MACPAC

Payment and Coverage of High-Cost Specialty Drugs: Report from Technical Advisory Panel

Medicaid and CHIP Payment and Access Commission

Chris Park

Overview

- Technical advisory panel meetings
  - Pipeline analysis
  - Model framework and selection
  - Stakeholder perspective
- Differential rebate for accelerated approval drugs
- New benefit for cell and gene therapies
- Next steps

Technical Advisory Panel

Meeting 1

Analyze specialty drug pipeline in order to identify specific types of drugs that may be challenging for Medicaid programs to manage.

Meeting 2

Based on the pipeline priorities, identify alternative coverage and payment models and discuss model design, potential barriers, etc.

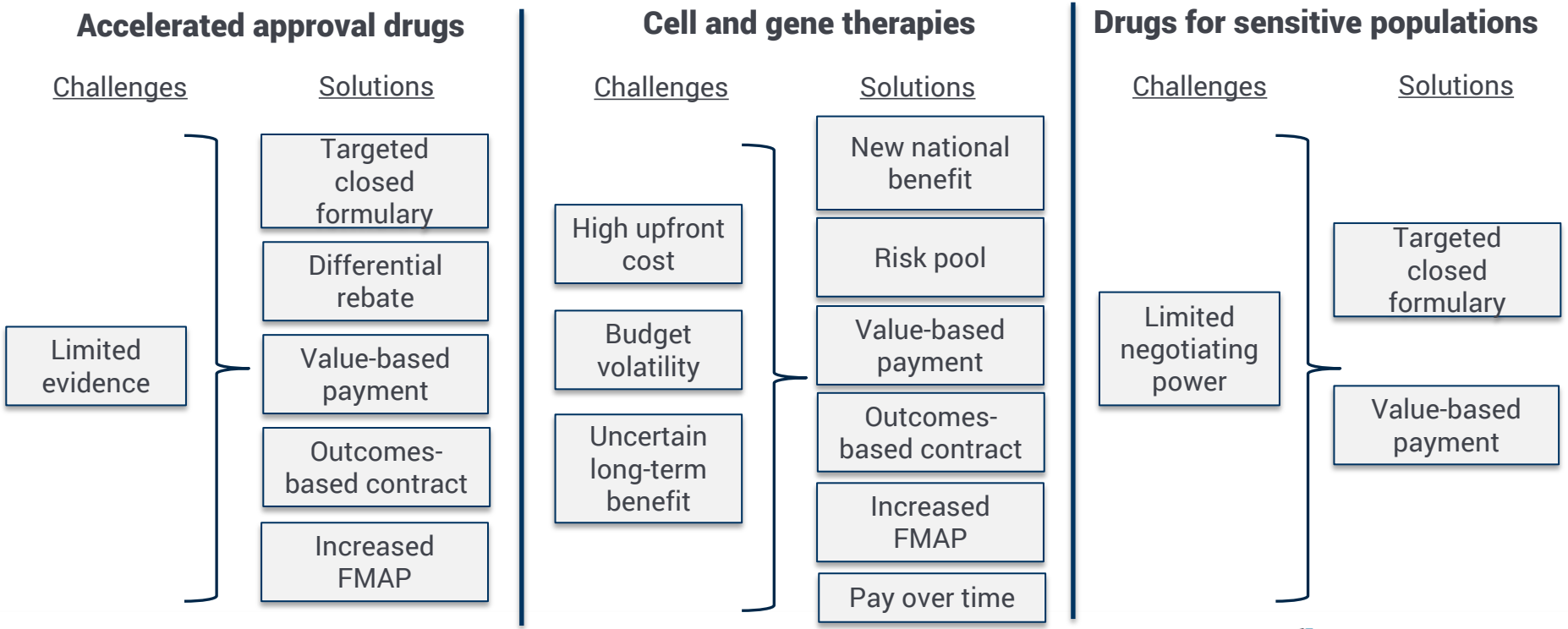
Meeting 3

Understand the effect of each model on stakeholders. Refine policy and design of each model.

Summary of Pipeline Analysis

- Analysis of drugs in clinical trials likely to have the greatest effect on Medicaid in the next three to five years based on expected cost and patient population
- Focus on three groups of drugs
  - Cell and gene therapies
  - Drugs receiving accelerated approval
  - Specialty drugs for sensitive populations

Challenges and Potential Solutions by Drug Type



Model Design Elements

- Participation – Is it mandatory? Include other payers?
- Inclusion – Which products are included?
- Price – How is net price determined?
- Supply chain – Does supply chain change?
- Duration – Would model change over time?
- Funding – How is model funded?

Differential rebate for accelerated approval drugs

Differential Rebate

- Higher rebate applied until drug gets full approval
  - Reduce Medicaid spending while there is limited evidence of clinical effectiveness
  - Create incentive for manufacturers to complete confirmatory trials
- Could increase inflationary rebate if confirmatory trial not completed after a set number of years

Differential Rebate Model Design Elements

Design Elements			
Participation	Change to MDRP would include all state Medicaid programs.	**Supply Chain**	The drug supply chain would remain unchanged.
Inclusion Criteria	All drugs that have been approved via the FDA's accelerated approval pathway that have not yet completed confirmatory trials.	**Duration**	Model would be a permanent change to the MDRP. Once manufacturers complete confirmatory trials the rebate would revert to the standard amount.
Price	A higher mandatory rebate from launch through completion of confirmatory trials. This could be coupled with an increased inflationary penalty to mitigate increasing list prices.	**Funding**	No new funding required. Increased manufacturer rebates would reduce Medicaid spending.

Note: MDRP is Medicaid Drug Rebate Program.

Differential Rebate – Stakeholder Perspective

- Beneficiaries
  - Keep mandatory coverage of these products under MDRP
  - May lose early access to some products
- Manufacturers
  - Still have incentive to pursue accelerated approval for early access
  - Needs to weigh against the cost of the additional rebate
- Payers could get evidence from the confirmatory trials in a more timely manner
- Providers would not change prescribing patterns

New benefit for cell and gene therapies

New Benefit for Cell and Gene Therapies

- Carve-out coverage of durable cell and gene therapies from the Medicaid Drug Rebate Program (MDRP) into new benefit
  - Allows for new coverage, payment, or rebate requirements without disrupting the existing structure of the MDRP
  - Could create more flexibility in coverage requirements
- Addresses states' concerns about high up-front costs and budget volatility by:
  - increasing federal funding
  - pooling utilization nationally to increase predictability
  - consolidating purchasing power

New Benefit Design Elements

Design Elements			
Participation	Mandatory for all state Medicaid programs. Could be expanded to include other payers (e.g., Medicare).	**Supply Chain**	Value-based payment would affect providers operating under buy-and-bill model.
Inclusion Criteria	Cell and gene therapies that are expected to have durable benefits.	**Duration**	Permanent change to program. Could include a mechanism so that drugs would move out of the benefit if sufficient competition becomes available.
Price	• Standard minimum rebate (separate but similar to MDRP). • Negotiate outcomes-based contract. • Value-based payment based on an independent assessment of product value.	**Funding**	Full federal funding or increased FMAP.

Note: MDRP is Medicaid Drug Rebate Program.

New Benefit – Stakeholder Perspective

- Beneficiaries
  - Could create better access by adopting a unified approach to coverage and payment
  - Need to protect access through strong appeals process
- Manufacturers
  - Important to ensure access in Medicaid
  - Value-based assessment could be used to start negotiation but shouldn't be used as a price ceiling
- Providers
  - Could result in additional authorization requirements but probably wouldn't change decision making
  - Could disrupt revenue stream through buy-and-bill

Next Steps

- Feedback on the two model options
  - Differential rebate for accelerated approval drugs
  - New benefit for cell and gene therapies
- Whether to move forward with either model as a potential recommendation

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