Such cases demonstrate vividly the significant, real life sensibility connected to reimbursement negotiations, pricing, and procurement, and how they can damage the European Commission Strategy fundamental objectives of prioritising unmet medical needs, and ensuring patients' optimal access to medicines [8,11,20,21].

SO WHAT ABOUT WOUND CARE REIMBURSEMENT IN EUROPE?

Looking at the European reimbursement of wound care, it is not difficult to conclude that it currently is still far removed from the vision of the European Commission. This is because first of all, the bulk of wound healing therapies are medical devices, of which reimbursement is not considered, nor discussed in the strategic reimbursement reflections of the European Commission [11]. Second, the reimbursement of medical devices, contrary to that of medicinal products, is in most cases not managed on a national level, but has been delegated to sub-national regions and authorities. Third, together with the delegation of responsibility

of care, also the budgetary burden of the reimbursement of these (wound healing) products has often been transferred downstream. Fourth, as a consequence of devolving care commitments, wound healing medical device reimbursement does not only vary wildly between, but also within European countries. Hence, wound care professionals "on the ground" report that patients living in one city do, while similar patients in the neighbouring region do not receive reimbursement for their wound care needs. To make matters even more confusing for patients, it is also not uncommon that their wound care therapy is reimbursed when costs are carried by for example dispensing hospital budgets, while (more budget efficient!) home care patients do not receive any compensation. The clinical every day reality of wound care was shown vividly in a 2024 EWMA study, where 71% of the queried European wound care professionals report to experience reimbursement challenges affecting medical treatment availability, while 80% see insufficient reimbursement, limiting the chronic wound treatment of their patients [22].

PENNY WISE, POUND FOOLISH WOUND CARE?

Considering wound healing reimbursement in general, it is surprising that the large, every day growing unmet need of wound care patients is not addressed right here, right now. More than a decade ago in 2010, the World Health Organization (WHO) already declared chronic wounds an epidemic [23]. Since then however, curative and health strategic approaches are lacking, and wound patient burden increases, leading to significant healthcare expenditures and a pressing need for innovative treatment strategies [24–29]. It is therefore not surprising that the U.S. Food and Drug Administration (FDA) stated publicly in 2022 that it is critical to address the ever growing burden of wound healing patients by boosting the development of new wound healing solutions [30]. At the same time one should also ask oneself what good those innovative wound healing therapies are going to do when they never reach the patient's bedside due to regulatory or financial hurdles. Perversely, many health economic studies have shown that non and badly treated wound healing pathology does not only impact health care budgets significantly short term, but also economies of countries as a whole long term [25–29,31,32]. Therefore, the European Commission, politicians, regulators, and healthcare insurers might want to avoid to be penny wise, but pound foolish when drafting and implementing the next wound care reimbursement strategies [33].

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19.
About EWMA and EIA

European Wound Management Association

The European Wound Management Association (EWMA) is a European not-for-profit umbrella organisation, that connects national wound management organisations, individuals, and groups interested in wound care.

The association aims to promote the advancement of education and research into native epidemiology, pathology, diagnosis, prevention, and management of wounds of all aetiologies.

Web: www.ewma.org

EWMA Innovation Alliance

Through the EWMA Innovation Alliance (EIA), we aim to create a membership-based European Wound Management Innovation Eco-system.

The vision is to improve wound care and the quality of life of individuals with a wound and their families by supporting the development and adoption of new and better solutions, while strengthening Europe as a hub for wound care innovation.

Members include established companies, startups and spinouts, growth companies, service providers, investors, regional authorities, hospitals, and research organisations.

Web: www.ewmainnovationalliance.org

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