Health Alliance™ Pharmacy Drug Policy Checklist

POLICY NAME	Experimental Medications	POLICY #	561P

Criteria

Pharmacist

- ☐ Experimental and investigational are terms used to describe medications. These terms may be used interchangeably by Health Alliance, FirstCarolinaCare, and the Pharmacy and Therapeutics Committee.
- ☐ Experimental (and investigational) is defined as relating to medications which are still the subject of ongoing Phase I, Phase II, or Phase III trials to establish the medication's effectiveness, optimal dosage, toxicity, and side effects, or to compare the medication's maximum tolerated dose, its toxicity, its safety, its effectiveness, or its effectiveness compared with the standard medications for treatment or diagnosis.
- ☐ Reliable evidence shows that experts agree that further studies or clinical trials are needed on the experimental treatment, procedure, device, drug, or medicine.
- ☐ Experimental medications may be medications that have not been approved by the FDA or may be medications that have usages which are not approved by the FDA.
- ☐ The pharmacist will work with a medical director to make a determination if a requested medication, product, or device is being used for an experimental or investigational purposes.
  - FCCI only: The pharmacist will work with a physician licensed in the State of North Carolina to make a determination if a requested medication, product, or device is being used for an experimental or investigational purpose.

Pharmacy & Therapeutics (P&T) Committee

- ☐ In determining whether or not a medication is experimental, the P&T Committee may refer to the standard of care in the medical community.

☐ In determining whether or not a medication is experimental, The P&T Committee may refer to any, or all, of the following sources:

- Index Medicus Policy & Procedure
- Medline
- FDA publications
- Peer-reviewed medical or pharmacy articles published in medical and scientific literature
- Pharmaceutical manufacturer literature
- Proprietary drug review literature
- Expert opinion and consultation
- The written protocol(s) used by the treating facility or the protocol(s) of another facility studying the same treatment, procedure, device, drug, or medicine
- The written informed consent used by the treating facility or by another facility studying the same treatment, procedure, device, drug, or medicine
- The standard of care in the medical community References