

Raldesy™ (trazodone oral solution)

Policy # 00956

Original Effective Date: 03/01/2026

Current Effective Date: 03/01/2026

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.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

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 Raldesy™ (trazodone oral solution) to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility will be considered for Raldesy (trazodone oral solution) when the following criteria are met:

- Patient has a diagnosis of major depressive disorder (MDD); AND
- Patient is 18 years of age or older; AND
- Patient meets ONE of the following:
 - Patient has tried and failed (e.g., intolerance or inadequate response) at least THREE generic alternative antidepressants unless there is clinical evidence or patient history that suggests the generic alternative antidepressants will be ineffective or cause an adverse reaction to the patient; OR
Note: Generic alternative antidepressants must include ONE generic selective serotonin reuptake inhibitor (SSRI) (e.g., citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline), ONE generic serotonin-norepinephrine reuptake inhibitor (SNRI) (e.g., desvenlafaxine, duloxetine, venlafaxine), and ONE other generic antidepressant (e.g., amitriptyline, clomipramine, desipramine, imipramine, nortriptyline, nefazodone, trazodone, vilazodone, bupropion).
 - Patient meets BOTH of the following:
 - Patient is unable to swallow tablets and/or capsules; AND

Raldesy™ (trazodone oral solution)

Policy # 00956

Original Effective Date: 03/01/2026

Current Effective Date: 03/01/2026

- Patient has tried and failed (e.g., intolerance or inadequate response) at least ONE generic alternative antidepressant solution (e.g., escitalopram oral solution, fluoxetine oral solution, sertraline oral concentrate) unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers use of Raldesy (trazodone oral solution) when the patient has not tried and failed at least THREE generic alternative antidepressants, including one generic SSRI, one SNRI, and one other generic antidepressant as denoted in the patient selection criteria OR when the patient is able to swallow tablets and/or capsules AND has not tried and failed at least ONE generic alternative antidepressant solution to be **not medically necessary**.**

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 use of Raldesy (trazodone oral solution) when the patient selection criteria are not met (EXCEPT those denoted as **not medically necessary****) to be **investigational**.*

Background/Overview

Raldesy is indicated for the treatment of major depressive disorder (MDD) in adults. It is an oral solution formulation of trazodone, a serotonin modulator that exhibits selective serotonin reuptake inhibitor (SSRI) activity and 5-hydroxytryptamine-2 (5HT₂) receptor antagonism, supplied at a concentration of 10 mg/mL. The initial dose of Raldesy for the treatment of MDD in adults is 150 mg daily, taken orally in divided doses. The dosage should be initiated at a low dose and increased gradually, depending on clinical response and tolerance. The dose may be increased by 50 mg daily every 3 to 4 days. Occurrence of drowsiness may require the administration of a major portion of the daily dose at bedtime or at a reduced dose. The maximum recommended dosage for outpatient treatment usually should not exceed 400 mg daily in divided doses. Raldesy is contraindicated in patients taking, or within 14 days of stopping, monoamine oxidase inhibitors (MAOIs), including MAOIs such as linezolid or intravenous methylene blue, because of an increased risk of serotonin syndrome.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Raldesy is indicated for the treatment of major depressive disorder (MDD) in adults.

Raldesy™ (trazodone oral solution)

Policy # 00956

Original Effective Date: 03/01/2026

Current Effective Date: 03/01/2026

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

Raldesy was approved by the Food & Drug Administration (FDA) via the 505(b)(2) pathway relying on safety and efficacy information with trazodone tablets to support approval. No clinically significant difference in pharmacokinetics of trazodone was observed between Raldesy and immediate-release trazodone hydrochloride tablet administered under fed conditions. The intent of this policy is to ensure FDA approved label usage. The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests alternative anti-depressant agents will be ineffective or will cause an adverse reaction to the patient and whether or not the patient can swallow tablets and/or capsules.

References

1. Raldesy [package insert]. Validus Pharmaceuticals, LLC. Parsippany, New Jersey. Updated March 2025.

Policy History

Original Effective Date: 03/01/2026

Current Effective Date: 03/01/2026

02/05/2026 Medical Policy Committee review

02/11/2026 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 02/2027

*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 technology evaluation center(s);

Raldesy™ (trazodone oral solution)

Policy # 00956

Original Effective Date: 03/01/2026

Current Effective Date: 03/01/2026

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: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.