Reimbursement in Healthcare

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OBJECTIVES:

1. Introduce the process of translating basic research and clinical trial results into tangible societal benefits in the healthcare sector

2. Learn the key steps and requirements for successfully entering the healthcare market with innovative hepatology products

3. What is required for presenting research findings to relevant stakeholders and securing reimbursement for new treatments or technologies

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About IMAC

- Boutique firm specialized in Market Access
- Founded in 2006 in Zug, Switzerland
- Established in Canada since 2010
- Global reach: European and North American focus

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TOP PHARMA CONSULTING COMPANY IN EUROPE 2022
AWARDED BY Life Sciences Review
IMAC

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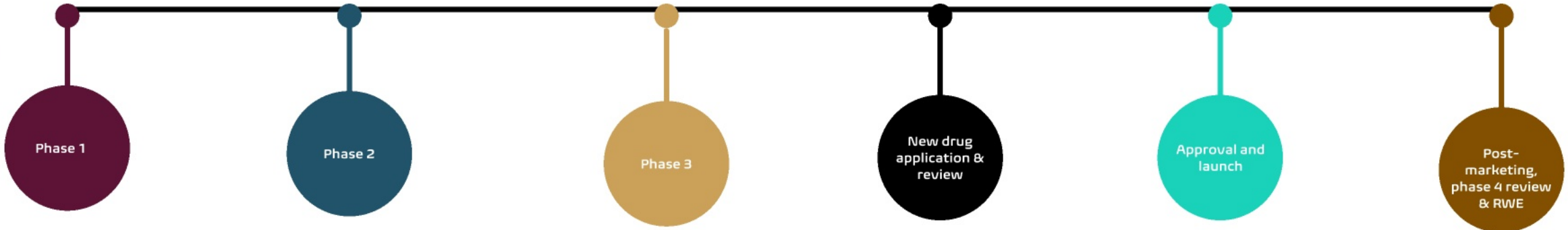
IMAC supports the product lifecycle

From early planning to post-launch



- Adapting landscape analysis
- Update living SLR
- Writing GVD

- Early landscape analysis
- Defining the patient population (Phase 2 and 3)
- Defining outcomes relevant for reimbursement
- Conducting an early SLR (especially relevant for rare disease)
- Working with KOLs to define standard of care
- Early economic model

- Data gap analysis and RWE (prepare for HTA)
- Customised market entry strategy
- Leveraging earlier experience to develop HTA submissions that address challenges
- Innovative economic model for reimbursemen

- RWE strategy to address challenges from HTA agencies

Abbreviations: GVD, Global value dossier; HTA, health technology assessment; KOL, key opinion leader; RWE, real-world evidence; SLR, systematic literature review

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OVERVIEW

1. UK Healthcare Landscape
2. Introduction to Drug Reimbursement/ UK Landscape
3. Considerations for Commercialisation
4. Recommendations/Future Outlook

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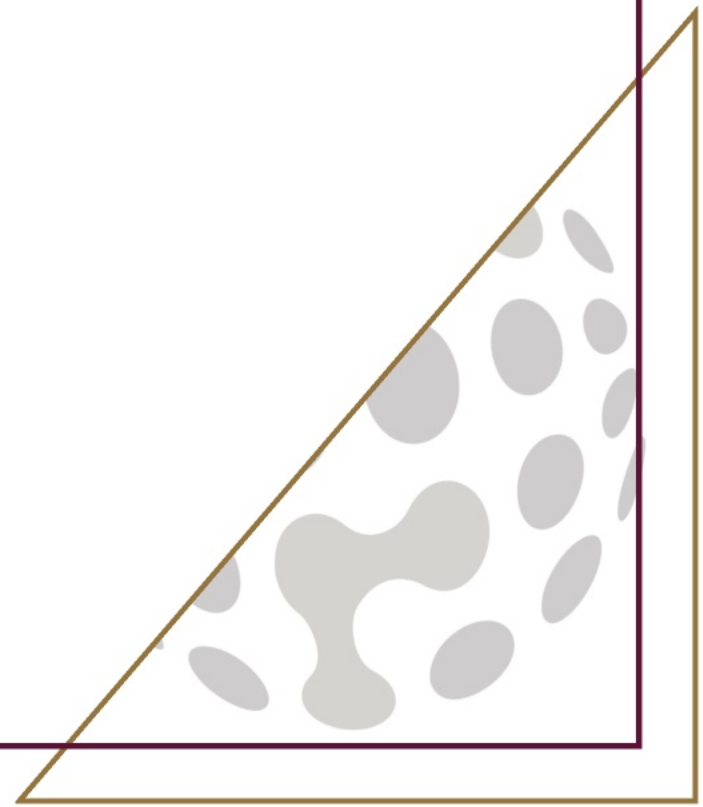
1 UK Healthcare Landscape

- The UK Healthcare System
- Drug Commissioning



After pandemic and Brexit challenges, the UK pharma industry is expected to experience a positive shift in 2024

The UK has faced three major unexpected events in the past eight years: the Brexit referendum and implementation, a global pandemic, and a major conflict in Eastern Europe

UK's economic outlook is strengthening, and public finances have improved, with a narrowing deficit

The UK's "Life Sci for Growth" budget of £650 million, announced by the Chancellor, includes support for innovation and clinical trials in the sector

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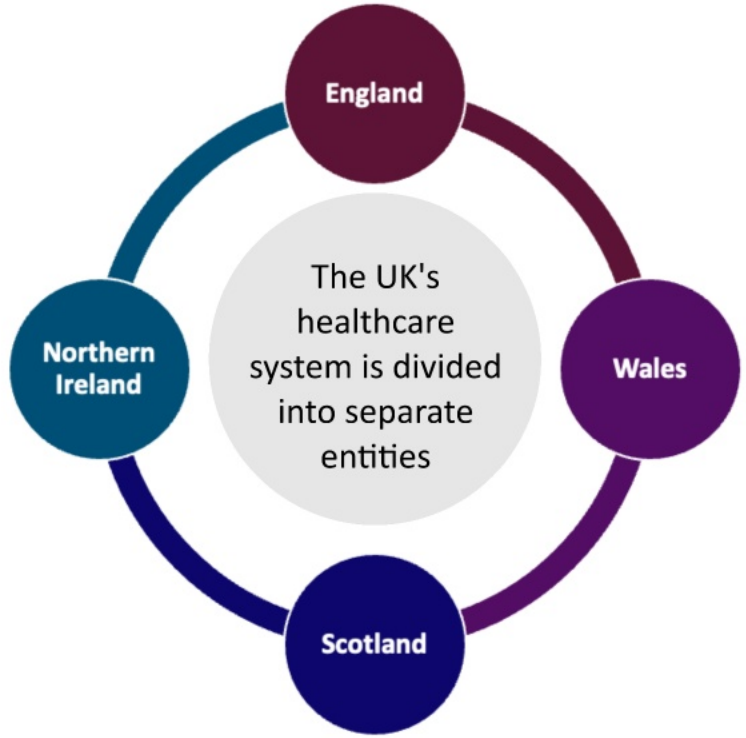
The NHS is the dominant force in the UK's healthcare system, which comprises public and private provisions

Dominated by NHS

NHS varies across UK nations but shares key concepts. NHS in England is the largest market

Universal Access (for most)

Everyone in the UK receives emergency and some mental health care, regardless of residency status. Residency may be required for non-emergency services



Public Funding

Primarily funded by taxes, ensuring affordability at the point of service for most treatments

Private sector exists

A growing private healthcare market also exists, funded by patients or insurance.

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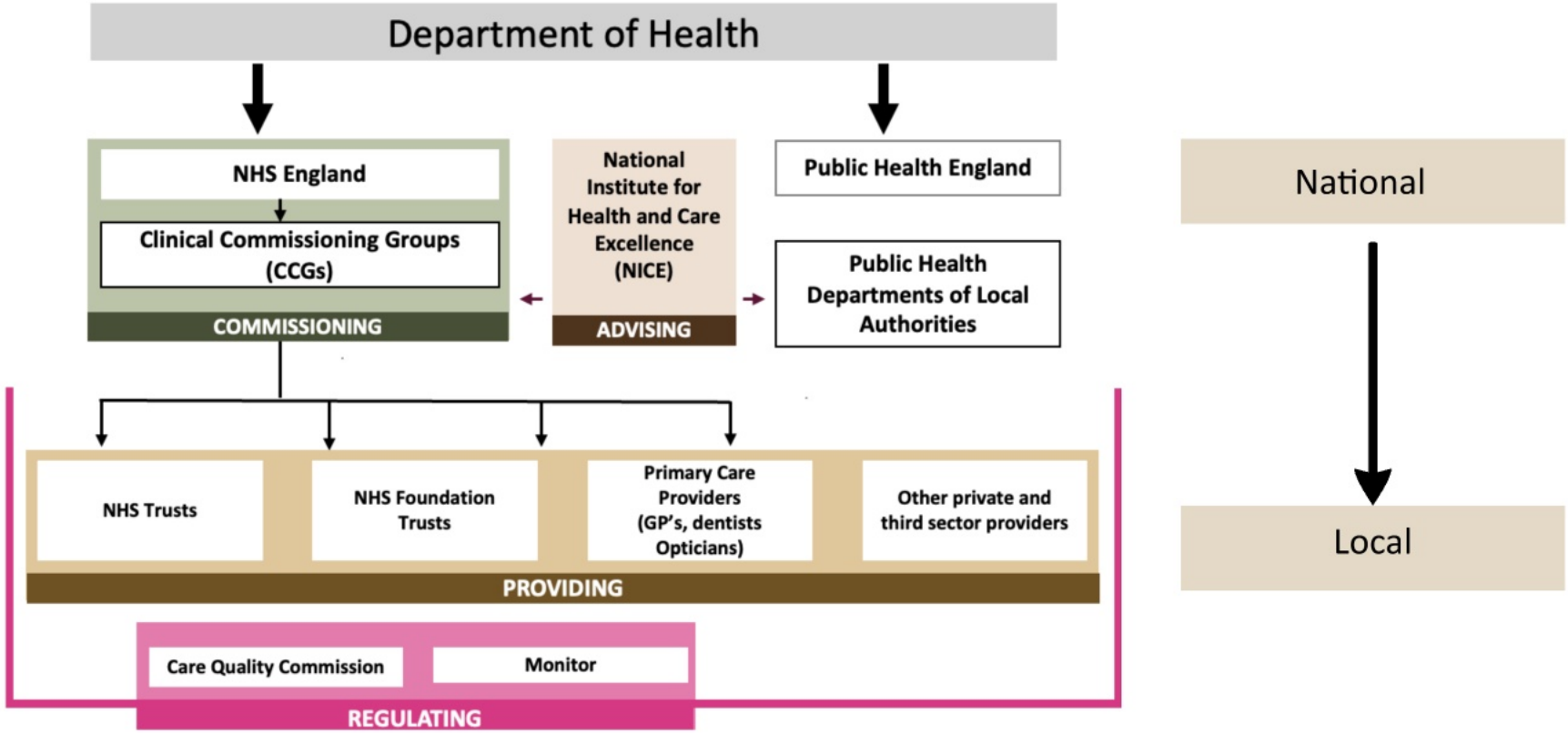
Abbreviations: NHS, national health service

NHS England is a central body responsible for commissioning most healthcare services in England



The structure of NHS England is evolving

Source: National Assembly for Wales, 2015

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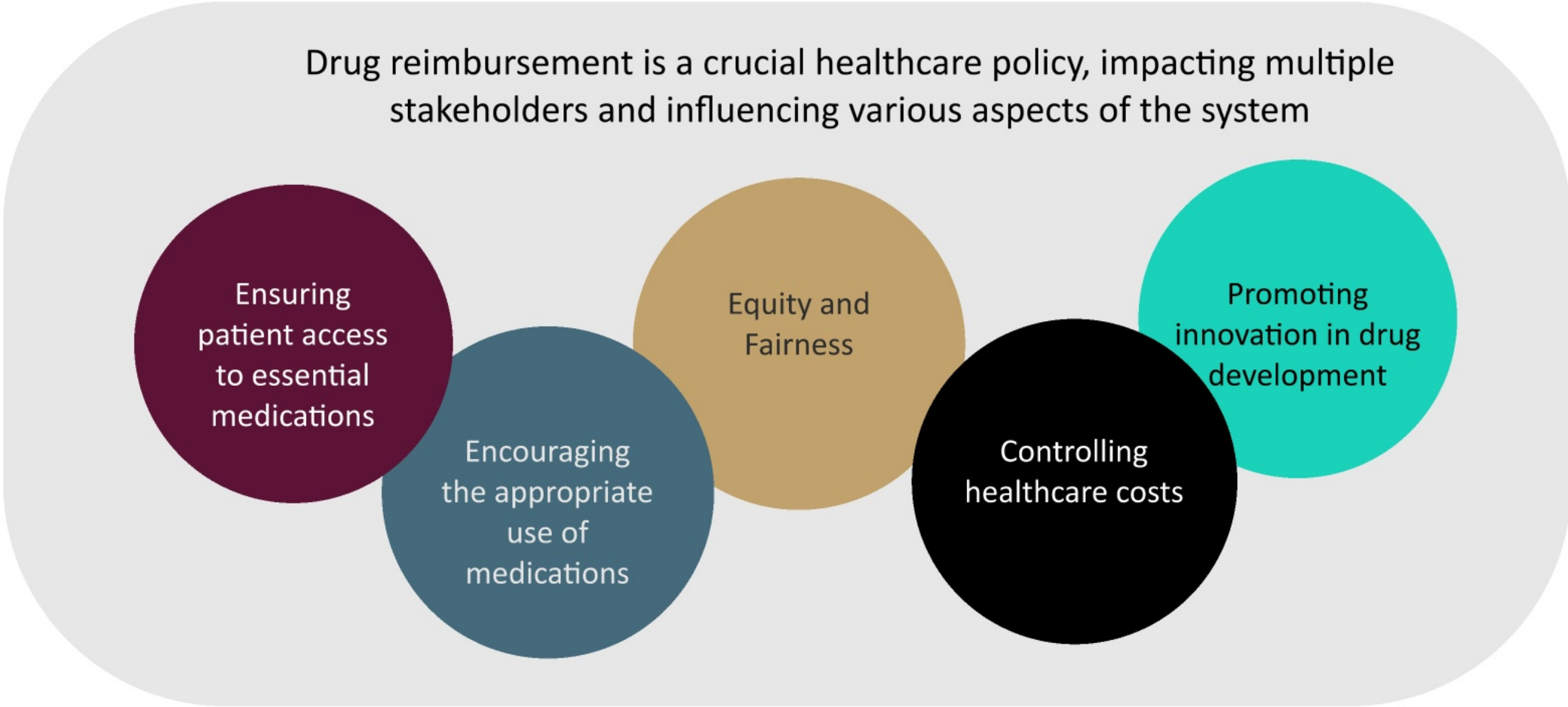
Abbreviations: GP, general practitioner; NHS, national health service

Reimbursement policies are vital for patient access, health outcomes, and healthcare affordability and efficiency



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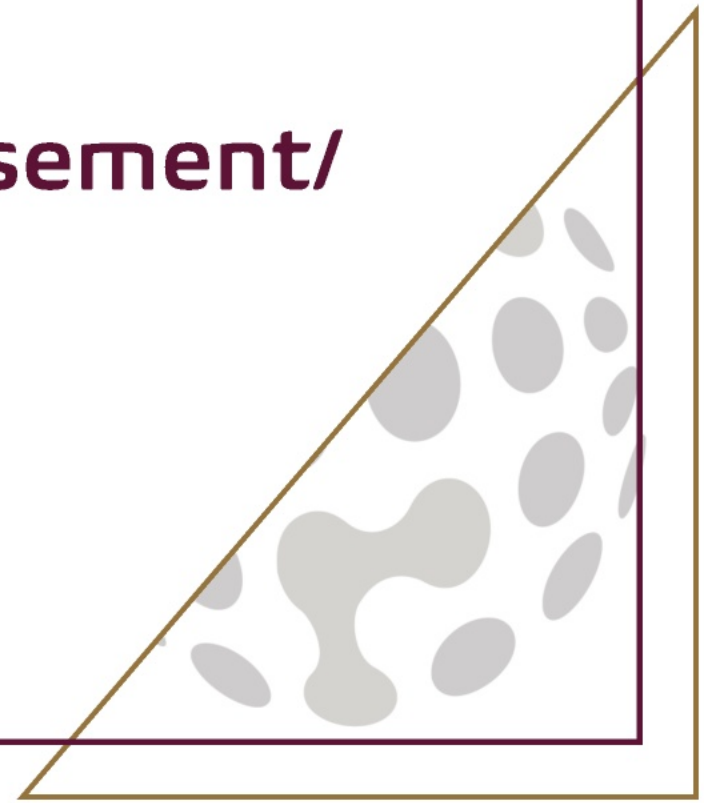
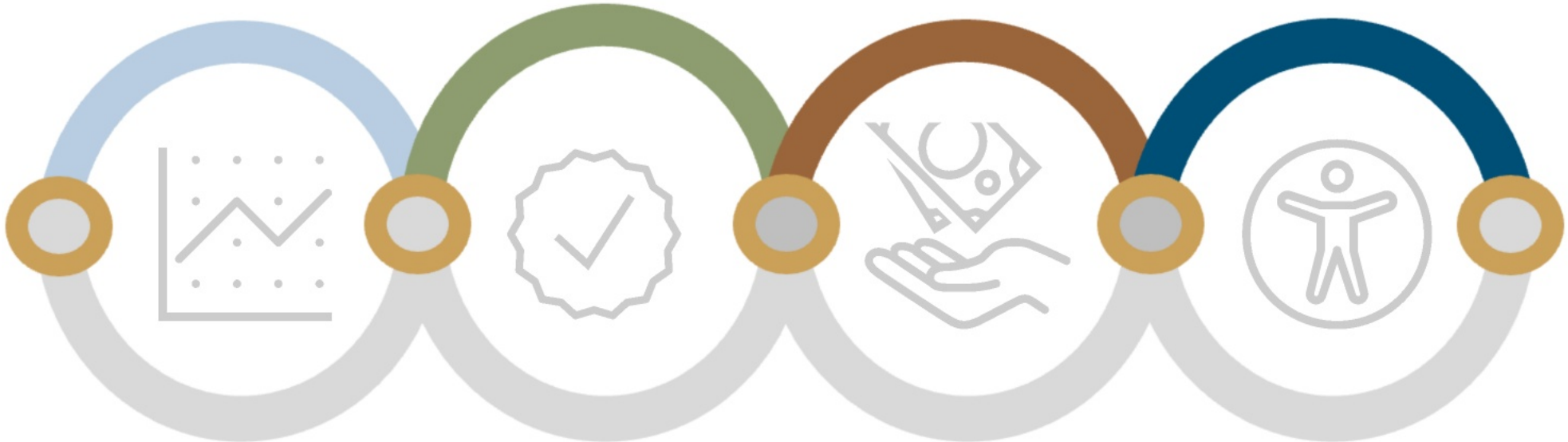
2 Introduction to Drug Reimbursement/ UK Landscape



Preparing for reimbursement success is crucial; regulatory approval alone is not sufficient for patient access



Clinical development

MHRA approval

Reimbursement (NICE) and pricing

Patient Access (launched product)

Drug reimbursement refers to the process by which the cost of prescription medications is covered or subsidised, either partially or fully, by the National Health Service (NHS) or other healthcare schemes

The reimbursement system aims to ensure that patients have access to essential medications without facing significant financial burden

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Abbreviations: MHRA, Medicines and Healthcare Products Regulatory Agency; NICE, National Institute for Health and Care Excellence

Regulatory ensures drug safety and efficacy, while reimbursement assesses value for healthcare decisions

MHRA ASSESSMENT

- Assessed by national/EU regulatory bodies
- The regulatory process ensures:

EFFICACY

SAFETY

QUALITY

NICE (HTA) ASSESSMENT

- Evaluated by health technology assessment (HTA) agencies/health insurance systems
- Assesses an intervention's potential benefits and value compared to other available options
- Varies from country to country
- Assessment can include the following :

CLINICAL EFFECTIVENSS

SAFETY

AND

COST-EFFECTIVENESS

BUDGET IMPACT

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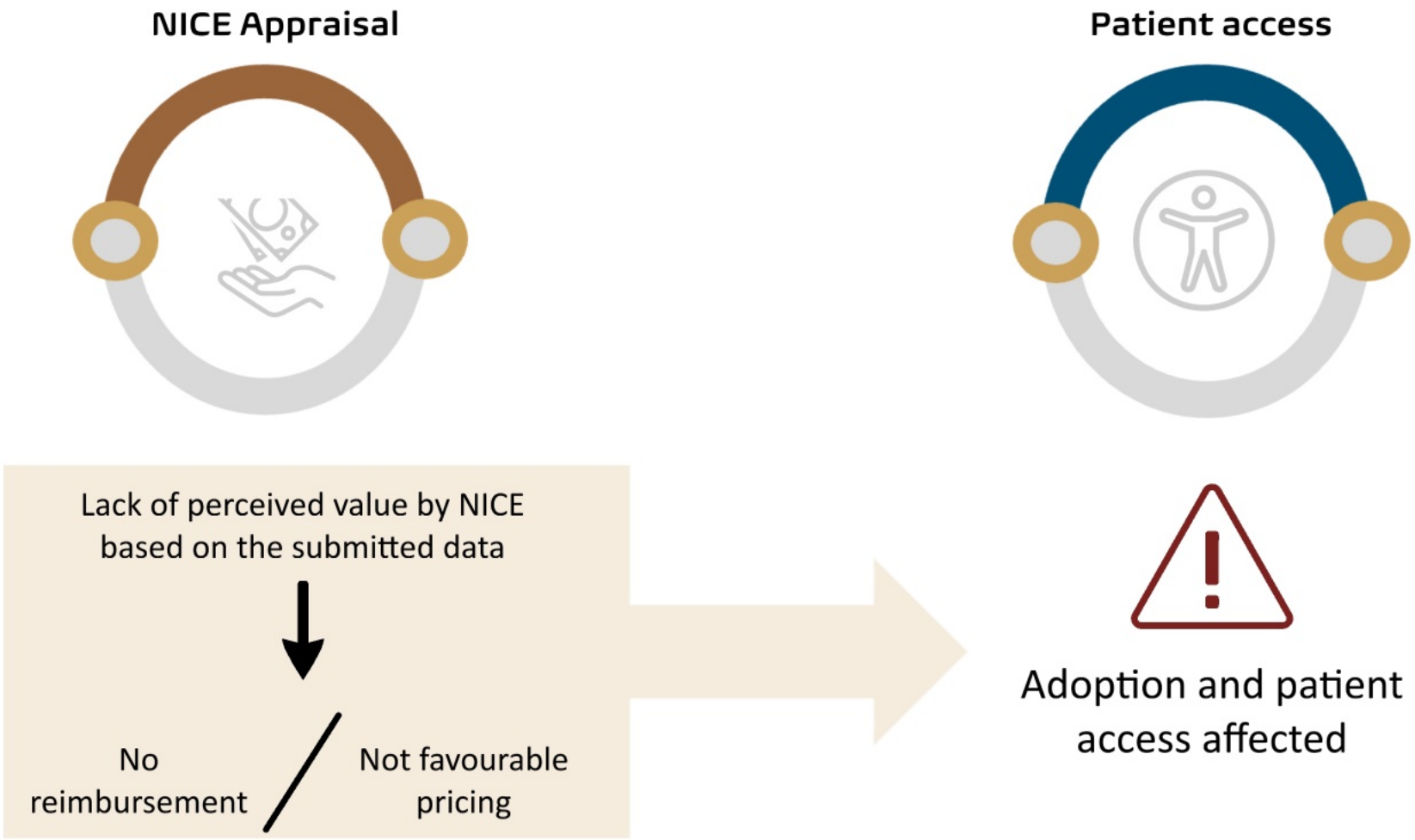
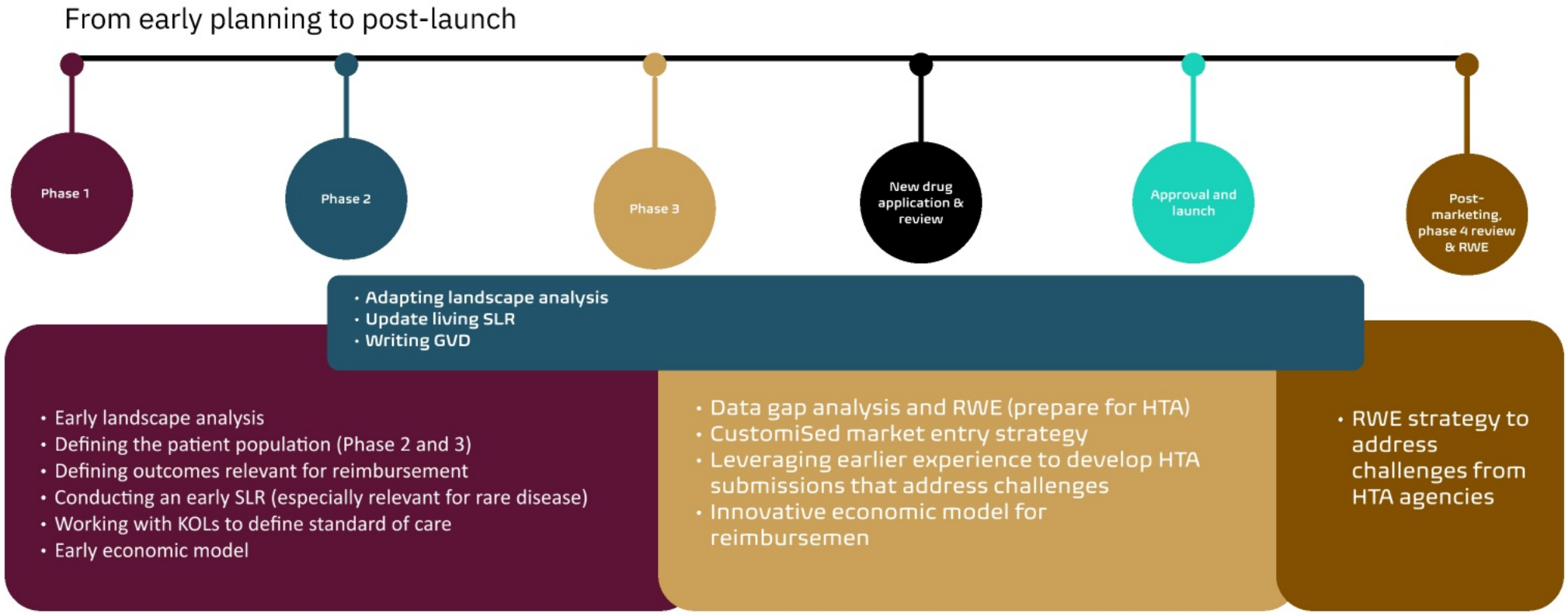
Abbreviations: HTA, health technology assessment; MHRA, Medicines and Healthcare Products Regulatory Agency; NICE, National Institute for Health and Care Excellence

A robust Pricing and Reimbursement strategy is essential for achieving commercial success



Abbreviations: NICE, National Institute forHealth and Care Excellence

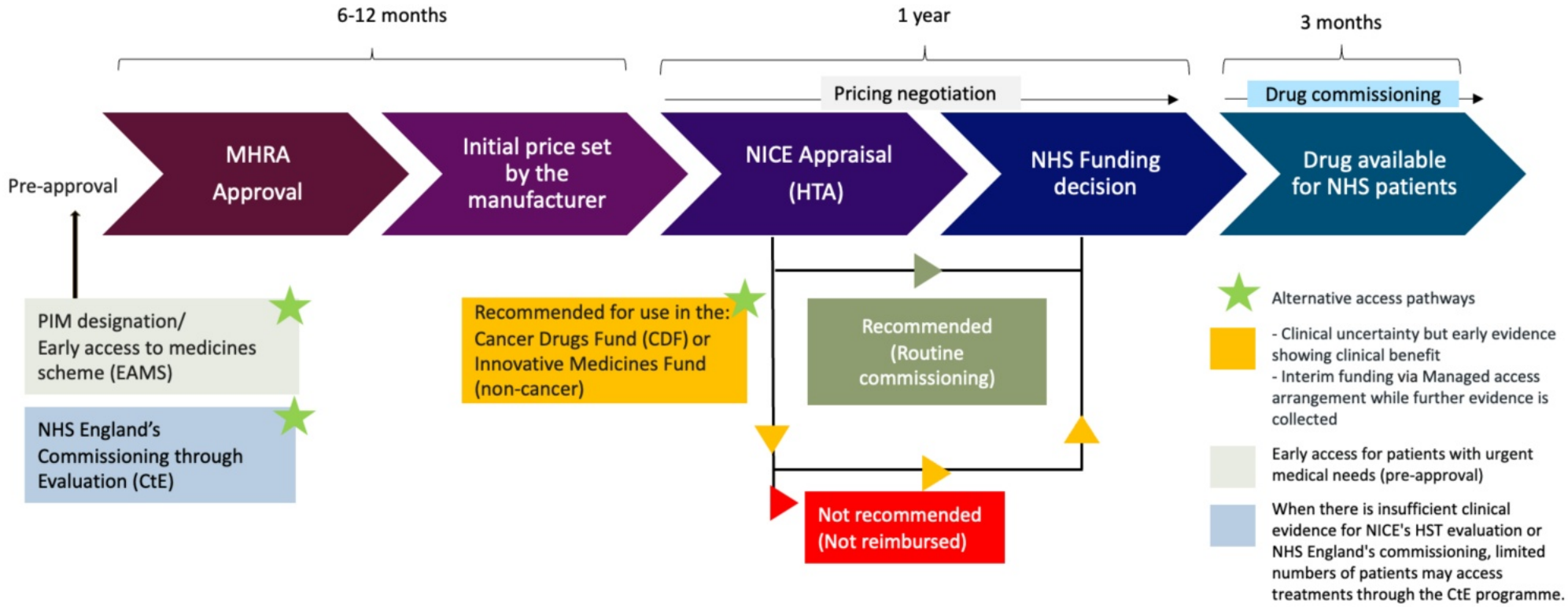
Strategic planning should start early, to ensure alignment with payer requirements



Abbreviations: GVD, Global value dossier; HTA, health technology assessment; KOL, key opinion leader; RWE, real-world evidence; SLR, systematic literature review

While the NICE appraisal is the main route, there are alternative access pathways for promising interventions with limited data

The UK's drug reimbursement pathway is a multi-step process that determines whether a medication is covered by the NHS



Abbreviations: CDF, Cancer Drugs Fund; HTA, health technology assessment; CtE, Commissioning through Evaluation ; HST, highly specialised technology; IMF, Innovative Medicines Fund; Medicines and Healthcare Products Regulatory Agency; NHS, national health service; PIM, promising innovative medicine designation

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NICE conducts a detailed review of the treatment's clinical and cost-effectiveness based on submitted evidence

NICE appraisal includes a review of:

- Clinical benefits compared to existing treatments (including health-related quality of life, HRQoL)
- Cost-effectiveness (CE) compared to existing treatments considering the price of the product
- Impact on the healthcare budget (medications costing more than £20m/year for the NHS in the first three years)

NICE's assessment process for new treatments includes:

1 Scoping

The scope defines the disease, the patients and the technologies covered by the appraisal and the questions it aims to answer

2 Assessment

Assesses the clinical and cost-effectiveness evidence of the treatment and considers input from various stakeholders (clinicians, patient groups and manufacturers)

3 Appraisal

- An appraisal committee decides whether the new treatment should be funded by the NHS
- Decision-making considers:
  - the strength of clinical evidence
  - patient clinical needs
  - cost-effectiveness
  - the robustness of economic evaluation
  - budget impact (if applicable)

NICE Outcome:

- Recommended
- Optimised (restricted patient populations)
- Recommended for use in the CDF/IMF
- Only in research
- Not recommended

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Abbreviations: CDF, Cancer Drugs Fund; HRQoL, health-related quality of life; Innovative Medicines Fund; NHS, National Health Service; NICE, National Institute for Health and Care Excellence

Cost-effectiveness evaluation is a key consideration in NICE's decision-making process, with CE thresholds needing to be met for a positive recommendation

NICE evaluates the cost-effectiveness (CE) of new drugs compared to existing treatments to determine which drugs offer the most benefits for their costs

$$\text{Incremental cost-effectiveness ratio (ICER)} = \frac{\text{Cost (new treatment)} - \text{Cost (standard treatment)}}{\text{effectiveness (new treatment)} - \text{effectiveness (standard treatment)}}$$

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Abbreviations: ICER, Incremental cost-effectiveness ratio; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year

Various types of NICE Technology appraisals are available to help improve access to treatments, each associated with different CE thresholds

Appraisal Type		NICE's CE threshold
Single Technology Appraisals (STA)	One medical technology for a specific indication	£20,000 to £30,000 per QALY (higher if severity modifier applied)
Fast Track Appraisals (FTA)	Quicker assessments for highly promising technologies with a threshold below £10,000 per QALY	£10,000 per QALY
Multiple Technology Appraisals (MTA)	Compare multiple related technologies or different uses of one technology and are more complex and time-consuming than STAs	-
Highly Specialised Technologies (HSTs)	Treatments for rare diseases	£100,000 - £300,000 per QALY (to account for high development costs and limited patient population)

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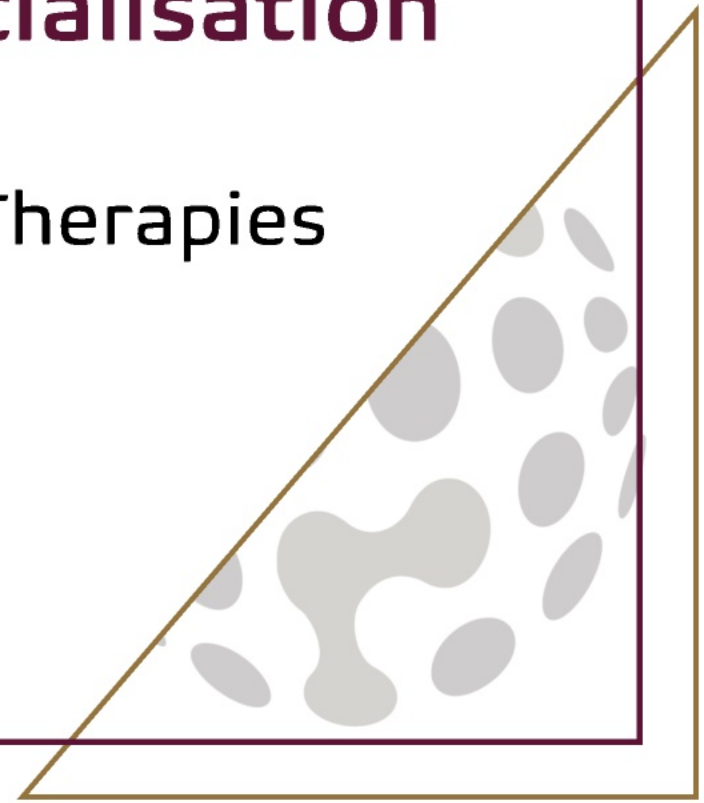
Abbreviations: ICER, Incremental cost-effectiveness ratio; NICE, National Institute for Health and Care Excellence; QALY, quality-adjusted life year

3 Considerations for Commercialisation

- Key Reimbursement Challenges
- Considerations for Combinations Therapies



The reimbursement landscape is evolving, with companies requiring innovative strategies such as value-based pricing and real-world evidence, to ensure timely access to effective treatments

- Budget constraints mean NHS prioritises treatments offering the most value (cost-effective), which can make access challenging for high-cost innovative treatments
- The reimbursement system has been slow to adapt to advancements such as ATMPs and treatments for rare diseases, causing delays in patient access to new treatments
- Increasingly, reimbursement decisions are being influenced by real-world evidence (effectiveness outside of trials). Generating real-world data adds to the cost and complexity
- Push towards value-based pricing requires linking the price of a treatment to its value to patients and the healthcare system
- Evolving regulations (Brexit and other policies) create uncertainty and challenges for companies

Manufacturers should be prepared to adapt their strategies as AI has the potential to impact the UK drug reimbursement landscape significantly, improving efficiency and resource allocation

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Abbreviations: ATMS, Advanced therapy medicinal products

Meeting cost-effectiveness requirements and cross-company pricing negotiations are key challenges for manufacturers launching combination/high-cost therapies

HTA Challenges

Challenging for combination therapies to reach the required 'cost-effectiveness' threshold to obtain a recommendation

Pricing/Commercial agreement challenges

Competition law prohibits companies from negotiating agreements on product prices

While customised pricing is allowed for combination therapies, meeting the criteria for pricing flexibility can be challenging

Demonstrating the combined and individual value of the products to negotiate prices effectively is challenging

Granular prescribing data required for components of the combination for transacting commercial agreements

Potential solutions are being explored with various stakeholders involved

- A negotiation framework to support cross-company dialogue has been developed by the APBI
- Two potential methods to attribute value across components of combination therapies have been proposed
- Potential solutions to resolving implementation hurdles related to combination/indication-specific pricing and the data required to transact commercial agreements are being explored.

Abbreviations: ABPI, The Association of the British Pharmaceutical Industry; HTA, health technology assessment

4 Recommendations/ Future Outlook

Early strategic planning is recommended for commercialisation success

Early engagement with regulatory and reimbursement bodies

Generating robust clinical and economic evidence

Patient advocacy and stakeholder engagement

Pricing and reimbursement negotiations

Post-reimbursement market access strategies

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Due to a lack of long-term data, NICE recommended using IsaPD with the CDF, and a discount was needed to meet NICE's cost-effectiveness threshold

Regulatory

Product: Sarclisa (isatuximab) + Imnovid (pomalidomide) + dexamethasone (**IsaPD)**
Manufacturer: Sanofi
Indication: 3L+ treatment of Multiple Myeloma
EMA approval: 26 March 2020
Pivotal trial: ICARIA-MM (IsaPd vs Pd); Phase 3, multicenter, randomized open-label study

HTA

NICE Final Appraisal Date: 18 November 2020
HTA Indication: Manufacturer positioned the treatment for 4L+ treatment of MM in the UK (aligning with local clinical practice)
HTA Outcome: Recommended for use within the Cancer Drugs Fund with a Managed Access Agreement

Key decision drivers

- Benefits demonstrated in improving disease progression and overall survival compared to Id. However, the long-term benefits were unclear
- Cost-effectiveness estimates were also uncertain and exceeded the NICE threshold, due to limitations in clinical data, leading to the recommendation for use in the Cancer Drugs Fund with further data collection and a managed access agreement

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Abbreviations: ABPI, The Association of the British Pharmaceutical Industry; CDG, cancer drugs fund; NICE, National Institute for Health and Care