Clinical Policy: Quetiapine extended release (Seroquel XR)
Reference Number: HIM.PA.44
Effective Date: 12/14
Last Review Date:
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

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

Description
Quetiapine ER (Seroquel XR®) is an atypical antipsychotic.

FDA approved indication
Seroquel XR is indicated:
- For the treatment of schizophrenia
- For the treatment of bipolar I disorder, manic or mixed episodes
- For the treatment of bipolar disorder, depressive episodes
- For the treatment of major depressive disorder, adjunctive therapy with antidepressants

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

I. Initial Approval Criteria

A. Schizophrenia (must meet all)**:**
1. Diagnosis of schizophrenia;
2. Failure of ≥ 4 week trial of quetiapine immediate-release (IR) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Failure of ≥ 4 week trial of one additional formulary generic atypical antipsychotic indicated for schizophrenia at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed 800 mg per day.

Approval duration: 12 months

B. Bipolar Disorder (must meet all)**:**
1. Diagnosis of bipolar disorder;
2. Failure of ≥ 4 week trial of quetiapine IR at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
3. Failure of ≥ 4 week trial of one additional formulary generic atypical antipsychotic indicated for bipolar disorder at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;
4. Request does not exceed 800 mg per day.

Approval duration: 12 months

C. Major Depressive Disorder (must meet all)**:**
1. Diagnosis of major depressive disorder;

2. Failure of **THREE antidepressants** (e.g., SSRI, SNRI, TCA, bupropion, mirtazapine, etc.) from at least **TWO different classes** at up to maximally indicated doses, each trialed for ≥ 4 weeks, unless member is unable to satisfy this requirement due to clinically significant adverse effects or contraindication(s) to multiple antidepressants;
3. Failure of ≥ 4 week trial of aripiprazole used concurrently with an antidepressant at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Seroquel XR will be used concurrently with an antidepressant;
5. Dose does not exceed 300 mg per day.

Approval duration: 12 months

D. Other diagnoses/indications:
1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized);

II. Continued Therapy

A. All Indications (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Seroquel XR for schizophrenia, bipolar disorder, or major depressive disorder and has received this medication for at least 30 days;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed FDA approved maximum recommended dose for the relevant indication.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 policy – HIM.PHAR.21 or evidence of coverage documents

B. As a sleep aid

IV. Appendices/General Information

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

V. References

1. Seroquel XR® drug monograph. Clinical Pharmacology. Available at: http://clinicalpharmacology-ip.com. Accessed January 17, 2017
2. Seroquel XR® [Prescribing information] Wilmington, DE: AstraZeneca; June 2016Available at http://www.azpicentral.com/seroquel-xr/seroquelxr.pdf#page=1. Accessed January 17, 2017.
3. 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 February 9, 2017.
4. 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 February 9, 2017.
5. 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 February 9, 2017.
6. 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 February 9, 2017.
7. 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 February 9, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Changed guidelines to new format	05/16	05/16
Clinical changes made to criteria -Created separate criteria for each indication Non-clinical changes -Converted to new template -Updated continuation criteria to allow continuity of care -Updated references	01/17	

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.