Background

What are QALYs?

QALYs are a tool used in health services research to estimate the effectiveness of a medical intervention. QALYs combine measurements of effectiveness including mortality (life years) as well as morbidity (quality of life) as part of one assessment for medical intervention effectiveness, allowing for researchers to compare changes in health status within and across conditions (Carlson et al, 2020).

Medical interventions have often been assessed based on the impact they have on mortality, which can also be defined as the extension of "life years." When calculating an impact on life years, a researcher may assess how many years of life, on average, are extended with a medical intervention compared to no intervention at all or compared to another intervention.

In the case of a QALY calculation, a life year is further adjusted for its perceived quality. The quality-of-life determination is represented as a fraction of a healthy life year and is assigned a numeric or fractional value between 0-1, where 1 would represent the highest quality of life while a 0 would represent the lowest. For example, if a healthy life year is given the value of 1, then a year of life experienced with illness or disability may be valued at less than 1 year. This quality-of-life factor can be derived through a variety of means. However, it is most often elicited through surveys that seek to determine how a health condition is perceived to affect a person's quality of life. If an intervention improves quality of life, this difference in quality of life can be factored into the evaluation. This fractional number representing the improvement resulting from the intervention is then multiplied by the total life years extended to calculate the QALY as shown here:

Improvement in quality of life (0-1) x Life years extended = Number of QALYs gained

Example: A medical intervention is shown to extend life for a population with pre-existing disability on average by 10 years. The disability is estimated to reduce quality of life by 50% each year. However, the intervention does not improve the quality of life. The QALY for this medical intervention would be: 0.5 x 10 = 5 QALYs. For a population with no disability, this calculation would be 1 (instead of 0.5) x 10 = 10 QALYs.

Some interventions improve both quality of life and life expectancy, so QALYs will show benefits for interventions which substantially improve quality of life, length of life, or both.

QALYs are also used to assess the balance between the cost of an intervention and the benefit from that intervention, also known as the cost-effectiveness. If the cost of the intervention in the example above is $100,000, then the cost per QALY ($100,000 divided by 5 QALYs) would be $20,000 for the individual with pre-existing disability, compared to $10,000 ($100,000 divided by 10 QALYs) for the for a person living without disability. In some cases, a service may be assessed to have a low-level health benefit and relatively low cost resulting in a high cost-per-QALY. Alternatively, an effective service may have a high initial cost, but a low cost-per-QALY because it provides substantial health benefit over many years.

This cost per QALY has been used to evaluate cost vs. benefit for individual medical interventions, and to compare cost effectiveness across multiple interventions. Cost-effectiveness data including cost per QALY have been used internationally and in the US to make healthcare coverage decisions, including by the HERC on a limited basis.

Concerns raised regarding HERC's use of QALYs

The HERC's inclusion of QALYs has been an area of concern for individuals with disabilities, disability rights advocates and pharmaceutical industry representatives. The overarching concern is that the use of QALYs is discriminatory against those with disabilities and chronic illness and that QALYs devalue life with a disability.

Some specific concerns that have been raised include but are not limited to:

- QALYs may result in a higher prioritization for treatments that extend life years for healthy or younger individuals compared to those with disability, chronic disease or older age.
- The surveys used to determine impact on quality of life for the purposes of QALY calculations have validity and reliability concerns.
- QALYs may not account for subgroup differences or for individuals with rare conditions.
- Use of QALYs in determining coverage will systematically create inequities for people whose disabilities and chronic conditions can be managed but not cured.

For a detailed review of the concerns with the use of QALY, see the 2019 report from the National Council on Disability, Quality-Adjusted Life Years and the Devaluation of Life with Disability: Part of the Bioethics and Disability Series.

HERC's use of QALYs to date

Transparency is a priority for the HERC's work. In keeping with this priority, HERC staff conducted an analysis of the role of QALYs in HERC decision-making since 2017. The results appear in Appendix A.

Since 2017, all prior HERC considerations for adopting a more central role of the use of QALYs have been either rescinded, not adopted or never implemented due to concerns for their potential discriminatory effects.

In recent years, the HERC has used QALYs in a limited fashion to inform decisions about coverage based on cost-effectiveness. When HERC has considered QALY data, it has almost always resulted in expanded coverage. Further, QALYs are always used to compare treatments for the same condition, rather than different conditions. Since QALY calculations remain prominent in the medical literature, QALY data are sometimes included in the meeting materials reviewed by Commissioners, and HERC staff may reference QALYs in issue summaries to support recommendations or inform HERC considerations. This information may inform a general understanding of relative effectiveness or cost-effective of services, even when not used in the active decision-making process. Any use of QALYs in meeting materials is referenced along with other factors, including relevant information about benefits and harms, professional society recommendations, and patient values and preferences.

Alternatives to using QALYs in decision making about cost effectiveness

Cost effectiveness analysis remains a necessary component of medical decision making and, because of this, QALYs have remained in prominent use within the medical literature despite noted challenges and concerns. However, there are alternatives to QALYs when determining cost effectiveness.

Listed below are alternative measures to the use of QALYs as proposed in the NCD's report about QALYs, pp. 61-68. Examples include:

- Equal Value Life Years Gained Supplemental Measure (EvLYG)
    - An unweighted measure of years of extended life without a reduction in value of a life year by the use of a disability weight. The Institute for Cost Effectiveness Research (ICER) has announced its intent to calculate this measure as a supplement to QALYs in its reviews going forward.
- Not using QALYs when determining cost effectiveness, but evaluating the cost per positive outcome
    - For instance, a drug for rheumatoid arthritis might be evaluated in terms of "cost per remission" achieved.
- Multi-Criteria Decision Analysis
    - Consider different factors relevant to a health care decision, using QALYs as one component in that decision analysis. All factors are assigned a weight according to their importance for the decision at hand; however, there are known equity challenges in the determination and application of weights in health services decision making (Wailoo, 2009; Claxton, 2015).
- Patient Perspective Value Framework
    - A five-domain healthcare decision tool that centers patient goals, patient-centered outcomes, financial costs, quality of the evidence, and usability to determine the value of the treatment. Note that this framework has never been operationalized (Jalpa, 2018).
- The Efficiency Frontier
    - A visual modeling metric that expresses treatments as points on a graph, where cost per patient is one axis (x), and benefit is another (y); cost effectiveness is determined when a treatment scores "above" a pre-determined efficiency slope.

These alternative measures are cited in the 2019 NDC report as potential substitutions for QALYs. However, these are infrequently referenced in the published medical literature. As noted above, some of these measures are hypothetical. The absence of robust alternatives to QALY metrics in the literature poses a longstanding challenge among health services researchers who acknowledge the limitations of QALYs but find few feasible alternatives (Carlson, 2020). To the extent that cost effectiveness will remain a necessary component of medical decision-making for health payers, future research to develop alternative measures or models is warranted.

References

Carlson, J. J., Brouwer, E. D., Kim, E., Wright, P., & McQueen, R. B. (2020). Alternative approaches to quality-adjusted life-year estimation within standard cost-effectiveness models: Literature review, feasibility assessment, and impact evaluation. Value in Health, 23(12), 1523-1533.

Claxton, K., Sculpher, M., Palmer, S., & Culyer, A. J. (2015). Causes for concern: is NICE failing to uphold its responsibilities to all NHS patients?. Health economics, 24(1), 1-7.

Jalpa A. Doshi, Ellen Miller Sonet, Justin T. Puckett, and Henry Glick, "The Need for a New Patient Centered Decision Tool for Value-Based Treatment Choices in Oncology," HealthAffairs (blog), Health Affairs, March 19, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180309.241877/full/

National Council on Disability (NCD). (2019). Quality-adjusted life years and the devaluation of life with disability. Retrieved 9/27/22 at https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf.

Wailoo, A., Tsuchiya, A., & McCabe, C. (2009). Weighting must wait. *Pharmacoeconomics*, *27*(12), 983-989.

Appendix A: Historic use of QALY calculations in HERC decisions

All meeting materials and minutes are available on HERC's Archived Meeting Materials page.

Previous examples of HERC's use of QALYs in decision-making processes

Use Cost/QALY as a threshold for topic review or in adding new treatments

In 2017, HERC considered using a cost-per-QALY threshold for determining which services should be considered cost-effective. Discussion occurred at the March 9, 2017 and May 18, 2017 meetings. The policy had been proposed to inform research plans by the state's Pharmacy and Therapeutics Committee and the Commission regarding potential decisions to give low priority to certain non-pharmaceutical services for selected indications, or all indications. The proposed use of a cost-per-QALY threshold was abandoned due to other considerations. (March 2017 Materials Minutes, May 2017 Materials Minutes, August 2017 Materials, Minutes)

As a part of this same dialogue, the Commission discussed an algorithm (Figure 1.9, shown in Appendix A) previously developed to aid in determining which new services should be added to the Prioritized List for potential coverage or which existing services should be removed from the list based on new information.[1] The Commission voted to stop using Figure 1.9 in its biennial report and did not adopt any new rubric since each decision requires unique consideration. The meeting minutes indicate that "parts [of Figure 1.9] are unclear and other parts are incorrect."

Consideration of QALYs in end-of-life cancer care

The Health Services Commission (HERC's predecessor, which maintained the Prioritized List through 2011) added policy in October 2009 related to the treatment of cancer with little or no benefit. While this statement of intent greatly expanded coverage for advanced cancer care, it still excluded coverage for some treatments based on their predicted impact on expected median survival. It also included this language related to QALYs: "The Health Services Commission is reluctant to place a strict $/QALY (quality adjusted life-year) or $/LYS (life-year saved) requirement on end-of-life treatments, as such measurements are only approximations and cannot take into account all of the merits of an individual case. However, cost must be taken into consideration when considering treatment options near the end of life. For example, in no instance can it be justified to spend $100,000 in public resources to increase an individual's expected survival by three months when hundreds of thousands of Oregonians are without any form of health insurance." Due to staff concerns about discrimination, this policy was completely revised for the October 2014 Prioritized List, and the resulting new guideline note omitted the criteria related to QALYs, further expanding coverage for advanced cancer treatment.

Other use of QALYs on individual topics

In late 2021, staff searched meeting materials and minutes for any references to QALYs to better understand how they have been used in the Commission's decision-making. All discrete topics where

[1] In 2005, the legislature added a requirement for the HSC to consider cost effectiveness in developing the Prioritized List. In response, the HSC developed a figure which used QALYs to inform an effectiveness score which had a significant role in the ranking methodology. The role of QALYs was not determinative, but was one factor considered in the methodology. In practice, however, QALYs were only used, when available, to compare multiple treatments for the same condition.

QALYs were presented in studies provided to the Commission or referenced in discussion or issue summaries since 2017 are included in the table below. Some decisions prior to 2017 are also included in the table when relating to disability. Each decision is characterized by how the use of QALYs influenced (or may have influenced, if not discussed) a given decision.

Decisions resulting in new, expanded or reaffirmed coverage

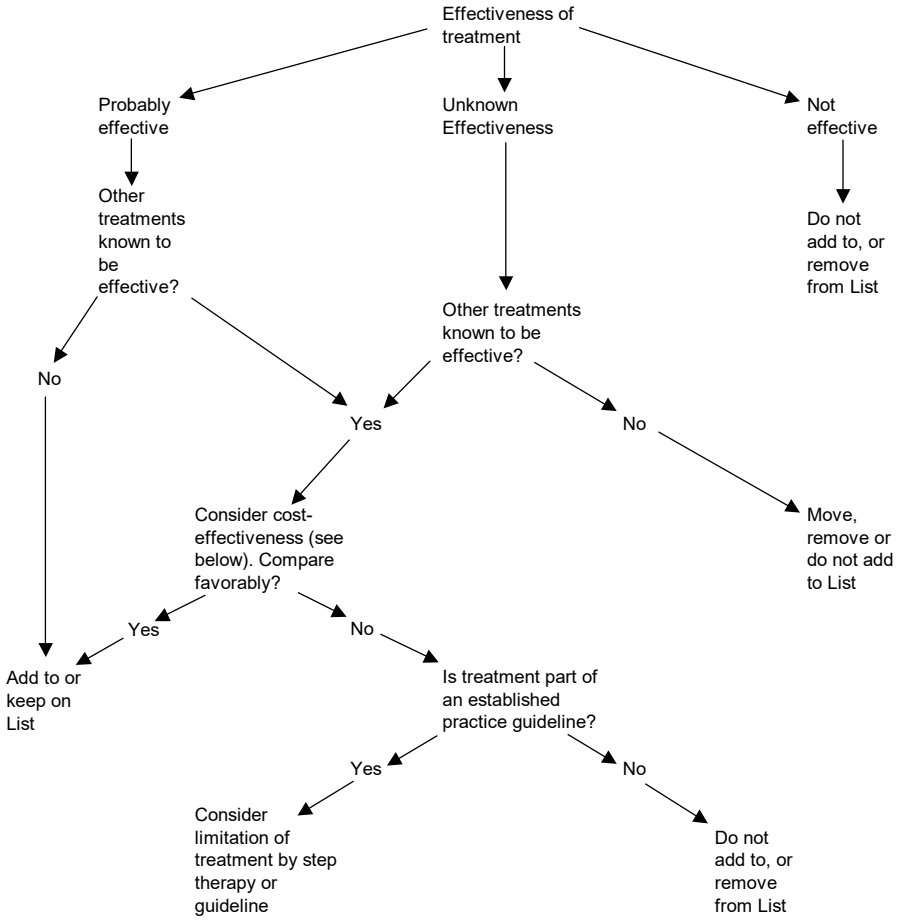
Service	Use of Cost per QALY or QALY	Meeting date(s)
Treatments for varicose veins	Minor factor supporting coverage	1/16/2020 11/14/2019 11/9/2017
Drug eluting stents	Significant impact on the decision to cover, as initial higher cost is offset by savings from fewer reoperations.	8/9/2019
Sacroiliac joint fusion	Minor factor in support of coverage	1/17/2019
Diabetes prevention program added	Significant factor supporting coverage	8/9/2018
Community health workers [race/ethnicity related]	Moderate factor supporting use of community health workers to increase cancer screening attendance	3/8/2018
Cataract coverage expansion [disability/age related]	Preventable loss in QALYs a significant factor in favor of coverage	1/18/2018
Subcutaneous cardiac rhythm monitors	Minor factor in support of coverage	11/8/2018
Deep brain stimulation for Parkinson's disease [disability/age related]	Significant factor in support of coverage	1/18/2018
Medical treatment for early stage liver fibrosis from hepatitis C	One report cited higher cost/QALY for early-stage disease. HERC made no change to coverage	2/2/2017
Cochlear implants—clarified coverage for bilateral implants [disability related]	Higher cost/QALY for second cochlear implant Cost/QALYs mentioned in 2015 report cited but not relevant to question about hearing loss threshold	3/12/2015 5/9/2013

Decisions resulting in noncoverage or restricted coverage

Service	Use of Cost per QALY, or QALY	Meeting date(s)
PET scanning for staging and restaging for breast cancer	Mentioned but not a factor in the decision (Coverage was later added in 2021, based on updated clinical practice guidelines)	3/8/2018
Digital breast tomography	High cost/QALY cited as a reason for noncoverage (due to low clinical benefit) 2/2/2017 VBBS/HERC meeting	2/2/2017

FIGURE 1.9
PROCESS FOR INCORPORATING INFORMATION ON CLINCAL INFORMATION AND COST-EFFECTIVENESS INTO THE PRIORITIZED LIST

HERC will review evidence as outlined in Figure 1.9. Evidence regarding the effectiveness of a treatment will be used according to the following algorithm:



The cost of a technology will be considered according to the grading scale below, with "A" representing compelling evidence for adoption, "B" representing strong evidence for adoption, "C" representing moderate evidence for adoption, "D" representing weak evidence for adoption and "E" being compelling evidence for rejection:

- A = more effective and cheaper than existing technology
- B = more effective and costs < $25,000/LYS or QALY > existing technology
- C = more effective and costs $25,000 to $125,000/LYS or QALY > existing technology
- D = more effective and costs > $125,000/LYS or QALY > existing technology
- E = less or equally as effective and more costly than existing technology

List of Abbreviations

- EvLYG: Equal Value Life Years Gained Supplemental Measure
- LYS: Life-year saved
- HERC: Health Evidence Review Commission
- HSC: Health Services Commission
- NDC: National Council on Disabilities
- PET: Positron emission tomography
- QALY: Quality Adjusted Life Year
- VBBS: Value-based Benefits Subcommittee