

# Managed Entry Agreements for Advanced Therapy Medicinal Products: Interviews with HTA bodies and Reimbursement authorities in England, the Netherlands, and Spain

Andrea Greco, M.Sc. (1), Geert WJ Frederix, Ph.D. (1), Lotty Hooft, Ph.D. (1,2), Renske MT ten Ham, Ph.D. (1)

1)University Medical Centre Utrecht, Julius Centre for Health Sciences and Primary Care, Department of Epidemiology & Health Economics, Utrecht The Netherlands. 2)Cochrane Netherlands, University Medical Center Utrecht, Utrecht University, Utrecht, The Netherlands.



## Key Findings

- Negotiations in the Netherlands are particularly focused on budget impact. Despite interest in outcome-based agreements (OBAs), simple discounts are preferred. Recently, an OBA for Atidarsagene autotemcel was proposed but not implemented.
- In Spain, reimbursing CAR-T therapies through OBAs has proven challenging given time lag between apheresis and infusion. This delay complicates liability management since patients may deteriorate during that period.
- Similarly, in England, liabilities related to treatment failures or non-treatment-related deaths have been problematic during negotiations. Moreover, use of registries is challenging given the need to avoid conflicts of interest, especially since companies often fund them.

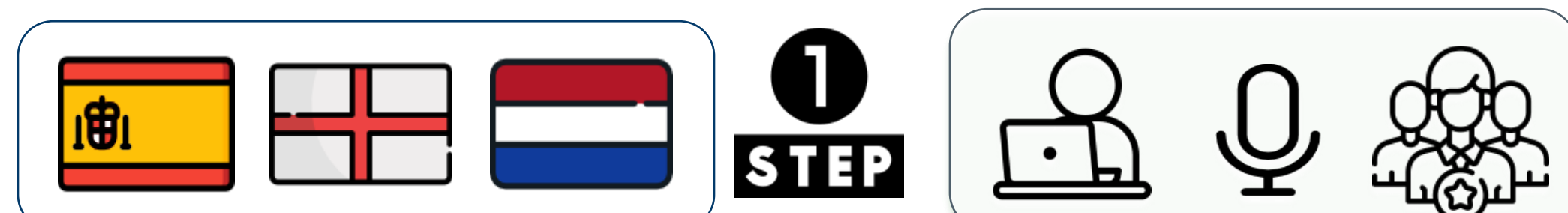
## Background & Objectives

Advanced therapy medicinal products (ATMPs) are cutting-edge therapeutic innovations that could transform patients' health. Yet, their costs and uncertain value claims pose challenges for healthcare payers and Health Technology Assessment (HTA) bodies, ultimately leading to heterogeneous coverage decisions globally.

This study aims to explore the experiences of HTA & reimbursement authorities with the Managed Entry Agreements (MEAs) in England, the Netherlands, and Spain, to identify and assess challenges and best practices.

## Methods

We conducted a qualitative study using in-depth scoping interviews. A purposive sampling approach was used to select respondents with experience in negotiations, reimbursement, and implementation of MEAs for ATMPs. Current and former representatives affiliated with NHS England, the National Institute for Health, and Care Excellence (NICE), Zorginstituut Nederland (ZIN), The Dutch Ministry of Health, Welfare, and Sport, The Spanish Ministry of Health, Catalan Health Service (CatSalut), and the Health and Social Consortium of Catalonia (CSC) were interviewed.

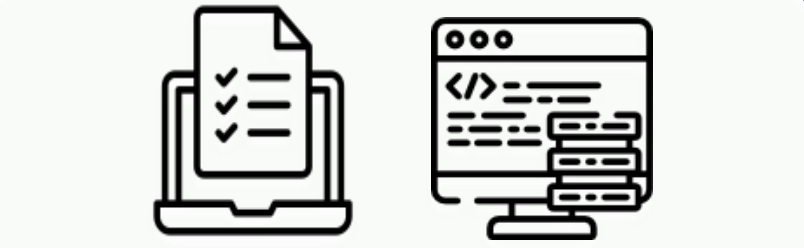


**1**  
STEP



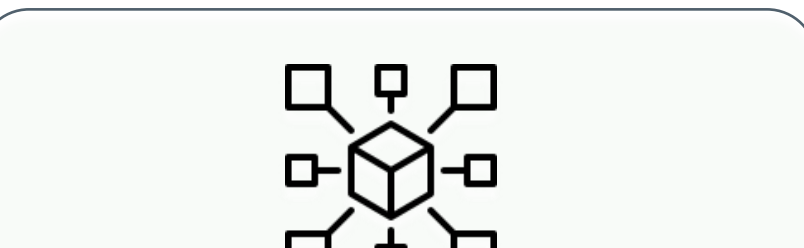
Interviews were transcribed verbatim and entered in NVivo 1.7.2

**2**  
STEP



After transcript familiarization, we conducted thematic content analysis.

**3**  
STEP



## Results

### Step 1: Health Technology Assessment of ATMPs

#### Theme: REA

##### Sub-themes:

- Heterogeneity in response
- Durability & Long-Term Effect
- Adverse events
- Comparators
- Patient Sample Size

#### Theme: CEA

##### Sub-themes:

- High Upfront Costs
- One shot Administration
- Treasury Rules

### Step 2: Appraisal and Decision Making

#### Theme: Stakeholders

##### Sub-themes:

- Role of Stakeholders & Autonomy
- Stakeholder involvement & interactions
- Navigating HTA
- Value articulation
- Ethical & Risk Considerations

#### Theme: Decentralized and Regional Appraisal Processes

##### Sub-themes:

- Governance
- Regional Liabilities and Responsibilities
- Data Collection and Registry Infrastructures
- Resource Coordination

#### Theme: Routines & Practices

##### Sub-themes:

- Protocol Development and Public Documentation
- Negotiations Dynamics & Complexities
- Pathways and Specific Funds
- Decision Making for MEAs

### Step 3: Managed Entry Agreements Implementation

#### Theme: Selection Criteria and Policy Considerations for MEAs

##### Sub-themes:

- Disease Characteristics
- High Price and Budget Impact
- Short Term vs Long-Term benefit
- Uncertainty in Effectiveness and Outcomes

#### Theme: Practical Consideration in MEA Design

##### Sub-themes:

- Data flow and completeness
- Time Windows for Data Collection
- Treatment Administration (One shot vs. CAR-Ts)

#### Theme: Moving Forward

##### Sub-themes:

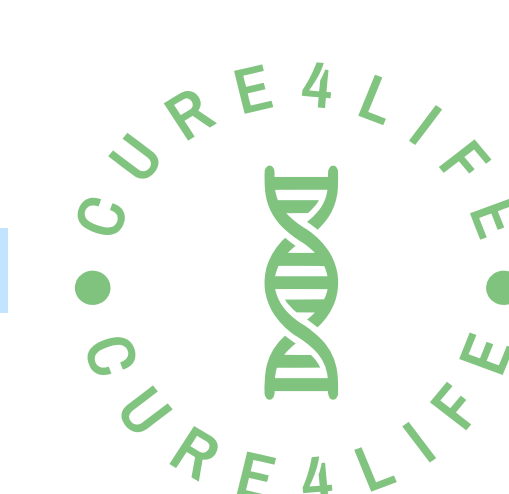
- Data Consolidation and Accessibility
- Standardization Across Borders
- Policy and Infrastructure Needs

## Discussion

The current ATMP oncological pipelines pose additional threats to limited budgets. The dissemination of experiences in negotiating and reimbursing ATMPs is crucial as provides valuable insights for shaping future practices and exploiting learnings gained elsewhere. This work has few limitations; despite several invitations being sent, a small sample of participants took part in the interviews. Yet, saturation according to pre-established criteria has been reached.

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## Contact Information



Andrea Greco, M.Sc.  
a.greco@umcutrecht.nl