What Would (Should) CMS Do?

A Debate on Options for Drug Price Negotiations

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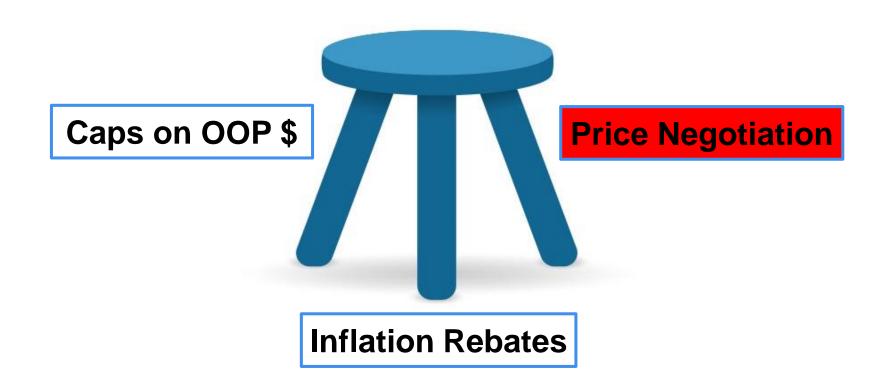
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Disclosures

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The Inflation Reduction Act



CMS Guidance (March 2023)

- "Therapeutic alternatives" to guide:
 - Assessment of clinical benefit of chosen drugs
 - Foundation for price setting
- All indications/doses grouped together
- Alternatives selected based on:
 - Clinical guidelines
 - Other published evidence
 - Submissions from industry and others
- Up to 3 negotiating sessions



What CMS Can Consider

- R&D costs
- Federal R&D support
- Production/distribution costs
- Data on pending and approved patents
- Market data on revenues in US
- Alternative treatments
- Comparative effectiveness and prescribing information on drugs and alternatives
- Unmet need

What CMS Cannot Consider





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Directions CMS Could Go

- (Non-QALY) CEA
- Clinical benefit rating
- "Multi-modal" (e.g., MCDA, SROI)
- +/- reference pricing?

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Potentia	al Measure	es for Drug F	Pricing Nego	otiation
🖫 🖇 Summarizing Health				
MEASURE	HOW IS IT USED?	PROS	CONS	HOW COULD PAYERS USE IT?
LY Life Year	$\begin{array}{l} \text{LY=Life expectancy given} \\ \text{a certain age, disease,} \\ \text{and other risk factors} \\ \text{Cost per LY gained} \\ \\ \hline $	 Allows for comparison across diseases and treatments Does not require a measure of quality of life 	Does not adjust for quality of life Requires robust data on life expectancy	Pay lower of: • Price that meets cost/ LY threshold (e.g., \$100k) • Ceiling price set in IRA
QALY Quality-Adjusted Life Year	QALY = LY saved * Utility Cost per QALY gained Cost _{in} - Cost _{ean} QALY _{in} - QALY _{con}	 Allows for comparisons across diseases and treatments Straightforward method to measure gain in length AND curdity of life 	Disadvantages for severe/ disabling disease Value to whom? Assumes all QALYs carry the same social value	Pay lower of: • Price that meets cost/ QALY threshold • Ceiling price set in IRA

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Our Experts



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Thank You!

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