Policy & Procedure

Policy Name:	Experimental Medications	Policy #:	561P

Purpose of the Policy

It is the purpose of this policy to establish clarity and consistency regarding experimental or investigational medications.

Statement of the Policy

This policy applies to medications that are determined to be experimental or investigational.

Health Alliance Drug and Procedural Policies are developed and reviewed annually in compliance with the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008. MHPAEA requires group health plans and health insurance issuers to ensure that financial requirements (such as copays, deductibles) and treatment limitations (prior authorization, step therapy) applicable to mental health or substance use disorder (MH/SUD) benefits are no more restrictive than the predominant requirements or limitations applied to substantially all medical/surgical benefits.

Procedures

Medications used in an approved clinical cancer phase I–IV trial are exempt from this policy.

1. Pharmacist

1.1 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.

1.2 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.

1.3 Reliable evidence shows that experts agree that further studies or clinical trials are needed on the experimental treatment, procedure, device, drug, or medicine.

1.4 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.

1.5 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.

2. Pharmacy & Therapeutics (P&T) Committee

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

2.2 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

- 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

1. https://www.ncleg.gov/Sessions/2019/Bills/Senate/PDF/S361v8.pdf

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