Health Technology Assessment for Molecular Diagnostics: Practices, Challenges, and Recommendations from the Medical Devices and Diagnostics Special Interest Group

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ISPOR's Medical Devices and Diagnostics Special Interest Group (SIG) has reviewed the use of health technology assessments (HTAs) for molecular diagnostics (MDx), identified several challenges, and issued 9 specific recommendations to address them. This brief report summarizes our findings and recommendations.

Health technology assessment is "the systematic evaluation of the properties and effects of a health technology, addressing the direct and intended effects… as well as its indirect and unintended consequences… aimed mainly at informing decision making regarding health technologies." Health technology assessments are increasingly used to inform coverage, access, and utilization of medical technologies including molecular diagnostics.

Our proposed recommendations may help address major challenges that many systems currently face by enhancing collaboration and transparency.

Although MDx are used to screen patients and inform disease management and treatment decisions, there is no uniform approach to their evaluation by HTA organizations/bodies. Without such guidance, HTA is left to subjective judgment rather than objective assessment as to which tests meet, exceed, or fail to meet standards.

To help fill this gap, the ISPOR Medical Devices and Diagnostics Special Interest Group (established in 2013) undertook a review of diagnostic-specific HTA programs. Working together with researchers experienced in this field, the SIG developed several case studies to illustrate the current evaluation processes and challenges for HTA of MDx. The case studies highlight similarities and differences in evaluation approaches across HTAs in the performance metrics used (analytic and clinical validity, clinical utility), evidence requirements, and how value is measured. Our report was published in the July/August 2016 issue (Volume 19, Issue 5) of *Value in Health*. We recommend that HTA agencies/bodies incorporate several elements into molecular diagnostic HTAs to address the challenges identified (see Table).

Our proposed recommendations may help address major challenges that many systems currently face by enhancing collaboration and transparency, which would be well received by manufacturers and clinical stakeholders. Establishing a true and open dialogue will mark a productive next phase of HTA for diagnostics in which patients, clinicians, payers, and health systems will benefit from timely access to innovative and beneficial diagnostics.

Ultimately, the HTA process for MDx is still evolving. There is significant opportunity at regional, national, and international levels to inform this development. ■

Table. Recommended changes to molecular diagnostic HTA processes.

1. Clear guidance as to the characteristics of MDx that will be assessed, study design preferences and prioritization criteria for HTA at a regional and/or national level;
2. Early and ongoing opportunities for dialogue between health care decision makers, heath technology assessors, payers, clinicians, patients, and industry;
3. Early guidance to manufacturers on evidence development, comparator, or likelihood of an HTA for MDx;
4. Opportunities for stakeholders to comment on evaluation methods and evidence used to analyze the test;
5. A checklist summarizing all required documents and communication streams associated with the submission;
6. An overview of the timing for HTA, and re-evaluation details (the timing, requirements) if a negative assessment is reached;
7. Where possible, harmonized HTA requirements across national/regional HTA groups to enhance timely access to MDx and streamline the process and reduce workload for manufacturers and HTA bodies;
8. Clear definition of how criteria assessed in HTA translate into molecular diagnostic pricing and reimbursement decision making; and
9. Explicit recognition of and rationale for differential approaches to LDTs versus IVDs, and whether HTA-related reimbursement outcomes are consistently applied to both.

Abbreviations: HTA indicates health technology assessment; IVD, in vitro diagnostic; LDT, laboratory-developed test; MDx, molecular diagnostics.

Additional information:
The complete SIG Report, Health Technology Assessment for Molecular Diagnostics: Practices, Challenges, and Recommendations from the Medical Devices and Diagnostics Special Interest Group can be found at: http://www.ispor.org/sigs/MedDevicesDiagnostics.aspx