

Medical Policy



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Title: Selective Serotonin Reuptake Inhibitor Prior Authorization Criteria

Professional

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Institutional

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Prior Authorization Form:

http://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth_ACEI-ARB-SSRI-SNRI.pdf

DESCRIPTION

Brand	generic	Dosage Form
Celexa [®]	citalopram	oral tablet ^a , oral solution ^a
Lexapro [®]	escitalopram	oral tablet, oral solution
Paxil [®]	paroxetine hydrochloride	oral tablet ^a , oral suspension ^a
Paxil CR [®]	paroxetine hydrochloride	controlled-release tablet
Pexeva [®]	paroxetine mesylate	oral tablet
Prozac [®]	fluoxetine ^b	oral capsule ^a , oral tablet ^a , oral solution ^a
Zoloft [®]	sertraline	oral tablet ^a , oral solution ^a

^a currently available as generic

^b Prozac Weekly and Sarafem brand are not included in this prior authorization program

FDA APPROVED INDICATIONS¹⁻⁸

Available Products	Depression	Maintenance Phase Depression	OCD *	Bulimia Nervosa	PD *	GAD *	SAD *	PMDD *	PTSD *
Celexa (citalopram)	✓	✓							
fluvoxamine			✓ 8 yo-adult						
Lexapro (escitalopram)	✓	✓				✓			
Paxil (paroxetine)	✓	✓	✓		✓	✓	✓		✓
Paxil CR (paroxetine controlled release)	✓				✓		✓	✓	
Pexeva (paroxetine mesylate)	✓	✓	✓		✓	✓			
Prozac (fluoxetine)	✓ 8 yo-adult	✓	✓ 7 yo-adult	✓	✓				
Sarafem (fluoxetine) †								✓	
Zoloft (sertraline)	✓	✓	✓ 6 yo-adult		✓		✓	✓	✓

*OCD= obsessive compulsive disorder; PD= panic disorder; GAD= generalized anxiety disorder; SAD= social anxiety disorder or social phobia; PMDD= premenstrual dysphoric disorder; PTSD= post traumatic stress disorder, yo= years old.

† Sarafem brand is not included in the edit for the prior authorization program

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POLICY**RATIONALE FOR SELECTING SELECTIVE SEROTONIN REUPTAKE INHIBITORS FOR PRIOR AUTHORIZATION**

The intent of the selective serotonin reuptake inhibitor (SSRI) prior authorization program is to encourage the use of generic SSRI agents prior to brand-name SSRIs. In the treatment of depression, systematic reviews and practice guidelines have found comparable efficacy among the SSRIs.⁹⁻¹⁴ In addition, there are now AB-rated generic SSRI products Food and Drug Administration (FDA)-approved for use in obsessive compulsive disorder, panic disorder, generalized anxiety disorder, social anxiety disorder or social phobia, premenstrual dysphoric disorder, post-traumatic stress disorder, and bulimia.^{1-8,14} These generics may also have unlabeled uses supported by the pharmaceutical compendia, systematic reviews, or practice guidelines.¹⁶⁻²³

The American Psychiatric Association (APA) in practice guidelines for the treatment of patients with major depressive disorder report comparable efficacy between classes and also within classes.⁹ Other guidelines and systematic reviews comparing SSRIs have found no consistent evidence of a difference in efficacy among SSRIs for the treatment of depression.¹⁰⁻¹⁵

For indications other than depression, the following table summarizes the FDA-approved uses for AB-rated generic SSRIs and the SSRIs that have accepted unlabeled uses documented in the pharmaceutical compendia, USP/DI (accepted indications) and Micromedex DrugDex (treatment considered useful in some or most cases), and systematic reviews such as Clinical Evidence Concise 2005 (beneficial or likely to be beneficial), or practice guidelines.¹⁷⁻²⁹

Generically-available SSRIs, FDA Approved Indications and Unlabeled Uses

Indication	FDA-approved agents ^{1-8,17}	Accepted Unlabeled agents ¹⁷⁻²⁹
OCD	fluvoxamine, fluoxetine, paroxetine, sertraline	citalopram ^{19,26}
PD	fluoxetine, paroxetine, sertraline	citalopram ^{18,20,27} fluvoxamine ^{18,20,27}
GAD	paroxetine	sertraline ^{21,27,28}
SAD	paroxetine, sertraline	fluvoxamine ^{18,27,28}
PMDD	sertraline	citalopram ^{18,22} , fluvoxamine ²² , paroxetine ²²
PTSD	paroxetine, sertraline	fluoxetine ^{18,23,24,27,28}
Bulimia	fluoxetine	fluvoxamine ¹⁸

*OCD= obsessive compulsive disorder; PD= panic disorder; GAD= generalized anxiety disorder; SAD= social anxiety disorder or social phobia; PMDD= premenstrual dysphoric disorder; PTSD= post traumatic stress disorder.

Of the SSRI agents, Celexa (citalopram), Paxil immediate-release (paroxetine hydrochloride), Prozac (fluoxetine), and Zoloft (sertraline) are available as AB-rated generics in the oral solid dosage forms. Exceptions are Prozac Weekly (90 mg fluoxetine extended-release capsules) and Sarafem[®] (20 mg fluoxetine capsules). Fluvoxamine is available as a generic only; brand Luvox[®] is no longer being marketed. The oral solutions

of Prozac and Celexa are available as AA-rated generics; the generic sertraline oral concentrate is AB-rated to Zoloft oral concentrate; the generic paroxetine hydrochloride oral suspension is AB-rated to Paxil. Lexapro (escitalopram), Paxil CR (paroxetine hydrochloride controlled-release), and Pexeva (paroxetine mesylate) are not available in generic formulations.

The FDA has approved the generic alternatives to the brand SSRIs as therapeutically equivalent products.¹⁶ Generics are considered therapeutic equivalents if they contain the same active ingredients, are of the same dosage form, route of administration, and are identical in strength or concentration.¹⁶ Generics may differ in shape, scoring, configuration, release mechanisms, packaging, excipients (including colors, flavors, preservatives), expiration time, and, within certain limits, labeling. All of the solid oral dosage forms of the generics and the sertraline oral concentrate available are AB-rated to the brand innovator drug; the oral solutions are AA-rated to the brand innovator drug.¹⁶ AB-rated agents have had actual or potential bioequivalence problems resolved with adequate in vivo and/or in vitro evidence supporting bioequivalence.¹⁶ AA-rated agents are products that the FDA considers to be equivalent with no known or suspected bioequivalence problems.¹⁶

Electronic Claims Edit

The overall process for the electronic claims edit requires that another drug or drugs be tried for a specific quantity of drug in the previous time period before the claim drug. If the patient has met any of the requirements outlined below, the requested prior authorization medication will be paid under the patient's current prescription benefit. If the patient does not meet the electronic claims edit criteria, then the system will reject with the message indicating that prior authorization is necessary or that higher co-pay(s) will be applicable. The PA criteria for approval would then be applied to requests submitted by the patient's practitioner for evaluation.

The initial electronic claims edit will identify patients who are taking or have taken a generic SSRI in the 365 days prior to the brand-name SSRI claim. The initial electronic edit will also look for the identical GPI to the claim drug within the previous 90 days. The 365-day timeframe was selected because therapy for all of the above-listed diagnoses may be long-term and may require numerous changes in agents and dose adjustments. The 90-day parameter identifies previous therapy with a brand agent and assures continuation of therapy.

Manual Prior Authorization (PA) Criteria for Approval

The intent of the prior authorization criteria for approval is to ensure that patients who require brand SSRIs and who have not met the electronic claims edit criteria will be evaluated for use of brand SSRI therapy. The PA criteria for the SSRIs will approve the requested brand SSRI if the patient has tried and failed a generic SSRI. Brand SSRIs will also be approved when the patient is allergic to, or intolerant of, generic agents; if the patient has contraindications to the SSRIs that are available as generics; if the patient has responded to the target drug in the past; if the patient is currently taking the target brand, has had an adequate response, and switching may cause harm or health risk; or if

the prescriber has considered all generic SSRIs and determined that the brand SSRI prescribed will best treat the patient's condition.

Brand SSRIs will be approved indefinitely in patients with a documented diagnosis of Major Depressive Disorder, Recurrent, due to their high risk for significant disease morbidity. Indefinite approvals granted through the Clinical Review PA process may be re-evaluated at some future time if new information changes selection criteria or safety issues develop that may place these patients at higher risk from drug therapy.

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

Brand SSRIs

Initial and Renewal Evaluation

1. Does the patient have a documented diagnosis of Major Depressive Disorder, Recurrent (ICD-9 296.3X)?
If yes, approve indefinitely. If no, continue to 2.
2. Has the patient previously responded to the requested brand SSRI or is the patient currently receiving and responding to the requested drug and switching could potentially cause harm or a health risk?
If yes, approve indefinitely. If no, continue to 3.
3. Does the patient's past prescription history include the use of a generic SSRI?
If yes, approve indefinitely. If no, continue to 4.
4. Is the patient allergic to, intolerant of, or have a contraindication to a generic SSRI?
If yes, approve indefinitely. If no, continue to 5.
5. Has the prescriber submitted documentation in support of the requested therapeutic use for a brand SSRI in this patient?
If yes, pharmacist may approve indefinitely based on review of information provided. If no, deny.

CONCLUSION

Electronic claims edits are designed to identify patients electronically by their medication history. The SSRI electronic claims edit allows for automatic payment of claims when the patient's medication history indicates prior use of a generic SSRI bypassing the manual PA process. The edit also allows for automatic payment if a medical diagnosis of Major Depressive Disorder, Recurrent is documented and identified as an exemption to the PA process. The manual process provides a member-specific review process where practitioner provided patient-specific parameters are taken into consideration and are reviewed by a physician. The Prior Authorization protocol for SSRIs optimizes the utilization of cost-effective agents for the individual benefit plan.

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