

Participation in clinical trials and subsequent access to drugs appraised by NICE: position statement

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A statement on the applicability of technology appraisal guidance for patients who have previously received the same medication as part of a clinical trial.

Patients taking part in clinical trials may receive drugs which have been evaluated by NICE technology appraisal guidance. Queries have been raised regarding the applicability of NICE technology appraisals for patients who have previously received the same medication as part of a clinical trial.

Research is a core function of the NHS. Use of NICE appraised medicines within the clinical trial context should be viewed as use in new and experimental circumstances. It should be noted that in these circumstances the drug is not being prescribed as part of routine clinical practice.

Arrangements for the supply and funding of the technology provided in clinical trials after the trial ends should be agreed with appropriate commissioners before the trial commences. Once the clinical trial ends, the patient will need to discuss with their doctor whether it is clinically appropriate to continue receiving the medication.

For the avoidance of any doubt, if a patient's clinical condition falls within the recommendation of a NICE technology appraisal, they should be prescribed the medication as recommended in the guidance, regardless of any previous participation in a clinical trial in which they may have received medicines for their condition.

On occasion, NICE will make a recommendation that a drug should not be prescribed, but that patients who are currently receiving it as part of their routine clinical care should continue to do so. It is important to note that this recommendation does not cover situations where patients are receiving the medication as part of a clinical trial.

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