

STEP THERAPY POLICY

- POLICY:** Antidepressants – Selective Serotonin Reuptake Inhibitors Step Therapy Policy
- Brisdelle® (paroxetine mesylate 7.5 mg capsules – Sebela [brand discontinued 5/2022], generic)
 - Celexa® (citalopram tablets and oral solution – Allergan, generic)
 - Citalopram capsules – Almatica
 - Fluoxetine capsules (generic to discontinued Sarafem® capsules [brand discontinued 12/2021])
 - Fluoxetine delayed-release capsules (generic to discontinued Prozac® Weekly™)
 - Fluoxetine tablets (generic only)
 - 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 – Sebela [discontinued 5/2023])
 - Prozac® (fluoxetine capsules, tablets, and oral solution – Lilly, generic)
 - Sertraline capsules – Almatica/Viking
 - Trintellix™ (vortioxetine tablets – Takeda)
 - Viibryd® (vilazodone hydrochloride tablets – Allergan, generic)
 - Zoloft® (sertraline tablets and oral solution – Pfizer, generic)

REVIEW DATE: 03/13/2024

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

Table 1 (continued). FDA-Approved Indications.¹⁻¹⁴

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; ^ FDA-approved indication includes children and adolescents 7 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.

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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: Brisdelle, Celexa, 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, Lexapro, Paxil, Paxil CR, Pexeva, Prozac, Sarafem, sertraline capsules (brand product), Trintellix, Viibryd, 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.

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 [prescribing information]. Indianapolis, IN: Lilly; August 2023.
2. Paxil[®] tablets and oral suspension [prescribing information]. Weston, FL: Apotex; August 2023.
3. Zoloft[®] tablets, oral concentrate [prescribing information]. New York, NY: Pfizer; August 2023.
4. Celexa[®] tablets and oral solution [prescribing information]. Irvine, CA: Allergan; August 2023.
5. Paxil CR[®] controlled-release tablets [prescribing information]. Weston, FL: Apotex; February 2024.
6. Lexapro[®] tablets/oral solution [prescribing information]. Irvine, CA: Allergan; August 2023.
7. Pexeva[®] paroxetine mesylate tablets [prescribing information]. Roswell, GA: Sebela; August 2023.
8. Fluvoxamine maleate tablets [prescribing information]. Baudette, MN: ANI; August 2023.
9. Fluvoxamine extended-release capsules [prescribing information]. Chestnut Ridge, NY: Par; October 2023.
10. Viibryd[®] tablets [prescribing information]. Madison, NJ: Allergan; August 2023.
11. Trintellix[™] tablets [prescribing information]. Lexington, MA and Deerfield, IL: Takeda and Lundbeck; August 2023.
12. Brisdelle[®] capsules [prescribing information]. Roswell, GA: Sebela; August 2023.
13. Sertraline capsules [prescribing information]. Morristown, NJ: Almatica; August 2023.

14. Citalopram capsules [prescribing information]. Morristown, NJ: Almatica; August 2023.