Upper Payment Limits: Example Framework

September 18, 2023

Prescription Drug Affordability Board Staff

MARYLAND
Prescription Drug Affordability Board

Agenda

- Key Decisions for Upper Payment Limit (UPL) Action Plan
  - What drugs are most appropriate for UPLs?
  - How do you set a UPL?
  - How do you apply a UPL?

Determining which drugs to set UPLs for

- Should all drugs that the board determines cause an affordability challenge be subject to UPLs?
- If not, how should the board determine which are appropriate for UPLs?
  - Dealing with manufacturer market power
  - Dealing with Gross-to-Net Bubble
- Focusing on specific reasons may guide the methodology for setting the UPL

Dealing with Market Power

- Curbing monopoly pricing
- Discouraging collusion and promoting competition
- Discouraging anticompetitive behavior
- **Key Point for setting UPLs**: UPLs in this situation need to determine the fair payment amount for the product
    - Fairness can be based on value, budget, innovative incentive, or across payors

Dealing with Gross-to-Net Bubble

- Because of PBM-Insurer market power, they can make money while passing the costs on to patients
- **Key point**: UPLs can be used so that patients do not pay an unfairly large share of the net cost as out-of-pocket payments
- **Example Proposal**: The UPL should focus on the net cost of the drug and should not specifically target the gross-to-net bubble

How to set UPLs

- Previous discussions on different frameworks focused on specific methodologies as if they were discrete choices
- It is possible to use different methods and frameworks in different circumstances
- Other countries have made decisions on how to set payment amounts in different situations

Lessons from Other Drug Payment Systems

- Often a 2-part assessment
  - Are there existing therapeutic alternatives?
    - If not, how do you calculate an appropriate amount?
  - If yes, is the drug an improvement over existing therapies?
    - If no, reference to existing therapies
    - If yes, set amount for the additional improvement

Unique Challenges for UPLs in Maryland

- UPLs have not been set in Maryland
- As a result, assessments based on comparators may still result in unaffordable drugs if the comparators are not affordable
- A potential value assessment-based framework must take that into account

Efficiency Frontier

- Compared price and effectiveness of drug with therapeutic alternatives
- Most useful if several (>2) treatment alternatives
- Pros: Can use disease-specific measurements of health benefits, no need to standardize across diseases
- Cons: Most effective when alternatives are priced affordably

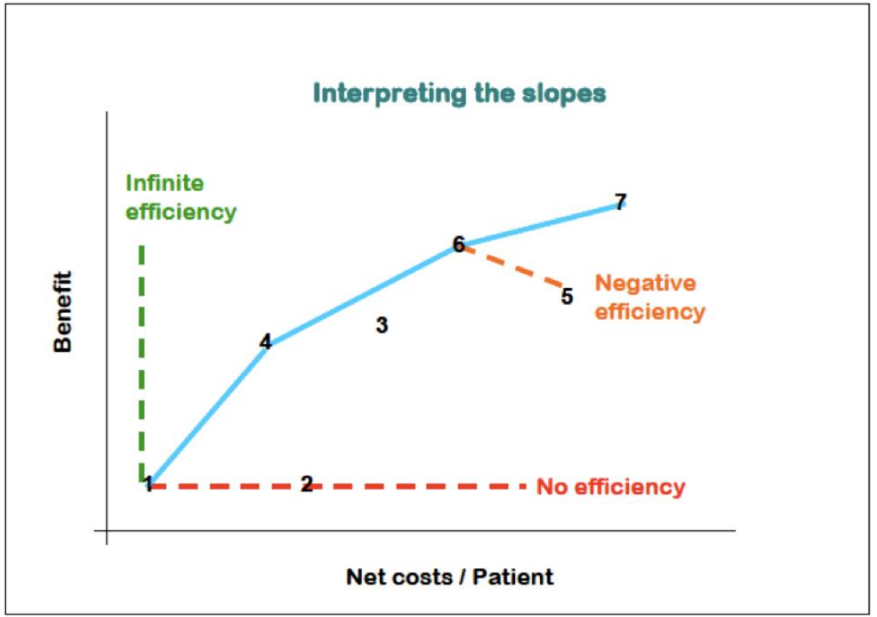

Figure 5: Interpreting the slopes of the theoretical efficiency frontier

The horizontal gradient (= 0°) indicates no efficiency (e.g. 2 versus 1) while the vertical gradient (= 90°) indicates infinite efficiency. Positive gradients (e.g. between points 6 and 7) reflect additional benefit for increased cost while negative gradients (e.g. between points 6 and 5) indicate less benefit yet more costs.

An Example Framework for UPLs

- Step 1: Establish an efficiency frontier for the indication, including other drugs in the same class
- Step 2: Determine the appropriate comparators based on the frontier
- Step 3: Determine if the UPL needs to bring the product back to the frontier (i.e., therapeutic reference pricing) or needs to alter the frontier (i.e., cost effectiveness analysis)

Modifications After Assessment

- The result from the assessment can be altered based on other factors
  - Budget assessment: Is the total expected spending still too high after adjusting the the payment amount?
  - Rate of Return: Manufacturer information on whether there should be some increase in payment amount specific to the market to promote information
  - Penalties for anticompetitive behavior
    - Reductions in the UPL below the value assessment if manufacturers engage in anticompetitive behavior
- The resulting upper payment limit will set a maximum net amount for the prescription drug

Additional Questions to Consider

- Source of Data: Published literature? New real-world evidence? New randomized controlled trial evidence? Models?
- Who is conducting the analysis: Board Staff? Potential for expert input? Potential for manufacturers to submit information?
- Should data be Maryland-specific or can we extrapolate from other data including data from other countries?
- **Example Proposal:** Staff conducts an analysis of existing literature, but manufacturers can submit new information that is Maryland-specific

Implementing the UPL

- Current authority applies to state entities
  - Dealing with current contracts
  - Different state entities are engaging at different parts of the supply chain
- How to implement UPLs
  - Payment amount
  - Rebates
  - Charge-backs

Flow of the UPLs through Supply Chain

- The impact of UPLs across the supply chain is complex
  - CMS in the proposed MFN rule assumed payment limits to physicians would flow back through the supply chain and reduce manufacturer reimbursement
  - The current CMS negotiation process intends to use a retrospective refund model
- Other countries often regulate manufacturer prices, but also have regulations on mark-ups throughout the supply chain

Implementing UPLs as Payment Amount

- Upper payment limits can be the amount paid from the payor/PBM to entities that dispense or administer the drug to the patient (pharmacy)
- Clear mechanism, but unclear how it will impact the supply chain
- Pros:
  - Simple process
- Cons:
  - Unclear how the payments will flow through the supply chain

Implementing UPLs Through Rebates

- Upper payment limits can be applied use the existing rebate structure (i.e., payment from the manufacturer to the payor/PBM to achieve the upper payment limit)
- Pros:
  - Provides savings to the state with the least disruption to the supply chain
- Cons:
  - Does not broadly address the distortions in the prescription drug market that make the drugs unaffordable

Implementing UPLs Through Charge-backs

- Upper payment limits can be implemented through amount paid from the payor/PBM to the entity that dispenses or administers the drug to the patient (pharmacy), and then that entity (pharmacy) can recover a charge-back from the manufacturer for the difference between its acquisition cost and the upper payment limit
- Pros:
  - Clarifies how the upper payment limit will affect the supply chain
- Cons:
  - Complex process

UPLs for Government as a Payor (non-Medicaid)

- Likely initial process for upper payment limits
- State, county, and local governments have contracts with payors and pharmacy benefit managers to manage employee prescription drug benefits
- Payors managing the employee health benefits can use upper payment limits to achieve savings
- **Example Proposal:** Implement upper payment limits for employee health plans through rebates

UPLs and Medicaid

- Medicaid is a highly structured and regulated program that is a federal/state partnership
  - Medicaid Drug Rebate Program (MDRP) means that different drugs cause affordability challenges than in the commercial market
  - Patient cost share is less likely to be an issue in Medicaid
- **Example Proposal:** Medicaid should be a separate process from the commercial market, and should be implemented through additional supplemental rebates

UPLs and the Government as a Purchaser

- The state is a direct purchaser of drugs (e.g., state hospitals, corrections, public health)
- The drugs that cause affordability challenges for the state as a purchaser will likely be different than the drugs that cause challenges for the state as a payor
- **Example Proposal**: Explore charge-backs as mechanisms to implement upper payment limits for direct purchases

Next Steps

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- Stakeholder Council Meeting- October 23, 2023
  - Present Feedback from Board to Stakeholder Council

- Board Meeting- November 27, 2023
  - Present Feedback from Stakeholder Council and Recommendations for Upper Payment Limit Action Plan

- Draft of Upper Payment Limit Action Plan

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Appendix

Canada

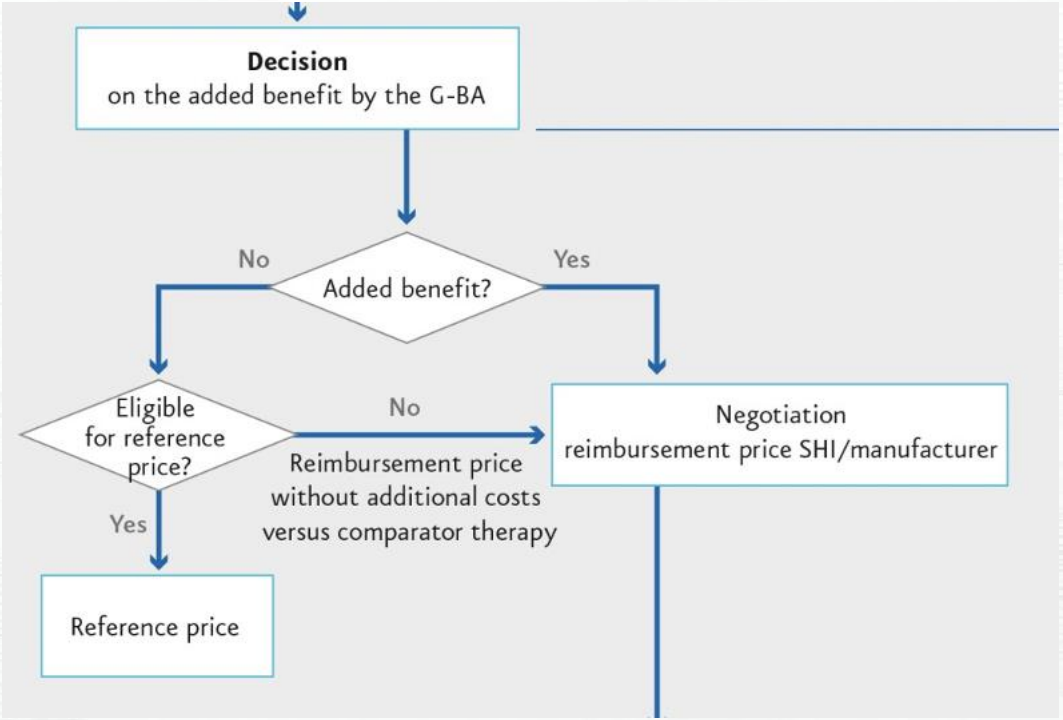
- Clinical effectiveness (Therapeutic Criteria Level: I-IV)
  - Primary: higher efficacy, reduction in adverse effects
  - Secondary: route of administration, compliance improvements, caregiver convenience, avoidance of disability, etc…
  - QALYs
- Cost effectiveness
  - Category I: high priority (12-month treatment > 150% GDP/capita or >$12 million market size)
  - Category II: low priority
  - Market size
- Index pricing:
  - 7 (prior to 2022): France, Germany, Italy, Sweden, the UK, Switzerland, the U.S.
  - 11 (2022 onwards): took off Switzerland and the U.S., added Australia, Belgium, Japan, the Netherlands, Norway, Spain

France

Transparency Commission Added Therapeutic Value (ASMR) Rating of New Drugs, 2009–2016

ASMR rank	ASMR I: Major improvement	ASMR II: Important improvement	ASMR III: Moderate improvement	ASMR IV: Minor improvement	ASMR V: No improvement
Annual average number of drugs	1.4	3.3	8	22	51
Pricing	By reference to prices in U.K., Germany, Italy, and Spain: Neither higher than the highest price nor lower than the lowest price.	By reference to prices in U.K., Germany, Italy, and Spain: Neither higher than the highest price nor lower than the lowest price.	By reference to prices in U.K., Germany, Italy, and Spain: Neither greater than the highest price nor lower than the lowest price.	Treatment costs cannot exceed the French price of the comparator.	5% to 10% lower than the French price of the comparator.

Germany



No cost per QALYs*

United Kingdom (NICE)

- Main Metric: cost per QALY
  - ICER = $\frac{\text{Incremental cost}}{\text{Incremental QALY}}$
- Threshold for cost effectiveness: £20,000-30,000
  - ICER threshold around $100,000-150,000 per QALY
- Modifiers: move QALY up or down
  - Severity of disease
- Healthcare perspective + Personal social services (caregiver)