1. What is indication-specific pricing (ISP) and why is it important?

“Setting different prices for the same product across indications or in distinct patient sub-populations”

- A wave of new and often expensive therapies, including novel combinations, provide different levels of clinical benefit across different indications/patient sub-populations; yet in most countries, a manufacturer can charge only one price
- Indication-specific pricing is one potential solution to this challenge, benefiting the manufacturer, payer and patients

2. In which situations should ISP be considered?

**A** Varying clinical value across indications

- **Case Study: Tarceva®**
  - Median survival gain of 3.4 months in NSCLC versus 10 days in pancreatic
  - **Challenge:** Assigning a different price for each indication based on clinical value is challenging in the US due to administrative, regulatory, and legal hurdles (e.g. Medicare Best Price)
  - **Solution:** Express Scripts began piloting the Oncology Care Value Program in 2016, using a single, weighted-average price based on estimates of indication usage across their patient population

- **Case Study: Tenapanor**
  - Ardelyx plans to file for FDA approval of and OFDS (Price and rebates in Switzerland), Express Scripts began piloting the Oncology Care Value Program
  - **Challenge:** Launching in a large indication first could limit molecule’s pricing potential for follow-on indications
  - **Solution:** Developing an indication-specific pricing strategy can help a manufacturer realize pricing potential of any follow-on indications with high unmet need

**B** Indications with different dosing

- **Case Study: Zometa®/Reclast®**
  - Zoledronic acid is dosed once per year in osteoporosis and once every 3-4 weeks in the molecule’s lead indication, cancer bone metastasis
  - **Challenge:** In the US, a single HCPCS code is used to bill for a Part B drug across indications
  - **Solution:** Novartis launched Zomet in bone metastasis and later pursued a separate NDA for Reclast in osteoporosis to operationalize differential pricing on a per milligram basis and maximize total revenue for the molecule

- **Case Study: Revlimid® and Kyprolis®**
  - Revlimid costs $6,500 per cycle but Kyprolis in combination costs a total of $14,300 per cycle in the same indication (relapsed multiple myeloma)
  - **Challenge:** Combination of Revlimid and Kyprolis offers incremental PFS of 9 months over Revlimid alone but some payers unwilling to pay the stacked price
  - **Solution:** Both manufacturers agreed indication-specific discounts for use of their respective drug when used in combo beyond 12 cycles

3. Are global markets ready for ISP?

- Pricing in some countries already takes into account different levels of clinical benefit by indication via a single, weighted-average price
- However, a single price reflecting overall value across indications dis-incentivizes manufacturers from launching additional indications with lesser clinical benefit

**Feasibility Assessment**

- **US**
  - Historically, legal, regulatory, & administrative hurdles have prevented ISP
  - Nevertheless, some PBMs are piloting ISP to move towards value-based formularies. CMS now allows indication-based formulary design in Part D, which could lead to ISP or weighted average pricing in Part D plans

- **DE**
  - There are a number of issues with implementing ISP in Germany due to high levels of data protection and because a weighted-average price is already used
  - Diagnosis data is collected by payers but is not sufficient for ISP

- **UK**
  - ISP not being carried out although some indication tracking infrastructure may already exist for onc. drugs through SACT & PAS®
  - In Scotland, ISP is implemented for oncology indications only via Chemocare

- **ES**
  - ISP is implemented for oncology using software and collect data and this is held at the central level

- **BE**
  - ISP not formally in place but tools exist for indication tracking, e.g. TARDIS® platform allows for the tracking of patient data in RA
  - In addition, e-scripts are to be introduced by 2020, which could support indication tracking for ISP

- **FR**
  - Govt. moving towards indication-based discounting
  - Two national databases to soon merge, which will improve data tracking
  - Currently only expensive hospital drugs are tracked by indication

- **IT**
  - ISP already applied to some extent with MEAs
  - Data collection already by indication, which could facilitate ISP implementation
  - Uncertainties remain on how to fund creation & maintenance of a new registry

- **CH**
  - ISP previously implemented
  - Different rebates by indication for:
    - Drugs with multiple indications, e.g. Avastin
    - Drugs used in combination, e.g. Revlimid combo with Kyprolis vs. Empliciti

4. What must be considered when implementing ISP?

**Step 1 – Evaluate**

- For inline and pipeline products that could benefit from ISP, evaluate feasibility by country and prioritize those with high potential for implementation

**Step 2 – Implement**

- Manufacturers can propose and help set up ISP in these countries by working with health systems – e.g., data from ODN can help manufacturers negotiate flexible price payments agreements

**Step 3 – Result**

- By agreeing on prices that reflect the value of a product by indication, payers no longer risk paying too much for limited value and manufacturers are not dis-incentivized to commercialize all indications that offer incremental value over existing treatments