

Funding for Post Clinical Trial or Innovation Treatment Exceptional Funding Request

The ICB will not routinely make funding available to enable continuing access to treatments provided under clinical trials or innovation programmes. 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.

It is recommended that agreement is sought at outset from the ICB should there be an expectation of continuation of funding.

Note If a Clinical Drugs trial, please seek guidance from the ICB for assurance of the correct pathway.

Bristol North Somerset and South Gloucestershire Integrated Care Board (BNSSG ICB) is responsible for making the best use of the NHS funds allocated to us to meet the health needs of our local population. The demand for services is greater than the resources available and therefore we have to prioritise the use of funds carefully. Our approach is to prioritise commissioning treatments, operations or drugs that are most effective in meeting the health needs of the population. All operations carry significant risks and where symptoms are mild or moderate it is likely that the risks outweigh the benefits. Not all conditions progress and when symptoms can be managed conservatively, that is the safest option.

Plain Language Summary - Funding for Post Clinical Trial or Innovation Treatment

A number of patients are provided with treatments or devices through clinical trials which are not routinely commissioned by the ICB. This includes drugs, devices and treatments which are either still in development or are established as a treatment but the ICB has been unable to secure resources to fund the treatments. This includes funding following treatments which are:

- Undertaken or sponsored by the NHS,
- Commercially funded,
- Non-commercially funded such as charity or compassionate trials, and
- Patients self-funding a trial of treatment.
- Innovations funded through routes such as the Innovations and Technology Payment (ITP)

This policy has been developed with the aid of the following:

- Ash. (2016). Ash.org.uk. Retrieved Sept 24, 2018, from www.ash.org.uk: www.ash.org.uk/briefings
- <https://www.england.nhs.uk/ourwork/innovation/innovation-and-technology-payment-itp2019-20/>
- Thelwall, S. P. (2015). Impact of obesity on the risk of wound infection following surgery: results from a nationwide prospective multicentre cohort study in England. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases*, , vol. 21, no. 11, p. 1008.e1.

Due regard

In carrying out their functions, the Bristol, North Somerset and South Gloucestershire Clinical Policy Review Group (CPRG) are committed to having due regard to the Public Sector Equality Duty (PSED). This applies to all the activities for which the CCGs are responsible, including policy development and review.

Document Control

Document Title	Funding for Post Clinical Trial or Innovation Treatment
Author(s) job title(s):	Commissioning Policy Development Manager, BNSSG ICB Clinical Lead for Policy Development
Document version:	2223.01.01
Supersedes:	1819.02.02
Discussed at Commissioning Policy Review Group (CPRG):	25 th April 2023
Approval Route (see <u>Governance</u>):	Level – 1
Approval Date	25 th April 2023
Date of Adoption:	1 st August 2023
Publication/issue date:	1 st August 2023
Review due date:	Earliest of either NICE publication or three years from approval.

Governance

Commissioning policies are assessed for their likely level of impact on BNSSG ICB and the population for which it is responsible. This determines the appropriate level of sign off. The below described the approval route for each score category.

Policy Category	Approval By
Level 1	Commissioning Policy Review Group.
Level 2	Chief Medical Officer, or Chief Nursing Officer, or System Executive Group Chair
Level 3	ICB Board

OPCS Procedure codes

N/A

Support

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on BNSSG.customerservice@nhs.net.