Funding for Post Clinical Trial Treatment

INDIVIDUAL FUNDING REQUEST APPROVAL REQUIRED

Background
A number of patients are provided with treatments or devices through clinical trials which are not routinely commissioned by Wiltshire Clinical Commissioning Group (WCCG). This includes drugs, devices and treatments which are either still in development or are established as a treatment but WCCG has been unable to secure resources to fund the treatments.

Types of Trials

- **Commercially Funded**

In order to assess the efficacy of treatments they are developing, commercial companies will often sponsor trials on patients offering free access to the treatment for a limited time. Responsibility for providing on-going access to a treatment lies with those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment.

- **Non-commercially Funded**

Similarly to commercially funded trials, organisations such as charities will on occasion fund clinical trials in order to assess the efficacy of treatments by offering free access to the treatment for a limited time.

- **Self-funded**

Patients, or their family and friends, will on occasion fund trials with treatments or devices in order to assess whether they will benefit from the treatment. This is often for treatments which are established and have been previously considered by the Commissioner but they have been unable to identify resources to routinely commission the treatments for a cohort of patients.

Informed Consent Prior to Commencing a Trial
It is the responsibility of the organisation participating in the trial and the patient's clinician to ensure that patients are fully informed about the circumstances in which funding for a trial is being provided; that is it will not be continued routinely by WCCG; how long this funding will be provided for; and what will happen when it is withdrawn. The patient should agree to their management plan on discontinuation of treatment. Patients should be made aware of this commissioning policy in advance of treatment commencing and their consent should be documented.

It is also the responsibility of the organisation participating in the trial and the patient's clinician to ensure that such arrangements are explicitly approved by the relevant governance body of the provider trust (Clinical Advisory Group).

It is the responsibility of the pharmaceutical/medical device company, the organisation conducting the trial (usually a provider trust), and the patient's clinician, to ensure that patients are fully informed that funding for the continuation of treatment delivered as part of a clinical trial, that has been sponsored by a pharmaceutical or medical devices company, will not be provided unless it is agreed in writing by WCCG and the sponsoring pharmaceutical/medical devices company at the outset of the trial.

Requests for "pick-up funding"

Commonly the timing of requests for funding for patients who have been in clinical trials is around the time that a license for the drug/indication is granted. There is an assumption by some clinicians conducting clinical trials that once the drug is licensed then WCCG should assume responsibility for funding the drug. This is incorrect. WCCG has a responsibility to consider and prioritise new treatments being made available, but this in no way places any obligation on the commissioner to fund patients already on treatment funded by Industry by whatever route.

WCCG will not routinely make funding available to enable continuing access to treatments provided under clinical trials. This includes where it can be shown that the patient has individually benefitted from the treatment provided during a trial.

Responsibility for providing on-going access to a treatment lies with those individuals or parties that have initiated and sponsored either the clinical trial or sponsored treatment. WCCG do not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial AND that those benefiting from treatments provided within the trial setting will have ongoing access to those treatments. The initiators of the trial (provider trusts and drug companies) have a moral obligation to continue funding patients benefiting from treatment until such time as NHS WCCG agree to fund through the annual commissioning round. Where the treatment is not prioritised through the annual commissioning round, the responsibility remains with the trial initiators. The Research Ethics Committee should require this assurance as part of the approval for the trial.

Requests for the routine pick-up of funding will therefore be rejected.

Commissioning of Treatments or Devices

The appropriate time for a commissioner to assume responsibility for on-going funding is if, and when, a decision has been made to fund the service development, and access to the treatment is opened to all patients meeting treatment criteria under the policy. This includes treatments mandated by NICE under a NICE Technology Appraisal or where services/treatments are explicitly commissioned by WCCG.

Auditing of Prescribing Post Clinical Trial

To ensure conformity with this policy a list of all approved trials, and relevant dates, will be held within WCCG. Regular audits will be carried out of the data from those practices and results published.