20 December 2019

Dear Doctor,

Non-payment for Syndromic PCR testing (BioFire FilmArray)

We write to you to keep you informed of developments within the medical scheme industry that affect the funding of some tests, specifically BioFire, used for diagnosis in acute respiratory disease, suspected meningitis/encephalitis and diarrhoeal disease for the rapid identification of the pathogenic cause.

Standard of Care

Although the method is revolutionary in it being available close to the patient for rapid diagnosis where we believe it contributes to the improved management of the patient through identification of a causative organism, appropriate treatment option and in the decision on admission, according to many schemes it does not meet the standard of care for payment as a PMB in South Africa as BioFire or other syndromic panels are not offered in the state sector.

International Experience

In addition to identifying more infectious disease targets than most other laboratory tests, published evidence suggest that the use of BioFire panels result in shorter admission to hospital and/or reduced duration of antibiotic use for respiratory and gastrointestinal infections[1,2,3,4,5], fewer chest X-rays for respiratory infections[1,3], and result in more appropriate isolation of patients[1,2,6]. The majority of these publications were not assessed during the HTA and can be provided on request.

PathCare Experience

In our hands we've also been able to analyse the effect in over five-thousand patients in the Western Cape. In a retrospective analysis the benefit was seen in that in patients who had PCR investigation the number of days in hospital was significantly decreased compared to patients who did not have PCR-based investigations. In purely financial terms this is also likely to be a significant saving to both the funder and the patient.

Health Technology Assessment

We were recently informed that a health technology assessment (HTA) submitted in 2016 to Discovery Medical Aid by the manufacturer with our assistance, which included references to multiple published articles on the clinical value, does not meet the requirements of proving the clinical benefit to patients.

Patients Funds

This means many medical schemes will not be including BioFire panels as a benefit, and the responsibility will revert to the patient to fund the testing directly out of their own pocket.

PCR technology

It is expensive (PCR based) technology imported from the USA and although we are working with the manufacturer in an attempt to bring down the landed costs so as to be able to decrease our tariff, this is not proving to be easily achieved, particularly as cost of manufacture is incurred in strong currencies, viz. the US Dollar.

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In the immediate future the options are to revert to previously used technologies entirely and cease to use BioFire with consequent prolonged turn-around times or to try to retain the technology in South Africa through the judicious use of the methodology in clinical situations where patient benefit is maximized.

Proposed utilisation

In light of this unfortunate situation and to ensure patients' healthcare budget is used to the most benefit, we suggest that it be used in the following clinical situations and especially where syndromic testing would result in a clinically relevant faster time to result availability compared to centralised laboratory testing:

1. **Respiratory disease in immunocompromised patients, critically ill patients or any patient in whom the identification or exclusion of particular pathogens will influence the therapeutic approach.**
2. **Community-acquired diarrhoea for ≥ 7 days, travel-related diarrhoea or diarrhoea with warning signs for severe disease.**
3. **Respiratory and gastrointestinal disease where the identification of selected organisms will inform infection prevention and control practices.**
4. **Suspected meningitis/encephalitis where the presentation isn't typical of a single pathogen (e.g. TB, Herpes simplex encephalitis, Cryptococcus meningitis). In South Africa, where we have a sizeable proportion of immunocompromised patients, Listeria is a common cause of meningitis and can be detected by the BioFire panel. The case fatality rate in the recent outbreak was 28%[7]. Molecular diagnosis of this organism is rapid, more sensitive than culture and informs specific therapy.**

Further information on the rationale for the recommendations can be obtained from https://news.mayocliniclabs.com/.

Yours,

Marthinus Senekal
Jean Maritz
AW Dreyer

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