



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 31, 2015 August 30, 2017, January 30, 2020, June 27, 2023

OFF LABEL USE CRITERIA

LENGTH OF AUTHORIZATION: INITIAL: UP TO 3 MONTHS
CONTINUATION OF THERAPY: UP TO ONE YEAR

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

- Documentation submitted with trial and failure or intolerance to all FDA- approved medications for the indication; **AND**
- Phase III clinical studies published in peer review journals to support the non-FDA approved use; **OR**
- 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:

- Patient met the above criteria; **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Documentation of clinical response, as measured by applicable laboratory tests, radiologic studies or other markers of disease response, to therapy must be submitted