Market Access pathway for Medical Nutrition in Europe and the US

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INTRODUCTION:

● Standard products, either oral nutrition supplements (ONS) or enteral nutrition (EN) formulas are offered to patients either malmalnourished or not able to eat normally (case of EN enteral nutrition via tube feeding/nasogastric or nasojejunal or PEG). Usually their reimbursement processes are straightforward (notification letter, or simple dossier to fit into an existing reimbursed code/category for medical nutrition), which is the case in most European countries and the USA.

● This publication aims at presenting different market access pathways for standard and innovative products of Medical Nutrition (MN) products in the US, France, Germany and the UK.

METHODS:

● Systematic review of submission processes for MN (including FSMP (European terminology of this food category) and Medical Food (US terminology)), combined with experience of the authors from previous research on health economics, Market Access and reimbursement.

● A systematic literature search was being conducted analysing the reimbursement pathways and requirements reported for France, Germany, UK and France.

● Additionally relevant institutional sites were screened for relevant documents (e.g. G-BA, HAS, etc.).

● Search terms for MN (definition above):
  - Reimbursement, Market Access, Funding
  - Health Economics, Health Policy
  - France, Germany, UK, USA

RESULTS:

● Pathways for market access are provided in the table below.

<table>
<thead>
<tr>
<th>Country</th>
<th>National regulatory pathway</th>
<th>Outpatient process – Generic products</th>
<th>Outpatient process – Generic products</th>
<th>Inpatient process</th>
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</thead>
<tbody>
<tr>
<td>France</td>
<td>Notification letter to the DSSCOF; Scientific assessment may be requested by the AFS-SA for new non generic products.</td>
<td>Notification letter and generic price</td>
<td>Full HTA dossier with clinical evidence, safety to the HAS (CNESMMT). Full economics dossier to the MHG (CEPS) with budget impact model and price referencing. Timeline: 180 days. Reimbursed agreed for 3-5 years.</td>
<td>Covered by the French DRG system (GHTM) for generic products. Tender processes for standard enteral tube feeding and ONS. Pharmacists of the hospital may request a mini HTA dossier for expensive innovative products.</td>
</tr>
<tr>
<td>Germany</td>
<td>Direct launch after sending a notification letter to the BfArM.</td>
<td>Reimbursement dossier should be submitted to the GB-A to have the product reimbursed. The product composition and intended usage should fit with the conditions stated in the Social Code Book VI (Chapter 6, Bruch No. 165 P 13 241 of 01 09 2005). Prices are negotiable with sickness funds.</td>
<td>No process; outside of the list stated in the Social Code Book VI (Chapter 6, Bruch No. 165 P 13 241 of 01 09 2005), there is no reimbursement opportunity.</td>
<td>Covered under the German DRG system for EN and feeding tubes. Non-standard products should be listed on hospital drug list. Tender processes for generic products, or individual contract for innovative products.</td>
</tr>
<tr>
<td>United-Kingdom</td>
<td>A notification letter should be sent to the PSI. Thereafter a dossier should be sent to the MHRA in order to obtain an exemption from drug’s regulation.</td>
<td>For generic products or products comparable to the competitors' one, a mini HTA dossier with rational, composition of the product should be submitted to the MCDS. For any changes in products’ composition, a dossier should also be submitted with rational for this change and the new composition. All products should fit within one of the 5 categories listed in the ACBS application guidance, categories which cover most of the diseases. The ACBS decides on reimbursement agreement and reimbursed price.</td>
<td>A HTA dossier should be submitted with composition of the product, rational for it, disease targeted, safety and clinical data, medico-economics data can be submitted as well. All products should fit within the 5 categories listed in the ACBS application guidance for requesting coverage by the NHS of nutritional products. The ACBS decides on reimbursement agreement and reimbursed price. The reimbursement is granted for 5 years.</td>
<td>Covered by the British DRG system (MAP) or by clinicians’ budget. Tender process exists for generic products. For innovative products, the rational for it with clinical data should be brought to pharmacy and dieticians.</td>
</tr>
<tr>
<td>USA</td>
<td>For most medical food products: free access to market; however products should be compliant with existing rules in case of post-launch control. For infant products, FDA requires trials to be done before launch. Covered by Medicare in homecare setting for tube feeding if deemed medically necessary and if fitting with products coded into the HCPCS code. For getting a HCPCS code a dossier including rational and composition of the product should be submitted. Medicaid cover standard nutritional products only in specific programs. Private health plans cover medical food in outpatient care.</td>
<td>Covered by Medicare in homecare setting for tube feeding if deemed medically necessary and if fitting with products coded into the HCPCS code. For getting a HCPCS code a dossier including rational and composition of the product should be submitted. Medicaid cover standard nutritional products only in specific programs. Private health plans cover medical food in outpatient care.</td>
<td>There is little opportunity for innovation, as the medical food HCPCS categories but should be modified accordingly.</td>
<td>Covered by Medicare in acute-care and long-term care under DRG funding system. Medicaid covers mainly EN with TF, by a per diem rate. Private Health Plans cover EN by a per diem rate.</td>
</tr>
</tbody>
</table>

CONCLUSIONS:

● The market access pathways for granting reimbursement or coverage of the medical nutrition category are very heterogeneous between the analyzed countries.

SUMMARY:

● When considering MN delivered in the ambulatory care setting, only in France, innovative MN presenting with therapeutic value faces the medical device reimbursement process.

● In the UK, the process is handled by the ACBS and focus mainly on clinical outcome and safety; additionally this process sets a reimbursed price and allows innovation.

● In the US and Germany, there are reimbursed categories for MN linked to composition of the product and dedicated to patients with inability to have their nutritional needs covered by normal food intake (set by CMS in the US and G-Ba in Germany).

● Creating new reimbursed categories linked to new MN either bringing innovative therapeutic value or targeting new disease area is highly difficult in all countries.

● For MN delivered in hospital settings, products delivered enterally or orally are mainly covered by hospital budget.

● The budget can be either from the hospital’s kitchen for thickened and thickened products, under the diagnosis-related group funding scheme related to each countries, by the nutritional budget (mainly UK and US) or by the hospital’s pharmacy budget for specialties.

● For standard products, access is obtained based on tenders. In long-term care and nursing home, coverage and funding are more heterogeneous: they vary from highly regulated reimbursed scheme based on composition of the products and disease area to per diem fee per patient covering both food and MN.

List of acronyms – Market Access for medical nutrition

France

- DSSCOF – Direction Générale de la Concurrence, de la Consommation et de la Reprisal des Fraudes
- HASA – Agence Française de la Sécurité des Aliments
- BfArM – Bundesinstitut für Arzneimittel und Medizinprodukte
- G-BA – Gemeinsame Bundesausschuss
- FSHH – Bundesministerium für Gesundheit

- AFS-SA – Agentur für die Arzneimittel- und Gesundheitswirtschaft
- HAS – Haute Autorité de Santé
- HAS – Haute Autorité de Santé
- AMR – Arzneimittel-Richtlinien
- GkV – Gesetzliche Krankenversicherung
- GB-A – Gemeinsame Bundesausschuss

UK

- FSA – Food Standards Agency
- MHRA – Medicines and Healthcare Products Regulatory Agency
- NICE – National Institute for Health and Care Excellence
- NHS – National Health Service
- DSSCOF – Department of Social Security
- HSCIC – Health and Social Care Information Centre
- HSPC – Health and Social Care Information Centre
- HTA – Health Technology Assessment
- NICE – National Institute for Health and Care Excellence
- AMR – Arzneimittel-Richtlinien
- HCPCS – Healthcare Common Procedure Coding System

USA

- CMS – Centre for Medicare & Medicaid Services
- FDA – Food and Drug Administration
- HCPCS – Healthcare Common Procedure Coding System
- GHTM – Gesetzliche Krankenversicherung
- AFS-SA – Bundesinstitut für Arzneimittel und Medizinprodukte
- G-BA – Gemeinsame Bundesausschuss
- AMR – Arzneimittel-Richtlinien
- DRG – Diagnosis-Related Group
- G-BA – Gemeinsame Bundesausschuss
- CREST – Center for Research and Evaluation in Clinical Therapeutics
- CMS – Center for Medicare & Medicaid Services
- DSSCOF – Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes
- HAS – Haute Autorité de Santé
- AMR – Arzneimittel-Richtlinien
- HCPCS – Healthcare Common Procedure Coding System
- CMS – Center for Medicare & Medicaid Services
- G-BA – Gemeinsame Bundesausschuss
- AMR – Arzneimittel-Richtlinien
- GHTM – Gesetzliche Krankenversicherung
- HAS – Haute Autorité de Santé
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- GHTM – Gesetzliche Krankenversicherung
- HAS – Haute Autorité de Santé


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