

rilpivirine tablet for suspension (Edurant[®] PED)

Policy # 00946

Original Effective Date: 12/01/2025

Current Effective Date: 12/01/2025

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 rilpivirine tablet for suspension (Edurant[®] PED)[‡] for the treatment of human immunodeficiency virus type 1 (HIV-1) to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for rilpivirine tablet for suspension (Edurant PED) will be considered when the following criteria are met:

- Patient has a diagnosis of HIV-1 infection; AND
- Patient is 2 to 12 years of age.

*Note: (The use of this product in patients over 12 years of age is an additional Company requirement for coverage eligibility. Requests for patients 13 years of age and above will be denied as not medically necessary**)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of rilpivirine tablet for suspension (Edurant PED) when a member is 13 years of age or older 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 the use of rilpivirine tablet for suspension (Edurant PED) when the patient selection criteria are NOT met (with the exception of those denoted above as not medically necessary**) to be **investigational**.*

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Background/Overview

Edurant PED is a human immunodeficiency virus type 1 (HIV-1) specific, non-nucleoside reverse transcriptase inhibitor (NNRTI) indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients 2 years of age and older and weighing at least 14 kilograms with HIV-1 RNA less than or equal to 100,000 copies/mL. The package insert includes the following limitation of use: “more Edurant treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure (HIV-1 RNA $\geq$ 50 copies/mL) compared to Edurant treated subjects with HIV-1 RNA less than or equal to 100,000 copies/mL.” Edurant PED was approved by the Food and Drug Administration (FDA) via the 505(b)(2) pathway relying on safety and efficacy information of the Edurant tablet formulation to support approval. Edurant PED is available as 2.5 mg tablets for oral suspension which must be dispersed in 5 mLs of water before administration, and Edurant tablets are supplied as 25 mg film-coated tablets. Due to differing pharmacokinetic profiles, Edurant tablets and Edurant PED tablets for oral suspension are not substitutable on a milligram-per-milligram basis. Edurant PED is dosed based on body weight and should be taken with a meal; see the package insert for complete dosing details.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Edurant PED is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve patients 2 years of age and older and weighing at least 14 kilograms with HIV-1 RNA less than or equal to 100,000 copies/mL.

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.

The safety and efficacy of Edurant and Edurant PED in treatment naïve pediatric subjects 2 to less than 6 years of age is supported by evidence from adequate and well-controlled studies of Edurant in adults with additional population pharmacokinetic data from adults and pediatric subjects 6 years and older. The pharmacokinetics, safety, tolerability and efficacy of Edurant and Edurant PED weight-adjusted doses 25, 15 and 12.5 mg once daily in combination with an investigator-selected background regimen containing two NRTIs, was evaluated in a single-arm, open-label Phase 2 trial in antiretroviral treatment-naïve HIV-1 infected pediatric subjects 6 to less than 12 years of age and weighing at least 17 kg. The Week 48 analysis included 18 subjects, 17 (94%) subjects completed the 48-week treatment period, and 1 (6%) subject discontinued the study early due to reaching a virologic endpoint. The number of subjects with HIV-1 RNA < 50 copies/mL at Week 48 was 13/18

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(72%), while 3/18 (17%) subjects had HIV-1 RNA ≥ 50 copies/mL at Week 48. Two out of 18 (11%) participants in the 15 mg once daily (20 to ≤ 25 kg) dose-weight group had missing viral load data at Week 48 but remained on study. The viral load for these 2 subjects was < 50 copies/mL, post-Week 48. The mean increase (SE) in CD4+ from baseline was 215.9 (62.42) cells/ μ L at Week 48.

Based on a review of the data, if the above mentioned criteria are not met, there is no clinical advantage to the use of Edurant PED over other dosage forms for the treatment of HIV-1 infection.

References

1. Edurant & Edurant PED [package insert]. Janssen Products, LP. Horsham, PA. Updated November 2024.

Policy History

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11/06/2025 Medical Policy Committee review

11/12/2025 Medical Policy Implementation Committee approval. New policy.

Next Scheduled Review Date: 11/2026

*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);
 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;

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- 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.