Clinical Policy: Quetiapine Extended-Release (Seroquel XR)

Reference Number: CP.PMN.64
Effective Date: 09.01.15
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Quetiapine extended-release (Seroquel XR®) is an atypical antipsychotic.

FDA Approved Indication(s)

Seroquel XR is indicated for the treatment of:

- Schizophrenia in adults and adolescents (13-17 years)
- Bipolar I disorder, manic or mixed episodes, in adults and children/adolescents (10-17 years)
- Bipolar disorder, depressive episodes, in adults
- Major depressive disorder, as adjunctive therapy with antidepressants, in adults

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Seroquel XR is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia (must meet all)**:**

1. Diagnosis of schizophrenia;
2. Age ≥ 13 years;
3. Failure of a ≥ 4-week trial of quetiapine immediate-release (IR) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 800 mg (2 tablets) per day.

Approval duration:
HIM – 12 months
Commercial/Medicaid – Length of Benefit

B. Bipolar Disorder (must meet all)**:**

1. Diagnosis of bipolar disorder;
2. Age ≥ 10 years;
3. Failure of a ≥ 4-week trial of quetiapine IR at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 800 mg (2 tablets) per day.

Approval duration:
HIM – 12 months

Commercial/Medicaid – Length of Benefit

C. Major Depressive Disorder (must meet all)**:**
1. Diagnosis of major depressive disorder;
2. Age ≥ 18 years;
3. Failure of THREE antidepressants (e.g., selective serotonin reuptake inhibitor [SSRI], serotonin-norepinephrine reuptake inhibitor [SNRI], tricyclic antidepressant [TCA], bupropion, mirtazapine) from at least TWO different classes at up to maximally indicated doses, each used for ≥ 4 weeks, unless member is unable to satisfy this requirement due to clinically significant adverse effects or contraindication(s) to multiple antidepressants;
4. Failure of a ≥ 4-week trial of aripiprazole at up to maximally indicated doses, used concurrently with an antidepressant, unless contraindicated or clinically significant adverse effects are experienced;
5. Seroquel XR is prescribed concurrently with an antidepressant;
6. Dose does not exceed 300 mg (2 tablets) per day.

Approval duration:
HIM – 12 months
Commercial/Medicaid – Length of Benefit

D. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Documentation supports that member is currently receiving Seroquel XR for schizophrenia or bipolar disorder and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed:
   a. Schizophrenia, bipolar disorder: 800 mg (2 tablets) per day;
   b. Major depressive disorder: 300 mg (2 tablets) per day.

Approval duration:
HIM – 12 months
Commercial/Medicaid – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
IR: immediate-release
SNRI: serotonin/norepinephrine reuptake inhibitor
SSRI: selective serotonin reuptake inhibitor
TCA: tricyclic antidepressant

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Antipsychotics		
quetiapine immediate-release (Seroquel®)	**Schizophrenia** Initial: 25 mg PO BID; target: 400 to 800 mg/day **Bipolar Disorder** Initial: 50 mg PO BID; target: 400 to 800 mg/day	800 mg/day
Selective Serotonin Reuptake Inhibitors (SSRIs)		
citalopram (Celexa®)	**Major Depressive Disorder** Refer to prescribing information	40 mg/day
escitalopram (Lexapro®)		20 mg/day
fluoxetine (Prozac®)		Immediate-release: 80 mg/day (20 mg/day if pediatric) Delayed-release: 90 mg/week
fluvoxamine* (immediate-release) (Luvox®)		150 mg/day
paroxetine (Paxil®, Paxil CR®, Pexeva®)		Immediate-release: 50 mg/day (40 mg/day if geriatric)

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
		Extended-release: 62.5 mg/day (50 mg/day if geriatric)
sertraline (Zoloft®)		200 mg/day (20 mg/day if age 6-11 years*)
Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)		
desvenlafaxine (Pristiq®)	**Major Depressive Disorder** Refer to prescribing information	400 mg/day
duloxetine (Cymbalta®)		120 mg/day
Fetzima® (levomilnacipran)		120 mg/day
venlafaxine (Effexor®, Effexor XR®)		Extended-release: 225 mg/day
Tricyclic Antidepressant (TCAs)		
amitriptyline (Elavil®)	**Major Depressive Disorder** Refer to prescribing information	150 mg/day
amoxapine		400 mg/day (300 mg/day if geriatric)
clomipramine* (Anafranil®)		250 mg/day (200 mg/day if pediatric)
desipramine (Norpramin®)		300 mg/day (100 mg/day if pediatric)
doxepin (Sinequan®)		300 mg/day
imipramine HCl (Tofranil®)		200 mg/day (150 mg/day if geriatric or pediatric)
imipramine pamoate (Tofranil PM®)		200 mg/day (100 mg/day if geriatric or pediatric)
nortriptyline (Pamelor®)		150 mg/day
protriptyline (Vivactil®)		60 mg/day (30 mg/day if geriatric or pediatric)
trimipramine (Surmontil®)		200 mg/day (100 mg/day if geriatric or pediatric)
Monoamine Oxidase Inhibitors		
isocarboxazid (Marplan®)	**Major Depressive Disorder** Refer to prescribing information	60 mg/day
phenelzine (Nardil®)		90 mg/day
selegiline (EMSAM® transdermal; Eldepryl®, Zelapar®, Carbex®)		Transdermal: 12 mg/24 hr Oral*: 30 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
tranylcypromine (Parnate®)		60 mg/day
Other Antidepressants		
bupropion (Aplenzin®, Budeprion SR® , Budeprion XL®, Forfivo XL®, Wellbutrin®, Wellbutrin SR®, Wellbutrin XL®)	**Major Depressive Disorder** Refer to prescribing information	Immediate-release: 450 mg/day (300 mg/day if pediatric) Sustained-release: 400 mg/day Extended-release (HCl): 450 mg/day Extended-release (HBr): 522 mg/day
mirtazapine (Remeron®)		45 mg/day
perphenazine/ amitriptyline (Triavil®)		16 mg/day perphenazine and 200 mg/day amitriptyline
maprotiline (Ludiomil®)		150 mg/day
nefazodone (Serzone®)		600 mg/day
trazodone (Desyrel®, Oleptro®)		Immediate-release: 400 mg/day Extended-release: 375 mg/day
vortioxetine (Trintellix®)		20 mg/day
vilazodone (Viibryd®)		40 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to Seroquel XR or any components in the formulation
- Boxed warning(s): increased mortality in elderly patients with dementia-related psychosis; and suicidal thoughts and behaviors in children, adolescents, and young adults taking antidepressants.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia	Adults: Initial: 300 mg PO QD Target: 400 to 800 mg/day Adolescents: Initial: 50 mg PO QD Target: 400 to 800 mg/day	800 mg/day

Indication	Dosing Regimen	Maximum Dose
Bipolar I disorder	**Manic or mixed episodes** Adults: Initial: 300 mg PO QD Target: 400 to 800 mg/day Children and adolescents Initial: 50 mg PO QD Target: 400 to 600 mg/day **Depressive episodes** Adults: Initial: 50 mg PO QD Target: 300 mg/day	Manic or mixed episodes Adults: 800 mg/day Children and adolescents: 600 mg/day Depressive episodes 300 mg/day
Major depressive disorder	Adults: Initial: 50 mg PO QD Target: 150 to 300 mg/day	300 mg/day

VI. Product Availability

Extended-release tablets: 50 mg, 150 mg, 200 mg, 300 mg, 400 mg

VII. References

1. Seroquel XR Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 30, 2019. Available at: www.seroquelxr.com. Accessed November 30, 2019.
2. Lehman AF, Lieberman JA, Dixon LB, et al. Practice guideline for the treatment of patients with schizophrenia, second edition. Arlington, VA: American Psychiatric Association; February 2004. Available online at http://www.psych.org/psych_pract/treatg/pg/prac_guide.cfm. Accessed November 30, 2019.
3. Dixon L, Perkins D, Calmes C. Guideline watch: practice guideline for the treatment of patients with schizophrenia. Arlington, VA: American Psychiatric Association; September 2009. Available online at http://www.psych.org/psych_pract/treatg/pg/prac_guide.cfm. Accessed November 30, 2019.
4. Hirschfeld RMA, Bowden CL, Gitlin MJ, et al. Practice guideline for the treatment of patients with bipolar disorder, second edition. Arlington, VA: American Psychiatric Association; April 2002. Available online at http://www.psych.org/psych_pract/treatg/pg/prac_guide.cfm. Accessed November 30, 2019.
5. Hirschfeld RMA. Guideline watch: practice guideline for the treatment of patients with bipolar disorder. Arlington, VA: American Psychiatric Association; November 2005. Available online at http://www.psych.org/psych_pract/treatg/pg/prac_guide.cfm. Accessed November 30, 2019.
6. Gelenberg AJ, Freeman MP, Markowitz JC, et al. Practice guideline for the treatment of patients with major depressive disorder, third edition. Arlington, VA: American Psychiatric Association; May 2010. Available online at http://www.psych.org/psych_pract/treatg/pg/prac_guide.cfm. Accessed November 30, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New guideline created – replaces CP.PMN.56	08.15	08.15
For bipolar disorder: removed the criterion requiring that member does not have contraindication to active quetiapine; For schizophrenia: modified criteria to require the use of quetiapine IR and one other generic PDL agent indicated for schizophrenia; For depression: Added requirement for trial of 3 PDL antidepressants and added additional instruction on aripiprazole use and approval since aripiprazole requires a prior authorization.	10.15	11.15
Converted to new integrated template. Updated references to include current practice guidelines rather than UpToDate. Removed age restrictions as they are not absolute contraindications per FDA labeling. Modified generalized FDA approved limit to specific dosing requirement; MDD: Added trial duration of 4 weeks. Modified requirement for trials to be of PDL antidepressants to include any antidepressants. Removed instruction on aripiprazole use and approval since member will qualify for aripiprazole so long as all other MDD criteria are met.	08.16	11.16
Converted to new template. All indications: Added age limits based on established safety and efficacy per PI. Schizophrenia and bipolar: Removed requirement that trialed antipsychotics must be generic to give credit to members who have tried branded products. Re-auth: Removed MDD from COC criteria as it is not a diagnosis eligible for COC. Removed the following from schizophrenia and bipolar disorder Per SDC guidance: Failure of a ≥ 4 week trial of one additional PDL atypical antipsychotic indicated for schizophrenia at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;	07.28.17	11.17
1Q18 annual review: Policies combined for Centene Medicaid, Marketplace and Commercial lines of business; No significant changes; References reviewed and updated	12.01.14	02.18
Medicaid: changed approval duration from 12 months to length of benefit	03.04.18	05.18
1Q 2019 annual review: no significant changes; references reviewed and updated.	10.30.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.30.19	02.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy; HIM.PA.103.