Experience with hospital-based pay-for-performance agreements in the UK

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Outline

Why do we need price arrangements

How are they defined

Examples of Pay for Performance schemes and

How are they working in the NHS

Future trends and pressures

Price variation

To address

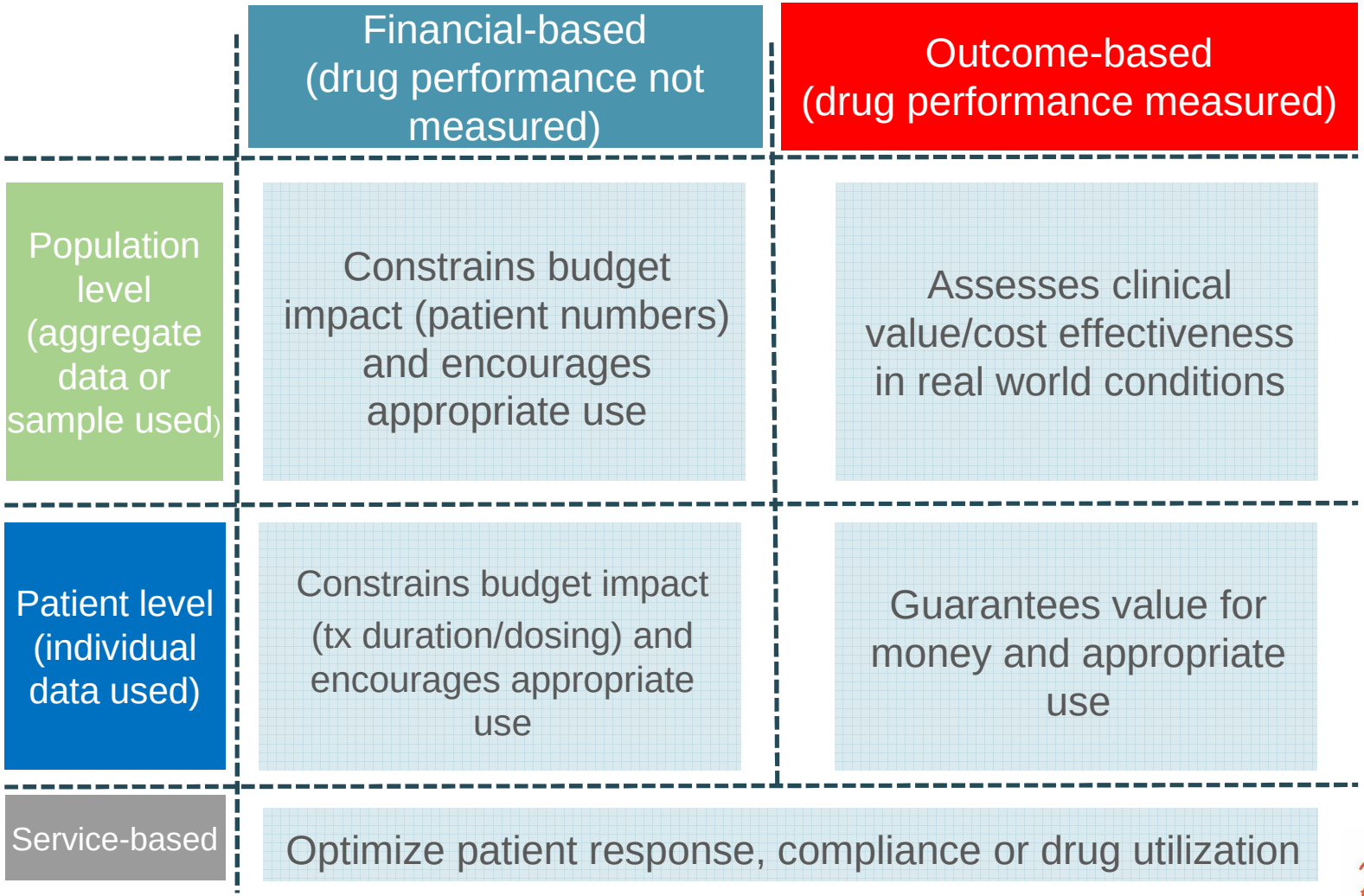
- High ICER (Incremental Cost Effectiveness Ratio) in the indication
- Financial uncertainties in the overall value of in the indication
- Clinical uncertainty about initial responders
- Clinical uncertainty about benefits in the longer term (modelled)
- Issues related to duration of treatment short course vs chronic (many years)

Governed by

- Rules set in the Pharmaceutical Price Scheme (PPRS) agreement between Government and Industry

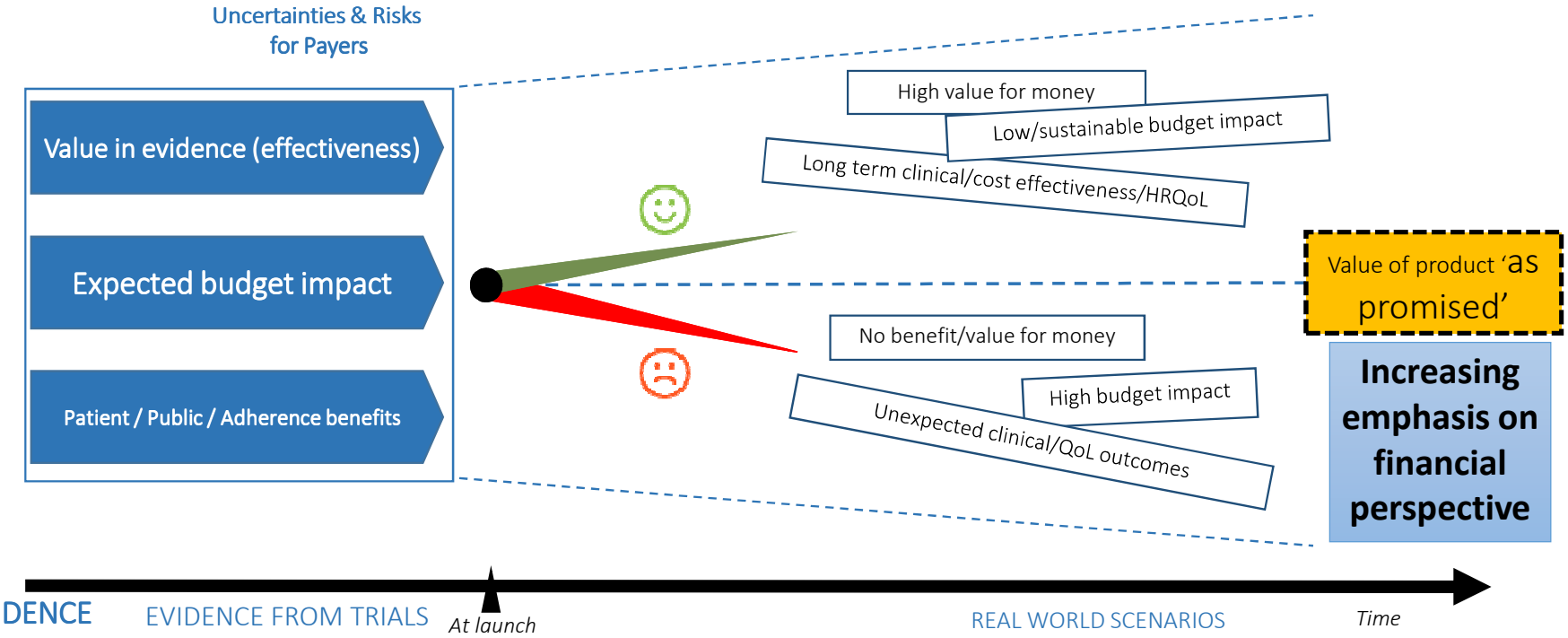
MEA Classification

…MEAs can mitigate payer uncertainties; various broad categories of MEAs exist



Payer Uncertainties

Budgets are finite so payers in all countries seek ways to mitigate clinical economic and usage uncertainties…



"An arrangement between a manufacturer and a payer that enables reimbursement of a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize effective their use, or limit their budget impact."

M Klemp et al. International Journal of Technology Assessment in Health Care, 2011, 27:77–83.

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Examples of Outcome based schemes in the NHS in England

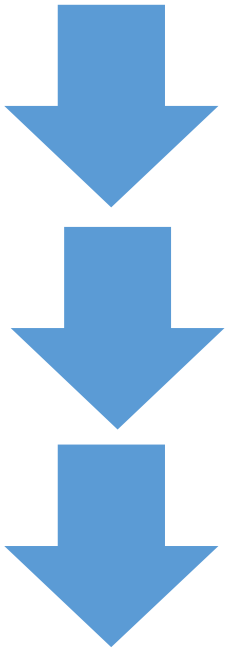
Outcome MEAs

Where performance based MEAs can be used to address finanacial and clinical uncertainty

The Velcade Response Scheme NICE TAG 127

- Velcade (bortezomib) used as monotherapy was slightly above NICE's usual £30k per QALY.
- Senior Haematologists and Pharmacists considered the scheme to be practical and workable in the NHS.
- The company estimated response rate would deliver a to rebate of 15% of the total cost of Velcade used in the
- Cost-effectiveness
- Using a response scheme, with a 4-cycle stopping rule, the incremental cost
- probability of cost-effectiveness at a QALY of £35k.

The scheme provided a mechanism to facilitate access through addressing the uncertainty about response – the NHS only pays for those who obtain benefit

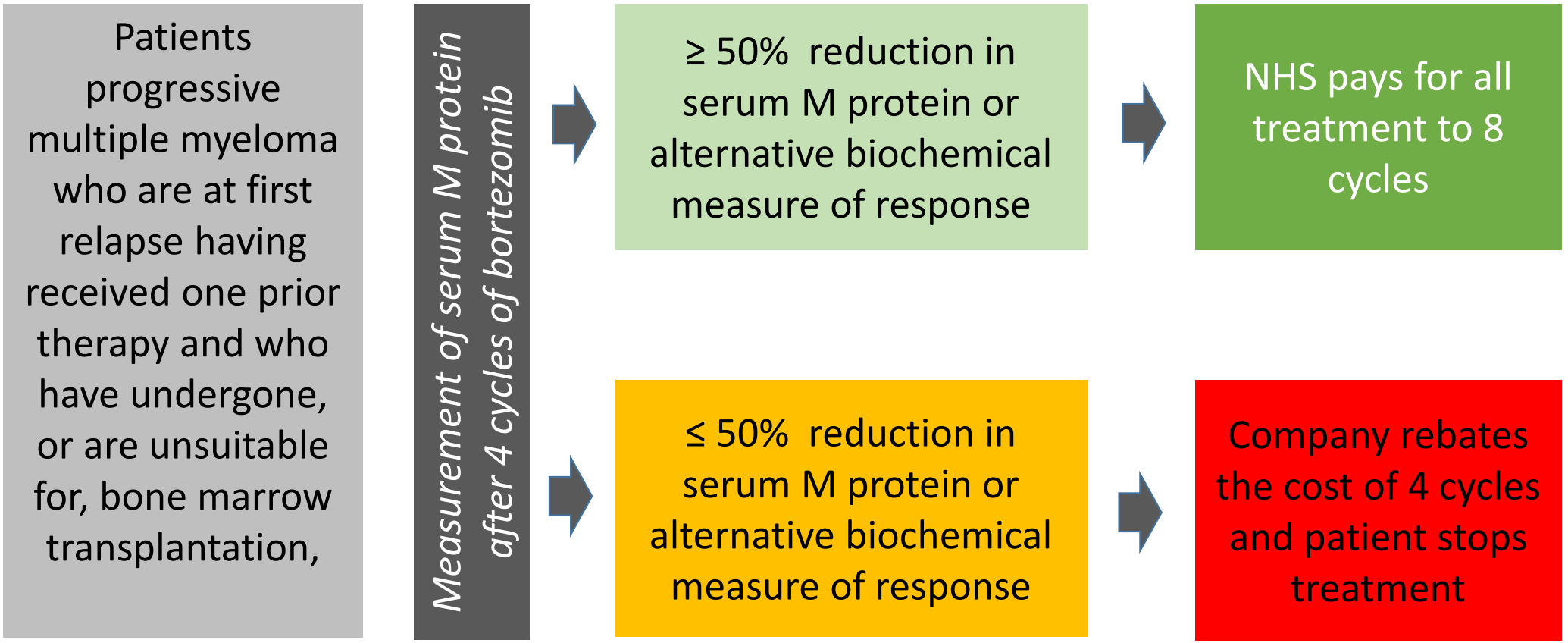


Scheme Process

- The NHS will fund patients at first relapse who achieve a response to Velcade
- The company will provide replacement stock or credit for those patients at first relapse who fail to respond to Velcade.
- Response = patient achieving at least a Minimum Response (a 50% or greater reduction in serum M-protein) within the first 4 cycles of treatment. Paid for by NHS to 8 cycles max.
- Non-response is less than a 50% improvement in serum M-protein) within the first 4 cycles. Rebated by company no cost to NHS

This scheme was launched in 2007. Many initial issues tracking and organising the rebate claims Admin time 37.5 minutes and NICE estimated it would be necessary to identify almost 785 patients receiving treatment to locate the 377 patients eligible for a refund.

Velcade Response Scheme



Hybrid MEAs

There are variations to the classic MEAs designs

The Iressa (gefitinib) SPA Scheme NICE TAG 192

- Single EGFT-positive NSCLC
- **First two 30 day packs free for registered patients**
- NHS **invoiced only when the third pack is ordered**
- **Trust invoiced £12,200** at this point regardless payment for Iressa in of duration of treatment (fixed price equivalent to 5.6 packs)
- Mean number of **packs per invoiced patients is 13.2 (vs. benchmark 0f 8.8 months for CE)**
- Online registration for patients and ordering facility with alternative delivery options
- **This single platform provides control over supply and demand with alternative sites ordering and patient validation**

Scheme Process

- EGFR positive NSCLC diagnosis
- Decision to prescribe Iressa
- Register patient online for scheme

- Iressa pack 1 ordered through online platform
- Check patient response

- Iressa pack 2 ordered through online platform
- Check patient response
- Billing upon pack 3 and treatment continued as required

This scheme was launched in 2009 but **fine-tuned over the following 4 years**, to make it easier to use. This included: delayed invoicing, introduction of administrator, web-based ordering, direct linking from registration to order, validation procedures, admin support to NHS from AZ

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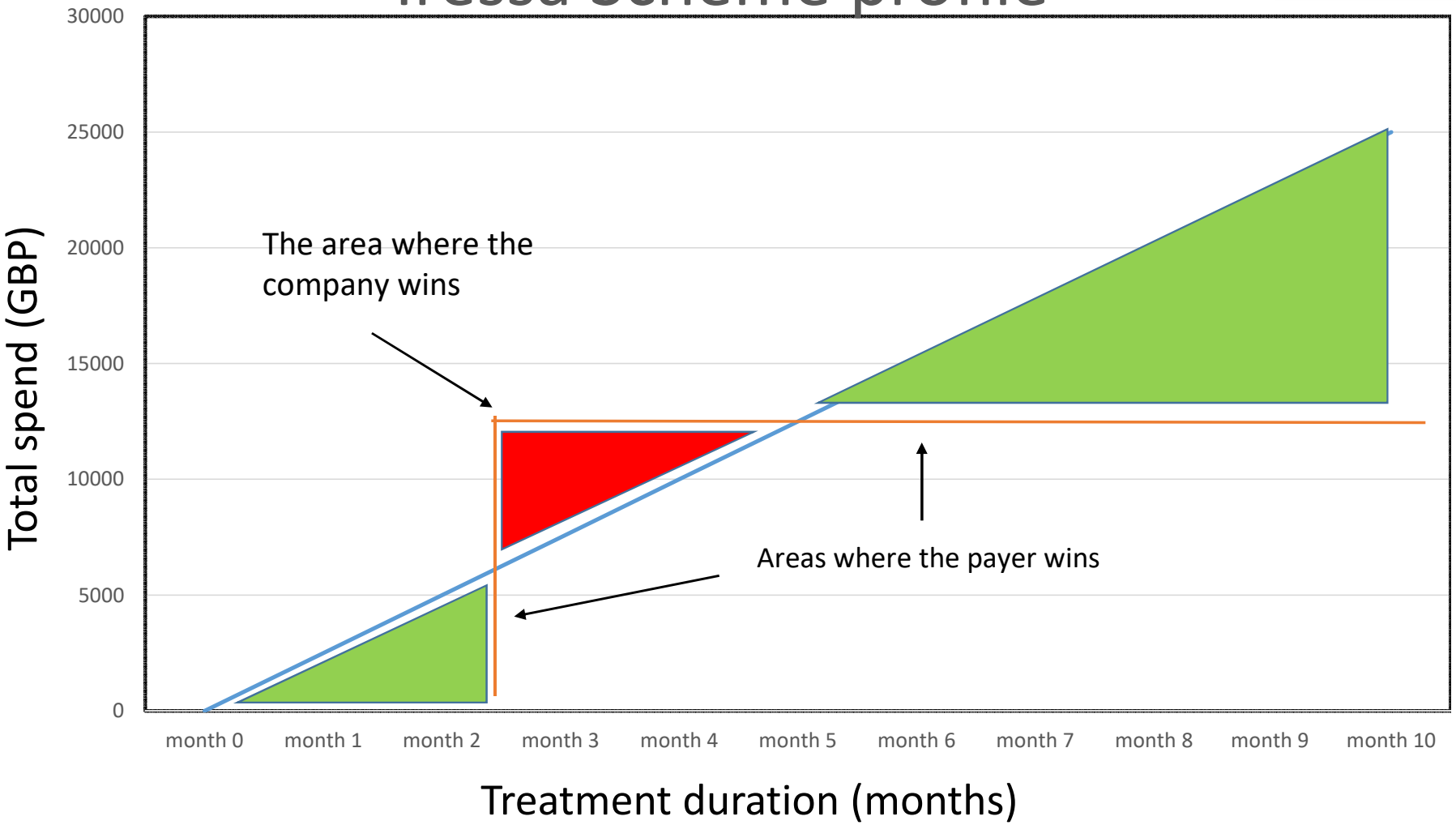
Iressa Scheme profile



CED MEAs

Vimzim has had a multi-component MEA including start/stop criteria approved in the UK driven by patient advocacy despite payer uncertainties

Vimizim (elosulfase alfa) by BioMarin	
Indication	**Enzyme replacement therapy** for Mucopolysaccharidosis Type IVA (inherited lysosomal storage disease)
Status	HST guideline was published in Dec 2015
Outcome	**Likely recommended for funding, but only within the MAA context** (Cost of Vimizim (incorporating PAS) was considered too high to be recommended outside the context of a managed access agreement)

Managed Access Agreement (via EMA registry)

- F — **Confidential discount** (PAS) to list price with DoH
- F — **A protocol that sets out the clinical criteria for starting and stopping** treatment (details in note below)
- F — **Set the total costs of elosulfase alfa** during data collection, in addition to PAS
- O — **Enrol all patients into a 12 year disease registry**

The data will be used by NICE to inform a review ≤ 5 years after guideline publication

If NICE does not recommend Vimizim at the end of the 5 year, NHS England funding will cease

F Finance-related O Outcome-related

Key Payer Uncertainties

- **The high acquisition cost** is not fully justified (estimated at £394,680 per patient per year)
- **Financial risk** – e.g. the precise number of patients who will be treated with Vimizim is uncertain
- **Long-term outcomes remain uncertain**
- **Real world benefit uncertain -** Clinical trial data was not substantiated by patient testimonies

Budget impact
Appropriate patient population
Clinical Effectiveness

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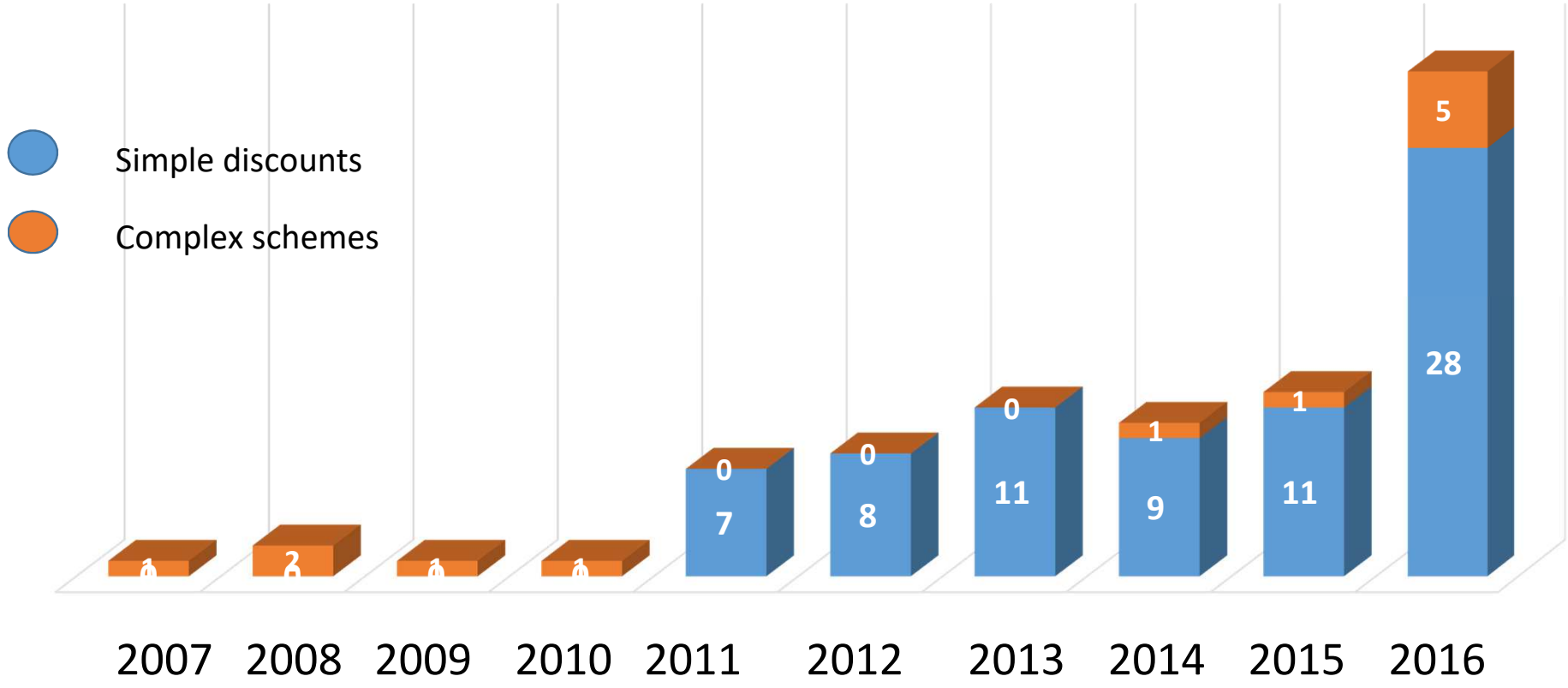
Increase in MEAs in England since 2007



Future Trends/Pressures

- Pressures on Budgets – directly and indirectly
- New medicines and mechanisms (including cures)
- Multi-indications
- Pricing/costs will remain high
- Innovation in MEAs will match the innovation in medicines
- HTA and MEA in diagnostics and devices.
- Relationships between companies/payers/clinicians/patients
- Systems to improve tracking and management

Gracias

Dispuesto a responder a cualquier pregunta