Step Therapy
Antidepressants – Selective Serotonin Reuptake Inhibitors

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Product Identifier(s)

Effective 1/1/23 to 2/6/23: 107541

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INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

- Brisdelle® (paroxetine mesylate 7.5 mg capsules – generic)
- Celexa® (citalopram tablets and oral solution – generic)
- citalopram capsules
- fluoxetine capsules (generic to discontinued Sarafem® capsules)
- fluoxetine delayed-release capsules (generic to discontinued Prozac® Weekly™)
- fluvoxamine extended-release capsules (generic only)
- fluvoxamine tablets (generic only)
- Lexapro® (escitalopram tablets and oral solution – generic)
- Paxil® (paroxetine hydrochloride tablets and oral suspension – generic)
- Paxil CR® (paroxetine hydrochloride controlled-release tablets – generic)
- Pexeva® (paroxetine mesylate tablets)
- Prozac® (fluoxetine capsules, tablets, and oral solution – generic)
- Sarafem® (fluoxetine tablets – generic only [brand discontinued in 12/2020])
- Trintellix™ (vortioxetine tablets)

- Viibryd® (vilazodone hydrochloride tablets – generic)
- Zercapli™ (sertraline capsules)
- Zoloft® (sertraline tablets and oral solution – generic)

This program has been developed to encourage the use of one Step 1 Product (Standard Criteria) or two Step 1 Products (High Impact Criteria) 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.

Step 1: generic citalopram tablets, generic citalopram oral solution, generic citalopram capsules, 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: Brisdelle, Celexa, 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, Lexapro, Paxil, Paxil CR, Pexeva, Prozac, Sarafem, Trintellix, Viibryd, Zercapli, Zoloft

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

Standard Criteria

1. If the individual has tried one Step 1 Product, approve a Step 2 Product.

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

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

4. If the individual has suicidal ideation, approve Pexeva, Viibryd, or Trintellix.

High Impact Criteria

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

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

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

4. If the individual has suicidal ideation, approve Pexeva, Viibryd, or Trintellix.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

The selective serotonin reuptake inhibitors (SSRIs) comprise 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).[1-14]

Table 1. FDA-Approved Indications.[1-14]

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	
Trintellix™ [vortioxetine tablets]	X								
Viibryd® (vilazodone tablets, generic)	X								
Zercapli™ (sertraline capsules)	X	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.

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™ 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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	**Removed Products:** Brand Prozac Weekly and brand Luvox CR were removed from Step 2 (obsolete ≥ 3 years). No criteria changes.	03/02/2022
Selected Revision	**Citalopram capsules:** Citalopram capsules were added to Step 1.	03/09/2022
Selected Revision	**Generic vilazodone tablets:** Generic vilazodone tablets were added to the policy as Step 2. **Generic fluoxetine delayed-release capsules:** Generic fluoxetine delayed-release capsules were moved to Step 2. **Generic escitalopram oral solution:** Generic escitalopram oral solution was moved to Step 2. Criterion was added to the Standard and High Impact Criteria to approve for patients who cannot swallow or have difficulty swallowing tablets or capsules. **Generic paroxetine oral suspension:** Generic paroxetine oral suspension was moved to Step 2. Criterion was added to the Standard and High Impact Criteria to approve for patients who cannot swallow or have difficulty swallowing tablets or capsules. **Trintellix:** Throughout the policy, the note "(formerly Brintellix)" was removed. The brand name was changed from Brintellix to Trintellix in 2016.	09/14/2022