Key strategic implications from the new NICE Methods and Process Guide: who will benefit and who will lose out?

1 Flexibility

- NICE may now accept higher uncertainty for severe (not rare) disease, paediatrics and complex/innovative technologies, with greater emphasis on early engagement
- In recent years, access to NICE has been challenging, priority review may expedite access
- Eligible companies should consider early access methods (EAMS, ILAP) to get priority review and leverage any potential increased flexibility

2 New severity index

- In the past higher value was given to technologies used at EOL. This is removed & increased weight is now placed on health benefits in 'the most severe' conditions
- Some technologies e.g. adult cancers, will lose the EOL benefit. Medicines with long term benefits in severe diseases will benefit
- Companies need to be proactive; generate the necessary HRQoL evidence to demonstrate they meet the new criteria for high severity and increased value

3 Creation of the IMF

- An innovative medicines fund to fast-track access for non-oncology medicines has been created, similar to the CDF
- Companies can now obtain conditional approval for non-cancer therapies & access the UK market whilst collecting new evidence. However, CDF showed this route can be expensive & uncertain, with low interim price
- Early economic modelling can support strategic decisions to balance early access vs. the burden of data collection and price

4 More changes to come

- The RWE framework is not yet finalised & more frequent modular changes to NICE guidance is anticipated. Industry have characterised this as a 'missed opportunity'
- More changes will bring additional uncertainty with UK market requirements and possibly additional burden of evidence generation
- Companies should make sure their voice is heard in future updates; opinions are most influential when channeled through organisations such as the ABPI

The new guidance may allow for faster access for innovative technologies, particularly in paediatrics and severe disease, however careful planning will be required to benefit from the changes and maximise outcomes.

Abbreviations: ABPI: The Association of the British Pharmaceutical Industry, CDF: cancer drugs fund, EAMS: early access to medicines scheme, ILAP: Innovative licensing and access pathway, IMF: innovative medicines fund, QALY: quality adjusted life year, RWE: real world evidence. Source. . https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation

Changes with a high potential impact will require careful strategic consideration, low impact changes clarify the process

NICE Methods and Process [PMG36]

High — ***Low*** **Client impact**

Severity Index - *new*

- The ***end-of life-criteria is removed***
- Emphasis on the most severe diseases in line with preferences of UK population
- ***Weighting of x1.2 and x1.7 based on proportional and absolute QALY 'shortfall'***
- ***Opportunities*** *for technologies previously not qualifying for EOL* ***and threats*** *to those who previously did qualify for EOL*

RWE and clarifications on the decision- making process

- ***Guiding principals on RWE generation*** (expect more from RWE framework once finalised)
- More ***structured approaches to expert elicitation***; importance of ***patient perspectives*** in decision making
- ***Probabilistic base case*** remains preferred for decision making
- Clarification ***HST process for very rare indications***

Managed Access

- Emphasis throughout for early ***managed access discussions, with the new IMF*** *for non-oncology innovative technologies this may have implications for pricing*
- ***'Flexibility' which is already adopted by NICE*** for treatments for severe or paediatric diseases and complex/ innovative technologies

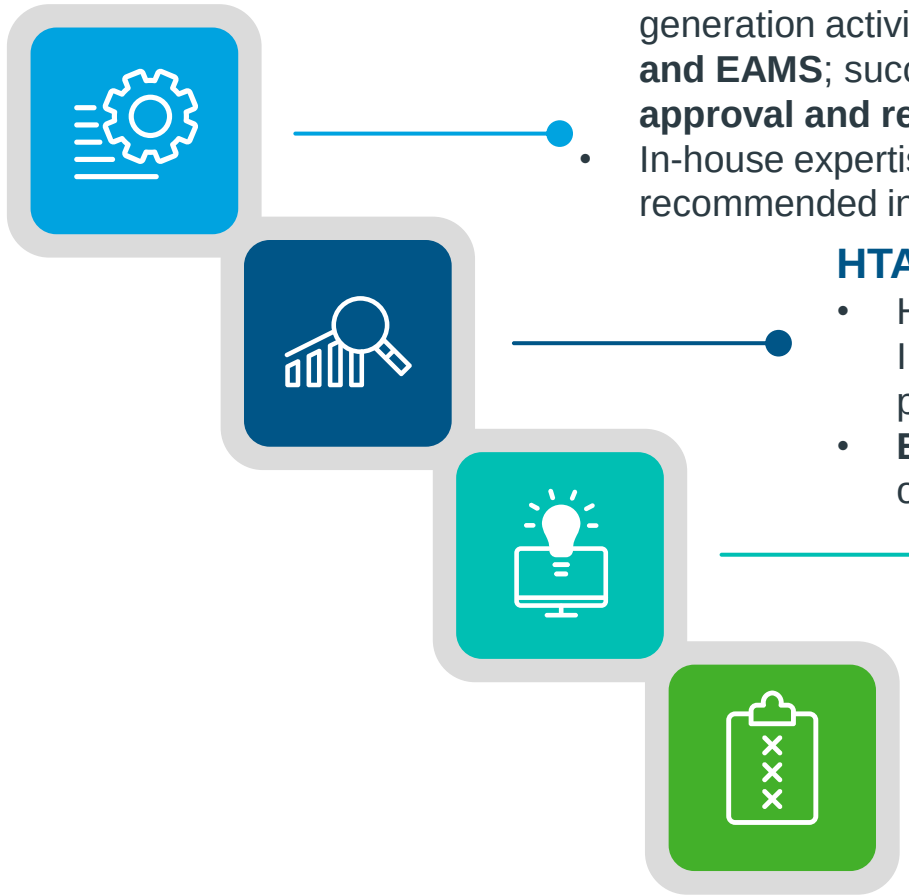
Discount rate

- ***Remains at 3.5%*** for costs and benefits
- **However, 1.5% may also be presented** where there is near-full restoration to full health that is sustained in a population that would otherwise die or be severely impaired
- Whilst not the radical change we were expecting, this is **a step forward** particularly for technologies such as **gene-therapies and novel ultra-orphan therapies,** who may benefit from a lower discount rate in addition to the existing QALY weightings

1. IQVIA HTAi Oral presentation. Caverly et al. Real-World experience with NICE's willingness to accept less costly, less effective healthcare technologies. June 25-29 2022.

Abbreviations: CDF: cancer drugs fund, EOL: end-of-life, HST: highly specialised technology, HRQoL: health-related quality of life, ICER: incremental cost-effectiveness ratio, IMF: innovative medicines fund, MRC: medical research council, QALY: quality adjusted life year, SW, south-west, RWE: real world evidence. Source. . https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation

With bespoke solutions and in-house expertise, IQVIA can support our clients navigate the changes & optimise outcomes with NICE



Early evidence planning & engagement

- IQVIA HTA, regulatory and patient engagement experts can support with early evidence generation activities & engagement, including the **new UK ILAP process, Scientific advice and EAMS**; succesful Innovation passport designation will be eligible for **faster routes to approval and reimbursement**
- In-house expertise on **formal methods of expert eliciation** in line with **MRC guidance**, as recommended in the new guidance

HTA submission strategy and planning

- HTA experts to support with **strategic HTA planning**, understanding the new IMF, higher thresholds and possible flexible routes to access to optimise positioning and faster access.
- **Experience with ILAP, ESA, SA, NICE technology appraisals** in both oncology and non-oncology indications

Economic modelling

- IQVIA economic model template with **in-built absolute QALY shortfall calculator**, net-health benefit and probabalistic analysis (EVPI) to support with fast and early pressure testing and core modelling needs

Evidence generation

- **Unparalleled access to UK RWD** to support NICE submissions
- IQVIA have **in-house SLR expertise and developed templates for the ROBINS I tool** for use in NICE HTA, now a preference for the QA of non-randomised studies

Abbreviations: EAMS: early access to medicines scheme, ESA: Early scientific advice, EVPI: expected value of perfect information, HTA: health technology assessment, ILAP: Innovative licensing and access pathway, IMF: Innovative medicines fund, MRC: medical research council, QALY: quality adjusted life year, ROBINS: Risk Of Bias In Non-randomised Studies- of Interventions, RWD: Real-world data, SA: Scientific advice, SLR: Systematic literature review