In Europe, the reimbursement and funding process for biologic therapies is highly complex, with substantial differences between countries and further variations at regional and local levels in some countries. The process for a biologic obtaining a license in a second indication is even less clear.

OBJECTIVE

We sought to gain a better understanding of the pricing and reimbursement processes, and evidence requirements at national, regional, and local levels with regard to a biologic obtaining a license in a second non-oncology indication. (United Kingdom [UK], France, Italy, and Spain)

METHODS

In late 2013 and early 2014, we undertook a series of telephone interviews with papers and payer advisors (Table 1). These discussions lasted one hour and followed a structured interview guide in advance.

– In countries with a large national system and no major local variations in terms of funding flow for biologics (UK [England], and France), five telephone interviews were conducted.
– In countries with large variations at local and regional levels (Italy, and Spain), a greater number of interviews were conducted to capture these variations (12 and 17 interviews, respectively).

RESULTS

RESULTS: UK (England)

In the UK (England), the pricing and reimbursement process is agreed at a national level, with few restrictions or local levels. National Health Service (NHS) formularies should not be an issue for new drugs.

Reimbursement and Funding Flow for Biologics

Reimbursement is agreed at a national level, following the recommendation issued by NICE.

Biologics are likely to be commissioned by NHS England, in agreement with NICE’s recommendation (Figure 1).

RESULTS: France

In France, the pricing and reimbursement process is agreed at a national level, with few restrictions or local levels. Funding usually is through the groupe homogène de séjour (GHS).

Reimbursement and Funding Flow for Biologics

Reimbursement is agreed at a national level following the recommendation by the Transparency Commission (TC).

Funding depends on the intended usage or dispensing: drugs are reimbursed within the cost of an average hospital stay or by health insurance, as long as the drug is used within the Marketing Authorisation Authority (Figure 2).

RESULTS: Italy

In Italy, the Italian Medicines Agency (Agenzia Italiana del Farmaco [AIFA]) must approve a new biologic on a national level, with further pricing and reimbursement processes at regional and local levels. Evidence requirements vary at each level (national, regional, and local).

Reimbursement and Funding Flow for Biologics

Reimbursement is agreed at national, regional, and local levels (with variation by region or hospital). (Figure 3)

Formulary decisions may be influenced by decisions taken in other regions or areas.

Regionally, biologics are funded according to their classification. Class A includes approved and reimbursed biologics, whereas Class B drugs are fully reimbursed by the NIS; Class H drugs are fully reimbursed in the hospital setting only. In some regions, such as Campania, Friuli-Venezia Giulia, and Sardegna, biologics are funded through special funding “Fissino”

Market Access Considerations

Regional formularies generally focus on efficacy and safety data, whereas local and hospital formularies require local epidemiology and budget-impact data.

A product can be considered in innovative medicine, patient access must be guaranteed across all regions.

CONCLUSIONS

A biologic obtaining a license in a new indication must undergo the same process as a new product.

The processes and restrictions for biologics may be stricter than for other medicines because of their high cost.

The level of national, regional, and local requirements and restrictions varies; material that appears to constitute evidence is submitted to decision makers at each level.

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