THE LAST WORD:

ICER's Review of Benlysta (belimumab) and Lupkunis (voclosporin) for Lupus Nephritis

In its Final Report for Benlysta and Lupkynis in lupus nephritis, ICER announced that while the current prices for these products met ICER's imagined range for an assumption driven socially acceptable price, the price was such as to effectively exclude a significant proportion of Americans from these therapies given ICER's assumed budget impact constraints. In the case of Benlysta, some 80% of eligible patients could afford to be treated, with the estimate falling to 35% with Lupkynis. These are clearly nonsense recommendations in line with the ICER pricing.

It has been argued for some time that ICER recommendations, created as they are from invented evidence, should never be taken seriously. The modeled claims that support ICER's recommendations are a charade. ICER has ignored for years the standards of normal science and, most egregiously, the limitation imposed by measurement theory. This is not an exotic academic claim, but one that goes to the core of ICER's business case.

For many years, the principal charge ICER has faced is that its attempts to create simulation models to invent lifetime claims for competing pharmaceuticals amount to pseudoscience. That charge is once again appropriately leveled in this case.

If ICER in its recommendation for lupus nephritis is to have any shred of credibility, then all claims made for these products in cost-effectiveness terms must be empirically evaluable. They are not. The claims are invented and the more credulous formulary committees, insurers, and media representative are asked to take them at face value – and many do.

ICER is not alone in its commitment to worlds of the imagination. Alone among the social sciences technology assessment itself is committed to the invention of imaginary evidence. This shared mythical certainty has now persisted for more than 30 years, ensuring that approximate imaginary evidence replaces real world evidence.

Claims driven by assumption fail the test of simple logic. What has happened in the past cannot be assumed to hold in the future. Relying on selected assumptions from clinical trials, the literature, and even informed guesswork is just nonsense. Yet ICER persists, asking its audience to believe that imaginary claims driven by assumption-based simulations stretching decades into the future have a role in formulary decisions, pricing and access recommendations. The lupus nephritis imaginary claims should be ignored. This where ICER falls down. We have this odd conundrum in the lupus nephritis report where imaginary socially acceptable prices determined by ICER are inconsistent with open access to the products based on ICER's imaginary budget constraints.

But more to the point is ICER's profound ignorance of the limitation of measurement standards. ICER continues to insist, and this is repeated once again in comments on criticisms of its modeling, that the quality adjusted life year (QALY), a centerpiece of its simulation modeling, is a viable construct. It is not. It is mathematically impossible because the preferences on which it rests are ordinal scores, not the required ratio score. Indeed, there is always the possibility of negative utilities, which would lead to negative QALYs for states worse than death. ICER is well aware of this criticism, yet continues to ignore it because the QALY is central to the ICER business case and its claim to be the leader in the US for imaginary non-evaluable cost-effectiveness simulations. ICER cannot defend itself, and if we recognize that the ICER-modeled invented reports have no scientific merit, what are the options? How do we return to the scientific mainstream?

There are two criteria to be met. First, respect the limitations of fundamental measurement and develop quality of life measures that reflect patient and caregiver needs. This was achieved in lupus nephritis some 15 years ago with the development of the L-QOL, a patient-centric measure of the quality of life expressed in terms of lupus nephritis patient needs and the extent to which they were being met. ICER, or its academic model builders, seem unaware of this instrument.

Second, insist on formulary guidelines that are committed to real world evidence; the development of evidence platforms that can, for example, support value contracting.

This is not just a focus on quality of life. Clinical endpoints are also critical, but these should be assessed separately in the real world. The intent is to discover new yet provisional facts about the therapeutic and quality of life impact, in this case of lupus nephritis interventions, to complement pivotal trials recognizing that pricing and access are evolving and subject to negotiation. But this has to be driven by evidence not guesswork and flights of the imagination.

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