

# Value-Based Pricing for Cancer Drugs

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# “Value”: What and Why Use It?

- **“Value”**: Outcome per \$ spent
  - inverse of the cost-effectiveness (CER)
  - CER = \$ spent per unit outcome
- **“Incremental value”**: additional value, *relative* to alternative treatment
  - ICER = Incremental cost-effectiveness ratio
- **Value-based pricing and utilization promote efficiency and equity** in use of resources
  - Maximum health gain for the budget
  - Equity across diseases and patients

$$\frac{\text{Outcome}}{\$ \text{Cost}}$$

$$\frac{\Delta \text{Outcome}}{\Delta \$ \text{Cost}}$$

# Measurement of Outcome and Cost

- “Outcome” incorporates all patient-centric dimensions of health: response rate, survival, functional status etc.
  - Multiple dimensions, differ by disease
- QALYs (Quality-Adjusted Life Years) is a comprehensive outcome metric, incorporates quantity + quality of life
  - Used to combine multidimensional outcomes and compare health gain consistently across disease classes
    - Enables consistency across patients and classes
- “Cost” is Total treatment cost: includes drug price  $P$  + all related costs: e.g. infusion, inpatient days etc.

# Overview of Value-based Pricing <sup>1</sup>

- Outcomes assessment: An independent agency (or individual payer) evaluates outcomes evidence for new drugs vs. comparators
- Each payer sets its value threshold (WTP) required for reimbursement e.g. \$100,000 per QALY (could differ by indication)
  - Based on its budget, enrollees' income and preferences etc.
- Manufacturer set the price, given their drug's outcomes evidence and the payer's value threshold required for reimbursement
- Payers reimburse for patients if the drug meets the expected value threshold
- Co-payments are modest, to assure affordability for patients
- <sup>1</sup> "Value-Based Differential Pricing: Efficient Prices for Drugs in a Global Context" . Danzon, Towse and Mestre-Ferrandiz. *Health Economics* 2013.

# Value-based Pricing: Each Payer Requires that Drugs Meet a Value Threshold for Reimbursement

$$\Delta C_n / \Delta E_n = ((P_n - P_o) + (c_n - c_o)) / (E_n - E_o) \leq K \text{ for reimbursement}$$

$C_i = P + c =$  Total treatment cost

$P =$  price of the drug (new or comparator)

$c =$  other direct (and indirect) costs

$n =$  new drug,  $o =$  old drug/comparator

$E =$  health outcome measure e.g. QALYs, OS, PFS

$K =$  payer's value threshold or maximum willingness-to-pay (WTP) per unit outcome

e.g. \$100,000 per QALY

# Manufacturer Sets the Drug Price, Given the Payer's Value Constraint or WTP for Health

- Reimbursement requires:  $(\Delta P + \Delta c) / (\Delta E) \leq K \Rightarrow$
- The maximum, value-based price is:  $P_n^{\max} \leq P_o + \Delta c + K \Delta E$ 
  - $P_o$  = price of comparator
  - $\Delta c = c_o - c_n$  = incremental cost savings
  - $\Delta E = E_n - E_o$  = incremental health gain to patient
- $P_n^{\max}$  = value-based price =  $P_o$  + health gain + cost savings
- VBP rewards innovation that improves health or reduces costs
- The payer's WTP for health (K) is critical to placing a \$ value on health consistently across drugs and patients

# A Value Requirement for Reimbursement Implies a Limit on Price, Proportional to Incremental Value

- Manufacturer sets price, but the payer's value requirement for reimbursement implies a constraint on price
  - No incremental value => no price premium
  - Significant incremental value => significant premium
- Payers reimburse for all patients who meet the value threshold
  - => Consistent value of resource use across patients
- Value-based pricing rewards manufacturers for improved effectiveness and/or cost savings => incentives for innovation

# Modifications: Addressing Plan and Patient Heterogeneity; Uncertainty

- Individual health plans could use their own value assessment and/or value thresholds: lower WTP => deeper discounts and lower premiums but more restrictive patient access
  - Enrollees could choose among plans
- Value thresholds could differ by disease e.g. cancer, orphan drugs
- If a drug's effectiveness differs by indication, price/reimbursement could differ by indication, if practical
- Provisional reimbursement + post-launch data collection and price adjustment if pre-launch outcomes evidence is limited
  - Clinical trials may be small and unrepresentative

# Cost and/or Risk Sharing Agreements Could be Negotiated by Payers

- Cost-sharing by manufacturer:
  - Manufacturer pays for first X doses per patient, payer then pays for patients who respond
  - Manufacturer pays if payer's cost exceeds \$Y per patient or \$Z in aggregate for the drug
    - Caps payer's cost per patient or in aggregate
- Risk sharing by manufacturer based on outcomes:
  - Price is adjusted ex-post based on average patient outcome
  - Payer only pays if patient responds
    - Implementation of risk sharing can be costly

# How does Value-based Pricing (VBP) relate to the ASCO Value Framework (in process)

## VBP

- Outcome: benefits + risks
- Standard, best-practice CEA/CUA methods
- Assessment by Independent expert body
- All related medical costs
- Drug prices are constrained
  - \$/outcome is consistent
- Value guides utilization

## ASCO: Details TBD

- Outcomes: benefits + risks
- Value scoring, weights, cost vs. outcome trade-offs tbd
- Assessment by ASCO?
- Drug cost + infusion only?
- Drug prices not constrained directly.... Maybe indirectly
  - \$/outcome not consistent
- Value guides utilization

# Lessons from other countries: 1. General

- Some payer constraint on price/reimbursement is necessary to control prices when patients are insured and price-insensitive
- Many countries require (comparative) effectiveness data as input to approving price/reimbursement: FR, GR, UK, SW, CA, JP, NE etc.
- Countries differ in details of implementation:
  - Role of govt. vs. independent bodies in outcome assessment
  - Outcomes metrics: survival, morbidity, functional status, QALYs
  - Comparators; Subgroup analysis
  - Explicit/implicit limit on \$/Outcome (Value threshold)
  - Updating post-launch; risk or cost sharing

# Lessons from other countries: 2. UK's NICE

- UK NICE uses a VBP approach
- Requires a consistent, rigorous methodology for measuring outcomes (mortality, morbidity and QALYs) and costs
- £/QALY limit reflects opportunity cost of NHS resources
  - To maximize value gained from NHS budget and assure equity among patient groups
  - £20-60,000 per QALY, higher for some end-of-life conditions
- Cost or risk-sharing Patient Access Schemes negotiated for some cancer drugs: avoids ex-UK price spillovers

# Lessons from other countries:

## 3. Germany's AMNOG pricing system

- Company sets its price freely for one year
- IQWiG evaluates comparative effectiveness
  - Comparator, outcome measures etc. set by GBA
- If new drug has no additional benefit, gets Reference Pricing
  - All drugs in Reference Price group get same reimbursement
- If additional benefits exist, GBA negotiates the price premium
  - Using a disease-specific “efficiency frontier” (€/outcome, K)
  - => Consistent value *within (not between)* disease classes

# 3. Germany (continued)

- Only 29% (34 of 116) AMNOG assessments so far found some additional benefit (Scrip, Feb. 2014)
- Partly due to “inadequate data”
  - GBA requires current treatment comparator, which often differs from that used in clinical trials
  - GBA prefers clinical outcomes, not surrogate endpoints
    - E.g. survival, not progression-free survival
    - GBA is less willing to use modelling than NICE
- Important implementation lessons e.g. earlier discussions with industry about data requirements

# Conclusions

- US lags in requiring value to support price and reimbursement
- VBP incentivizes pricing proportional to value created
  - Patient outcomes + cost savings, relative to status quo
  - Preserves incentives for innovation
- VBP would constrain US price growth, but not reduce current US prices or access to UK or German levels
  - New US prices benchmarked to current US prices
  - US WTP for health exceeds WTP of UK or Germany
- Outcomes measurement in cancer is already underway
- Measuring value (outcome/\$cost) is the important next step