Clinical Policy: Quetiapine ER (Seroquel XR)

Reference Number: ERX.NPA.50
Effective Date: 01.11.17
Last Review Date: 11.17 Revision Log

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

Description
Quetiapine ER [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 (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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/day (2 tablets/day).

Approval duration: 12 months

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/day (2 tablets/day).

Approval duration: 12 months

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, serotonin/norepinephrine reuptake inhibitor, tricyclic antidepressant, bupropion, mirtazapine, etc.) 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 used concurrently with an antidepressant at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   **Aripiprazole requires prior authorization; if criterion 4 has NOT been met, but member has met criteria 1, 2, and 3, reviewer MUST recommend the use of aripiprazole concurrently with*

an antidepressant; enter a 12 month approval for aripiprazole in the pharmacy benefit system (allow all tablet strengths and 1 tablet/day), and inform prescriber of this approval

5. Seroquel XR will be used concurrently with an antidepressant;
6. Dose does not exceed 300 mg/day (2 tablets/day).

Approval duration: 12 months

D. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 a health plan affiliated with Envolve Pharmacy Solutions 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/day (2 tablets/day);
   b. Major depressive disorder: 300 mg/day (2 tablets/day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ER: extended-release
FDA: Food and Drug Administration
IR: immediate-release

Appendix B: Therapeutic Alternatives

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Quetiapine IR (Seroquel®)	Bipolar Mania or Maintenance *Adults*: 50 mg PO BID, increased in increments of 100 mg/day as tolerated to 400 mg/day on Day 4; may further increase to 800 mg/day by Day 6 *Children*: 25 mg PO BID on Day 1, 50 mg BID on Day 2, 100 mg BID on Day 3, 150 mg BID on Day 4, and 200 mg BID beginning Day 5; may increase to 600 mg/day as needed Bipolar Depression *Adults*: 50 mg QHS on Day 1, 100 mg on Day 2, 200 mg on Day 3, 300 mg on Day 4 and thereafter	Bipolar mania/ maintenance: *Adults*: 800 mg/day *Children*: 600 mg/day Bipolar depression: *Adults*: 300 mg/day Schizophrenia: *Adults, adolescents*: 800 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Schizophrenia *Adults*: 25 mg PO BID on Day 1, increased by 25-50 mg on Day 2 and 3 to a target of 300-400 mg/day in divided doses 2-3 times per day by Day 4; may increase up to 800 mg/day *Adolescents*: 25 mg PO BID on Day 1, 50 mg BID on Day 2, 100 mg BID on Day 3, 150 mg BID on Day 4, and 200 mg BID beginning Day 5; may increase up to 800 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.

V. Dosage and Administration

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

VI. Product Availability

ER tablets: 50 mg, 150 mg, 200 mg, 300 mg, and 400 mg

VII. References

1. Seroquel XR Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2017. Available at: www.seroquelxr.com. Accessed September 21, 2017.
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.psychiatryonline.org/guidelines. Accessed July 28, 2017.
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.psychiatryonline.org/guidelines. Accessed July 28, 2017.
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.psychiatryonline.org/guidelines. Accessed July 28, 2017.

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.psychiatryonline.org/guidelines. Accessed July 28, 2017.
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.psychiatryonline.org/guidelines. Accessed July 28, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	12.16	01.17
4Q17 Annual Review Converted to new template. All indications: Added age limits based on established safety and efficacy per PI. Schizophrenia and bipolar: Removed requirement for trial of PDL generic atypical antipsychotics as Seroquel XR is now available as a generic. Re-auth: Removed MDD from COC criteria as it is not a diagnosis eligible for COC.	09.21.17	11.17

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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