UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2049-7
Program	Prior Authorization/Medical Necessity Oxford - Select Brand Medications
Medication/Therapeutic Class	Select Brand Medications – Aplenzin (bupropion extended-release), Celexa (citalopram), Effexor XR (venlafaxine extended-release), Forfivo XL (bupropion extended-release) and Pexeva (paroxetine)
P&T Approval Date	4/2015, 5/2015, 11/2015, 2/2016, 10/2016, 10/2017, 10/2018
Effective Date	Oxford: 2/1/2019

1. Background:

FDA approved generic drug products are required to met the same rigid standards as the brand innovator drug. All FDA approved generics have the same high quality, strength, purity and stability as brand drug, and generics must meet the same manufacturing quality standards.[1]

This program requires a member to try a generic product(s) with the same active ingredient(s) prior to receiving coverage for Aplenzin, Celexa, Effexor XR, Forfivo XL, and Pexeva.

2. Coverage Criteria[a]:

A. The brand medications **Aplenzin, Celexa, Effexor XR, Forfivo XL and Pexeva** will be approved based on **one** of the following criteria:

1. **Both** of the following:

   a. History of greater than or equal to 4 week trial of the therapeutically equivalent generic (Document date and duration of trial. For Aplenzin a trial of bupropion extended-release (generic Wellbutrin XL) is required. For Pexeva a trial of paroxetine (generic Paxil) is required)

-AND-

   b Submission of medical records documenting the inadequate response to the therapeutically equivalent generic

-OR-

2. **Both** of the following:

   a. Documented history of intolerance to the therapeutically equivalent

generic which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. take with food to minimize nausea, take prior to bedtime to manage fatigue, take in the morning to manage insomnia, eat high-fiber diet with plenty of water to minimize constipation, etc.)

-AND-

b. Submission of medical records documenting the adverse effect of the therapeutically equivalent generic

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Supply limits may also apply.

4. References:

1. U.S Food and Drug Association. Generic Drug Facts. www.fda.gov. Assessed September 2018.
2. Aplenzin Prescribing Information. Valeant Pharmaceuticals Inc. Steinback, MB. July 2014.
3. Celexa Prescribing Information. Allergan. Irvine, CA. January 2017.
4. Effexor XR Prescribing Information. Wyeth Pharmaceuticals Inc. Philadelphia, PA. March 2018.
5. Forfivo XL Prescribing Information. Almatica Pharma, Inc. Pine Brook, NJ. January 2017.
6. Pexeva Prescribing Information. Noven Therapeutics, LLC. Miami, FL. January 2017.

Program	Prior Authorization/Medical Necessity - Oxford- Select Brand Medications
Change Control	
Date	Change
4/2015	New program
5/2015	Added Abilify to program and changed program name from Brand Antidepressants to Select Brand Medications.
11/2015	Changed authorization period. Added clarification to therapeutic equivalent language.
2/2016	Added Treximet to program.
10/2016	Removed Abilify, Cymbalta, Lexapro, Prozac, Treximet, Wellbutrin SR, Wellbutrin XL and Zoloft from Oxford only criteria.
10/2017	Annual review. State mandate language added. References updated.
10/2018	Annual review. Updated references.