

Implications of Reliance on Health Technology Assessment in the VA and TRICARE Formularies

Veterans, members of the military and their families often have unique health care needs and preferences. It is important they are given options for high quality health care that meets their needs. No patient is average, which is why there has been a movement towards personalized medicine in health care with the goal of empowering the patient and clinician so that each person receives the right treatment at the right time. Yet, the U.S. Department of Veterans Affairs (VA) and the Department of Defense (DoD) TRICARE program rely on methods to lower costs by relying on assessments of clinical and cost effectiveness that use flawed and discriminatory methods to determine which treatments it will and will not cover, without considering the holistic value of treatments to the patient and his or her family.

The VA's Use of Health Technology Assessment

The VA has long used health technology assessment (HTA, also known as value assessment) to determine the value of medicines. In 2017, the Department of Veterans Affairs (VA) Pharmacy Benefits Management Services office (PBM) announced an agreement to work with the Institute for Clinical and Economic Review (ICER) to use of ICER drug health technology assessments (HTAs). Under this agreement, ICER works with VA staff to integrate ICER's academic reports into the VA formulary management process of evaluating the value of drugs. On November 13, 2017, organizations representing veterans, military families, patients and people with disabilities expressed concern to the VA about their partnership with ICER, stating, "Prescription drug coverage determinations based on flawed analyses like those conducted by ICER are not the answer and can only serve to further limit access to care for veterans with disabilities and serious chronic conditions, thereby exacerbating the challenges that they and their caregivers often face." The VA formulary is already more limited than Medicare's formulary.

TRICARE's Use of Health Technology Assessment

Tricare's Uniform Formulary Beneficiary Advisory Panel (BAP) meets after the Pharmacy and Therapeutics (P&T) Committee deliberations and provides advice and recommendations on the development of the uniform formulary. In BAP and P&T Committee meeting minutes, ICER's cost and clinical effectiveness assessments have been referenced to inform decisions about placement of medications on the uniform formulary, leading some to be excluded from the formulary with restricted access through utilization management. ICER's involvement is more concerning now that Tricare has power to exclude medications from coverage under a Tier 4. The P&T Committee and BAP openly reference ICER's studies leading to concerns that certain medications are being excluded from Tricare coverage that are needed by service members and their families who fall outside the average, discriminating against those with disabling conditions.

VA's Flawed Methods for Determining Value of Medications

The VA has long used health technology assessment, or HTA, to determine the value of medicines. There are three key problems with government use of HTA:

1) HTA often discriminates against persons with disabilities, the chronically ill and older adults. Many forms of HTA utilize a quality-adjusted life year (QALY) metric as the basis for determining cost effectiveness, known for its discriminatory implications for people with disabilities and serious chronic conditions. Experts agree that referencing discriminatory metrics such as QALYs, whether in reference to QALY-based decisions from foreign governments or to value assessments conducted by ICER, risks limiting access to needed medical treatments. QALY-based assessments assign a financial value to health improvements provided by a treatment that do not account for outcomes that matter to people living with the relevant health condition and that attribute a lower value to life lived with a disability. When

applied to health care decision-making, the results can mean that people with disabilities and chronic illnesses, including older adults, are deemed not worth the cost to treat. In 2019, experts at the National Council on Disability (NCD), an independent federal agency advising policymakers on disability issues, published a report finding that use of the QALY would be contrary to United States civil rights and disability law and stated that payment decisions should not rely on cost-effectiveness research or reports that are developed using QALYs.

2) HTA is typically based on what is right for the “average” patient and often ignores what matters to them. HTA tends to be overly simplistic and defers to the average patient, rarely considering subpopulations. This is particularly concerning in relation to care for veterans and military families, as often their needs are more complex and there are nuanced factors that contribute to their treatment preferences.

3) HTA is often criticized by patients for failing to incorporate patient input or focus on outcomes that matter to them. That could include real costs such as lost time at work, risk of disability, and the potential need for caregiving.

Bipartisan History Opposing One-Size-Fits-All Standards in Federal Programs

The United States has a thirty-year, bipartisan track record of opposing one-size-fits-all standards, including the QALY and similar discriminatory metrics, and has established legal safeguards to mitigate their use:

- Section 504 of the Rehabilitation Act ensures that people with disabilities will not be “excluded from participation in, be denied the benefits of, or otherwise be subjected to discrimination,” under any program offered by any Executive Agency, including Medicare.
- Title II of the Americans with Disabilities Act (ADA) extended this protection to programs and services offered by state and local governments. Based on the ADA’s passage in 1990, in 1992 the George H.W. Bush Administration established that it would be a violation of the ADA for state Medicaid programs to rely on cost-effectiveness standards, as this could lead to discrimination against people with disabilities.
- The Affordable Care Act (ACA) passed under President Barack Obama directly states that the Secretary of Health and Human Services has no authority to deny coverage of items or services “solely on the basis of comparative effectiveness research” nor to use such research “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.” Additionally, the ACA specifically prohibits the development or use of a “dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended.” The ACA also states, “The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII” (Medicare).”
- Most recently, the U.S. Department of Health and Human Services (HHS) reiterated in a final rule that it is a violation of section 504 of the Rehabilitation Act, the ADA, the Age Discrimination Act, and section 1557 of the ACA for state Medicaid agencies to use measures that would unlawfully discriminate on the basis of disability or age.

The VA and TRICARE should be models for putting their members first by engaging them in benefit management decisions and embracing shared decision-making tools and decision aids that will ensure patients get care tailored to their needs.