



Upper Payment Limits

August 28, 2023

Prescription Drug Affordability Board Staff



MARYLAND

Prescription Drug Affordability Board

Agenda

- Overview of Maryland Authority
- Key Decisions for Upper Payment Limit (UPL) Action Plan
 - When should UPLs apply?
 - How do you set a UPL?
 - How do you apply a UPL?
- Next Steps



Maryland Authority for UPLs

§ 21-2C-14. Upper payment limits

In General

(a) If a plan of action is approved under § 21-2C-13(d) of this subtitle, the Board may set upper payment limits for prescription drug products that are:

- (1) Purchased or paid for by a unit of State or local government or an organization on behalf of a unit of State or local government, including:
 - (i) State or county correctional facilities;
 - (ii) State hospitals; and
 - (iii) Health clinics at State institutions of higher education;
- (2) Paid for through a health benefit plan on behalf of a unit of State or local government, including a county, bicounty, or municipal employee health benefit plan; or
- (3) Purchased for or paid for by the Maryland State Medical Assistance Program.



Key Decisions for UPL Action Plan

- When should an upper payment limits apply?
 - What drugs do we select for an upper payment limit?
- How do you determine an upper payment limit?
 - Frameworks for Setting Upper Payment Limits
 - Application and Factors for Consideration
- How do you apply an upper payment limits?



When Should Upper Payment Limits Apply?

§ 21-2C-14. Upper payment limits

(b) The upper payment limits set under subsection (a) of this section shall:

(1) **Be for prescription drug products that have led or will lead to an affordability challenge;** and

(2) Be set in accordance with the criteria established in regulations adopted by the Board.



When UPLs Should Apply

Market Conditions

- UPLs are a tool to address market distortions due to market power
- May be situations where there is an affordability challenge where a UPL is not the appropriate policy



Feedback from the Board

- Agree that an Upper Payment Limit may not be the correct tool in every circumstance
- Did not think that it would be a useful exercise to preemptively try identify circumstances where a UPL would not apply



Key Decisions for UPL Action Plan

- When should an upper payment limits apply?
 - What drugs do we select for an upper payment limit?
- How do you determine an upper payment limit?
 - Frameworks for Setting Upper Payment Limits
 - Application and Factors for Consideration
- How do you apply an upper payment limits?



Frameworks for Setting UPLs



VALUE
ASSESSMENT



BUDGET
ASSESSMENT



RATE OF
RETURN



ADDITIONAL
CRITERIA



How Do You Set an Upper Payment Limit?

- Value Assessment
 - Clinical Effectiveness and Efficacy
 - Comparative Effectiveness
 - Cost Effectiveness
 - Efficiency Frontier
- Budget Assessment
- Rate of Return
- Additional Considerations
 - External Reference Pricing



Value Assessment

- Assigns Value to a Drugs
- Set a UPL based off this value
- Note there are different ways to determine value
 - Clinical Effectiveness and Efficacy: Value determined by the clinical benefit from trials
 - Comparative Effectiveness: Value determined by the additional clinical benefit compared to an alternative
 - Cost-Effectiveness: Value determined by the additional benefits and costs of the drug compared to an alternative
 - Efficacy Frontier: Value determined by alternatives based on the the most efficient alternatives



Value Assessment

Pros:

- Based on the idea that you are willing to pay for value
- Pay more for higher value drugs
- Incentivizes investment in high value drugs over low value drugs

Cons:

- In new and risky area manufacturers don't know the value beforehand
- Value of health improvement is subjective
- High value drugs can still be unaffordable



Budget Assessment

- Based off the idea that the amount paid for the drug cannot exceed the amount that the health system has to pay
- A drug can be extremely high value, but if the health system or patient cannot afford the high price, then it will be inaccessible and underutilized

Pros:

- Accounts for total affordability to the system, payer, and patient
- Allows for consideration of priorities for the health system as a whole

Cons:

- May not always align with value



Rate of Returns

- Based off the idea that companies should be able recover the cost of development of a drug, including opportunity costs
- Price = R&D costs + profit markup
 - Consider revenue to date

Pros:

- Ensures compensatory reimbursement for investment in research and development
- Incentivizes continued research in specific spaces
- May pay less for drugs that have low development costs

Cons:

- May reward research and development costs for low-value drugs
- Hard to do proper accounting



Additional Criteria

Other means for determining UPLs available that do not fit in these framework:

- External Reference Pricing: Basing prices on the prices in other countries
 - Based on the idea that price discrimination is proof of market power and ERP eliminates price discrimination between countries
 - Lower prices in other countries may reflect the manufacturer's willingness to receive
- Internal Reference Pricing: Basing prices on the prices that other payors pay in the U.S
 - Based on the idea that price discrimination is proof of market power and Internal Reference Pricing eliminates price discrimination within the US
 - Lower prices by other payors may reflect the manufacturer's willingness to receive



Additional Criteria- Continued

- Therapeutic Reference Pricing: Basing prices on the prices of pre-existing alternatives of similar clinical effectiveness
 - Based on the idea that new competition should be lowering prices if not for market power
 - Aimed at adjusting the market to promote more competitive pricing



Combining Criteria

- The board can consider all (or some) of these frameworks individually to create multiple options for the UPL
- The board can also stack these options together to create hybrid ways for determining a UPL



Feedback from the Board

- Do not want to take any of the methodologies off of the table yet
- Board had concerns with putting a lot of weight on a Rate of Return methodology because of the quality of the data and the sources of funding for research



Key Decisions for UPL Action Plan

- When should an upper payment limits apply?
 - What drugs do we select for an upper payment limit?
- How do you determine an upper payment limit?
 - Frameworks for Setting Upper Payment Limits
 - Application and Factors for Consideration
- How do you apply an upper payment limits?



How Do You Apply Upper Payment Limits

How UPLs will Flow through the Supply Chain

- There are many transactions in the pharmaceutical supply chain
- Must consider how an upper payments will flow through the supply chain



Feedback from the Board

- Generally agreed that this will be an important consideration





Next Steps

Next Steps

|

- Board Meeting- September 18, 2023
 - Present Feedback from Stakeholder Council and Recommendations for Upper Payment Limit Action
- Draft of Upper Payment Limit Action Plan





MARYLAND

Prescription Drug Affordability Board

andrew.york@maryland.gov

pdab.maryland.gov



MARYLAND

Prescription Drug Affordability Board