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Funding breakthrough therapies: A systematic review and recommendation

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Abstract

Background: Advanced therapy medicinal products (ATMPs) are innovative therapies likely associated with high prices. Payers need guidance to create a balance between ensuring patient access to breakthrough therapies and maintaining the financial sustainability of the healthcare system. **Objective:** The aims of this study were to identify, define, classify and compare the approaches to funding high-cost medicines proposed in the literature, to analyze their appropriateness for ATMP funding and to suggest an optimal funding model for ATMPs. **Results:** Forty-eight articles suggesting new funding models for innovative high-cost therapies were identified. The models were classified into 3 groups: financial agreement, health outcomes-based agreement and healthcoin. Financial agreement encompassed: discounts, rebates, price and volume caps, price-volume agreements, loans, cost-plus price, intellectual-based payment and fund-based payment. Health outcomes-based agreements were defined as agreements between manufacturers and payers based on drug performance, and were divided into performance-based payment and coverage with evidence development. Healthcoin described a new suggested tradeable currency used to assign monetary value to incremental outcomes. **Conclusion:** With a large number of ATMPs in development, it is time for stakeholders to start thinking about new pathways and funding strategies for these innovative high-cost therapies. An "ATMP-specific fund" may constitute a reasonable solution to ensure rapid patient access to innovation without threatening the sustainability of the health care system.