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EBMA is a periodic report produced by BioMedCom Consultants for those who need to keep on top of trends in market access globally.

Grounded in more than 10 years of experience in evidence-based market access, EBMA provides relevant and up-to-date information to support successful global market access for healthcare interventions.

Hypertension: global treatment guidelines and formulary listings

Knowledge of current treatment practices is essential to rationalize the position of your product. In each issue, this column compares treatment guidelines from selected countries around the world for one specific disease, drawing on international, national, and regional organizations, as well as professional societies.

There is global consensus on the importance of treating hypertension, a silent killer. Management of this disease is based on risk stratification, which varies across countries, and on recommended first line pharmacological options and their coverage.

What is hypertension?

Current consensus defines hypertension as chronically elevated blood pressure (BP) with systolic BP (SBP) of 140 mm Hg or above and/or diastolic BP (DBP) of 90 mm Hg or above. Hypertension is a major risk factor for cardiovascular disease (CVD), stroke, kidney disease, heart failure and death.^{1,2} Worldwide, hypertension is estimated to contribute to 7.1 million premature deaths.³ Evidence suggests that BP reduction of 5-6 mm Hg decreases the risk of stroke by 40%, of coronary heart disease between 15% and 20%,⁴ as well as reducing the likelihood of dementia,⁵ heart failure, and mortality from vascular disease.¹ Antihypertensive measures are therefore essential for prevention of CVD and are influenced by a patient's absolute risk of CVD, determined by the presence and magnitude of other risk factors.

Risk assessment

Guidelines for the management of hypertension have been issued by a multitude of organizations^{3,6-11} and recommend treatment strategies based on patient risk for heart disease. Recommendations from the World Health Organization-International Society of Hypertension (WHO-ISH)³ and the seventh report of the Joint National Committee (JNC VII)⁸ are used worldwide as a basis for hypertension guidelines. Systolic blood pressure (SBP) is a stronger, more consistent predictor of cardiovascular risk than diastolic blood pressure (DBP);⁷ however, when SBP and DBP fall into different risk categories, the value attributing higher risk is used in risk classification.^{8,11}

Decisions about hypertension management not only consider blood pressure, but also the presence of other cardiovascular risk factors (gender, advanced age, obesity, excessive sodium intake, smoking, hypercholesterolemia and sedentary lifestyle), target organ damage (TOD) and associated clinical conditions (ACC) (diabetes,

cerebrovascular disease, renal disease and peripheral vascular disease).³ Risk status of individuals varies greatly, i.e., 10-year CVD risk for someone with a blood pressure of 140/90 mm Hg can vary from 5% to 50% depending on the number of concomitant risk factors. Risk stratification from European, Japanese and British guidelines⁹⁻¹¹ are shown below indicating increasing likelihood of a major cardiovascular event. Categories of low, moderate, high and very high risk are calibrated based on Framingham data to indicate absolute 10-year CVD risk below 15%, 15-20%, 20-30% or above 30%, respectively.^{3,12} These categories can also be used as indicators of relative risk, which increases approximately 1.5 times from one level to the next.⁹ US and Canadian guidelines have combined the mild, moderate and severe categories into two classification groups, stage 1 and stage 2. For stage 1, BP treatment thresholds are 140-159/90-99 mm Hg^{6,8} and for stage 2, they are 160-180/100-105 mm Hg (Canada)⁶ and above 160/100 mm Hg (US).⁸ In Australia,⁷ BP lower than 120/80 mm Hg is categorized as normal and high normal when 120-139/80-89 mm Hg. The aim of treatment is control of BP, defined as readings below 140/90 mm Hg for most patients, and lower in patients such as those with TOD or ACC.

Non-pharmacological management

Many studies have shown that modification of patient lifestyle is an essential part of hypertension treatment. Reducing sodium intake,¹³ caloric restriction to reduce weight,¹³ decreased alcohol consumption,¹⁴ smoking cessation,¹⁵ and regular aerobic exercise (30-45 min for at least four days per week)¹⁶ are all means by which blood pressure can be lowered. These lifestyle measures are recommended because they also decrease cardiovascular risk. It is difficult to achieve target blood pressure levels with lifestyle modifications alone; however, they may contribute to reducing the number and dosage of antihypertensive medications required to control BP.

Pharmacological management

The goal of antihypertensives is to prevent cardiovascular and renal complications associated with elevated BP, prolonging life and improving the quality of life. Antihypertensives are prescribed alone or in combination until they control BP and produce minimal side effects. Each added drug can reduce systolic blood pressure by 5 to 10 mm Hg, and multiple drugs are often necessary to achieve BP control.¹⁰ The six major classes of antihypertensive medications consistently recommended by guidelines worldwide include diuretics, β -blockers, angiotensin converting enzyme inhibitors (ACE-inhibitors), calcium channel blockers (CCBs), and angiotensin receptor blockers (ARBs). Choice of medications is influenced by many factors such as patient risk profile, presence of TOD or ACC, and drug cost. For instance, β -blockers are effective for patients with coronary disease or heart failure¹⁷ but are ineffective as a first-line treatment option in the elderly,¹⁸ while ACE-inhibitors are recommended for diabetic patients who have evidence of kidney disease, because they have been shown to reduce blood pressure and slow the progression of diabetic nephropathy.^{19,20}

Initiation of antihypertensive treatment is based on BP levels and risk stratification.¹¹ A summary of treatment approaches from guidelines, illustrated in the figure below,^{3,6,7,10,11} indicates that lifestyle measures alone are recommended for patients in the low and medium-risk groups, but drug treatment is initiated if BP does not decrease below 140/90 mm Hg after six or three months respectively. Patients in the high risk group are prescribed both lifestyle measures and drug treatment.^{3,8,11} Patients at very high risk require hospital admission, as well as drug treatment and lifestyle management.^{3,8,11} Frequency of blood pressure monitoring also differs between risk groups.

Stratification of risk to quantify prognosis of patients with hypertension

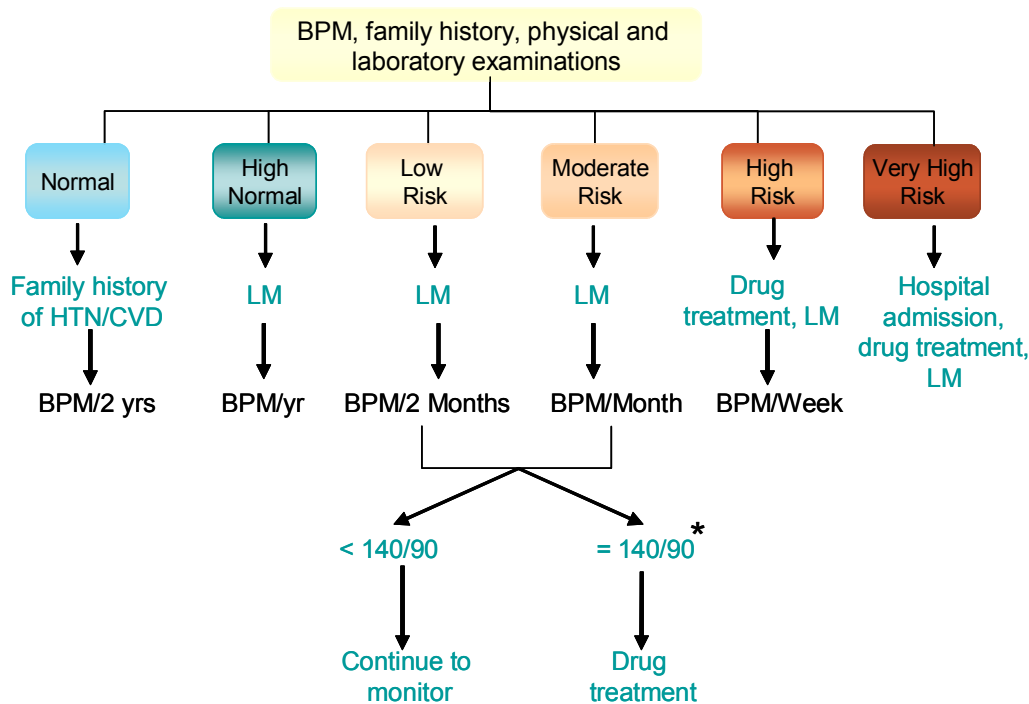
	Blood pressure (SBP/DBP) (mm Hg)				
	Normal (120-129/80-84)	High Normal (130-139/85-89)	Mild HTN (140-159/90-99)	Moderate HTN (160-179/100-109)	Severe HTN ($\geq 180/\geq 110$)
• No risk factors	No added Risk	No added Risk	Low Risk	Moderate Risk	High Risk
• 1-2 risk factors	Low Risk	Low Risk	Moderate Risk	Moderate Risk	Very High Risk
• 3 or more risk factors, or TOD	Moderate Risk	High Risk	High Risk	High Risk	Very High Risk
• ACC	High Risk	Very High Risk	Very High Risk	Very High Risk	Very High Risk

Adapted from: Whitworth JA.³

Classification based on either a high SBP reading or a high DBP reading.

SBP: systolic blood pressure; DBP: diastolic blood pressure; HTN: hypertension; TOD: target organ disease; ACC: associated clinical conditions





* If blood pressure is greater than or equal to 140/90 after 6 months or 3 months (low risk and medium risk, respectively), then initiate drug treatment
 BPM: blood pressure measurement; HTN: hypertension; CVD: cardiovascular disease; LM: lifestyle measures

Formulary listings from a global perspective

Antihypertensives are essential medication that decrease the risk of other debilitating diseases such as CVD, renal disease and stroke.^{1,2} Although the majority of antihypertensive drugs are inexpensive, their chronic use and daily requirement can be costly. Anti-hypertensive medications are covered to varying degrees by formularies worldwide.²¹⁻²⁵ The WHO model formulary lists diuretics, β -blockers and ACE inhibitors as first-line treatments of HTN, while CCBs are first-line only in specific populations such as Africans or the elderly. ARBs are not specifically mentioned on the WHO model formulary.²⁶

In Canada, most provinces offer full coverage for all antihypertensive classes without restriction.^{23,27-29} In the US (e.g., California),²² all antihypertensive classes except ARBs have full coverage (tier 1). Most drug plans in the US (e.g., AETNA, CIGNA)^{30,31} offer tier-2 or tier-3 coverage (where patients have to contribute a greater proportion of the cost of the product) for ARBs, and often, the dosage of ARB is restricted to one pill per day.^{22,30,31}

In Australia, patients are only eligible for ARB treatment if their BP is not adequately controlled with other antihypertensive drugs, while other antihypertensive classes are covered without restriction.²¹ In Japan²⁴ and the UK,²⁵ all classes of antihypertensives are covered without restriction.

The various classes of antihypertensive medication are well covered by formularies in industrialized countries. First line recommendations of current guidelines are not always reflected by formulary restrictions, most likely because recommendations vary according to underlying conditions, and physicians require a full range of products to optimally tailor treatment. In certain jurisdictions, ARBs have restricted coverage, possibly because of their slightly higher cost over other antihypertensives, their relatively new emergence as a hypertension treatment option, or the lack of generic ARB options on the market. Currently, in most jurisdictions, the decision about which antihypertensive will be prescribed results more from patient requirements than formulary coverage.

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NICE Technology Appraisal: the key process and new developments

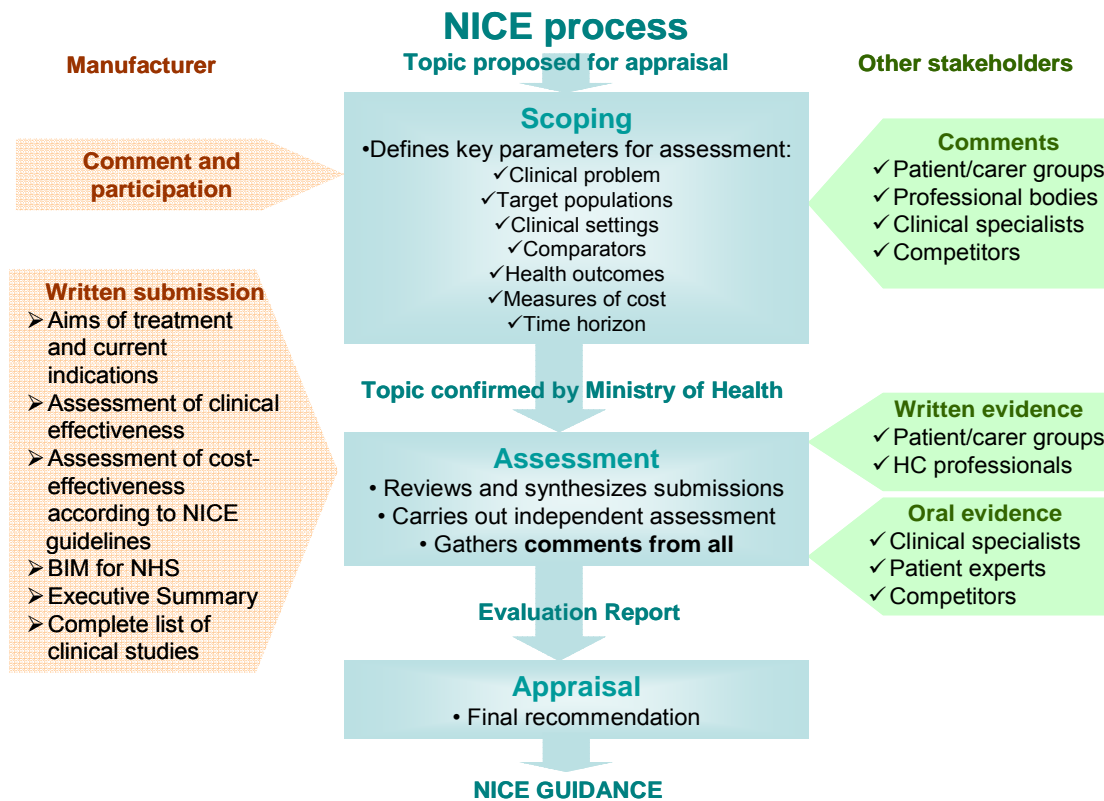
How does your market compare to the rest of the world. Are there lessons to be learned from other regions? Drawing on market access guidelines and formulary submission requirements from many of the key markets around the world, in each issue this column provides a bird's-eye view of one regional or national sector, existing evidentiary requirements, and how these evolve over time.

The National Institute for Health and Clinical Excellence (NICE) was established in 1999 with the purpose of providing healthcare professionals with advice on the highest attainable standards of care and to increase equal access to healthcare across England and Wales within the National Health Service (NHS).¹ The NICE mandate includes conducting healthcare technology appraisals based on a rigorous assessment of clinical and cost-effectiveness.¹ Implementation of NICE appraisals is mandatory; every local healthcare body within the NHS is legally required to provide funding for treatments

recommended by an appraisal within three months of its release.¹ However, compliance with this requirement still varies between local health trusts.²

Any member of the public or governmental body can suggest topics for appraisal. A technology appraisal begins with the scoping process that determines whether a technology should be appraised and defines the framework for its assessment.^{3,4} The initial draft scope—developed by NICE—sets forth the parameters to be used for evaluating clinical and cost-effectiveness (see figure). Manufacturers and other stakeholders (patient/carer groups, professional bodies, clinical specialists, manufacturers of competitor technologies) have the opportunity to influence these important parameters by providing comments on the scope and actively participating in a meeting (scoping workshop) that will discuss key questions and lead to development of the Assessment Protocol.³ The final decision on which topics should go forward to appraisal lies with the Minister of Health.^{3,4}

Following a positive decision to undertake an appraisal, manufacturers are officially invited to take part in the appraisal process and asked to prepare a written submission. This should include:^{3,4}



BIM: Budget Impact Model; NHS: National Health Service; HC: healthcare



- a description of the aims of treatment listing current approved indications;
- an assessment of clinical effectiveness based on studies (published and unpublished) that meet inclusion criteria outlined by the Assessment Protocol;
- an assessment of cost-effectiveness according to NICE guidelines (an electronic copy of the model must be included); and
- a Budget Impact Model for the NHS built on evidence-based estimates of current and expected treatment rates and, ideally, including estimates of the potential population health impact of the appraised technology.

An executive summary and a complete list of clinical studies (published and unpublished, including follow-up studies and registry evidence) also form part of the submission. Patient/carer groups and healthcare professional bodies are also invited to submit written evidence that may inform the appraisal. In addition, clinical specialists, patient experts, and competitors may provide oral evidence and comments. All submissions are gathered, reviewed, and synthesized by a panel of academic experts (the Assessment Group), which may also conduct its own assessment of cost-effectiveness. This assessment, together with submissions and comments from stakeholders, forms the Evaluation Report that is used by the Appraisal Committee (consisting of doctors, nurses, pharmacists, NHS managers, health economists, statisticians, and lay representatives) to make a final recommendation published as a NICE guidance.^{3,4}

The NICE preferred measure of cost-effectiveness is the incremental cost per quality-adjusted life-year (QALY).⁵ While rejecting a specific threshold, NICE requires special reasons for supporting interventions with an incremental cost-effectiveness above £25,000 to £35,000 per QALY. These reasons may relate to the public health impact of the intervention (such as for communicable diseases), level of innovativeness, lack of other effective interventions for the disease, and fairness considerations. In its appraisal, NICE does not explicitly consider the impact of its guidance on healthcare budgets. However, although the government may advise the NHS to ignore NICE guidance, it has never done so.⁵ In reality, adoption of new healthcare technologies and drugs has increased considerably since NICE has begun its work.

Although implementation of NICE guidances is mandatory for the NHS, the degree to which they are adopted varies and depends on the level of professional support for a specific recommendation,

cost implications, and organizational structure of the local health trust.²

Recently, NICE has introduced a revised appraisal process—the Single Technology Appraisal (STA)—that is applied to a single product with a single indication, for which the manufacturer holds most of the evidence, such as a new pharmaceutical close to launch.⁶ The STA process is more rapid than current practice (at present 32–39 weeks) to allow NICE to produce guidance close to the time the new product is introduced into the UK market. The main element of the new process is the *Evidence Submission* that manufacturers are asked to prepare based on a detailed template.^{6,7} As of August 2006, one guidance has been produced using the STA process (herceptin for early-stage breast cancer), draft guidances on paclitaxel and docetaxel (also for early-stage breast cancer) have been released, and assessments of other drugs, such as bortezomib for multiple myeloma and rituximab for non-Hodgkin's lymphoma, are forthcoming.⁸

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Guidelines for economic evaluations: QALYs

Today, demonstrating full value of your product usually requires economic assessment, and not every decision-maker has the same needs. Drawing on health economic standards and guidelines published around the world, this column will highlight one aspect of this subject in each issue, clarifying similarities and differences.

What is a QALY?

The quality-adjusted life-year (QALY) is a standard measure for integrating effects of a healthcare intervention on both longevity and health-related quality of life (HRQL).¹ To calculate QALYs requires weights—known as “utilities”—to adjust each year of life for HRQL. For a given health state, a utility can be assigned on a scale ranging from zero (death) to one (full health). Utilities are calculated from preferences for different health states; to capture society’s preferences for health, it is generally recommended to use preferences elicited from laypeople rather than either patients or physicians.¹

For example, a study assessing preferences of elderly community-dwelling women found they would trade a year of life following a hip fracture that resulted in severe loss of independence for just 18 days of life in full health (see Figure).² Thus, the utility of this post-hip fracture health state would be $18 \div 365 = 0.05$.

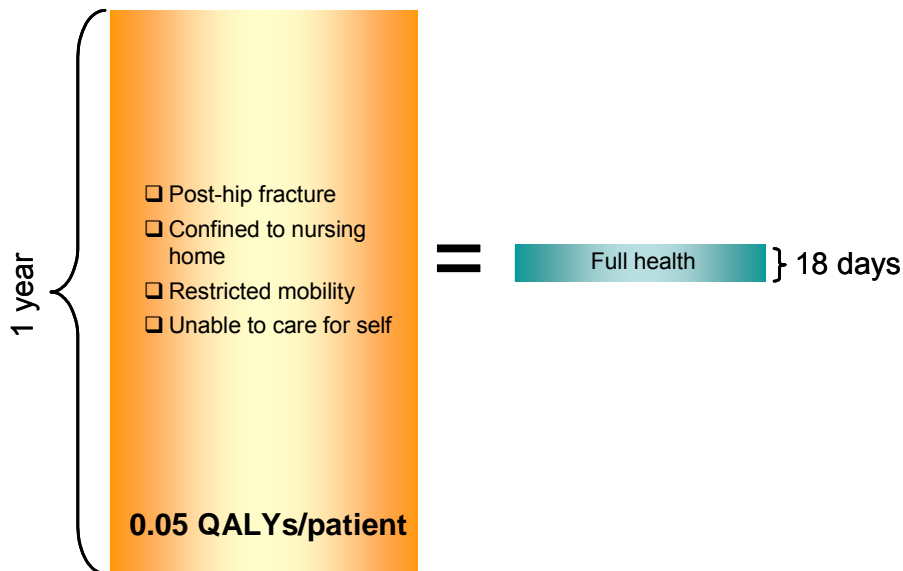
A hypothetical new treatment that prolonged life after hip fracture by an average of one year without returning patients to independence would therefore achieve a benefit of only 0.05 QALYs per patient.

Why use QALYs?

QALYs are widely considered the most acceptable generic measure of health gain currently available.³ Funding decisionmakers find in the QALY a common currency that can be used to compare vastly different healthcare interventions across a wide range of diseases and patient populations. Analysts find in the QALY an effect measure that lends itself to incremental cost-effectiveness calculations more satisfactorily than less comprehensive, disease-specific outcomes.³

Health economic guidelines in most major markets either explicitly require QALYs for reference-case analyses, or else recommend use of QALYs for those analyses that incorporate HRQL effects. QALYs are explicitly requested in guidelines from Canada,⁴ the Netherlands,⁵ New Zealand,⁶ Sweden,⁷ the UK,^{8,9} and by the US Panel on Cost Effectiveness in Health and Medicine.¹ Some US private-sector health plans, such as WellPoint Pharmacy Management, also ask for QALYs to be presented in reference-case results of formulary submissions.¹⁰ QALYs are recommended when modeling HRQL effects in Australia¹¹ and Spain.¹²

If a year of life following a bad hip fracture is worth only 18 days lived in full health, then a year of life post-hip fracture is worth only 0.05 QALYs



How much is a QALY worth?

Since decisionmakers in many markets ask sponsors to report results as cost per QALY, one might assume that they have in mind some pre-established cost-utility ratio below which they would fund a healthcare intervention, and above which they would not. In fact, no healthcare system anywhere admits to using a fixed threshold for acceptable cost-effectiveness. WellPoint, for example, explicitly states that they have no cost-per-QALY threshold, instead evaluating each product on its overall merits.¹⁰ The National Institute for Health and Clinical Excellence (NICE) in the UK comes closest to advertising a cost-utility threshold. Current NICE guidelines state that below £20,000/QALY, cost-effectiveness is the primary basis for decisions about the acceptability of health technology, whereas factors other than cost-effectiveness must be increasingly strong for an intervention to be recommended the further above £30,000/QALY the cost-utility ratio creeps.⁸ Nevertheless, the same guidelines declare that NICE has no fixed cost-utility threshold, and indeed that “the use of a threshold is inappropriate”.⁸ Analysis of past decisions made by NICE suggests that the critical cost-utility range for acceptability is somewhat higher than the £20,000 to £30,000 publicly identified,¹³ possible more in the range of £25,000 to £35,000/QALY.¹⁴

True, analysts in the US often treat \$50,000/QALY as the cost-utility ratio to beat, but it is important to understand that this is an outmoded figure, bandied about since the early 1980s,¹⁵ when a dollar was worth more than twice what it is today. Even when it first appeared, \$50,000/QALY was an essentially arbitrary value, perhaps gaining traction simply by virtue of being a nice, round number.¹⁶ More to the point, analysis of past funding decisions in Australia,¹⁷ the UK¹³ and the US¹⁸ have found no consistent cost-effectiveness threshold being applied in practice, \$50,000/QALY or otherwise. Clearly, the cost-utility ratio is but one of several factors weighed by decisionmakers.

In short, it is not possible to state the value of a QALY.¹⁶ Academics have suggested approaches to resolve this issue, such as willingness-to-pay for a QALY,¹⁹ but these proposals have difficulties of their own, and have yet to be implemented.

The trouble with QALYs

A number of conceptual and methodological problems adhere to QALYs,²⁰ and the QALY approach is

received with much skepticism by French health economic guidelines.²¹ A description of these technical objections is beyond the scope of this summary, but a number of situations in which QALYs fall short can be outlined. For a short-term intervention for treating an acute medical condition (e.g., an anesthetic used during surgery), the difference between health states with and without the intervention may be experienced over too brief a time span to register as much of an improvement when measured in QALYs—other outcome measures may provide a more meaningful picture of benefit.²² QALYs are difficult to apply in pediatric populations, since we lack appropriate tools to measure utilities in children, and using parents or other proxies for valuing child health is fraught with difficulty.²³ The QALY approach has also been accused of discriminating against the elderly because, for example, a full recovery from a life-threatening condition for an elderly person will be smaller in terms of QALYs gained than a full recovery from the same condition in a young person.²⁴ Despite these difficulties, no other candidate currently threatens to unseat QALYs as the most widely useful health measure.

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Selected Health Technology Assessments – new releases from around the world

Each issue, this column will highlight some recent health technology assessments produced around the world by well known health technology assessment bodies. These are often first level sources of credible information and provide excellent support for clinical and economic rationales.

Australia

MSAC Assessment reports – available at:

www.msac.gov.au/internet/msac/publishing.nsf/Content/completed-assessments-lp-1

- ❖ Carbon labelled urea breath tests for diagnosis of Helicobacter pylori infection – Mar 2006
- ❖ Artificial Intervertebral Disc Replacement – Feb/Mar 2006
- ❖ Implantable cardioconverter defibrillators for the prevention of sudden cardiac death – Feb/Mar 2006
- ❖ Uterine Artery Embolisation – January 2006
- ❖ High-energy transurethral microwave thermotherapy for benign prostatic hyperplasia (He-tumt) – November 2005
- ❖ Coronary (Radi) pressure wire – November 2005
- ❖ UroVysion Fluorescence Insitu Hybridization (FISH) Assay – November 2005
- ❖ Positron Emission Tomography (PET) for non-small-cell lung cancer and solitary pulmonary nodules – November 2005

Belgium

KCE Reports – available at

http://kce.fgov.be/index_fr.aspx?SGREF=3470

- ❖ Imagerie par Résonance Magnétique – July 2006
- ❖ Traitement pharmacologique et chirurgical de l'obésité. Prise en charge résidentielle des enfants sévèrement obèses en Belgique – June 2006
- ❖ Trastuzumab pour les stades précoces du cancer du sein – June 2006
- ❖ Effets et coûts de la vaccination des enfants Belges au moyen du vaccin conjugué antipneumococcique – June 2006
- ❖ L'antigène prostatique spécifique (PSA) dans le dépistage du cancer de la prostate – May 2006
- ❖ Qualité et organisation des soins du diabète de type 2 – May 2006

Canada

CADTH/ACMTS Health Technology

Assessments/Evaluation des technologies de la santé – available at: www.cadth.ca/index.php/en/hta

- ❖ CT and MRI for Selected Clinical Disorders: a Systematic Review of Clinical Systematic Reviews – August 2006

- ❖ BRCA1 and BRCA2 predictive genetic testing for breast and ovarian cancers: a systematic review of clinical evidence – March 2006
- ❖ Infliximab and etanercept in patients with rheumatoid arthritis: a systematic review and economic evaluation – March 2006
- ❖ Long-acting β 2-agonists for the maintenance treatment of chronic obstructive pulmonary disease in patients with reversible and non-reversible airflow obstruction: a systematic review of clinical effectiveness – March 2006
- ❖ Newborn screening for medium chain Acyl CoA Dehydrogenase deficiency using tandem mass spectrometry: clinical and cost-effectiveness – March 2006
- ❖ Portable ultrasound devices in emergency departments – March 2006

Denmark

DACEHTA Systematic Reviews – available at

http://www.sst.dk/Planlaegning_og_behandling/Medicinsk_teknologivurdering.aspx?lang=en

- ❖ Cross-sectorial cooperation between general practice and hospital - shared care elucidated using anticoagulant therapy as an example - a health technology assessment – 2006
- ❖ Ward rounds - a health technology assessment focused on production of knowledge – 2006
- ❖ Implementation of research: HTA-based guidelines for the treatment of men with lower urinary tract symptoms (LUTS) – 2005
- ❖ Colon Examination with CT Colonography – a health technology assessment – 2005

France

CEDIT – available at cedit.aphp.fr/index_pub.html

- ❖ Système d'ablation de l'endomètre (Novasure®) – January 2006
- ❖ Biologie délocalisée – January 2006
- ❖ Chimiohyperthermie intrapéritonéale (CHIP) – Oct 2005

ANAES – Etudes d'évaluation économique - available at

[http://www.has-sante.fr/anaes/anaesparametrage.nsf/Page?ReadForm&Section=/ANAES/presse.nsf/\(ID\)/E066EC2C11DD6F62C125709700341562?opendocument](http://www.has-sante.fr/anaes/anaesparametrage.nsf/Page?ReadForm&Section=/ANAES/presse.nsf/(ID)/E066EC2C11DD6F62C125709700341562?opendocument)

- ❖ Prise en charge des patients adultes atteints d'hypertension artérielle essentielle - Actualisation 2005 – October 2005

United Kingdom

NICE Technology Appraisals – available at:

www.nice.org.uk/page.aspx?c=153

- ❖ Breast cancer (early) – trastuzumab – August 2006
- ❖ Hepatitis C - peginterferon alfa and ribavirin – August 2006
- ❖ Colorectal cancer - laparoscopic surgery (review) – August 2006
- ❖ Conduct disorder in children - parent-training/education programmes – July 2006
- ❖ Psoriasis - efalizumab and etanercept – July 2006



- ❖ Psoriatic arthritis - etanercept and infliximab – July 2006
- ❖ Prostate cancer (hormone-refractory) – docetaxel – June 2006
- ❖ Colon cancer (adjuvant) - capecitabine & oxaliplatin – April 2006
- ❖ Renal transplantation - immunosuppressive regimens for children and adolescents – April 2006
- ❖ Attention deficit hyperactivity disorder (ADHD) - methylphenidate, atomoxetine and dexamfetamine (review) – March 2006
- ❖ Depression and anxiety - computerised cognitive behavioural therapy (CCBT) – February 2006
- ❖ Hepatitis B (chronic) - adefovir dipivoxil and pegylated interferon alpha-2a – February 2006

USA

AHRQ Evidence Reports – available at:

www.ahrq.gov/clinic/epcindex.htm

- ❖ Comparison of Endovascular and Open Surgical Repairs for Abdominal Aortic Aneurysm – August 2006
- ❖ Pediatric Anthrax: Implications for Bioterrorism Preparedness – August 2006
- ❖ Management of Small Cell Lung Cancer – July 2006
- ❖ Tobacco Use: Prevention, Cessation, and Control – June 2006
- ❖ Multivitamin/Mineral Supplements and Prevention of Chronic Disease – May 2006
- ❖ Cancer Care Quality Measures: Diagnosis and Treatment of Colorectal Cancer – May 2006
- ❖ Cancer Care Quality Measures: Symptoms and End of Life Care – May 2006
- ❖ Value of the Periodic Health Evaluation – April 2006
- ❖ Management of Eating Disorders – April 2006
- ❖ B Vitamins and Berries and Age-Related Neurodegenerative Disorders – April 2006
- ❖ Costs and Benefits of Health Information Technology – April 2006
- ❖ Cesarean Delivery on Maternal Request – March 2006
- ❖ Telemedicine for the Medicare Population—Update – February 2006
- ❖ Management of Adnexal Mass – February 2006

Oregon Drug Effectiveness Review Reports –

available at:

<http://www.ohsu.edu/drugeffectiveness/reports/final.cfm>

- ❖ Drug Class Review - Statins – August 2006
- ❖ Drug Class Review - Proton Pump Inhibitors – July 2006
- ❖ Drug Class Review - Newer Drugs for Insomnia – July 2006
- ❖ Drug Class Review - Drugs for Alzheimer's – June 2006
- ❖ Drug Class Review - ADHD – May 2006
- ❖ Drug Class Review - Antiepileptic Drugs-Bipolar Mood Disorder, Neuropathic Pain, Fibromyalgia – May 2006
- ❖ Drug Class Review - Thiazolidinediones – May 2006
- ❖ Drug Class Review - Newer Antihistamines – April 2006
- ❖ Drug Class Review - Atypical Antipsychotic Drugs – April 2006
- ❖ Drug Class Review - Long Acting Opioids – April 2006
- ❖ Drug Class Review - Second Generation Antidepressants – March 2006

- ❖ Drug Class Review - Angiotensin II Receptor Antagonists – February 2006

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From the editor...

Market access: is it marketing or is it science?

As most of the world's developed countries move towards more scientific and formulaic approaches to market access, the boundaries between pharmaceutical marketing and pharmaceutical science are breaking down. Traditional marketing strategies are no longer sufficient to ensure that healthcare decisionmakers accept new products. This has been a consequence of several factors. Healthcare decisionmakers:

- have become mistrustful of traditional marketing techniques; they are more able to recognize and avoid being influenced by traditional routes of persuasion;
- have tighter budgets and are under greater scrutiny by their constituencies (administrators, government, the public, etc.) to justify their decisions;
- have access to healthcare and scientific experts to help critique submissions and guide their decisions;
- with the help of such experts, are establishing ever more rigorous scientific evidential criteria for formulary acceptance.

On the other hand, without strategic marketing and a business approach to achieving acceptance by payers, the pharma industry would not be attaining full potential market for its new products—an outcome undesirable for business and undesirable for healthcare. Despite the adversarial relationship that often exists between industry and the various decisionmaking bodies, no one denies that there is continued public clamor for new and better healthcare interventions that address unmet need. The science behind the strategy requires marketing direction, and the marketing objective requires scientific expertise to effectively reach and persuade healthcare decisionmaking audiences. The key to successful market access today is finding the optimal blend of market strategy and scientific data.

Gap analysis is a case in point. By performing an evaluation of the available scientific evidence the scientific strengths and weaknesses of a product can be identified, and decisions made about market

positioning: where will a product fit into the current context, and what (evidence) is needed to re-position the product. This requires a strong scientifically analytical background to effectively sort through, critically evaluate and synthesize the vast amount of information available, in just such a way as will be done by experts at the decisionmaking stage. It also requires an understanding of the external market factors that will influence decisions concerning use of the product: opportunities and threats.

The six key areas that are relevant to this sort of information delving generally include:

- product specific information: whatever clinical, health outcomes, and safety studies have been carried out to date
- disease specific information: a clear understanding of the disease of interest
- epidemiological information: the population of interest, numbers and burden the disease places on that population
- economic information: costs of the disease and costs of treatment
- treatment guidelines: local, regional or global, as available
- current practice: usually for the population or region of interest, including competitive treatments already on the market

Disease-specific information provides a platform from which a case is developed. Assessing the population of interest allows determination of need, and evaluation of end-user constituency for the product. Examination of current treatment guidelines, treatment practices (not always in accord with the guidelines), and expert opinion of future treatment directions, can help establish the rationale for product position. Evaluation of costs and burden of illness in that population builds the story for potential benefit, e.g. reduction of pain, improvement of health-related quality of life, less financial burden (for patients, payers, or society), more efficient resource use.

A wealth of information can be gained from this material for market access, and it allows significant insight into any needs for further research to strengthen the submission. It permits testing the water prior to formulary submission, to see how well evidentiary requirements can be met, and how strong a value rationale can be made for a product. Is market access marketing or science? It is both, uniquely blended to meet the business needs of industry as well as the evidentiary needs of the healthcare community.





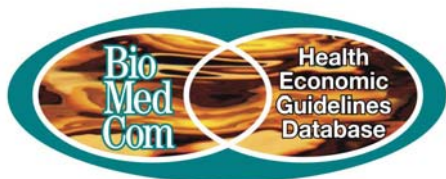
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