MEDICAL MUTUAL®

Drug Policy

Policy: **Impacted Drugs:**	Antidepressants – Selective Serotonin Reuptake Inhibitors Step Therapy Policy • paroxetine mesylate 7.5 mg capsules (generic) • citalopram capsules – Almatica (brand product) • fluoxetine delayed-release 90 mg capsules (generic to discontinued Prozac® Weekly™) • fluoxetine tablets (generic only) • fluvoxamine extended-release capsules (generic only) • fluvoxamine tablets (generic only) • escitalopram oral solution (generic) • Paxil® (paroxetine hydrochloride tablets and oral suspension – Apotex, generic) • Paxil CR® (paroxetine hydrochloride controlled-release tablets – Apotex, generic) • Sertraline capsules – Almatica/Viking • Trintellix™ (formerly Brintellix®) [vortioxetine tablets – Takeda] • vilazodone hydrochloride tablets (generic)	**Annual Review Date:** **05/18/2023** **Last Revised Date:** **05/18/2023**

OVERVIEW

The selective serotonin reuptake inhibitors (SSRIs) are a pharmacologic class of agents with antidepressant action and efficacy in the treatment of a wide range of mood and anxiety disorders (see Table 1).

Table 1. FDA-Approved Indications.

Brand (generic)	MDD	OCD	Panic Disorder	Bulimia Nervosa	PTSD	SAD	GAD	PMDD	VMS
Brisdelle® (paroxetine mesylate 7.5 mg capsules, generic)									X
Celexa® (citalopram tablets and oral solution, generic) and citalopram capsules	X								
Fluoxetine delayed-release capsules (generic to Prozac® Weekly™)	X*								
Fluvoxamine extended-release capsules (generic only)		X†				X			
Fluvoxamine (generic only)		X†							
Lexapro® (escitalopram tablets and oral solution, generic)	Xα						X		
Paxil® (paroxetine HCl tablets and oral suspension, generic)	X	X	X		X	X	X		
Paxil CR® (paroxetine HCl controlled-release tablets, generic)	X		X			X		X	

Pexeva® (paroxetine mesylate tablets)	X	X	X				X		

Table 1 (continued). FDA-Approved Indications.[1-14]

Brand (generic)	MDD	OCD	Panic Disorder	Bulimia Nervosa	PTSD	SAD	GAD	PMDD	VMS
Prozac® (fluoxetine capsules, tablets, and oral solution, generic)	X†	X†	X	X					
Sarafem® (fluoxetine capsules and tablets, generic only)								X	
Sertraline capsules	X	X†							
Trintellix™ (formerly Brintellix®) [vortioxetine tablets]	X								
Viibryd® (vilazodone tablets)	X								
Zoloft® (sertraline tablets and oral suspension, generic)	X	X†	X		X	X		X	

MDD – Major Depressive Disorder; OCD – Obsessive compulsive disorder; PTSD – Posttraumatic stress disorder; SAD – Social anxiety disorder; GAD – Generalized anxiety disorder; PMDD – Premenstrual dysphoric disorder; VMS – Vasomotor symptoms;
* Approved for the prevention of relapse during the continuation treatment phase of depression; † FDA-approved indication includes children and adolescents; α FDA-approved indication includes adolescents 12 to 17 years of age; CR – Controlled release; HCl – Hydrochloride;

POLICY STATEMENT

This program has been developed to encourage the use of two Step 1 Products prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of two Step 1 Products within the 130-day look-back period is excluded from Step Therapy. Patients > 18 years of age are targeted in this Step Therapy program.

Step 1: generic citalopram tablets, generic citalopram oral solution, generic escitalopram tablets, generic fluoxetine immediate-release capsules, generic fluoxetine oral solution, generic fluvoxamine immediate-release tablets, generic paroxetine HCl immediate-release tablets, generic sertraline tablets, generic sertraline oral solution

Step 2: citalopram capsules (brand product), generic escitalopram oral solution, generic fluoxetine delayed-release 90 mg capsule, generic fluoxetine immediate-release tablets, generic fluvoxamine extended-release capsules, generic paroxetine HCl controlled-release (CR)/extended-release (ER) tablets, generic paroxetine HCl oral suspension, generic paroxetine mesylate capsules, generic vilazodone hydrochloride tablets, Paxil, Paxil CR, Sarafem, sertraline capsules (brand product), Trintellix

CRITERIA

1. If the patient has tried two Step 1 Products, approve a Step 2 Product.

2. If the patient is currently taking or has taken vilazodone or Trintellix at any time in the past and discontinued its use, approve the Product that they have used.

3. If the patient cannot swallow or has difficulty swallowing tablets or capsules, approve generic escitalopram oral solution or generic paroxetine HCl oral suspension.

4. If the patient has suicidal ideation, approve vilazodone or Trintellix.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

Step Therapy Exception Criteria

In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

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Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Prozac® capsules, tablet, oral solution, Prozac® Weekly™ capsules [prescribing information]. Indianapolis, IN: Lilly; October 2021.
2. Paxil® tablets and oral suspension [prescribing information]. Weston, FL: Apotex; September 2021.
3. Zoloft® tablets, oral concentrate [prescribing information]. New York, NY: Pfizer; September 2021.
4. Celexa® tablets and oral solution [prescribing information]. Irvine, CA: Allergan; February 2022.
5. Paxil CR® controlled-release tablets [prescribing information]. Weston, FL: Apotex; September 2021.
6. Lexapro® tablets/oral solution [prescribing information]. Irvine, CA: Allergan; September 2021.
7. Pexeva® paroxetine mesylate tablets [prescribing information]. Roswell, GA: Sebela; September 2021.
8. Fluvoxamine maleate tablets [prescribing information]. Baudette, MN: ANI Pharmaceuticals: September 2021.
9. Sarafem® tablets [prescribing information]. Irvine, CA: Allergan; September 2021.
10. Luvox CR® extended-release capsules [prescribing information]. Palo Alto, CA: Jazz Pharmaceuticals; January 2017.
11. Viibryd® tablets [prescribing information]. Madison, NJ: Allergan; September 2021.
12. Trintellix™ (formerly Brintellix®) tablets [prescribing information]. Lexington, MA and Deerfield, IL: Takeda and Lundbeck; September 2021.
13. Brisdelle® capsules [prescribing information]. Roswell, GA: Sebela; September 2021.
14. Sertraline capsules [prescribing information]. Morristown, NJ: Almatica; October 2021.
15. Citalopram capsules [prescribing information]. Morristown, NJ: Almatica; January 2022.