SIDLEY

The NICE HST Manuals: A Model for the Swiss Federal Office?

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After a long process of thorough stakeholder consultations and reviews, NICE published its updated methods and processes manual and topic selection manual on January 31, 2022. The new health technology evaluations manual covers traditional technology appraisal and encompasses diagnostic assessment, highly specialized technologies (HST), and medical technologies evaluation, which interestingly includes digital and screening tools. NICE states that the new manuals will "give patients earlier access to innovative new treatments."

As previously reported, this change came after many years, during which time the multiple innovations that have emerged dictated a change in approach. Some of these areas include the need to adjust the appraisals to the necessities of rare and genetic disorders that require lengthier and more complex data collections; the incorporation of real-world evidence (RWE) in the review process; the evaluation of innovative treatments such as cell and gene therapies; more flexible approaches to data evaluation including from diverse sources such as patient input; and increasingly the assessment of the impact of a treatment on a patient's quality of life, which by nature is a crucial yet unquantifiable metric.

Criticisms of previous NICE methodologies included that the highly specialized technologies evaluation for very rare diseases was too restrictive in scope; the procedures in place resulted in considerable delays; and the benefit to some patients was not properly and comprehensively evaluated. These criticisms are echoed in Switzerland with regard to the Swiss Federal Office of Public Health (FOPH) procedures for listing new medicinal products on the list of medicinal products that are reimbursed by compulsory health insurance ("Spezialitätenliste" or SL) at the price FOPH sets for these products.

The changes brought about in the new manuals published by NICE aim to

- adjust the weight given to health benefits in the most severe conditions ("severity modifier") on the basis that there is increased need for treatments in those conditions, and therefore evidence of a positive effect should be evaluated differently and not be limited to end-of-life treatments

- increase and codify scope for systemic patient input to feed into the RWE that NICE will accept for and apply in its evaluation, which should help facilitate the availability of treatments to rare or poorly understood diseases with patient and healthcare professional input

- understand the difficulties of evidence generation either in conditions affecting pediatric or orphan populations or for complex innovative treatments, as NICE has empowered its independent committees to factor this uncertainty into their evaluation outside of the traditional strict criteria;

- clarify the criteria and principles underpinning the eligibility of treatments for very rare diseases into NICE's HST Programme to make it more predictable and fairer

- provide for the mantra of regulators and payers alike to "engage early" through the pathway to earlier engagement with NHS England, NHS Improvement and companies about commercial/managed access proposals, making it clearer when NICE can make a managed access recommendation

This is followed by a commitment from NICE to embrace a more agile methodology across all types of evaluations and adjust its methods and processes on a rolling basis through a modular approach, to reflect new needs and innovation, rather than performing more scarce whole-scale reviews.

In Switzerland, a number of industry stakeholders, physicians and patients have the impression that FOPH prioritizes general costs for healthcare over the individual patient's benefits from such innovative products, thus ignoring political initiatives in Switzerland that aim to allow patients suffering from orphan diseases to receive adequate treatment for their conditions. If FOPH adapted its procedures in line with NICE's HTS manuals, this could address such concerns.