AXA Health Patient Safety tool: introduction

Patient safety is key to our work. Our policies require authorised treatment to be NICE-approved or supported by substantive clinical trial evidence.

Patients deserve this standard of care.

For this reason, we've created a framework showing how we evaluate evidence-based treatment. With this framework, we aim to display the standards we work to and to help specialists and our members understand our decisions. We have adopted a traffic light rating system.

In the traffic light system, we define the following:

Green: **Conventional Treatments*** that have met the standards of evidence we've set for safety and efficacy.
Amber: **Unproven Treatments*** that have met the standards of evidence we've set for safety but not efficacy.
Red: **Unproven Treatments*** that have not met the standards of evidence we've set for safety.

* These are terms defined in our policy handbooks and may be amended by AXA Health from time to time at our absolute discretion.

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AXA Health Patient Safety tool

Level of evidence	Drugs	Surgical Procedure	Medical Devices (including surgical devices and implants) [3]	Other
Green: Conventional Treatments	Licensed and used according to that licence *and either* NICE approval [1] *or* high-quality clinical trial evidence defined as: systematic review of RCTs or a single large high-quality RCT either of which demonstrates moderate or high-quality evidence of safety and effectiveness. [2]	Listed in our Published schedule of procedures and fees *and either* NICE approval [1] *or* high-quality clinical trial evidence defined as: systematic review of RCTs or a single large high-quality RCT either of which demonstrates moderate or high-quality evidence of safety and effectiveness. [2]	Approved by current EU Medical Device Regulations and either NICE approval [1] *or* high-quality clinical trial evidence defined as: systematic review of RCTs *or* clinical trial evidence with three years of follow-up data either of which demonstrates moderate or high-quality evidence of safety and effectiveness. [2]	NICE approval [1] *or* High-quality clinical trial evidence defined as: systematic review of RCTs with moderate or high-quality evidence of safety and effectiveness. [2]
Amber: Unproven Treatments	Not meeting the definition of either red or green treatment e.g. NICE use with special arrangements for clinical governance, consent and audit or NICE use only in research or low-quality evidence of safety or effectiveness, which means further research is required. [2]			
Red: Unproven Treatments	No evidence of safety or effectiveness *or* evidence of GRADE certainty moderate or high-quality [2] of potential harm despite the presence of any green indicators *or* NICE "do not use" recommendation.			

- By clinical trial we mean a prospectively registered trial in humans registered on the World Health Organization's International Clinical Trials Platform (https://www.who.int/ictrp/en/) that includes a treatment group (the new treatment) and a control group (either usual care or a placebo). Randomized Clinical Trials (RCTs) are the best way to assess whether drug treatment is effective and safe. In an RCT patients are assigned randomly to the treatment group or the control group.
- Systematic reviews (SR) summarise the results of more than one RCT and can provide a high level of confidence in the effectiveness of interventions.

FOOTNOTES

1. NICE approval for “use with normal arrangements in place for clinical governance, consent and audit”.
2. Appraisal of the quality of evidence is based on the GRADE system (Grading of Recommendations, Assessment, Development and Evaluations); the most widely-adopted international tool for grading the quality of evidence. https://www.gradeworkinggroup.org/
   - The quality of a study defines the degree of confidence in the treatment effect. The higher the quality, the more confident we are that the treatment works.
   - The final grade for the quality of evidence is judged as ‘high’, ‘moderate’, ‘low’, or ‘very low’ for the important outcomes:
     - High: we are very confident that the effect in the study reflects the actual effect
     - Moderate: we are quite confident that the effect in the study is close to the true effect, but it is also possible that it is substantially different
     - Low: the true effect may differ significantly from the estimate
     - Very Low: the true effect is likely to be substantially different from the estimated effect

   For more details about GRADE, see NICE Manual Appendix K and the GRADE working group website.
3. A medical device is defined according to the EU’s Medical Device Directive (Regulation (EU) 2017/745). A ‘medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings. When a new treatment (either a new surgical procedure or ‘other’ treatment) involves a device, the levels of evidence will have to meet both relevant criteria for the procedure/treatment and device.