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Coverage Policy Number IP0328

Sertraline 150 mg, 200 mg Oral Capsules

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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.

Overview

This policy supports medical necessity review for formulary exceptions to the following non-covered sertraline products:

- sertraline 150 mg oral capsules
• sertraline 200 mg oral capsules

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products in below table:

Employer Group Non-Covered Products and Criteria:

| Non-Covered Product | Criteria |
|-----------------------------------|---|
| sertraline 150 mg, 200 mg capsule | <p>Sertaline 150 mg, 200 mg capsules is considered medically necessary when there is documentation of ONE of the following:</p> <ol style="list-style-type: none"> 1. Failure, contraindication, or intolerance to at least ONE generic sertraline formulation covered on formulary 2. Significant clinical concern such that the individual is unable to use the other generic sertraline products covered on formulary (for example, sertraline 100 mg scored tablet) |

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of sertraline 150 mg, 200 mg oral capsules are considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.

Reauthorization approval duration: up to 12 months.

Background

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).¹⁻¹⁴

Table 1. FDA-Approved Indications.¹⁻¹⁴

| Brand (generic) | MDD | OC D | Panic Disorde r | Bulimia Nervos a | PTSD | SAD | GA D | PMDD | VM S |
|---|----------------|----------------|-----------------------|------------------------|------|-----|---------|------|---------|
| 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 ^α | | | | | | 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 | | |
| 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™ [vortioxetine tablets] | X | | | | | | | | |
| Viiibryd® (vilazodone tablets, generic) | 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; January 2023.
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: Sebelia; September 2021.
8. Fluvoxamine maleate tablets [prescribing information]. Baudette, MN: ANI; July 2021.
9. Sarafem® tablets [prescribing information]. Irvine, CA: Allergan; September 2021.
10. Fluvoxamine extended-release capsules [prescribing information]. Chestnut Ridge, NY: Par; August 2021.
11. Viiibryd® tablets [prescribing information]. Madison, NJ: Allergan; July 2021.
12. Trintellix™ tablets [prescribing information]. Lexington, MA and Deerfield, IL: Takeda and Lundbeck; September 2021.
13. Brisdelle® capsules [prescribing information]. Roswell, GA: Sebelia; September 2021.
14. Sertraline capsules [prescribing information]. Morristown, NJ: Almatica; October 2021.
15. Citalopram capsules [prescribing information]. Morristown, NJ: Almatica; February 2022.

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