# PHARMACY PRE-AUTHORIZATION CRITERIA

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| **DRUG (S)** | **Off Label Policy** |
| **POLICY #** | **11115** |
| **INDICATIONS** | This policy applies to drugs where the drug requires prior-authorization. Drug-specific policies must be reviewed prior to applying the criteria listed below. This policy should be applied when a drug-specific policy does not address off-label use of an FDA approved drug.<br><br>FDA approved indication is an indication (diagnosis, illness, injury, syndrome, condition for which a drug may be given) depicted on the drug's official label with prescribing instructions, which includes, but is not necessarily limited to, dosage, route of administration, duration and frequency of administration and population to whom the drug would be administered.<br><br>Off label (also referred to as non-FDA approved) usage is drug usage for an indication that is not listed on the drug's official label; further defined as administration of the drug in a way that deviates significantly from the prescribing information on the official label for a particular indication. This includes but is not necessarily limited to, dosage, route of administration, duration and frequency of administration and population to whom the drug would be administered. |
| **CRITERIA** | Some off-label use may be medically appropriate and rational in certain circumstances. Off-label drug use will be reviewed for evidence of therapeutic value according to the following criteria:<br><br>1. The drug is FDA-approved<br>2. The member has tried and failed established FDA approved and/or clinical guideline recommended therapy unless contraindicated<br>3. Phase III* FDA clinical studies to support the non-FDA approved use.<br>4. **A**. The drug is recognized for treatment of the requested indication in one of the standard reference compendia<br>• American Hospital Formulary Service – Drug Information (AHFS-DI)<br>• Thomson Micromedex DrugDex<br>• Clinical Pharmacology (Gold Standard)<br>• National Comprehensive Cancer Network (NCCN)<br>• Facts & Comparisons<br>**OR**<br><br>**B**. In the absence of being listed in above named sources, a minimum of at least two articles from major peer-reviewed journals (from the United States or great Britain) which supports the proposed use for the specific medical condition as safe and effective.<br><br>Note: ConnectiCare requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended indication.<br><br>*In Phase III trials, the experimental study drug or treatment is given to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it to commonly used treatments and collect information that will allow the experimental drug or treatment to be |

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| | used safely. |
| LIMITATIONS | If the above criteria are met approval of an off label indication, initial authorization will be granted for three months. Subsequent approval will be based on efficacy and may be granted for up to one year. |
| REFERENCES | |
| P&T REVIEW HISTORY | 9/08, 9/09, 10/12, 10/13, 10/14, 11/15, 2/16, 2/17, 1/18 |
| REVISION RECORD | 2/16 (Policy update) |