



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## quetiapine-Low Dose (Seroquel)

Policy # 00358

Original Effective Date: 07/17/2013

Current Effective Date: 07/16/2014

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider low dose ( $\leq 100\text{mg/day}$ ) brand or generic Seroquel<sup>®†</sup> (quetiapine) use beyond 30 days to be **eligible for coverage** when one of the below patient selection criteria is met:

### Patient Selection Criteria

Coverage eligibility will be considered for low dose ( $\leq 100\text{mg/day}$ ) brand or generic Seroquel (quetiapine) use beyond 30 days when one of the following criteria is met:

- Prescriber is a Psychiatrist or Neurologist; or
- Patient is taking a concomitant oral or injectable antipsychotic e.g. Risperdal<sup>®†</sup> (risperidone), Haldol<sup>®†</sup> (haloperidol), Zyprexa<sup>®†</sup> (olanzapine), Abilify<sup>®†</sup> (aripiprazole); or
- Patient is taking a concomitant mood stabilizer e.g. Depakote<sup>®†</sup> (divalproex), Topamax<sup>®†</sup> (topiramate), Zonegran<sup>®†</sup> (zonisamide), lithium; or
- Patient is taking a concomitant anti-Parkinson's disease medication e.g. Cogentin<sup>®†</sup> (benztropine), Comtan<sup>®†</sup> (entacapone), Sinemet<sup>®†</sup> (carbidopa/levodopa), Eldepryl<sup>®†</sup> (selegiline), Mirapex<sup>®†</sup> (pramipexole); or
- Patient is taking a concomitant anti-dementia medication e.g. Aricept<sup>®†</sup> (donepezil), Reminyl<sup>®†</sup> (galantamine), Razadyne<sup>®†</sup> (galantamine), Exelon<sup>®†</sup> (rivastigmine) Namenda (memantine); or
- Patient is taking Seroquel (quetiapine) as augmentation therapy in the treatment of depression, obsessive-compulsive disorder (OCD), post-traumatic stress disorder (PTSD), or anxiety; or
- Patient is being treated for delirium; or
- Patient is being treated for Tourette's disorder.

### When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of low dose ( $\leq 100\text{mg/day}$ ) Seroquel (quetiapine) beyond 30 days for any usage not included in the above patient selection criteria (including, but not limited to the treatment/prevention of headaches, pain management, or the treatment of insomnia) to be **investigational**.\*



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Quetiapine-Low Dose (Seroquel)

Policy # 00358  
Original Effective Date: 07/17/2013  
Current Effective Date: 07/16/2014

## **Background/Overview**

Seroquel (quetiapine) is a psychotropic agent indicated for treatment of schizophrenia in patients  $\geq 13$  years of age, acute treatment of depressive episodes associated with bipolar disorder in adults, acute treatment of manic episodes associated with bipolar I disorder as either monotherapy or adjunctive therapy to lithium or divalproex in patients  $\geq 10$  years of age, as well as the maintenance treatment of bipolar I disorder as adjunctive therapy to lithium or divalproex in adults.

## **Rationale/Source**

Seroquel (quetiapine) has the potential to be used off label for certain conditions such as the treatment/prevention of headaches, pain management, or the treatment of insomnia. There is very little clinical evidence to support the use of Seroquel (quetiapine) in these conditions or any conditions not listed in the above patient selection criteria. The purpose of this policy is to limit the use of low dose Seroquel (quetiapine) to those uses mentioned in the patient selection criteria. Patient selection criteria are based on information collected in a review of the available data.

## **References**

1. Seroquel® tablets [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2011.
2. DRUGDEX® System. Thomson Reuters (Healthcare) Inc. Available at: <http://www.thomsonhc.com>. Accessed on January 23, 2013. Search terms: quetiapine.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2013. Available at <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed on: January 23, 2013. Search terms: quetiapine.
4. Agency for Healthcare Research and Quality. Off-label use of atypical antipsychotics: an update. September 2011. Available at: <http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=778&ECem=110927>. Accessed on: January 23, 2013.
5. Cohrs S, Rodenbeck A, Guan Z, et al. Sleep-promoting properties of quetiapine in healthy subjects. *Psychopharmacology*. 2004;174(3):421-9.
6. Wine JN, Sanda C, Caballero J. Effects of quetiapine on sleep in nonpsychiatric and psychiatric conditions. *Ann Pharmacother*. 2009;43:707-13.
7. Tassniyom K, Paholpak S, Tassniyom S, Kiewyoo J. Quetiapine for primary insomnia: a double blind, randomized controlled trial. *J Med Assoc Thai*. 2010;93:729-734.
8. Schutte-Rodin S, Broch L, Buysse D, et al. Clinical guideline for the evaluation and management of chronic insomnia in adults. *J Clin Sleep Med*. 2008;4:487-504.
9. Fishbain DA, Cutler RB, Lewis J, Cole B, Rosomoff RS, Rosomoff HL. Do the second-generation "atypical neuroleptics" have analgesic properties? A structured evidence-based review. *Pain Med*. 2004;5(4):359-365.
10. Hidalgo J, Rico-Villademoros F, Pita Calandre E. An open-label study of quetiapine in the treatment of fibromyalgia. *Prog Neuropsychopharmacol Biol Psychiatry*. 2007;31(1):71-77.
11. American Pain Society. Guidelines for the management of fibromyalgia syndrome pain in adults and children. 1st ed. Glenview, IL: American Pain Society; 2005.
12. Carville SF, Arendt-Nielsen S, Bliddal H, et al. EULAR evidence-based recommendations for the management of fibromyalgia syndrome. *Ann Rheum Dis*. 2008;67:536-541.
13. Krymchantowski AV, Jevoux C. Quetiapine for the prevention of migraine refractory to the combination of atenolol + nortriptyline + flunarizine: an open pilot study. *Arq Neuropsiquiatr*. 2008;66:615-618.
14. Migraine. American Headache Society. Copyright 2010.
15. Miyasaki JM, Shannon K, Voon V, et al. Practice parameter: Evaluation and treatment of depression, psychosis, and dementia in Parkinson disease (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2006;66:996-1002.
16. American Association for Geriatric Psychiatry. Comments on the US Food and Drug Administration's (FDA) advisory on off-label use of atypical antipsychotics in the elderly. Comment date July 13, 2005.

©2014 Blue Cross and Blue Shield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Quetiapine-Low Dose (Seroquel)

Policy # 00358

Original Effective Date: 07/17/2013

Current Effective Date: 07/16/2014

## **Policy History**

Original Effective Date: 07/17/2013

Current Effective Date: 07/16/2014

06/27/2013 Medical Policy Committee review

07/17/2013 Medical Policy Implementation Committee approval. New policy.

07/10/2014 Medical Policy Committee review

07/16/2014 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 07/2015

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

\*\*Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.