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Title Evaluation of Near Patient Cholesterol Testing Using the Cholestech LDX, August 2001

Agency MSAC, Medical Services Advisory Committee

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Reference MSAC application 1026. Assessment report, ISSN 1443-7120.

Aim

To assess the safety and accuracy and precision of the Cholestech LDX and under what circumstances public funding should be supported for the service.

Conclusions and results

Safety: The Cholestech LDX device does not come into contact with the individual undergoing lipid testing and no direct safety concerns were identified.

Effectiveness: Under ideal conditions the evaluation found the Cholestech LDX to be precise and accurate in its measurement of TC, HDL-C and TG. Although the pooled estimates for %bias and CV did not always fall within the NCEP guidelines for TC, HDL-C and TG, the pooled TE for these three measures always met the NCEP criteria. No clear conclusions can be drawn about the influence of site on the accuracy and precision of the Cholestech LDX because only a small number of studies were available and those that were available were not designed to assess differences in this parameter. In terms of operator, no relevant articles could be found in the literature reporting the effect of operator on results obtained by the Cholestech LDX. The evaluation found that lipid determinations derived from either fingerstick derived or venous blood samples are equivalent.

Cost-effectiveness: A decision analytic modeled evaluation was used to determine the costs and effectiveness of NPT for total cholesterol using the Cholestech LDX compared to current laboratory testing. In comparison to laboratory testing, the use of near patient testing resulted in an extra cost of $1.17 per patient presenting for a GP consultation. The incremental cost per additional patient detected with elevated cholesterol was $392; per additional patient achieving target lipid levels was $1,287; and per life year gained was $132,934. Sensitivity analysis indicated that these ratios were influenced most by the rate of growth of cholesterol testing due to the presence of NPT and the population in which the new tests were being performed.

Recommendations

The restricted use of near patient cholesterol testing, as an alternative to laboratory testing of lipids, should be considered in settings or circumstances where there is adequate training, accreditation and quality assurance. It is strongly recommended that further information be collected on the diagnostic performance of the NPT devices in the community setting and the impact of near patient testing on patient outcomes including changes in lipid management, compliance with lipid lowering therapies and amount of doctor visits.

Method

The medical literature was searched to identify relevant studies published on the Cholestech LDX that examined the accuracy and precision of the device or the influence of site, operator or sample type (fingerstick blood compared with venous blood) on the accuracy and precision of the device. Nineteen studies were reviewed in order to provide evidence regarding the accuracy and precision of the Cholestech LDX.

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