THE INFLUENCE OF ICER: COST-EFFECTIVENESS AND DECISION-MAKING FOR USA PAYERS

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Summary:

- To understand the relationship between cost-effectiveness and payer management decision-making, 10 therapies reviewed by ICER were analyzed to understand their coverage outcomes
- Within the ovarian cancer, SMA, cystic fibrosis, and ulcerative colitis disease spaces, none of the products assessed by ICER were found to be cost-effective based on the threshold of $100,000 per QALY
- Coverage outcomes for these 10 products across national MCOs are not largely influenced by WAC pricing
- Where steps or non-coverage were found to occur, it was often the more cost-effective treatment options that were disadvantaged on a given formulary
- Overall, there was limited correlation between cost-effectiveness and management decisions

Introduction & Objectives

Although many stakeholders in the USA advocate for lower pharmaceutical spending, few regulators agree how pricing should influence coverage decisions. While many EU markets, including GBR and SWE, utilize cost-effectiveness analysis to determine drug reimbursement, there is no similar requirement in the USA. However, the USA-based Institute for Clinical and Economic Review (ICER) conducts non-binding cost effectiveness analyses of therapies available in key high innovation therapy areas. Since its founding in 2006, ICER's profile and impact has grown exponentially.

Our research aimed to understand the impact of cost-effectiveness assessments on coverage decisions in the USA and, specifically, the payer access-related influence of ICER. While other forms of economic evidence (i.e., TCOC, HRU, Budget Impact, etc.) were not assessed as a part of the results, their impact on payer coverage was recognized when analyzing the relationship between cost and coverage.

Methods

Ten FDA-approved medicines assessed by ICER, representing four disease areas, were analyzed alongside their 2021 coverage and prior authorization criteria at five national commercial plans. This research aimed to understand the relationship between ICER evaluations and payer coverage decisions, with a supplemental review of media publications to assess reactions to cost-effectiveness outputs in the USA.

	PRODUCT	QALYs GAINED	COST / QALY GAINED (COMPARATOR)	COST EFFECTIVE?	ICER VALUE-BASED PRICE (TO ACHIEVE $100,000 / QALY) VS. WAC PRICE
OVARIAN CANCER[1]	Rubraca (rucaparib) 300 mg tablets	0.65	$294,593 (PLD+C)	N	$61,092 – $167,280
	Lynparza olaparib	0.67	$146,210 (PLD+C)	N	$107,160 – $164,148
SMA[2]	SPINRAZA (nusinersen)	1.46	$709,000 (BSC)	N	$36,400 – $382,500
	zolgensma (onasemnogene abeparvovec-xioi)	15.77	$243,000 (BSC)	N	$310,000 – $2,000,000
CYSTIC FIBROSIS[3]	kalydeco (ivacaftor)	4.71	$1,370,000 (BSC)	N	$58,600 – $311,704
	ORKAMBI	3.77	$1,480,000 (BSC)	N	$50,800 – $272,623
	trikafta	5.49	$1,160,000 (BSC)	N	$67,900 – $311,741
ULCERATIVE COLITIS[4]	Remicade INFLIXIMAB	0.07	$212,000 (CT)	N	$10,900 – $27,900
	HUMIRA adalimumab	0.02	$1,870,000 (CT)	N	$5,800 – $72,400
	Simponi golimumab	0.03	$1,455,000 (CT)	N	$6,300 – $75,300

Figure 1 | Cost Effectiveness Outcomes

ANNUAL TREATMENT COSTS: WAC PRICE; VALUE-BASED PRICE ($100K / QALY)

10 therapies across oncology, neuromuscular, immunology, and respiratory health were examined to understand their relative cost-effectiveness according to ICER. None of the products reviewed were found to be cost-effective compared to the current SoC, based on a threshold of $100K / QALY gained. Recommended discounts to achieve cost-effective prices ranged from 34-95%. However, ICER analysis showed that some options were more cost-effective relative to others within the same disease area (e.g., ZOLGENSMA vs. SPINRAZA in SMA).

	PRODUCT	NATIONAL MCO COVERAGE OUTCOMES				
		AETNA (5-TIER)	ANTHEM (4-TIER)	UHC (3-TIER)	CIGNA (3-TIER)	HUMANA (4-TIER)
OVARIAN CANCER	Rubraca (rucaparib) 300 mg tablets	TIER 4 – PA, QL, SP	TIER 3 – PA, QL	TIER 3 – PA, QL, SP, ST LYNPARZA	TIER 3 – PA	SPECIALTY – PA, QL
	Lynparza olaparib	TIER 4 – PA, QL, SP	TIER 3 – PA, QL	TIER 2 – PA, QL, SP	TIER 3 – PA	SPECIALTY – PA, QL
SMA	SPINRAZA (nusinersen)	MEDICAL BENEFIT	MEDICAL BENEFIT	MEDICAL BENEFIT	MEDICAL BENEFIT	MEDICAL BENEFIT
	zolgensma (onasemnogene abeparvovec-xioi)	MEDICAL BENEFIT	MEDICAL BENEFIT	MEDICAL BENEFIT	MEDICAL BENEFIT	MEDICAL BENEFIT
CYSTIC FIBROSIS	kalydeco (ivacaftor)	NPS – PA, QL	NF – PA, QL	NF	TIER 3 – PA, QL	SPECIALTY – PA, QL
	ORKAMBI	NPS – PA, QL	NF – PA, QL	NF	TIER 3 – PA, QL	SPECIALTY – PA, QL
	trikafta	NPS – PA, QL	NF – PA, QL	TIER 2 – PA, QL	TIER 3 – PA, QL	SPECIALTY – PA, QL
ULCERATIVE COLITIS	Remicade INFLIXIMAB	PSP – PA, QL, ST HUMIRA, XELJANZ	TIER 4 – DL, PA	NON-FORMULARY	TIER 3 – PA	NON-FORMULARY
	HUMIRA adalimumab	PSP – PA, QL, ST XELJANZ	TIER 4 – QL, PA	TIER 2 – PA, QL	TIER 2 – PA, QL	SPECIALTY – PA, QL
	Simponi golimumab	PSP – PA, QL, ST HUMIRA, XELJANZ	TIER 4 – DL, PA	TIER 2 – PA, QL	TIER 2 – PA, QL	NON-FORMULARY

Figure 2 | National MCO Coverage Outcomes

PRIOR AUTHORIZATION CRITERIA: PA TO LABEL; PA TO TRIAL CRITERIA; PA BEYOND LABEL & TRIAL CRITERIA

Coverage outcomes across 5 national MCOs were examined for each of the 10 therapies. Most therapies within the same disease class are managed at parity, though some products face differential management. In instances where a step is employed (e.g., RUBRACA stepped through LYNPARZA, or REMICADE stepped through HUMIRA), the product being disadvantaged is more cost-effective than the product it is being stepped through according to the respective ICER reports.

Conclusions:

Current payer management does not reflect ICER recommendations on cost-effectiveness. Although ICER's analysis of these products revealed that some offer greater value for cost than others, those that do were not managed preferentially in relation to less cost-effective competitors.

Instead, management outcomes reflect the numerous other clinical and financial factors that can impact access. For example, REMICADE is stepped through HUMIRA in UC despite being significantly more cost-effective (~$200K / QALY vs. ~$1.8M / QALY), likely due to the influence of payer contracting.

Although ICER is a leading USA advocate for drug cost-effectiveness, the dynamic between cost-effectiveness assessments and payers' willingness to manage drugs remains limited, especially with the impact of confidential net price discounts further complicating the relationship between cost-effectiveness and access.

Other types of economic evidence are more influential for MCO management decision-making than ICER analysis. MCO management decisions are informed by TCOC, especially for chronic diseases such as the four analyzed in this research (e.g., payers may weigh the one-time cost of ZOLGENSMA compared to the repeated, cumulative cost of SPRINRAZA in SMA). While HRU may not be universally influential for management decisions in the USA, it informs utilization management in instances where a therapy has a directly visible and readily quantifiable HRU impact (e.g., such as HUMIRA reducing hospitalizations for UC patients). Lastly, BI also likely influences management decisions as MCOs aim to accurately control per member costs and minimize unexpected spending.

Regardless of ICER's evolving influence moving forward, there may be value in manufacturers addressing cost-effectiveness concerns through other economic evidence to demonstrate the value of their therapies.

References

[1] Institute for Clinical and Economic Review (ICER). Antiandrogen Therapies for Nonmetastatic Castration-Resistant Prostate Cancer Final Evidence Report and Meeting Summary. https://icer.org/wp-content/uploads/2020/10/ICER_Prostate_Cancer_Final_Evidence_Report _100418.pdf, 29 March 2021

[2] Institute for Clinical and Economic Review (ICER). Spinraza and Zolgensma for Spina Muscular Atrophy Final Evidence Report and Meeting Summary. https://icer.org/wp-content/uploads/2020/10/ICER_SMA_Final_Evidence_Report_110220.pdf, 29 March 2021

[3] Institute for Clinical and Economic Review (ICER). Modulator Treatment for Cystic Fibrosis Final Evidence Report and Meeting Summary. https://icer.org/wp-content/uploads/ 2020/08/ICER_CF_ Final_Report_092320.pdf, 29 March 2021

[4] Institute for Clinical and Economic Review (ICER). Targeted Immune Modulators for Ulcerative Colitis Final Evidence Report and Meeting Summary. https://icer.org/wp-content/uploads/2020/08/ICER_UC_Final_Evidence_Report_101620.pdf, 29 March 2021

Abbreviations

BSC: Best Supportive Care; **BI:** Budget Impact; **DL:** Dose Limit; **CT:** Conventional Treatment; **HRU:** Healthcare Resource Utilization; **ICER:** Institute for Clinical and Economic Review; **MCO:** Managed Care Organization; **NF:** Nonformulary; **NPS:** Non-Preferred Specialty; **PA:** Prior Authorization; **PLD+C:** Pegylated Liposomal Doxorubicin + Carboplatin; **PSP:** Preferred Speciality Pharmacy; **QALY:** Quality-Adjusted Life Year; **QL:** Quantity Limits; **SMA:** Spinal Muscular Atrophy; **SoC:** Standard of Care; **SP:** Specialty Pharmacy; **ST:** Step Therapy; **TCOC:** Total Cost of Care; **WAC:** Wholesale Acquisition Cost

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