

STEP THERAPY POLICY

- POLICY:** Antidepressants – Selective Serotonin Reuptake Inhibitors Step Therapy Policy
- Brisdelle® (paroxetine mesylate 7.5 mg capsules – Sebel, generic)
 - Celexa® (citalopram tablets and oral solution – Allergan, generic)
 - citalopram capsules – Almatica
 - 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 – Allergan, generic)
 - Paxil® (paroxetine hydrochloride tablets and oral suspension – Apotex, generic)
 - Paxil CR® (paroxetine hydrochloride controlled-release tablets – Apotex, generic)
 - Pexeva® (paroxetine mesylate tablets – Sebel)
 - Prozac® (fluoxetine capsules, tablets, and oral solution – Lilly, generic)
 - Sarafem® (fluoxetine tablets – generic only [brand discontinued in 12/2020])
 - Trintellix™ (vortioxetine tablets – Takeda)
 - Viibryd® (vilazodone hydrochloride tablets – Allergan, generic)
 - Zercapli™ (sertraline capsules – Almatica/Viking)
 - Zoloft® (sertraline tablets and oral solution – Pfizer, generic)

REVIEW DATE: 03/02/2022; selected revision 03/09/2022 and 09/14/2022

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)	X ^a						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

03/02/2022

© 2022. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

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; ‡ 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 one Step 1 Product (Standard Criteria) or two Step 1 Products (High Impact Criteria) prior to the use of a Step 2 Product in adults. 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 of one Step 1 Product (Standard Criteria) or two Step 1 Products (High Impact Criteria) 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 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

STANDARD CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.
2. If the patient 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 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 Pexeva, Viibryd, or Trintellix.

03/02/2022

© 2022. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

HIGH IMPACT 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 Pexeva, Viibryd, 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 Pexeva, Viibryd, or Trintellix.

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.

