Innovative Medicines: How the 'Sticker Price' is Determined

NUGEVITY: A Hypothetical Example

Consider Nugevity

Hypothetical new cancer treatment

- Treats nastanoma hypothetical cancer with limited treatment options
 - <1,000 working-age Canadian patients per year (i.e., small patient population)</p>
- First-line therapy
- Patients treated until the disease progresses
 - Average = 18 cycles
- Oral tablet replacing Cytokil, a hypothetical IV chemo, the Canadian standard of care (SOC)

Priced at \$ 5,000 per cycle (month) in Canada

How was the Nugevity price in Canada determined?



Nugevity Pricing Strategy Development

Inputs

Considerations

Nugevity Value Proposition



Does it warrant a 'premium' price vs. currently available treatments?

PMPRB Maximum Allowable Price (MAPP)



Should Nugevity be priced at or below the PMPRB ceiling?

Pricing & Reimbursement (P&R) Landscape



What is the probability of a positive HTA economic review?

Global Pricing Strategy



Will the Canadian price be within the global pricing corridor?

Stakeholder input/feedback



How do stakeholders react to the proposed price?

Other Factors



How do we strike the right balance between affordability and risk?



Nugevity – Strong Clinical Profile

Attribute	Nugevity	Cytokil	
Administration	oral	IV	
Efficacy			
Overall Survival	+4 mos (↑ 50%)		
Complete Response	+25%		
Progression-Free Survival	>2 yrs	15 mos	
Side Effects			
Fatigue	10%	30%	
Hair Loss	20%	35%	
Nausea	70%	95%	

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Nugevity - High-Value vs. Cytokil

Patient Benefits	N	С	Health System Benefits		С
Progression-free			Physician visits		
Survival			"Chair" time		
Response rate			Nursing time	Ţ	
Side effect frequency			Side effect medicines		
Side effect severity	Ţ.		Emergency room visits	Ţ	
Lost time from work			Hospitalizations		
Quality of life			Hospital days	Ì	

Nugevity - High-Value vs. Cytokil

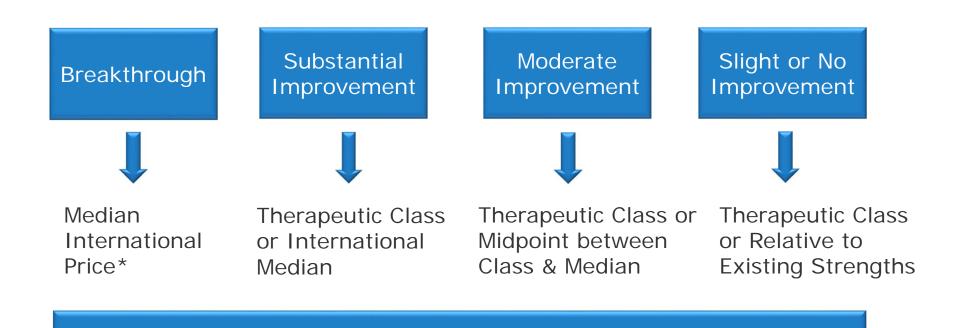
Patient Benefits	N	С	Health System Benefits		C
Progression-free			Physician visits	1	
Survival			"Chair" time		
Response rate			Nursing time		
Side effect frequency			Side effect medicines		
Side effect severity			Emergency room visits		
Lost time from work			Hospitalizations	1	
Quality of life			Hospital days	1	



How will PMPRB view Nugevity?

Current PMPRB Process: Scientific Review and a Price Test

3 Tests: Highest and Median International Price, Therapeutic Class



Prices can never be higher than Highest International Price

*France, Germany, Italy, Sweden Switzerland, UK, US

Nugevity Scientific Review Expectation

Primary indication:	First-line therapy for nastanoma (the only approved Nugevity indication)
Comparable medicines:	Cytokil (the only existing medicine indicated or used for first-line treatment of nastanoma)
Comparable dosage:	Nugevity: 1x50mg tablet per day for 28 days (total = 1,400mg per cycle)
	Cytokil: 0.5mg/kg for 15 days (total = 525mg per 28-day cycle based on 70kg patient)
Level of therapeutic improvement:	 Substantial (expected) Based on primary factors (efficacy); ≥ 25% relative improvement in survival vs. the comparator

Nugevity Price Test Expectation

- Substantial Improvement Price Test:
 - Higher of the Canadian Therapeutic Class Comparison (TCC) or the Median International Price Comparison (MIPC)
- Therapeutic Class Comparison (TCC) Calculation

Cytokil Canadian prices/mg					
AQPP	OPDP	RAMO	IMS CD&H	McKesson	PPS
\$ 5.00	\$ 6.50	\$ 5.00	\$ 7.82	\$ 6.17	n/a

- TCC Calculation = price x total dose = $$5 \times 525 \text{ mg} = $2,625/28 \text{ days}$

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- MIPC (estimated) = C\$ 5,500/28 days
 - Highest international price = \$ 7,500/28 days

Nugevity Price Test Expectation

- Substantial Improvement Price Test:
 - Higher of the Canadian Therapeutic Class Comparison (TCC) or the Median International Price Comparison (MIPC)

Nugevity PMPRB Ceiling Price = \$ 196.43/50 mg tablet (= \$5,500/cycle)

(based on Median International Price Comparison test)



Current Pricing & Reimbursement Landscape

- Considerations:
 - Who will be the primary payer?
 - What treatments are currently reimbursed and what will the new medicine displace?
 - How does the total cost (drug and non-drug) of the new medicine compare with existing treatments?
- Nugevity will displace Cytokil → first-line therapy for nastanoma
- Cytokil fully reimbursed by all Canadian cancer agencies / provincial drug plans, with criteria:
 - For first-line treatment of biopsy-confirmed nastanoma
 - For \leq 6 cycles: Treatment days 1 5 per week for 3 weeks, with 1 week off
- Public (transparent) price of Cytokil = \$ 5/mg
 - \$ 2,625/28-day cycle x 6 cycles/patient (average) = \$ 15,570/patient
 - Non-drug healthcare costs (side effect management, administration costs)
 - ~ \$ 25,000/patient (average)



Global Pricing Policy Guides Local Decisions

- Global processes are similar to local ones
- Important differences:
 - Global research includes many countries, large samples
 - Local regulatory nuances are often not considered
 - Global pricing policy: Multiple pricing tiers based on 'ability to pay' (countries with similar ability to pay in the same tier)

Nugevity Global Pricing Strategy for Tier 1 countries:

Global Target List Price (range): \$5,500-\$7,500/cycle

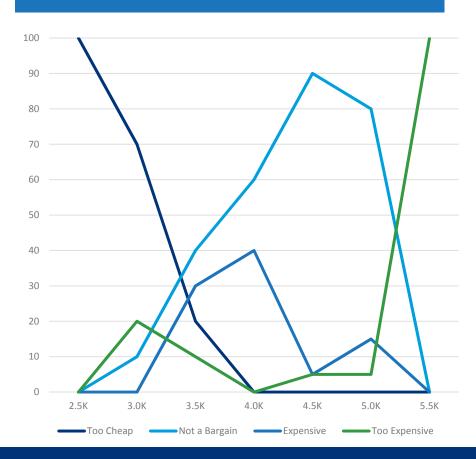


Stakeholder Feedback – Multiple audiences (patients, payers and physicians)

Range of Prices Tested

- Nastanoma background, treatment options presented
- Nugevity value presented
- Range of monthly prices tested
 - \$2,500-\$7,500 in \$500 increments
- Participants rate level of "expensiveness"

Range of acceptable prices \$3,500 - \$5,000/mth





Other Factors

Affordability Investment for future innovation

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High value for both patients & healthcare system warrants price premium vs. Cytokil

PMPRB Maximum Allowable Price (MAPP)



Value warrants price at the PMPRB ceiling

Pricing & Reimbursement (P&R) Landscape



Medium probability of a positive HTA economic review

Global Pricing Strategy



Acceptable Canadian price slightly lower than global range – need to negotiate

Stakeholder input/feedback



\$5,000/cycle is the upper limit of acceptable prices

Other Factors



Affordable for the payer, and recoup investment based on market size and treatment duration

Thank you