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ICER Analyses and Payer Use of Cost-effectiveness Results Based on the QALY and evLYG Are Consistent With ADA Protections for Individuals With Disabilities

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Introduction

The debate about how to pay the cost of pharmaceuticals and what constitutes "value" for specific drugs and therapies rages on. The issue of how much payers, both governmental and commercial, should pay for medications has widespread implications, from Medicare and Medicaid budgets stretched by therapies that can cost six figures, to employers concerned about funding their employees' drug benefits, to the health plans and insurers which must balance access and affordability. Drug manufacturers have reasonable concerns about obtaining fair compensation for expenditures on research and development, as well as being rewarded for innovative, life-enhancing therapies. The societal goal, of course, is to achieve better patient outcomes and more efficient utilization of limited health care resources.

Debate has arisen about whether federal anti-discrimination laws, such as the Americans with Disabilities Act (ADA), might stand in the way of governmental or private attempts to use cost-effectiveness analyses as part of an approach to evaluate the value of particular drugs or therapies. As states consider how to make optimal coverage and pricing decisions in their Medicaid budgets, taking the ADA into account, academic research groups and innovative private entities such as the Institute for Clinical and Economic Review (ICER) have emerged to develop objective assessments of the therapeutic value of drugs relative to their cost. The foundational academic method for this type of assessment is cost-effectiveness analysis.

Cost-effectiveness analysis looks at evidence for entire patient populations, comparing the health benefits and economic costs of different treatment options. Most clinical studies express health benefits in terms of disease-specific measures, such as the number of strokes avoided or the lessening of pain. Although useful for measuring effects of a particular treatment, such measures do not permit comparison across diseases. Health economists, researchers, and drug makers have turned to the quality-adjusted life year (QALY) as the standard metric to measure how well all different kinds of medical treatments lengthen and/or improve patients' lives. Some drugs can help patients live longer. Others may not lengthen life but can increase quality of life by reducing side effects of treatment, by improving patients' ability to function, or by reducing symptoms such as headache, fatigue, etc. Some drugs both lengthen life and improve quality of life. The QALY captures all of these benefits and can help distinguish the value of drugs based on what matters most to patients. Simply put, the more that patients benefit, the more added QALYs a drug gets, and the more QALYs, the higher the suggested fair price is within a cost-effectiveness analysis.

The QALY has served as a fundamental component of cost-effectiveness analyses in the United States and around the world for more than 30 years.[1] The use of QALYs in cost-effectiveness analysis was endorsed by the first U.S. Panel on Cost-Effectiveness in Health and

[1] *See* Neuman, Peter J., *Is the United States Ready for QALYs?* HEALTHAFFAIRS, September/October 2009. Available at https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.28.5.1366.

Medicine,[2] and was recently endorsed again by the Second Panel.[3] Cost-effectiveness analyses using QALYs have been used in studies sponsored by the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, and the National Institutes of Health.[4] The U.S. Office of Management and Budget has issued guidelines calling on federal agencies to estimate and report on the expected costs and benefits of major regulations, including the use of cost-effectiveness analyses with QALYs as one way to measure impacts.[5]

Cost-effectiveness based on the QALY can be done consistently across all areas of medicine and is uniquely suited to be able to generate recommended price ranges for drugs that improve patient outcomes across all clinical areas. ICER has recently introduced another measure of health gain to complement the QALY, the Equal Value of Life Years Gained (evLYG). The evLYG differs from the QALY only in that it attributes to all added lifetime gained from treatment the same "good" quality of life rating. This approach eliminates any hypothetical risk that treatments that extend life for patients with an underlying chronic condition or disability would be valued as producing less "health gain" than a treatment that extends life a similar amount for a condition without any underlying reduction in functional status or quality of life. As an example, using the evLYG as the measure of health gains from treatment, if a treatment adds a year of life for patients with a condition like muscular dystrophy, the treatment will receive the same evLYG "score" for that added life extension as would a different treatment that adds a year of life for a different condition with less functional limitations, such as hypertension.

Despite these features of the QALY and evLYG, concerns have been raised about whether the QALY, in its measurement of health outcomes, creates a risk of violating the ADA, inasmuch that individuals with disabilities could be judged as being worth "less" as a human being than an individual who is healthier. However, a combination of QALYs and the evLYG do not measure "health" in a way that is discriminatory and ICER has implemented protective language to ensure that the QALY and evLYG are not used in a discriminatory fashion. Additionally, the language of the ADA, pertinent Equal Employment Opportunity Commission (EEOC) enforcement guidance, and relevant case law have affirmed the notion that objective, cost-based distinctions are neither discriminatory nor impermissible. ICER takes a wider-angle view of the health system as a whole: balancing both what it calls costs that are difficult for the health system to absorb over the short term, without displacing other needed services or contributing to rapid and untenable growth in Medicaid and healthcare insurance costs that threaten sustainable access to high value care for all patients.

The ADA and Value-Based Drug Pricing

Under Title II of the ADA, individuals with disabilities must have an equal opportunity to participate in and benefit from state and local governments' programs, services, and activities. ADA Title II prohibits the denial of benefits or exclusionary conduct under programs and services

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[2] *See* Weinstein, *Recommendations of the Panel on Cost-effectiveness in Health and Medicine*. October 6, 1996. Available at https://www.ncbi.nlm.nih.gov/pubmed/0008849754.

[3] *See* Neuman, Peter J., *Cost-Effectiveness in Health and Medicine*. OXFORD SCHOLARSHIP ONLINE, November 2016. Available at: https://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780190492939.001.0001/acprof-9780190492939-miscMatter-7.

[4] Nueman, Peter J., *Using Cost-Effectiveness Analysis to Improve Health Care*. OXFORD UNIVERSITY PRESS, 2005.

[5] Office of Management and Budget. Circular A-4: regulatory analysis. Washington (DC): OBM; 2003 Sep 17.

operated by public entities. It incorporates and extends the reach of Section 504 of the Rehabilitation Act of 1973 (Rehab Act) by encompassing public entities generally, including not only executive agencies, but the legislative and judicial branches of state and local governments and their instrumentalities, regardless of the direct presence of federal funds. Together, the ADA and the Rehab Act require that health care providers provide individuals with disabilities full and equal access to their health care services and facilities.

Coverage Design and Discrimination Caw Law

Although there are few cases that directly challenge coverage design, taking a closer look at the case law reveals that plans that vary in their offerings and make distinctions, applied equally to all individuals, are not discriminatory. In *Alexander v. Choate*,[6] which arose under Section 504 of the Rehabilitation Act of 1973, the predecessor to ADA Title II, the United States Supreme Court unanimously determined that the claim, which amounted to benefit design, was a direct attack on the content of coverage, as well as a request for individually tailored coverage. The Court held that Section 504 required only that persons with "handicaps" be given meaningful access "to the benefit that the [program] offers." The question became whether all persons, regardless of disability, had equal access to the coverage. The Court rejected the effort to equate coverage with inadequacy of care and assumed that the equality of treatment standard was met under Section 504 as long as all persons, regardless of their disability, had equal access to whatever coverage was available. The court determined that ". . . Medicaid programs do not guarantee that each recipient will receive that level of health care precisely tailored to his or her particular needs. Instead, the benefit provided through Medicaid is a particular package of health care services . . . [that] has the general aim of assuring that individuals will receive necessary medical care, but the benefit provided remains the individual services offered – not 'adequate health care.'"

Recently, in *Doe One v. CVS Pharmacy, Inc*,[7] enrollees in an employer-offered prescription drug benefit plan argued that terms of the benefit plan had a disparate adverse impact on enrollees with HIV/AIDS. Although the benefit plan designated HIV/AIDS medications as "specialty medicines," which could only be obtained for in-network prices at in-network pharmacies, there were other medications, unrelated to HIV/AIDS, which were also designated "specialty medicines" and subject to precisely the same restrictions. The Court determined that "[g]iven the breadth of the drugs subject to the [p]rogram's restrictions, [p]laintiffs cannot show that they are discriminated against as HIV/AIDS patients or as patients with disabilities." The Court also referred to *Alexander*, stating, "*Alexander* makes clear that 'Section 504 [of the Rehabilitation Act] does not require the [benefit provider] to alter this definition of the benefit being offered simply to meet the reality that [Plaintiffs] have greater medical needs.'" Ultimately, the QALY takes into account that some individuals have greater medical needs, but neither discounts nor devalues the lives of individuals with disabilities. A treatment that produces higher quality of life will receive a higher price recommendation, but it does not determine who gets a limited treatment, separate patients into subgroups and judge individuals on who could benefit more, or reduce the value of a lifetime extended with successful treatment. ICER's QALY evaluation of treatments relies on not only cost-effectiveness analysis but also uses alternative measures of health gain, equalizing and applying the same value of a life year gained, no matter the individual's disability status. When

[6] 469 U.S. 287 (1985).
[7] 348 F. Supp. 3d 967 (N.D. Ca. Dec. 12, 2018).

the QALY-based price recommendation differs from the evLYG-based price recommendation, ICER presents both results for its formal value-based price recommendation, taking a broader view of cost effectiveness and reassuring policymakers that they are considering information that poses absolutely no risk of discrimination under the ADA or the Rehab Act.

Private Employer-Based Health Insurance and the Consideration of Treatment Costs

Moreover, the case for using QALY is equally strong under employer-sponsored health benefit plans. If plans that are being offered to employees by a private employer use similar methodology as the QALY, the ADA provides an additional provision that explicitly permits private employers to make distinctions in their insurance health insurance provisions, despite the provisions of Title I of the ADA. ADA Title V, Section 501(c), also known as the "safe harbor" provision, provides that bona fide insured or self-insured employee benefit plans are entitled to make some health related distinctions for risk classifications based upon, or not inconsistent with, state law. *See* 29 C.F.R. § 1630.16(f). Sections 501(c)(2) and (3) of the ADA protect employers from liability for conduct that might otherwise violate the ADA, if it were taken pursuant to an insured or self-insured benefit plan, so long as the plan is not "a subterfuge to evade the purposes of the ADA." 42 U.S.C. § 12201(c). The EEOC has also taken the position that if a benefit plan contains disability-based distinctions, the plan is a subterfuge, unless the sponsor can establish that the distinction is justified by cost justifications and/or risk classification, such as age, occupation, personal habits, and medical history. Accordingly, disability-based insurance plan distinctions are permitted if they are within the protective ambit of Section 501(c) of the ADA. *See* Appendix to 29 C.F.R. § 1630.16(f).

Private Employer Health Plan Distinctions Based on Type of Disability Do Not Violate the ADA

The ADA has been found to allow benefit distinctions, even when the resulting plan provides for longer or shorter benefit periods based on the type of disability a patient has. In *Parker v. Metropolitan Life Ins. Co.*,[8] an employee sued her employer and its insurance carrier, alleging that the long-term disability plan offered by her employer and administered by carrier violated the ADA because it provided greater benefits for physical disabilities versus mental/nervous disabilities. The Sixth Circuit held that ADA's prohibition against disability discrimination in public accommodations did not prohibit employers from providing long-term disability plans which contained longer benefit periods for employees who become disabled due to physical illness than for those who become disabled due to mental illness. With respect to the use of the QALY and accompanying factors, in deciding fair pricing of health care interventions, policies that ensure standardized and equally-applied benefits for all patients, that are then applied to Medicaid or health insurance benefits, are not discriminatory, but provide fairly priced treatments that align with the amount of improvement in health experienced by patients for entire patient populations. The QALY methodology is designed to increase benefits for all patients by using a variety of factors that do not target individuals with a disability, but aim to increase the availability of treatments to all patients. Such program or plan design is thus appropriate under the ADA (and the Rehab Act). The QALY can help distinguish the value of drugs based on what matters most

[8] 121 F.3d 1006 (6th Cir. 1997), cert. denied, 522 U.S. 1084 (1998).

to patients, developing price in accordance with instances where the more patients benefit, the more added QALYs a drug gets, not on the basis of the health outcomes of a human being.

Other courts have confirmed this analysis and conclusion. In *E.E.O.C. v. Staten Island Sav. Bank*,[9] the Second Circuit joined six other Courts of Appeals in concluding that the ADA "does not bar entities covered by [the ADA] from offering different long-term disability benefits for mental and physical disabilities." The Second Circuit also looked at the legislative history of the ADA, noting that the Reports of the House Judiciary Committee and the Senate Committee on Labor and Human Resources "contain identical language stating that 'it is permissible for an employer to offer insurance policies that limit coverage for certain procedures or treatments,' so long as persons with disabilities 'have equal access to the . . . insurance coverage that is provided by the employer to all employees.'"[10] The decision explicitly states that the ADA does not specifically "condemn the historic and nearly universal practice inherent in the insurance industry of providing different benefits for different disabilities." With respect to the procedures implemented by ICER through the QALY and evLYG, ICER does not divide patients into subpopulations and determine treatments by creating distinctions based on disability. Instead, cost-effectiveness is utilized as one tool to diminish barriers to effective treatments for all patients, measuring the extended life of every patient, regardless of their type or degree of disability. Ultimately, the majority of circuit court decisions, ADA legislative history, case law interpreting the Rehab Act, and post-ADA legislative action all support the conclusion that the ADA does not require equal benefits for different disabilities, upholding the concept that the ADA does not prohibit distinctions in health insurance benefits offered, as long as everyone is offered the same plan, regardless of an individual's disability status.

The EEOC Guidance and Cost Based Distinctions

Furthermore, under the EEOC's 1993 Interim Enforcement Guidance regarding benefit distinctions in employer provided health insurance, as noted, individuals with disabilities must be accorded "equal access" to whatever health insurance the employer provides to employees without disabilities.[11] Like the Courts, the EEOC has concluded that health insurance distinctions that are not disability based do not violate the ADA, even if they have a disproportionate impact on individuals with disabilities. The Guidance provides that insurance distinctions may be used, so long as the distinctions uniformly to all employees. Using cost-effectiveness to decipher between effective treatments is not a disability-based distinction and insurance distinctions among benefits available, as long as they are not disability based, are permitted under the ADA. Thus, consideration of a drug or treatment's costs, so long as uniformly applied to all employees, is consistent with the EEOC's ADA guidelines. This is highly relevant to use of tools like QALY. Some drugs can help patients live longer, while others may not lengthen life, but can increase

[9] 207 F.3d 144 (2d Cir. 2000). *See also Weyer v. Twentieth Century Fox Film Corp*., 198 F.3d 1104, 1116 (9th Cir. 2000); *Kimber v. Thiokol Corp*., 196 F.3d 1092, 1101–02 (10th Cir. 1999); *Lewis v. Kmart Corp*., 180 F.3d 166, 170–71 (4th Cir. 1999), *cert. denied*, 528 U.S. 1136 (2000); *Ford v. Schering–Plough Corp*., 145 F.3d 601, 608–10 (3d Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999); *Parker v. Metro. Life Ins. Co*., *supra*, 121 F.3d at 1019; *EEOC v. CNA Ins. Cos.*, 96 F.3d 1039, 1044–45 (7th Cir. 1996).

[10] *See* H.R. Rep. No. 101–485(III), at 38 (1990).

[11] EEOC Notice, *Interim Enforcement Guidance on the application of the Americans with Disabilities Act of 1990 to disability-based distinctions in employer provided health insurance*, June, 8, 1993, located at: https://www.eeoc.gov/policy/docs/health.html.

quality of life by reducing side effects of treatment, by improving patients' ability to function, or by reducing symptoms. The QALY captures all of these benefits and can help distinguish the value of drugs based on what matters most to patients. The more that patients benefit, the more added QALYs a drug gets and the higher the suggested fair price is, applying equally to all patients. Nothing in the ADA bars such a data-driven approach.

Whenever it is alleged that a health-related provision of an employer provided health insurance plan violates the ADA, the EEOC must determine whether the challenged provision is, in fact, a disability-based distinction. If the EEOC determines that a challenged health insurance plan term or provision is in fact a disability-based distinction, the proponent of the provision will be required to prove that a disability-based distinction is within the protective ambit of Section 501(c) of the ADA. Methods that calculate cost effectiveness using both the QALY and evLYG provide results that, when a drug extends life, incorporates findings that weigh every single day of extended life of an individual at exactly the same value, no matter patients' degree of disability or age, refuting any notion that the distinction is being used as a subterfuge or in a discriminatory manner. Specifically, for any treatment that extends life, cost effectiveness results based on the evLYG weigh the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or pre-existing disability. Thus, the implementation of cost effectiveness outcomes based on health outcomes measured both by QALYs and evLYGs applies neutral limitations, in ways that are permitted by the ADA (for example, under the ADA, limiting the number of X-rays that the plan will pay for, even though this may have an adverse effect on individuals with certain disabilities, is not discriminatory), whereby a plan may exclude or provide lower levels of overage for broad categories of conditions, but not drawn along lines of disability.[12]

A plan or provision is disability based and impermissible under ADA only if it singles out a particular disability, a discrete group of disabilities, disability in general, or a treatment or procedure used exclusively or nearly exclusively to treat a particular disability. To be sure, QALY could be used inappropriately in three different ways that could be considered to be discriminatory. ICER has recognized the concerns surrounding the QALY and evLYG, with respect to discrimination against individuals with disabilities. Because a treatment that produces higher quality of life will receive a higher price recommendation, some members of the disability community have been worried that cost-effectiveness using the QALY might discount or "devalue" their lives in some way. First, using the QALY to determine who would receive a limited treatment, such as an organ transplantation, where a patient who had a pre-existing disability was judged to be able to achieve a lower quality of life even after receiving a transplant would be discriminatory. ICER, however, does not use the QALY in this way, but instead weighs the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or pre-existing disability. Second, if the QALY were used to divide patients into subgroups, some of whom would be judged to benefit less from treatment because even if cured they would have a lower function, this would be discriminatory; again, however, ICER does not use the QALY in this way. Instead, ICER uses an objective measurement of cost-effectiveness to inform pricing negotiations and timely evidence-based formulary placement decisions that equally take into account the value of all patients, regardless of disability. Third, many drugs improve quality of

[12] EEOC Notice, *Interim Enforcement Guidance on the application of the Americans with Disabilities Act of 1990 to disability-based distinctions in employer provided health insurance*, June, 8, 1993, located at: https://www.eeoc.gov/policy/docs/health.html.

life, but do not also extend life, and if so, it may only be for a small number of weeks or months. Other drugs may produce many additional years of life, and if patients with the condition have significant extended life, but remain at lower function/quality of life, devaluing this benefit would be discriminatory. Patients themselves might prefer a treatment that provides a shorter lifespan with a "cure" versus one of extended life at very low functional levels, so ICER continues to provide cost-effectiveness results using the QALY, but for every review ICER also use the evLYG that weights every single day of extended life at exactly the same value, no matter patients' age or degree of disability. This methodology does not violate the ADA as it does not make distinctions based on disability, but, rather, makes determinations on formulary placement decisions that are equally applied to all individuals. When the QALY-based price recommendation differs from the evLYG-based price recommendation, ICER uses the higher price range for its formal value-based price recommendation to avoid any potential issues.

Moreover, to ensure neither the QALY nor evLYG are improperly used, ICER has implemented formal "safeguard" language prohibiting its use in this way. ICER has set forth formal anti-discrimination language, to guide its own work and the use of its work by others, which states: "in considering cost-effectiveness, policymakers cannot use cost-effectiveness analyses that use the cost-per-quality adjusted life year or similar measure to identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or pre-existing disability. In addition, for any treatment that extends life, policymakers must use cost-effectiveness results that weigh the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or pre-existing disability." ICER explicitly seeks to guard against the use of the QALY in a discriminatory manner and, instead, provides flexible measurements of treatment effectiveness to advise pricing and formulary placement decisions. Consequently, even if the pricing and ultimate decision by policymakers regarding treatments might have a disproportionate impact on individuals with disabilities, the mechanisms implemented by ICER to measure the life of an individual are flexible and are not disability based, thus ultimately not in conflict with the ADA.

Conclusion

By considering a treatment's cost-effectiveness using the QALY and the evLYG, policymakers can take a broader view of cost-effectiveness and be reassured that they are considering information that poses absolutely no risk of discrimination against any patient group. An objective measurement of cost effectiveness is an important tool in the arsenal of public and private payers to be used to inform pricing negotiations and timely evidence-based formulary placement decisions. The use of QALYs and evLYGs will help individuals with a serious disability or illness in that when more QALYs are gained, there is justification for a higher price for a treatment. And, as noted, the incorporation of the evLYG alongside the QALY as a complementary measure of health gain eliminates the risk that treatments that extend life for patients with disabilities will be judged to merit a lower price than treatments that extend life the same amount for other, less disabling or shorter duration conditions.

Distinctions made to inform pricing and evidence-based formulary placement decisions do not fall into the ambit of discrimination, within the meaning of the ADA, pertinent case law, or guidance provided by the EEOC, but instead are vital to informing policy through evidence-based

analysis that will ensure that treatments that materially improve patients' lives are rewarded fairly, while neither patients nor society pays inappropriately for care that doesn't offer patients significant benefit. ICER's evaluations provide evidence-based data and are not prescriptive, but are a tool that can be used by public and private payers to assist in making pricing decisions in specific cases. ICER's approach to provide an evidence-based tool can inform rational and fair decision-making on treatments that can improve the current problem-plagued approach where drug prices might otherwise be set in a vacuum and Medicaid administrators and insurers respond with barriers to access, whereby patients struggle to afford and access the care they need. Implementing flexible metrics via the QALY and evLYG to allocate health resources, alongside with ICER safeguard language, will ultimately provide patients with more comprehensive treatment pricing.