Objective

• NICE evaluates medicines, medical devices, and diagnostics using different health technology assessment (HTA) methodologies in four specialised programmes: technology appraisal (TA), highly specialised technologies (HST), the medical technologies evaluation programme (MTEP), and the diagnostics assessment programme (DAP).

• This study explores differences between programmes in terms of HTA processes and requirements, and analyses output to date.

Methods

• Published NICE processes and guidance up to April 2018 were reviewed on the NICE website and verified by consultation with NICE technical staff.

• The processes and HTA requirements of each programme were compared.

Results

Four NICE HTA Programmes: TA, HST, MTEP, and DAP

• HTA methodologies used by the four NICE HTA programmes are compared in Table 1.

• Cost-effectiveness analysis (CEA) is used for decision making by TA, HST, and DAP, whereas MTEP assesses cost neutrality or cost-saving potential using cost-consequences analysis.

• Estimated timescales ranged from 25 weeks (HST without need for consultation) to 63 weeks (DAP).

NICE Recommendations by HTA Programme

• Recommendations published by each NICE HTA programme up to April 2018 (excluding withdrawn guidance) are shown in Figure 1.

• Recommendations varied between programmes, with MTEP publishing the highest number of positive recommendations (83%) and DAP publishing the highest number of research recommendations (40%).

Disease Areas Covered by NICE HTA Guidance

• NICE has published HTA guidance assessing pharmaceuticals, devices, and diagnostics across a broad range of disease areas (Figure 2).

• More than one-third of TA guidance (42%) assessed treatments for cancer as expected because all cancer medicines are referred to NICE.

• The types of technologies assessed by MTEP and DAP are likely to reflect the type of companies that have notified their products to NICE. HST assesses technologies only for rare diseases, and only 7 HSTs have been published since 2015.

Recent Changes to NICE HTA Processes

• NICE introduced an FTA process in 2017 (Table 1),

  – Three medicines have been recommended via FTA: TA486, aflibercept for choroidal neovascularisation; TA497, golimumab for non-radiographic axial spondyloarthritis; and TSAS21, guselkumab for plaque psoriasis.

  – These drugs were deemed highly cost-effective and received a funding mandate within 30 days of publication.16

• In April 2017, a budget impact test was introduced for TA and HST to assess financial impact. If the budget impact exceeds £20 million in any of the first 3 years, NHS England will have further commercial discussions with the company, including requesting a longer time to implement funding.22

• Other changes to TA include a new technical consultation prior to the first committee meeting, aiming to enhance dialogue between the company and NICE, allowing for more informed decision making.

Conclusions

• NICE uses a range of HTA methods to assess technologies in different programmes: cost-consequences analysis in place of CEA for cost-saving devices, and higher thresholds for orphan drugs and those that meet end-of-life criteria.

• New developments include a budget impact test and a new FTA process for technologies that are likely to be highly cost-effective.