



Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 31, 2015  August 30, 2017, January 30, 2020

## OFF LABEL USE CRITERIA

### LENGTH OF AUTHORIZATION:

INITIAL: UP TO 3 MONTHS

CONTINUATION OF THERAPY: UP TO ONE YEAR

### INITIAL REVIEW CRITERIA (ALL OF THE FOLLOWING BELOW IS REQUIRED):

1. Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication **AND**
2. Phase III clinical studies published in peer review journals to support the non-FDA approved use **OR**
3. Usage, **dosage and administration** supported by publications in peer reviewed medical literature and one or more citations in at least one of the following compendia:
  - American Hospital Formulary Service Drug Information (AHFS)
  - United States Pharmacopeia-Drug Information (or its successor publications); and
  - DRUGDEX Information System

### CONTINUATION OF THERAPY:

1. Documentation of clinical response, as measured by applicable laboratory tests, radiologic studies or other markers of disease response, to therapy must be submitted